Da Vinci | Xi

intuitive.com

System
User Manual



Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086 USA
intuitive.com

PN 551400-17 Rev. B 2023.08

Copyrights

© 2014–2023 Intuitive Surgical Operations, Inc. All rights reserved.

Portions of this software provided by QNX Software (www.qnx.com).
© 2015 QNX Software. All rights reserved.

Portions of this software provided by The FreeType Project (www.freetype.org).
© 2015 The FreeType Project. All rights reserved.

Third Party Acknowledgments: Portions of the software may utilize or include third party software and other copyrighted material. Acknowledgments, licensing terms and disclaimers for such material are found at https://www.davincisurgerycommunity.com/open_source, and your use of such material is governed by their respective terms.

Trademarks

Intuitive, Intuitive Surgical, da Vinci, da Vinci Si, da Vinci Xi, da Vinci X, EndoWrist, Firefly, Single-Site, and *OnSite* are registered trademarks of Intuitive Surgical. Product and brand names/logos are trademarks or registered trademarks of Intuitive Surgical or their respective owner. See www.intuitive.com/trademarks.

Equipment and Software Version

This user manual provides technical information about the use and operation of the da Vinci Xi Surgical System Model IS4000 (da Vinci Xi system). The equipment described herein is designed to work with the operating software version da Vinci OS4 v11.0.0 (A70_P11) and later.

Rx only

Terms and Conditions of End User Software License Agreement

1 LICENSE. The software ("Software") embedded within the da Vinci Surgical System ("System") and the accompanying documentation ("Documentation") are provided under license and are not sold to buyers. Intuitive Surgical, Inc. ("Intuitive") grants to buyers a non-exclusive, non-transferable, fully-paid, restricted license to (a) install and use the Software solely as incorporated in the System in machine-executable object code form and solely in connection with the operation of the System as described in the Documentation, and (b) use the Documentation for such Software solely for the purpose of using the Software in compliance with this license.

2 RESTRICTIONS.

(a) Buyer shall not (i) use, copy, translate, modify, create derivative works of, or transfer, (ii) merge with any other product, (iii) sublicense, lease, rent, loan, or otherwise transfer, (iv) reverse engineer, decompile, disassemble, attempt to derive the source code for, or otherwise manipulate, or (v) disclose, permit to be disclosed or publicly display or perform, the Software, in whole or in part, or any copy thereof. Notwithstanding the foregoing, manipulation of the Software is permitted if, and then only to the extent that, the foregoing prohibition on manipulation is required to be modified by applicable law; provided, however, that buyer must first request from Intuitive the information to be sought from the Software, and Intuitive may, in its discretion, provide such information to buyer under good faith restrictions, and/or impose reasonable conditions, including but not limited to a reasonable fee, on such use of the Software, to ensure that Intuitive's and any third party's proprietary rights in the Software are protected.

(b) Buyer may make a reasonable number of backup and archival copies of the Software as necessary to support the use of the Software in connection with the balance of the System, but shall not otherwise copy the Software under any circumstances. Buyer may not alter, obscure or remove any copyright, trademark, proprietary rights, disclaimer, or warning notice included on or embedded in any part of the Software (including those of third parties).

1 OWNERSHIP. The Software is licensed, not sold, to buyer. There is no implied license, right or interest granted in any copyright, patent, trade secret, Trademark, invention or other intellectual property right.

2 TERM. This license will begin on the date the Software is delivered to buyer, and will continue until the end of the useful life of the System. Notwithstanding the foregoing, this license shall terminate immediately upon written notice to buyer by Intuitive if buyer materially breach any term or condition of this license. Buyer agrees upon termination to promptly discontinue all use of and destroy the Software and all copies thereof (whether in tangible form or as installed on buyer equipment).

3 EXPORT LAW. The Software and related technology are subject to U.S. export control laws and may be subject to export or import regulations in other countries. Buyer agrees to strictly comply with all such laws and regulations and acknowledge that buyer have the responsibility to obtain such licenses to export, re-export or import as may be required.

4 U.S. GOVERNMENT BUYERS. The Software is a "commercial item" as that term is defined at 48 C. F.R. 2.101, consisting of "commercial computer software" and "commercial computer software documentation" as such terms are used in 48 C.F.R. 12.212. Consistent with 48 C.F.R. 12.212 and 48 C.F.R. 227.7202-1 through 227.7202-4, all U.S. Government end users acquire the Software with only those rights set forth therein.

This page intentionally left blank.

Table of Contents

Chapter 1 Introduction 1-1
1.1 How to Use this Manual 1-1
1.2 Compatibility 1-2
1.3 General Information 1-2
1.4 Important Regulatory Information 1-3
Clinical Benefits 1-6
Clinical Risks 1-6
Importer Address 1-6
1.5 General Warnings, Cautions, and Contraindications 1-7

Chapter 2 System Overview 2-1
2.1 Device Description 2-1
2.2 Surgeon Console 2-1
2.3 Patient Cart 2-3
2.4 Vision Cart 2-6
2.5 Endoscope and Instruments 2-7
2.6 Audio System 2-8
2.7 Troubleshooting Quick-references 2-9

Chapter 3 Configure Operating Room, Position System 3-1
3.1 Configure the Operating Room 3-2
3.2 Position Surgeon Console 3-5
3.3 Position Patient Cart 3-7
3.4 Position Vision Cart 3-8

Chapter 4 Connect System 4-1
4.1 Power Connections 4-1
Power Guidelines 4-2
4.2 Connect System Cables 4-2
System Cable Layout 4-4
Connect System Cables 4-4
4.3 Connect Endoscope Cable 4-7
4.4 Connect Electrosurgical Unit 4-8
Connect an Electrosurgical Unit to the System 4-9
4.5 Auxiliary Video and Audio Connections 4-10

Chapter 5 Startup 5-1
5.1 Start Up the System 5-1
5.2 Startup Sequence 5-1
Patient Cart 5-1
Surgeon Console 5-2
5.3 Power Button Color Indicators 5-2
5.4 Power Overview 5-3
5.5 Emergency Power Off 5-4
5.6 Component AC Power Switches 5-4
5.7 Guidelines on System Power 5-4

Chapter 6 Drape the System 6-1
6.1 Draping Overview 6-1
6.2 Deploy for Draping 6-3
Automated Deploy for Draping - Guided Setup 6-4
Manual Deploy for Draping 6-5

6.3 Column Draping Procedure 6-6
6.4 Arm Draping Procedure 6-8
6.5 Sterile Stow the Draped Patient Cart (Optional) 6-18
6.6 Remove the Patient Cart Drapes 6-19

Chapter 7 Set Up and Use Vision System 7-1
7.1 Vision System Components 7-1
7.2 Endoscope Features 7-3
Vision System Light Apertures 7-6
Endoscope Guidelines 7-6
Inspect the Endoscope 7-8
7.3 Connect the Endoscope to the Vision Cart 7-8
Connect the Endoscope to the Endoscope Controller 7-9
Dynamic Illumination 7-10
Endoscope Buttons 7-10
7.4 Endoscope Settings 7-11
Focus-free Endoscope 7-11
Digital Zoom 7-11
Working Distance 7-11
Targeting 7-12
7.5 Hand-held Endoscope Use 7-12
7.6 Endoscope Installation and Removal 7-14
Endoscope Cable Management 7-14
Endoscope Orientation 7-15
Endoscope Port Hopping Overview 7-16
Endoscope Installation 7-16
Remove and Change Endoscope 7-17
7.7 Endoscope Fogging and Intraoperative Cleaning 7-18
Endoscope Fogging 7-18
Intraoperative Endoscope Cleaning 7-19
7.8 Vision Cart Touchscreen 7-19
Arm Status from the Vision Cart Touchscreen 7-24
Endoscope Horizon Indicator 7-26
Off -Screen Indicator 7-26
Tool Association Icons 7-27
Take Photo 7-28
Telestration 7-29
7.9 Troubleshooting Image Quality 7-29
Image Too Bright or Dark 7-29
Correct Flickering Image 7-29
Correct Blurry Image 7-30
White Balance the Endoscope 7-30

Chapter 8 Prepare Patient and Place Ports 8-1
8.1 Position the Patient 8-1
8.2 Place Ports and Insert Cannulas 8-1
Port Placement Guidelines 8-2
Remote Center 8-4

Chapter 9 Patient Cart Use 9-1
9.1 Patient Cart Overview 9-1
Laser Indicators 9-1
Patient Cart Helm 9-3

Patient Cart Touchpad . . . 9-4
LED Status Indicators . . . 9-6
9.2 Patient Cart Positioning and Docking Overview . . . 9-9
Guided Setup . . . 9-9
Prepare for Positioning . . . 9-12
Deploy . . . 9-13
Position the Patient Cart . . . 9-15
Docking . . . 9-17
Targeting . . . 9-20
Docking and Arm Alignment after Targeting . . . 9-22
9.3 Manually Adjusting the Patient Cart Arms . . . 9-25
Manual Positioning Overview . . . 9-26
Instrument Clutch and Port Clutch . . . 9-27
Patient Clearance . . . 9-29
Boom Rotation . . . 9-30
9.4 Three-Arm Procedure . . . 9-32
9.5 Dual Docking . . . 9-33
9.6 EndoWrist Instruments . . . 9-35
9.7 Instrument Installation . . . 9-36
Manually Insert an Instrument . . . 9-37
Guided Tool Change . . . 9-38
9.8 Intraoperative Arm Management . . . 9-39
Work Behind Ports . . . 9-40
Arm-to-arm Interference . . . 9-40
Identifying and Resolving Instrument Collisions . . . 9-41
Increase Instrument Reach . . . 9-42
9.9 Instrument Removal . . . 9-45
Manual Grip Release . . . 9-47
9.10 Intraoperative Instrument Maintenance . . . 9-48
9.11 Manage Instrument Inventory . . . 9-49
View Uses Remaining . . . 9-49
9.12 Fluid Leakage Precautions . . . 9-50
9.13 Stow the Patient Cart . . . 9-50
Stow . . . 9-50
Sterile Stow . . . 9-51
9.14 Patient Cart Troubleshooting Quick-reference . . . 9-52

Chapter 10 Surgeon Console Use . . . 10-1
10.1 Surgeon Console Overview . . . 10-2
10.2 Set Up the Surgeon Console . . . 10-5
Manual Ergonomic Setup . . . 10-5
10.3 Surgeon Console Touchpad Controls . . . 10-7
Login, Settings, and User Accounts . . . 10-8
Instrument Tab . . . 10-30
Settings Tab . . . 10-32
Da Vinci Update Tool . . . 10-38
10.4 Surgical Controls . . . 10-42
10.5 3D Viewer Display . . . 10-47
Foot Pedal Activation Status Bar . . . 10-47
3D Viewer Messages . . . 10-47
Arm, Instrument, and Endoscope Information . . . 10-48
Arm and Instrument Status . . . 10-49

Arm Pop-up Information 10-50
Endoscope Status 10-50
Second Console Instrument Status Area 10-50
10.6 Integrated ERBE VIO dV 1.0 and VIO dV 2.0 Overview 10-51
VIO dV Settings 10-51
Adjust VIO dV 1.0 Settings on the Surgeon Console Touchpad 10-52
VIO dV Display Troubleshooting 10-53
Adjust VIO dV 2.0 Settings on the Surgeon Console Touchpad 10-54
Dual Generator Use 10-61
Troubleshooting 10-64
Activation Status in the 3D Viewer 10-65
Troubleshooting Activation Not Available 10-66
10.7 Dual Console Surgery 10-66
Dual Console Connection and Startup 10-66
Comparison Between Consoles 10-67
Dual Console Instrument Control Settings 10-67
Endoscope Control 10-69
Video Control 10-69
TilePro Control 10-69
Virtual Pointer (Dual Console Teaching Aid) 10-70
Virtual Pointer 10-71

Chapter 11 Shut Down and Store the System 11-1
11.1 Prepare to Shut Down the System 11-1
11.2 Remove the Patient Cart Drapes 11-1
11.3 Stow the Patient Cart 11-2
11.4 Stow the Vision Cart 11-2
11.5 Shut Down the System 11-2
Follow these steps to shut down the system: 11-2
Detaching the Blue System Cables 11-2
11.6 Store the System 11-3

Chapter 12 System Maintenance 12-1
12.1 Clean the System 12-1
12.2 Clean the Touchscreen Display 12-1
12.3 Preventive Maintenance 12-1

Appendix A OnSite for da Vinci Xi System A-1
A.1 General Information A-1
A.2 Introduction A-2
A.3 OnSite System Requirements and Connections A-2
A.4 Automatic Status and System Log Retrieval A-5
A.5 OnSite Servicing and Diagnostics A-6
Normal Mode A-6
Standby Mode A-6
Maintenance Mode A-6
System Service and Diagnostics A-7
A.6 Wireless Connectivity Option A-7
Wireless Overview A-7
Wireless Network Requirements A-8
Wireless Coexistence A-9
Common Wireless Devices Tested A-10
Devices Known to Interfere A-12

Wireless Connectivity Problems . . . A-13
A.7 IT Requirements . . . A-13
A.8 Electromagnetic Compatibility . . . A-15
A.9 Wireless Bridge Data . . . A-20
A.10 End-of-Service Deprovisioning . . . A-25
Removal of Stored Data . . . A-25

Appendix B System Troubleshooting . . . B-1
B.1 Customer Service . . . B-1
B.2 Convert to Open Surgery or Obtain Immediate Access to the Patient . . . B-1
B.3 Access the Event Logs . . . B-2
B.4 Troubleshooting the Patient Cart Drive . . . B-2
B.5 Unexpected Motion . . . B-4
B.6 System Power Issues . . . B-4
Check Connections . . . B-4
Hard-cycle Power On System . . . B-6
B.7 Restart the System . . . B-7
Restart from Automatic High Temperature Power Down . . . B-7
Cool Mode Restart from Individual Power . . . B-7
B.8 System Faults, Recoverable Faults, and Non-recoverable Faults . . . B-7
System Faults . . . B-8
Recoverable Faults . . . B-8
Disable Patient Cart Arms, Hand Controls, or Boom . . . B-8
Non-recoverable Faults . . . B-9
Emergency Stop – Surgeon Console . . . B-10
Emergency Stop – Patient Cart Helm . . . B-10
Emergency Power Off – Patient Cart . . . B-11
Battery Backup . . . B-11
Battery Low Condition . . . B-11
Troubleshoot a Non-responsive System . . . B-11
B.9 Troubleshoot the Endoscope Controller . . . B-12

Appendix C Technical System Information . . . C-1
C.1 Manufacturer Information . . . C-1
C.2 Compliance and Classifications . . . C-2
C.3 System Labels . . . C-3
C.4 Disposal Information . . . C-7

Appendix D Symbols, Icons, Audio Messages . . . D-1
D.1 Overview . . . D-1
D.2 Symbols and Icons Reference Table . . . D-1
D.3 Audio Messages (Voice Annunciation) . . . D-17

Appendix E System Specifications . . . E-1
E.1 Design Life . . . E-1
E.2 Power Requirements – Main Components . . . E-1
E.3 Power Specifications – Main Components . . . E-4
E.4 Power Specifications – Vision Cart Components . . . E-5
E.5 Power Specifications – Integrated Equipment . . . E-5
E.6 Laser Specifications – Patient Cart . . . E-6
E.7 Physical Dimensions . . . E-6
E.8 Environmental Specifications . . . E-7
E.9 Crate Dimensions . . . E-7

E.10 Electromagnetic Compatibility E-7
EMC Tables E-10
E.11 Wireless Communication E-16
Overview E-16
RFID Module and ZigBee Information E-16
RFID ACCRX01 and ACCRX02 . . . . . E-17
Wireless Connectivity Option Overview E-19
Wireless Coexistence E-20

Appendix F Video and Audio Connections F-1
F.1 Video and Audio Connections F-1
Vision Cart Video Outputs F-2
Video Processor Video Outputs F-2
Surgeon Console Video Outputs F-3
Audio Inputs and Outputs F-3
Video Inputs (TilePro) F-3
Core Connections Diagram F-4
F.2 Select Video Output F-4
Vision Cart Video Connections F-5

Appendix G Natural Rubber Latex G-1

Appendix H Representative Uses H-1
H.1 IS4000 Performance Data H-1
Bench Verification H-1
Human Factors H-11
H.2 Additional Performance Data H-12
IS3000 and IS4000 Performance Data H-12
Clinical Study Data - Inguinal Hernia Repair H-41
Clinical Study Data - Low Anterior Resection/Total Mesorectal Excision (LAR/TME) and Intersphincteric Resection (ISR) H-44
Clinical Study Data H-53
Umbrella Procedures H-53
Clinical Study Data H-72
Umbrella Procedure H-73
Ventral Hernia Repair H-79
Clinical Study Data H-94
Esophagectomy H-108
Heller Myotomy and Hiatal, Paraesophageal, and Sliding Hernia Repair H-117
Clinical Study Data - Hepatectomy H-124
Clinical Publications H-144

Appendix I Sterilization Methods I-1

Appendix J Glossary J-1

Index Index-1

Chapter 1 Introduction

Contents

1.1 How to Use this Manual 1-1
1.2 Compatibility 1-2
1.3 General Information 1-2
1.4 Important Regulatory Information 1-3
1.5 General Warnings, Cautions, and Contraindications 1-7

Da Vinci system users must follow all instructions for use supplied with the system, its components, instruments and accessories, including the Instruments and Accessories User Manual, the Reprocessing Instructions and any instructions for use (IFUs) provided with instruments or accessories.

1.1 How to Use this Manual

This manual uses the following conventions.

- Names of labeled items that appear on hardware or on screen are in bold (**Volume**).
- A greater than > sign indicates the path of progression through menu options (**Settings > Video Output**).
- Blue text is used for cross references. In electronic versions, cross references are active, clickable links.

Table 1.1 Note, Caution, and Warning

Symbol	Meaning
	Note: Highlights important information.
	Caution: Alerts the reader about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.
	Warning: Alerts the reader about a situation which, if not avoided, could result in death or serious injury.

This user manual provides information specific to the use of the da Vinci Xi system, also known as the Endoscopic Instrument Control System, Model IS4000 (referred to in this manual as the da Vinci Xi system or the system). The operating instructions and feature descriptions herein are specific to the software version listed in Equipment and Software Version on page ii.

Users must follow all instructions for use supplied with the system, its components, instruments and accessories, including the Instruments and Accessories User Manual, the Reprocessing Instructions and any instructions for use (IFUs) provided with instruments or accessories.

This user manual presents representative images of the system, instruments, accessories, and user interface. The representative images provide instruction on the use of the product. In some cases, the aesthetics or dimensions of the device shown in the representative images may be different from the product in use.

The following sections, including all Warnings, Cautions, System Labels, and symbols associated with the Surgeon Console, have information pertinent to the use of the Skills Simulator-only Surgeon Console:

- Cleaning Instructions (Chapter 12 System Maintenance on page 12-1)
- E.3 Power Specifications – Main Components on page E-4
- E.7 Physical Dimensions on page E-6
- E.8 Environmental Specifications on page E-7
- E.9 Crate Dimensions on page E-7
- Appendix F Video and Audio Connections on page F-1

The Skills Simulator-only Surgeon Console is compatible for use with the Skills Simulator only, and is not compatible for system use. For further information on use of the Surgeon Console for the Skills Simulator, see the *Skills Simulator User Manual*.

1.2 Compatibility

- Da Vinci Xi instruments and accessories are compatible with the da Vinci Xi System, unless otherwise noted.
- Intraoperative Table Motion (ITM) is compatible with the da Vinci Xi System.
- The column drape (PN 470341) is compatible with the da Vinci Xi System.
- The Instruments and Accessories User Manual covers both da Vinci Xi and da Vinci X instruments and accessories.
- Cleaning instructions are applicable to the da Vinci Xi system.

1.3 General Information

Contact Information

For Customer Service and Reporting of Complaints or Adverse Events

Use the following information for customer service, including ordering, reporting complaints or adverse events, general information regarding Intuitive or our products and services, if the system requires maintenance or service. Preventive maintenance is required and must be performed by authorized Intuitive personnel. There are no user-serviceable parts on the main system components, with the exception of system accessories. U.S. phones are staffed 24 hours a day, seven days a week.

In the U.S.
Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086 USA
Toll free: 1.800.876.1310
Direct: 408.523.2100
Fax: 408.523.2377

1.4 Important Regulatory Information

Essential Prescribing Information

- **Device Name:** Intuitive Surgical da Vinci Xi Endoscopic Instrument Control System (da Vinci Xi System) and Endoscopic Instruments.
- **Rx only:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Intended Use/Indications for Use

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Xi Surgical System Model IS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Precaution for Representative Uses

The demonstration of safety and effectiveness for the representative specific procedures did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

Representative Adult Uses

The following table shows the types of Representative Adult Use procedures. For more information on these procedures, see Appendix H Representative Uses on page H-1.

Table 1.2 Representative Adult Uses

Specialty	Representative Procedure	
General	• Nissen Fundoplication • Colectomy (Right, Left, Transverse, Total, Hemi And Sigmoidectomy) • Inguinal Hernia Repair • Small Bowel Resection • Rectopexy • Intersphincteric Resection (ISR) • Low Anterior Resection/Total Meso-rectal Excision (LAR/TME)	• Abdominoperineal Resection (APR) • Pancreatectomy (Partial, Distal, Segmental), Pancreaticoduode-nectomy (Whipple Procedure), Splenectomy, Cholecystectomy • Gastric bypass (Roux-en-Y) and Gastric Sleeve • Ventral Hernia Repair • Gastrectomy (Distal, Proximal, Partial, Subtotal, Total) • Esophagectomy • Heller Myotomy, Hiatal, Paraeso-phageal, and Sliding Hernia Repair, Dor Fundoplication, Toupet Fundoplication • Hepatectomy/Liver Resection
Gynecology	• Hysterectomy (Radical, Hyster-ectomy for Benign Disease) • Salpingectomy • Oophorectomy • Lymphadenectomy • Myomectomy	• Sacrocolpopexy • Endometriosis Resection • Adnexectomy • Omentectomy • Parametrectomy • Cyst Removal • Lysis of Adhesions
Thoracoscopic and Thoraco-scopically-assisted cardi-otomy procedures	• Mitral valve repair • Lobectomy • Mediastinal Mass Resection • Thymectomy	• Segmentectomy • Wedge Resection • Lymphadenectomy
Urology	• Prostatectomy (Radical) • Nephrectomy (Partial, Radical) • Cystectomy (Radical, Partial) • Pyeloplasty • Donor Nephrectomy	• Cyst Removal • Ureteral Implantation • Lysis of Adhesions • Lymphadenectomy

Note: For additional information and precautions related to cardiac tissue ablation, refer to the *Instruments and Accessories User Manual*.

Representative Pediatric Uses

The following table shows the types of Representative Pediatric Use procedures.

Table 1.3 Representative Pediatric Uses

Specialty	Representative Procedure
Pediatrics	• Pyeloplasty • Nissen Fundoplication

Additional Considerations–Precautions for Use in Smaller Patients

- Performance in pediatric surgical procedures is based on similarity of tasks performed in adult surgical procedures. As is appropriate with any surgical procedure, consideration must be given to patient size and workspace volume when using the system and instruments.
- As in any patient of smaller size, the possibility of misalignment of the remote center with the body exists. In order to minimize forces on the body wall, care must be taken to ensure the remote center is properly aligned with the body wall.

Training

WARNING: Only trained users and those who have developed adequate robotic skills to perform the tasks associated with each procedure should use the system. Training provided by Intuitive is limited to the use of the da Vinci system and does not replace the necessary medical training and experience required to perform surgery.

WARNING: Performance characteristics for conduct of totally endoscopic coronary artery bypass surgery (CABG) have not been fully established. The system should only be used for CABG when there is direct surgical access to the surgical field.

WARNING: Performance characteristics of autologous venous coronary artery bypass surgery (CABG) using the da Vinci Xi System have not been established.

CAUTION: The clinical evaluation of the da Vinci System supporting its use for mitral valve repair was not performed totally endoscopically. Introduction and manipulation of the endoscopic instruments were controlled by the da Vinci System through port incisions (<1 cm) while accessory technologies, for example, atrial retractor and cardioplegia line, etc., were introduced through a mini-thoracotomy. Performance characteristics for conduct of totally endoscopic mitral valve repair using the da Vinci System have not been established.

CAUTION: The friable nature of pulmonary tissue enhances the risk of vascular, bronchiolar, or other injury that will be difficult to control when using this device. Published clinical experience as well as clinical studies performed to support this marketing clearance have demonstrated that even surgeons considered expert in laparoscopy/thoracoscopy have substantial learning curves of 10 to 12 cases (Falk 2000).[1]

1. Falk, et al., Total endoscopic computer enhanced coronary artery bypass grafting, Eur J Cardiothorac Surg 2000, 17: 38-45.

Clinical Benefits

The overall benefits of the da Vinci® system include an expanded access to minimally invasive surgery for an increasing variety of procedures.

The potential clinical benefits of the da Vinci system as a minimally invasive tool include lower estimated blood loss, fewer complications and lower length of hospital stay when compared with the open approach and lower or similar rates of conversion, when compared to the laparoscopic approach. These clinical benefits/outcomes may depend on a number of factors, including, but not limited to patient characteristics, disease characteristics, surgeon experience, and hospital/ national patient care and recovery pathways.

Clinical Risks

Important Safety Information

Patients should talk to their doctor to decide if da Vinci surgery is right for them. Patients and doctors should review all available information on non-surgical and surgical options and associated risks in order to make an informed decision.

Serious complications may occur in any surgery, including da Vinci surgery, up to and including death. Serious risks include, but are not limited to, injury to tissues and organs and conversion to other surgical techniques which could result in a longer operative time and/or increased complications.

Individuals' outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics and/or surgeon experience.

Importer Address

European Union

Intuitive Surgical SAS
11 avenue de Canteranne
33600 Pessac, France

Switzerland

Intuitive Surgical Sàrl
1 Chemin des Mûriers
1170 Aubonne, Switzerland

1.5 General Warnings, Cautions, and Contraindications

The da Vinci System is to be used in accordance with this manual and should not be moved or used by any person who has not been trained by an Intuitive representative. Read all instructions carefully. Failure to properly follow instructions, notes, cautions, and warnings associated with this equipment may lead to serious injury or surgical complications for the patient. While these messages appear throughout the manual, this chapter provides some general precautions.

Any and all relative and absolute contraindications to endoscopic, thoracoscopic, laparoscopic, and transoral otolaryngology surgical techniques applicable to the use of conventional endoscopic surgical instruments apply to the use of the da Vinci Xi System. The device is not intended for use when endoscopic techniques are contraindicated.

WARNING: Use proper handling, cleaning, and sterilization of components within the sterile field to prevent breach of sterility.

WARNING: Use of the system in the presence of MRI, CT, diathermy, or Electromagnetic Security Systems has not been tested. The system should not be used in the vicinity of these devices to prevent potential patient or user harm.

WARNING: Inspect the instruments for broken, cracked, chipped, or worn parts. Do not use an instrument if it is damaged. Serious injury or surgical complications may occur to the patient.

WARNING: Be aware of hazards that may exist with over-insufflation, such as gas embolism.

WARNING: Failure to adhere to approved operating practices may result in damage to the instruments (surgical and endoscope). Examples of improper practices include: dropping of equipment, collisions, and improper cleaning and sterilization techniques. A damaged instrument may result in fragments falling into the patient.

Conversion to Non-Minimally Invasive Technique

WARNING: Always have a backup instrument available to complete the surgical procedure, in case of instrument failure or emergencies, to prevent delay in therapy, tissue injury, or patient harm.

CAUTION: Anatomical characteristics of a patient may preclude using minimally invasive techniques. Environmental or equipment failures may cause the da Vinci system to be unavailable. The surgical team should always have backup equipment and instrumentation available and be prepared to convert to alternative surgical techniques. The potential risk of such conversion should be communicated to the patient.

Endoscopic Procedure Precautions

Only physicians having adequate training and experience with endoscopic techniques should perform endoscopic procedures with the da Vinci Xi System. Medical literature should be consulted regarding techniques, complications, and hazards before performing any endoscopic procedure.

WARNING: Make sure there is contact between the endoscope cannula and the body wall. Lack of contact between the endoscope cannula and body wall can result in critical burn injury.

WARNING: Thermal hazards may exist from high temperatures. Eye hazards may exist from the high-energy light radiated by the endoscope and illumination system. Only personnel having adequate training and experience with the endoscope and illumination system should operate such equipment. All WARNING and CAUTION messages provided with the endoscope and illumination system must be followed.

WARNING: The system is not suitable for use in the presence of a flammable anesthetic mixture of air, oxygen, and nitrous oxide.

WARNING: The force feedback associated with the da Vinci system is different from feedback experienced when using conventional instruments. As with any endoscopic procedure, the surgeon should rely on visual cues to enhance force feedback.

WARNING: Do not clean instrument tips with another instrument intraoperatively, because this may damage the instrument. If an instrument tip requires cleaning, remove the instrument from the cannula and gently clean the tip.

CAUTION: When using the da Vinci system with insufflation, only CO_2 should be used as the insufflating gas. Insufflation should only be performed by personnel having adequate training and experience with this technique.

High Frequency Electrosurgery Precautions

The safe and effective use of endoscopic electrosurgery largely depends on factors solely under the control of the operating surgeon. Only surgeons having adequate training and experience with endoscopic electrosurgery should perform endoscopic procedures involving electrosurgery. The instructions, warnings and cautions provided with the electrosurgical unit must be followed or else serious injury or surgical complications may occur to the patient.

WARNING: To reduce the risk of explosion, do not use energy in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide and oxygen, or in close proximity to volatile solvents, such as ether or alcohol.

WARNING: Use the lowest power or effect setting possible for the minimum time necessary to achieve the desired effect, to prevent patient injury. See the Instruments and Accessories User Manual for detailed information on ESU settings.

WARNING: Be aware of potential sources of heat to prevent endoscope damage or burns.

WARNING: Avoid using instrument and cannula configurations that are electrically isolated from the body wall and that have the potential to enable the unintended transfer of monopolar energy, to prevent tissue injury and patient harm.

WARNING: Do not deliberately or unintentionally use one instrument to energize other instruments. Energizing other instruments may cause tissue damage inside or outside the field of view. This damage could occur at points near the tip or at the port site (cannula) of the energized instrument.

WARNING: Be aware of the risks associated with improper use of accessories related to energy delivery or grounding to prevent tissue injury.

WARNING: Electrosurgery may produce interference with internal or external pacemakers. Electrosurgery may cause these devices to enter an asynchronous mode or may inhibit pacemaker operation entirely. Consult the pacemaker manufacturer for further information when using electrosurgery in patients with cardiac pacemakers.

WARNING: The da Vinci monopolar electrosurgical instruments are designed for use with a maximum peak voltage of 3 kV (6 kV peak-to-peak). Only compatible electrosurgical units have been tested to ensure that they support this limit. To prevent procedure delay and patient harm, do not attempt to use the footswitch on the Surgeon Console with electrosurgical units that are not compatible for use with the da Vinci system.

WARNING: Always check the cables, electrosurgical unit, and instruments for insulation damage and proper function before use to prevent surgical delay and patient harm.

WARNING: To avoid inadvertent thermal damage to surrounding tissue and other hazards, observe the following.

- Ensure that the patient neutral pad is securely affixed to the patient, placed as close as possible to the operating field, and properly connected to the electrosurgical unit.
- For monopolar instruments, always use the lowest output setting that achieves the desired surgical effect while staying within 3kV maximum peak voltage. Maximum power levels to stay below this limit are listed in a table in the Instruments and Accessories User Manual.
- Do not deliberately or unintentionally use one instrument to energize other endoscopic instruments. Energizing other endoscopic instruments may cause tissue damage inside or outside the field of view. This damage could occur at points near the tip or at the port site (cannula) of the energized instrument.
- Secure and route the electrosurgical unit cable to the Intuitive instrument to prevent cable damage and unintended disconnection.
- Avoid patient contact with grounded metal parts.
- Place any monitoring electrodes as far as possible from the surgical electrodes or the patient neutral pad when high frequency (HF) surgical equipment and physiological monitoring equipment are used simultaneously on the same patient.
- Do not use flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen.
- Use only non-flammable agents for cleaning and disinfecting. If flammable agents are used for cleaning or disinfecting or as solvents, they must be allowed to evaporate before application of HF energy.

WARNING: The cables to the surgical electrode should be positioned in such a way that contact with the patient or other patient leads is avoided to prevent patient harm.

WARNING: Make certain that the electrosurgical unit audible output can be heard by the operating surgeon during electrosurgical unit use with the da Vinci System to prevent patient harm.

CAUTION: Avoid fire hazards, trip hazards, and alternate site burns when setting up energy instruments, to prevent user or patient injury.

Installation and Service Precautions

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: Do not use instruments repaired, refurbished, reconditioned, or serviced by a third-party, because the instrument may be damaged or its operation affected, and could cause injury to the patient or staff.

WARNING: No modification of this equipment is allowed.

Building Vibrations

It is possible for ambient vibrations in the building to be transmitted through the operating room floor to the instrument tips. When present, such vibrations may be more noticeable when using the system in procedures where cannulae are not inserted through the patient body wall. Be aware of this possibility when deciding where to install and when to use the system. The system has no specification for permissible levels of ambient vibration.

Floor Angle

The da Vinci Xi System must be installed on a level floor.

Laser Safety

Class 1 Laser Product: The Vision Cart circuit boards and Patient Cart may be equipped with optical communication transmitters, which have been evaluated and found to be in compliance with requirements found within 21 CFR (FDA-CDRH) and EN 60825-1 for Class 1 laser devices. The Patient Cart (PS4000) has been evaluated to IEC 60825-1 ED. 3 (2014).

WARNING: While Class 1 laser products are considered to be “eye safe” without the need for additional protection, when working around the circuit boards, the following general safety guidelines should be observed to reduce the risk of eye injury:

- Do not look or stare at optical fiber ports or optical fibers that are connected to a light source.
- Do not examine with optical instruments optical fiber ports or optical fibers that are connected to a source. The use of optical instruments (for example, a magnifying glass) may increase eye hazard.
- Adjustments, settings, maintenance, operational parameters, and procedures other than those specified and allowed herein and on the rating plate of the system may result in increased eye hazard.
- Do not attempt to perform any repair or maintenance on optical communications components. Repairs and maintenance outside that which is allowed herein must be performed only by an authorized repair facility.

WARNING: Use of controls, adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Transportation and Storage Precautions

When transporting or storing the system, the Patient Cart should have the instruments and endoscope removed, the setup joints folded-in toward the center column, and should be stowed as described in section 9.13 Stow the Patient Cart on page 9-50. The Vision Cart should always have the brakes released and the monitor stowed during transport. The Surgeon Console should always have both brakes released during transport. Always use the handles on the sides of the Surgeon Console to move the console. Always release the brakes and use the handles (on the Helm) of the Patient Cart to move the cart. Good practice is to watch for overhead obstacles while moving the equipment. For instructions on moving the Patient Cart, see section 3.3 Position Patient Cart on page 3-7.

Instrument and Endoscope Isolation Precautions

The cannula mounts, sterile adapters, and instrument insulation are isolation barriers to electrical current. These parts need to be maintained unmodified for patient safety.

Arm Positioning Precautions

WARNING: Do not place the instrument or endoscope cables through or over the Patient Cart arms when setting up or interacting with the system. Doing so may cause unintended motion of instruments or endoscopes, which may result in patient injury.

WARNING: Check for clearance between the patient and the Patient Cart arms throughout the surgery to prevent patient harm.

CAUTION: Be familiar with the location of all system buttons and understand their expected behavior across system modes, to prevent patient or user harm, or confusion due to unanticipated mode change.

CAUTION: Adjusting a Patient Cart arm may result in the instrument or cannula tip moving, which may lead to patient harm.

CAUTION: When activating the port clutch or instrument clutch buttons, keep fingers clear of the joints located on the arms to avoid injury.

This label indicates a pinch or crush hazard and appears in the following locations:



- Patient Cart: Above the port clutch button, at the arm joints, and at the top of column on the arms.
- Surgeon Console: On the top of the column, rear, and sides of the 3D viewer, and on the sides and top of the linkages connecting the 3D viewer to its supports.

CAUTION: Use proper strain relief on instruments, endoscopes, or accessories with external attachments, to avoid exerting external forces on an arm that could cause unintended motion.

CAUTION: Do not place endoscope cables or accessory cables over the Patient Cart arms. They can limit the range of motion of the arm, or become pinched or damaged.

Accessory Equipment Interconnection

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (that is, IEC 60950-1 or 62368-1 for information technology equipment and IEC 60601-1 for medical equipment.) All configurations shall comply with the requirements for medical electrical systems in standard IEC 60601-1. Anyone connecting additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with requirements of IEC 60601-1. If you have any questions, contact your Intuitive representative.

WARNING: Leakage current from interconnected electrical equipment may exceed safe levels. In order to maintain patient and user safety, it is important to interconnect only with devices in compliance with IEC 60601-1 requirements. It is the responsibility of the user to ensure that any interconnected equipment not supplied by Intuitive maintains compliance with IEC 60601-1 requirements. If current leaks, patient or user harm can result.

WARNING: Do not modify the cannula mounts, sterile adapters, endoscopes, or instruments. Modifications can result in electrical hazards or performance degradation.

Potential Equalization

Where required by national laws or local regulations, equipotential bonding of equipment may be accomplished by connecting an potential equalization conductor to the equipotential terminals located near the mains inlet on each sub assembly of the system. See the requirements for medical electrical systems in standard IEC 60601-1.

Viewing 3D Images Precaution

The following general caution derives from the general impact on some people of viewing 3D images, which is related to viewing certain flashing images or lights in video or television images. People with a history of epilepsy or stroke (including family history), should consult with a medical specialist before viewing 3D images in the 3D viewer of the Surgeon Console, or external third-party 3D monitors.

CAUTION: Some users who view 3D images in the 3D viewer or external third-party 3D monitors may experience seizures, altered vision, lightheadedness, dizziness, involuntary movements such as eye or muscle twitching, confusion, nausea, loss of awareness, convulsions, cramps, or disorientation. Viewing 3D images in the 3D viewer or external third-party 3D monitors may also cause motion sickness, perceptual after effects, eye strain, and decreased postural stability. Users that experience any of the above symptoms, immediately discontinue use of this device and do not resume until symptoms have subsided.

End of Section

Chapter 2 System Overview

This chapter introduces the system components in the following sections:

Contents

2.1 Device Description 2-1
2.2 Surgeon Console 2-1
2.3 Patient Cart 2-3
2.4 Vision Cart 2-6
2.5 Endoscope and Instruments 2-7
2.6 Audio System 2-8
2.7 Troubleshooting Quick-references 2-9

2.1 Device Description

The da Vinci Xi system (also referred to in this document as the system) is designed to enable complex surgery using a minimally invasive approach. The system consists of a Surgeon Console, a Patient Cart, and a Vision Cart and is used with an endoscope, da Vinci Xi EndoWrist instruments, and accessories. Setup and intraoperative use may require sterile and non-sterile tasks performed by the following users: surgeon, circulating nurse (non-sterile user) or scrub nurse (sterile user).

Figure 2.1 Main Components of the system

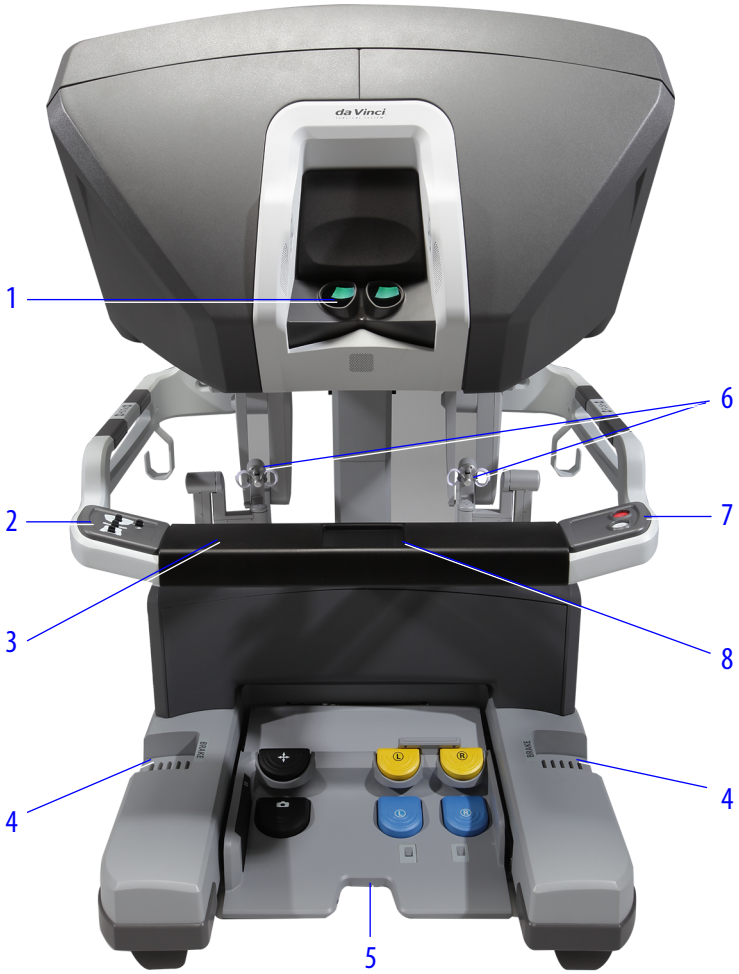


Surgeon Console Patient Cart Vision Cart

2.2 Surgeon Console

The surgeon seated at the Surgeon Console, controls all movement of the instruments and endoscope by using two hand controls and a set of foot pedals. The surgeon views the endoscopic image on a three-dimensional (3D) viewer, which provides a view of patient anatomy and instrumentation, along with icons and other user interface features. See Chapter 10 Surgeon Console Use on page 10-1 for more information.

Figure 2.2 Surgeon Console



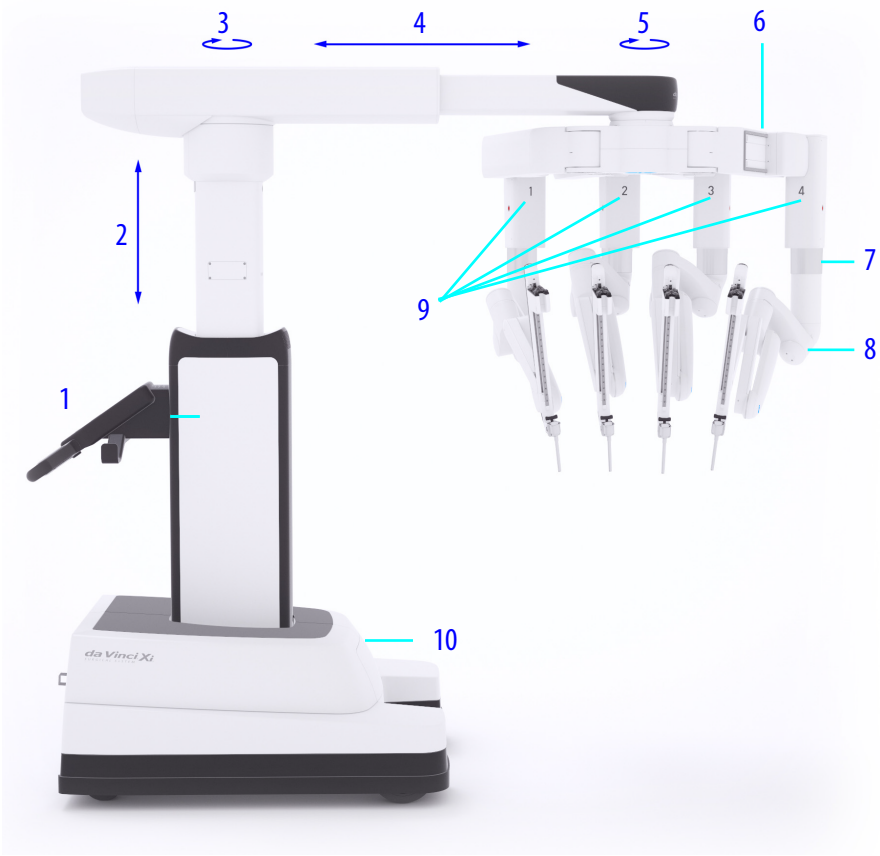
1. **3D Viewer:** The high-resolution stereo viewer consists of two independent LCD displays.
2. **Ergonomic controls:** for adjusting the ergonomics of the Surgeon Console.
3. **Armrest:** Contains a touchpad user interface, ergonomic controls, Power, and Emergency Stop buttons.
4. **Brakes:** There are two brakes located on the Surgeon Console base.
5. **Footswitch Panel:** Houses foot pedals used to activate various system modes, such as endoscope control, as well as activate various instrument functions, such as monopolar and bipolar cautery.
6. **Hand controls:** The two hand controls are positioned below the magnified, three-dimensional image of the surgical site. The surgeon grasps the hand controls while viewing the surgical site. The instrument tips, as seen in the 3D Viewer, appear aligned with the surgeon's hands at the controls.
7. **Power and Emergency Stop buttons**: The Power button turns the system on or off. The Emergency Stop button stops system operations.
8. **Touchpad:** The Surgeon Console user interface.

2.3 Patient Cart

The Patient Cart is positioned at the operating room table and contains four arms that are positioned with respect to the target patient anatomy. The endoscope attaches onto any arm and provides a high resolution, 3D view of the patient anatomy. The boom is an adjustable, rotating support structure that moves the arms into a position appropriate for the target anatomy and patient position. The column moves the boom up or down to adjust the height of the system. The patient-side assistant attaches and detaches the endoscope and EndoWrist instruments intra-operatively. See Chapter 9 Patient Cart Use on page 9-1 for more information.

⚠ **CAUTION:** Always use caution when moving large equipment to prevent user or patient injury.

Figure 2.3 Patient Cart main components



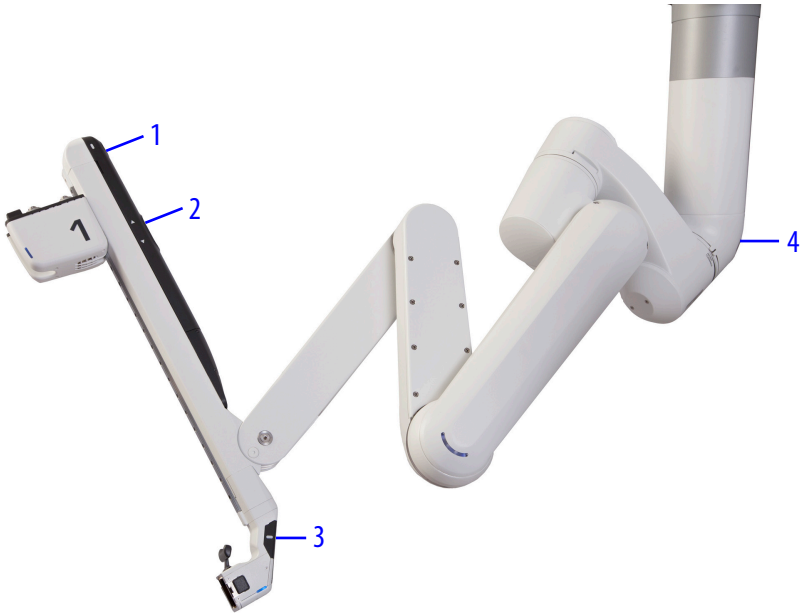
1. **Helm:** The helm (Figure 2.4) includes the handlebars with cart drive enable switches, a touchpad, two joysticks, power and Emergency Stop buttons, a cable holder, and a battery indicator. The handlebars and cart drive enable switches are used to maneuver the Patient Cart around the OR. The helm includes a touchpad for system messages and guided menu options, while the joysticks include boom position control and boom height control to manually orient the arms, boom and column. For details on moving the Patient Cart, see Chapter 9 Patient Cart Use on page 9-1.
2. **Column:** The column moves the boom up or down.
3. **Boom pivot:** Alignment and extension of the boom along the column.
4. **Boom:** The boom is an adjustable, rotating support structure for the arms.
5. **Boom rotation:** Rotation of the boom cluster of arms.
6. **Flex joint:** A joint that allows for the arm spacing to be adjusted.
7. **Arm height joint:** A joint that allows for the arm height to be individually adjusted.
8. **Patient clearance joint:** a joint that allows for adjustment of the arm to increase patient clearance.
9. **Arm (1,2,3,4):** The four Patient Cart arms (arms), hold and move the endoscope and instruments. The distal end attaches to the cannula. The arms include setup joints that allow the user to connect the arms to the cannulae during setup.
10. **Base:** The base includes a motorized cart drive for positioning and transportation, the Patient Cart electronics, and a connector panel.

Figure 2.4 Patient Cart Helm



1. Touchpad
2. Emergency Stop button
3. Cart drive enable switches
4. Boom position control
5. Battery LED indicator
6. Power button
7. Cable holder
8. Boom height control
9. Handlebars

Figure 2.5 Arm controls



1. **Instrument clutch:** User initiated movements to advance or retract the endoscope or instrument tip within the surgical site. User initiated movements of the arm about the remote center.
2. **Patient clearance:** Used to adjust the arm angle.
3. **Port clutch:** Used to reposition the arm to resolve and avoid potential arm interference during the procedure. Also used to raise or lower the boom, space the arms together or apart (like a fan), or reduce tension at the port site. Examples include, bringing the arm to the cannula for docking, or stowing an arm for a 3-arm procedure. For details on setting up for a 3-arm procedure, see 9.4 Three-Arm Procedure on page 9-32.
4. **Boom Rotation:** Used to rotate the boom (cluster of arms).

For further details on moving the arms manually and detailed descriptions of the Patient Cart features, see 9.1 Patient Cart Overview on page 9-1.

2.4 Vision Cart

The Vision Cart includes the supporting electronic equipment such as the light source and video and image processing equipment for the endoscope and the main electronic and software processing units. The Vision Cart also has a touchscreen to view the endoscopic image and adjust system settings. See Chapter 7 Set Up and Use Vision System on page 7-1 for more information.

Figure 2.6 Vision Cart main components and electronic equipment



1. **Touchscreen:** The touchscreen monitor provides a view of the surgical site from the patient-side and a set of controls for endoscope and video configurations.
2. **Endoscope Controller:** Contains a high-intensity light source to illuminate the surgical site and the electronics for processing the video images from the endoscope.
3. **System electronics (Core):** Contains the electronics for advanced processing of the video image, system control algorithms, and control of ESUs when the surgeon uses the instrument function foot pedals.
4. **Accessory Shelves:** Shelving units for accessory equipment, such as insufflators.
5. **ERBE VIO® dV:** Integrated electrosurgical unit (ESU) for instrument activation that can be used with robotic and laparoscopic instruments. For further information on the ERBE VIO dV (VIO dV), including use with da Vinci instruments, see the Instruments and Accessories User Manual.
6. **Video Processor:** Receives and processes video input from the endoscope and sends it through the system electronics to the touchscreen and 3D viewer.
7. **Tank holders:** Two tank holders support use of an insufflator. To accommodate various size tanks, the tank holders have adjustable straps. The tank holders can support two tanks, each weighing up to 50 lbs. (22.32 kg).

2.5 Endoscope and Instruments

The 8 mm endoscope is available in 0° and 30° tip angles. See Chapter 7 Set Up and Use Vision System on page 7-1 for more information.

Figure 2.7 Endoscope



EndoWrist instruments give surgeons natural dexterity and greater than natural range of motion, compared to unaided human hands, allowing for greater precision when operating in a minimally invasive environment. EndoWrist instruments, when used with the da Vinci, are designed to support rapid and precise suturing, dissection, and tissue manipulation. See 9.6 EndoWrist Instruments on page 9-35 and the Instruments and Accessories User Manual for more information.

Figure 2.8 EndoWrist instruments



2.6 Audio System

The audio system consists of a set of microphones and speakers installed on both the Patient Cart and Surgeon Console, used for voice communication between the OR staff and the Surgeon Console operator. In addition, the audio system produces a variety of audible sounds (such as error tones), and voice annunciation messages (in English only). For further explanation of voice annunciation messages, see D.3 Audio Messages (Voice Annunciation) on page D-17.

To adjust the volume on the Patient Cart speakers, or mute and unmute the Patient Cart microphone, see 7.8 Vision Cart Touchscreen on page 7-19.

To adjust the volume on the Surgeon Console speakers, or mute and unmute the Surgeon Console microphone, see 10.3 Surgeon Console Touchpad Controls on page 10-7

2.7 Troubleshooting Quick-references

Use the following information if the system requires maintenance or service. U.S. phones are staffed 24 hours a day, seven days a week.

In the U.S.

Toll free: 1.800.876.1310

- B.1 Customer Service on page B-1
- B.2 Convert to Open Surgery or Obtain Immediate Access to the Patient on page B-1
- B.3 Access the Event Logs on page B-2
- B.4 Troubleshooting the Patient Cart Drive on page B-2
- B.5 Unexpected Motion on page B-4
- B.6 System Power Issues on page B-4
- B.7 Restart the System on page B-7
- B.8 System Faults, Recoverable Faults, and Non-recoverable Faults on page B-7
- B.9 Troubleshoot the Endoscope Controller on page B-12

End of Section

Chapter 3 Configure Operating Room, Position System

This chapter explains how to arrange the da Vinci system (also referred to as the system) components in the operating room (OR) for safety, efficiency, and ergonomic benefit. The following subjects are covered:

Contents

3.1 Configure the Operating Room 3-2
3.2 Position Surgeon Console 3-5
3.3 Position Patient Cart 3-7
3.4 Position Vision Cart 3-8

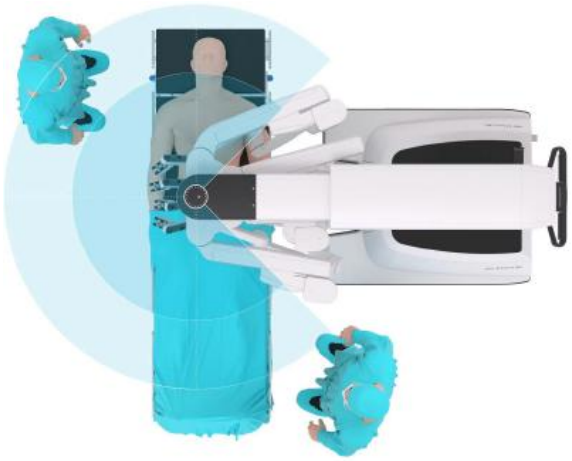
3.1 Configure the Operating Room

WARNING: Properly handle and clean the components within the sterile field to prevent damage to the instrument tip, resulting in patient harm due to unintended instrument motion or instrument component breaking off and falling into the patient.

- Operating rooms may vary in size and shape. Consider access to doors, outlets and overhead structures.
- Room restrictions may necessitate an alternate setup.
- For specialty-specific Patient Cart approaches, see published Intuitive Specialty Guides. Contact an Intuitive representative for available Specialty Guides.

To ensure maximum patient-side access, position the Patient Cart so it is on either side of the patient. The da Vinci system allows up to 270 degrees of patient access.

Figure 3.1 270 degree patient access example



The Patient Cart can be placed anywhere around the patient. The Guided Setup deployment settings offer positioning guidance (see Guided Setup on page 9-9). For procedures where the target anatomy is off mid-line, place the Patient Cart on the same side of the patient as the target anatomy.

Avoid setting up the system with the boom rotated 180 degrees, rotated to be opposite the base (Figure 3.2). In this configuration, access to the patient is limited, assistant access is constrained, and the assistant is often with their back close to the sterile draped column.

Figure 3.2 180 degree rotation



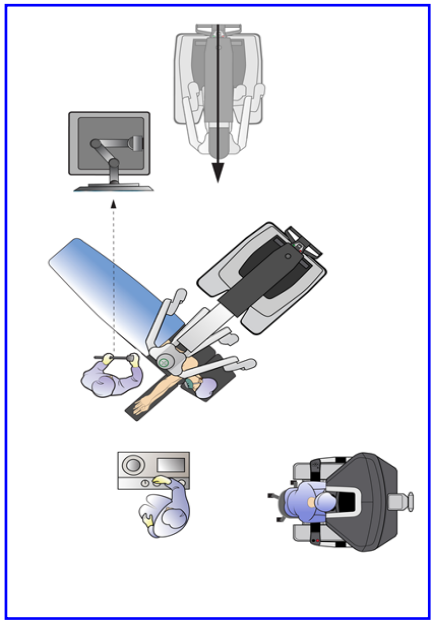
1. Place the Patient Cart opposite of the anesthesia cart (anesthesia) at the beginning of the procedure to minimize movement of anesthesia. Typically, this places the Patient Cart nearest the patient's feet.
2. Place the Vision Cart on either side of anesthesia or the Patient Cart.
   - Consider cable and cord connections.
   - Consider touchscreen visibility. The OR staff should have direct line of site to the touchscreen to view Guided Setup prompts and other messages.
3. Position the Surgeon Console in the non-sterile field.
   - Ensure that the Surgeon Console operator (surgeon) has direct line of sight to the operative field.
   - Ensure that the surgeon can communicate with the patient-side assistant(s).

Special considerations for procedures with off mid-line target anatomies (for example, in the cardiac, renal, and lower abdominal regions):

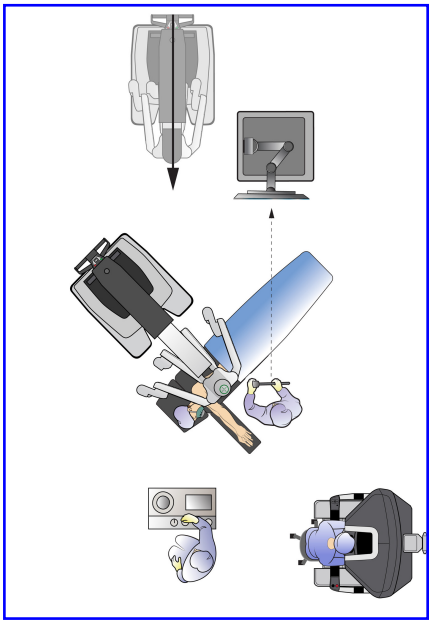
- Place the Patient Cart opposite of anesthesia.
- Consider a 45 degree patient rotation to allow side access to the Patient Cart, to minimize movement of anesthesia and the Patient Cart, and to provide the most patient-side access.

Figure 3.3 Examples: 45 degree patient rotation for left or right access

Example: patient left



Example: patient right



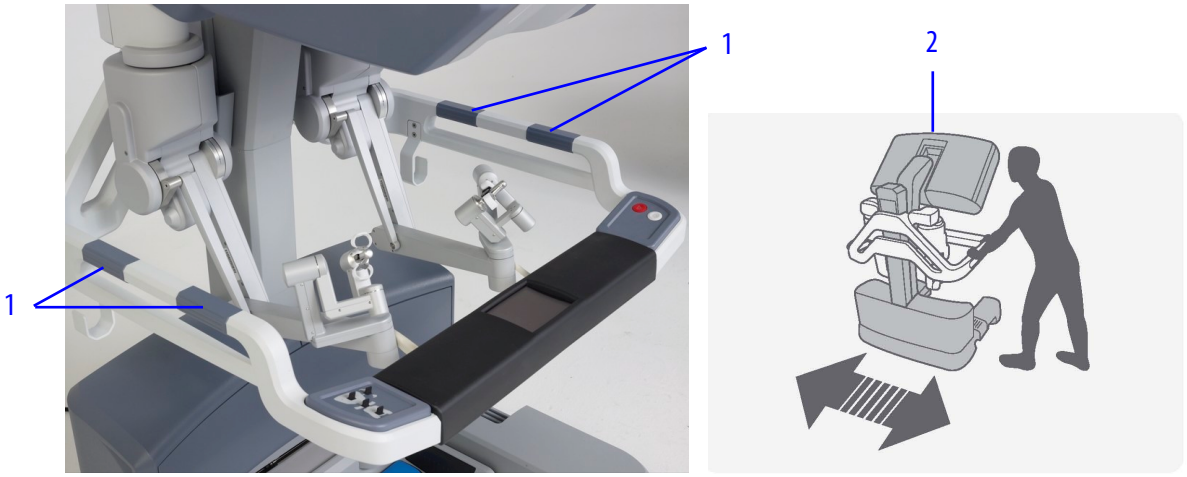
3.2 Position Surgeon Console

The Surgeon Console is placed outside of the sterile field. When possible, orient the Surgeon Console so the Surgeon Console operator has a view of the operative field and a clear line of communication with the Patient Cart operator.

Push from the Side Only

Use the handles on either side of the Surgeon Console for moving or positioning. Labels say “PUSH” near the handles for pushing on both sides.

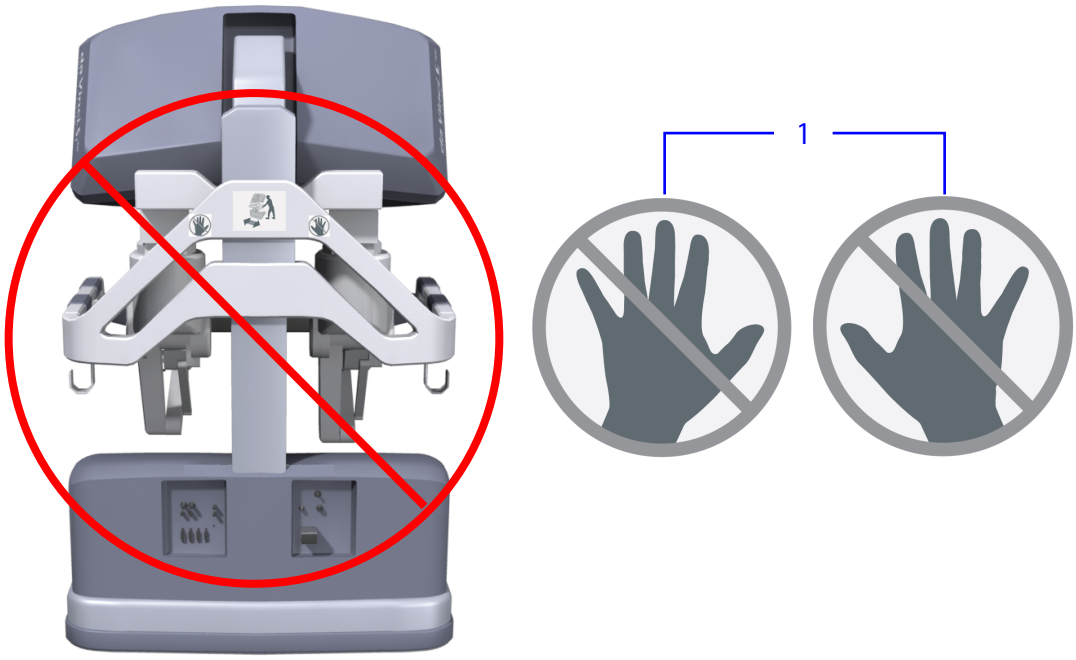
Figure 3.4 Push from either side using handles



1. Surgeon Console handles
2. Label on Surgeon Console: Move Surgeon Console using handles on side

Do not push or pull the Surgeon Console from the back or the front. A label near the top of the pillar on the back illustrates the correct way to move the console. Separate “no hands” labels on both lateral supports discourage placing hands there to move it.

Figure 3.5 Do not push or pull Surgeon Console from back or front

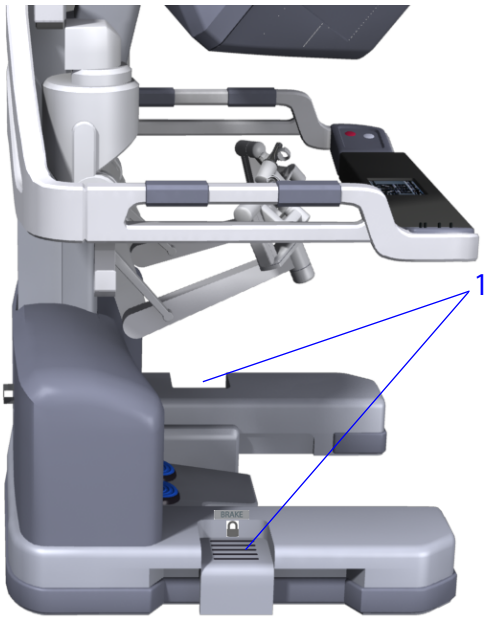


1. Labels on Surgeon Console: Do not move Surgeon Console from the back

Set Brake When Positioned

Set the brakes on the Surgeon Console once it is positioned for surgery.

Figure 3.6 Surgeon Console brakes



1. Brakes



- Step on the brake pedal to apply that brake; the “BRAKE” label and lock symbol is visible when the pedal is depressed, indicating the brake is applied. Brakes are located on each side of the base on the Surgeon Console (Figure 3.6).
- Only one brake needs to be activated to lower the footswitch panel. When possible, apply both brakes for best stability.
- Step on the depressed brake to release it. Both brakes must be released to raise the footswitch panel and enable Surgeon Console transport.

3.3 Position Patient Cart

The Patient Cart has a motorized drive that enables transport of the unit. The Patient Cart is moved into the sterile field for surgery. It takes two people to safely move the Patient Cart. One person operates the motor drive. The second person (positioned opposite the first) guides the driver to ensure the arms and cart do not collide with any obstacles.

- **For Draping:** Dedicate a space in the room where the Patient Cart can be draped before moving it into place for surgery. This should be an area where it will not easily contact non-sterile objects or impede traffic.
- **For Surgery:** Once the Patient Cart is draped and the patient is positioned, prepared and ports are placed, drive the Patient Cart into the sterile field (see Patient Cart Helm on page 9-3 below).
- **Brakes:** The brakes lock the Patient Cart into place to prevent movement during surgery. The Patient Cart brakes automatically engage when the motor drive is not in use.
- **Stabilization Feet:** To prevent motion, four stabilization feet automatically deploy at the base of the cart when a cannula is docked.

The Patient Cart operates at variable speed settings. The top speed is limited based on the position of the Patient Cart. For example, the maximum speed is allowed when the system detects the proper stow position for transport.

WARNING: Follow proper cart drive procedures and be aware of surroundings when moving the cart. Failing to do so may cause injury to operators or other personnel.

WARNING: To prevent injury to the user or patient, avoid collisions during cart drive operation in both motorized and manual modes.

Patient Cart Helm

Figure 3.7 Patient Cart Helm controls and indicators



1. Touchpad
2. Emergency Stop button
3. Cart drive enable switches
4. Boom position control
5. Battery LED indicator
6. Power button
7. Cable holder
8. Boom height control
9. Handlebars

Move the Patient Cart by grasping the handlebar and cart drive enable switches and pushing or pulling in the intended direction. The motor drive adjusts its speed to how hard you push. For detailed steps to position the cart for surgery, see 9.5 Dual Docking on page 9-33.

3.4 Position Vision Cart

Position the Vision Cart just outside of the sterile field. The Patient Cart operator should be able to easily view the Vision Cart components and touchscreen. Follow these instructions to transport and stow the Vision Cart.

WARNING: Always use caution when moving the Surgeon Console, Vision Cart, or Patient Cart to prevent injury to the user or patient.

CAUTION: Stow touchscreen and close rear door before moving the Vision Cart to avoid a tip or collision hazard.

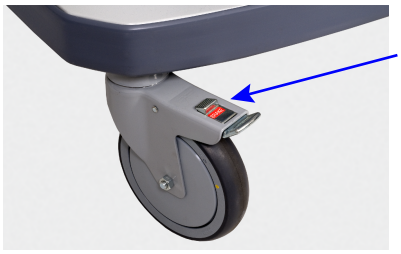
Transport or Position the Vision Cart

1. Close the rear door of the Vision Cart.

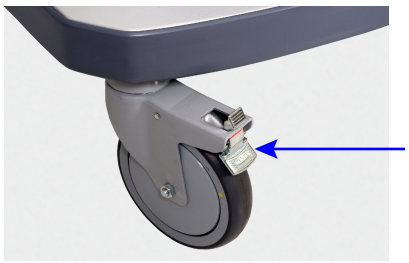
2. Stow the touchscreen in the transport configuration.



3. Unlock all Vision Cart wheel locks and position the cart for surgery.



4. Push the tab down on all four wheels to lock them into place.



End of Section

Chapter 4 Connect System

This chapter explains how to connect the individual system components, including:

Contents

4.1 Power Connections 4-1
4.2 Connect System Cables 4-2
4.3 Connect Endoscope Cable 4-7
4.4 Connect Electrosurgical Unit 4-8
4.5 Auxiliary Video and Audio Connections 4-10

Note: The only connections on the back of the Vision Cart that should be accessed are the power cords, blue system cables, auxiliary device cables, and audio/video cables as described in this chapter. Other cables on the back of the Vision Cart should remain connected at all times and should only be accessed by authorized Intuitive personnel.

4.1 Power Connections

Connect the AC power cords of the Surgeon Console, Patient Cart, and Vision Cart to wall outlets. To support continued use of the da Vinci system (referred to in this document as the system) in case of a site power failure, use wall outlets (often red) supported by backup power. Ensure adequate power is available at each wall outlet according to the table below:

Table 4.1 System Power Cords and Power Requirements

System Component	Cord Length	Power Requirement	Standby Power Draw
Surgeon Console	25 ft (7.6 m)	1000 VA Continuous 8.4 A at 115 V~ 4.2 A at 230 V~	95 VA 0.7 A at 115 V~ 0.35 A at 230 V~
Patient Cart	25 ft (7.6 m)	1200 VA Continuous 7.5 A at 115 V~ 3.8 A at 230 V~	75 VA 1.0 A at 115 V~ 0.3 A at 230 V~
Vision Cart	25 ft (7.6 m)	1500 VA Continuous 12 A at 115 V~ 6 A at 230 V~	145 VA 2.0 A at 115 V~ 1.2 A at 230 V~

WARNING: Follow the provided instructions to properly connect the generator to power, to prevent tripping the circuit breaker, and causing a deviation in workflow, or patient injury.

CAUTION: Do not use an extension cord with any system components to prevent loss of power due to circuit overload.

Note: Before first use, connect the Patient Cart to a wall outlet for at least 2 to 2.5 hours to allow the backup battery to fully charge.

Power Guidelines

- Cooling fans on the Patient Cart and Vision Cart run continually when either is connected to AC power. This is part of normal operation.
- The Patient Cart should remain connected to AC power when not in use to ensure the backup battery stays fully charged.
- The Patient Cart battery should be adequately charged. If not, an error message appears on the monitors. The error can be overridden if the Patient Cart is connected to AC power.
- The power cord plug of each cart provides electrical isolation from its power source in the operating room (OR). Position each cart and power cord so that its plug can be easily disconnected from the OR power source.

4.2 Connect System Cables

WARNING: Follow good cable management practices (for example, ensuring the cables are not placed on the Patient Cart arms or not positioned such that they are a tripping hazard, etc.). Failing to do so could lead to patient harm resulting from inadvertent movement of the endoscope or instruments, loss of instrument control, or loss of camera visualization.

The system cables are 65.6 ft. (20 m) in length and should be kept attached to the Vision Cart.

Figure 4.1 System cables



Figure 4.2 Cable end caps



End cap on system cable



End cap removed from system cable

The system cables:

- Are identical and can connect to either the Surgeon Console or Patient Cart
- Pass video, audio, and data during system operation
- Are stored on the cable hook located on the side of the Vision Cart

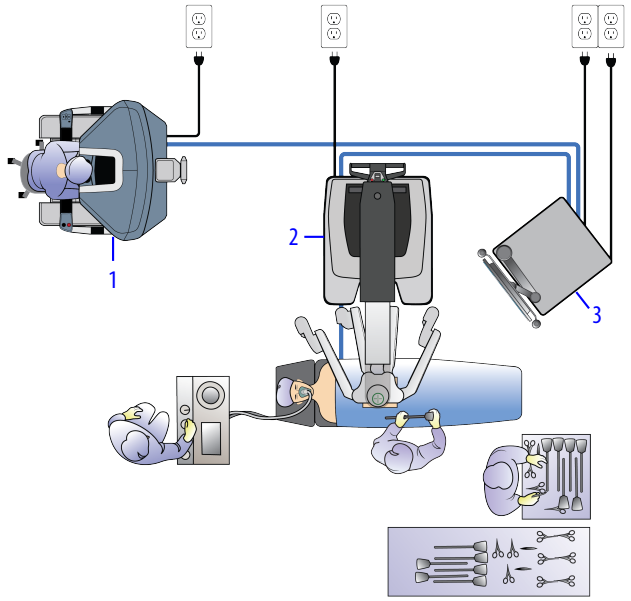
Note: Once the system is connected and powered on, the system cables should not be unplugged until the system has completely powered down. If the system cables become unplugged during use, a non-recoverable fault will occur. To restore system functionality, plug in the cable, remove all instruments, and restart the system. (See Non-recoverable Faults on page B-9 for more information on Restarting the System During a Procedure due to a non-recoverable fault.)

Note: The system cables have a fiber-optic core. Care should be taken to avoid bending the cable, as kinks can damage the cable and may prevent system operation. The minimum safe bend radius is 1 inch (2.54 cm). Take care to avoid stepping on the cable, since this can damage it.

System Cable Layout

The cables should be arranged so that they are out of the path of OR traffic, including other equipment, to avoid damaging the cables or creating an obstacle or hazard. The location of the cables should also facilitate easy movement of the Patient Cart between its preoperative (draping) and intraoperative locations.

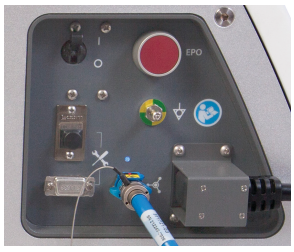
Figure 4.3 Laying out the system cables



1. Surgeon Console
2. Patient Cart
3. Vision Cart

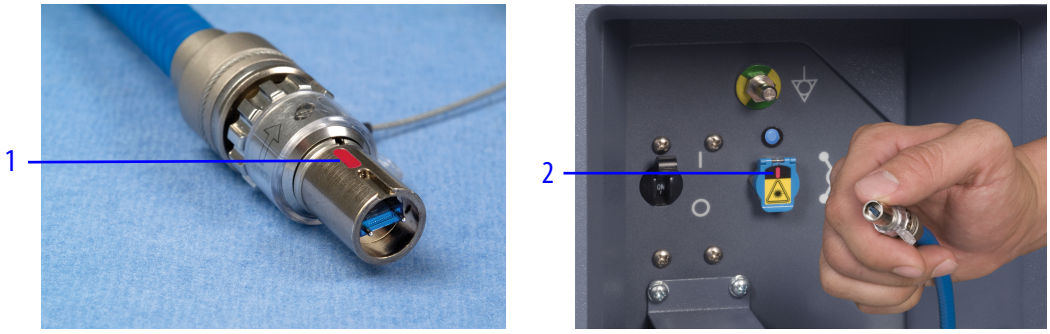
Connect System Cables

Figure 4.4 System fiber connections

Surgeon Console connection	Patient Cart connection — with system fiber strain relief	Patient Cart connection — without system fiber strain relief	Vision Cart Video Processor connection to Core— do not remove!
			

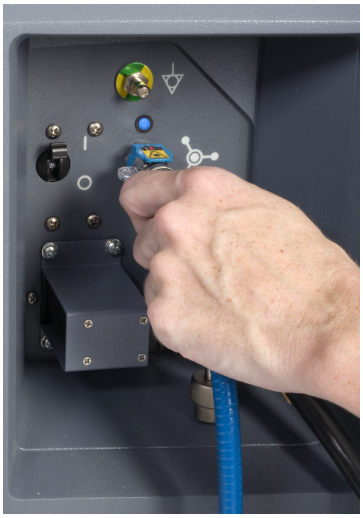
1. Remove the cable protective caps, inspect the cable connectors, and system receptacle for debris or bent pins.

2. Open the receptacle cover for each of the system fiber receptacles.
3. Connect the system cables between the components as shown in Figure 4.3 and the following steps.
   a. Line up the red mark on the cable connector with the red mark on the matching receptacle.



1. Red alignment mark on cable
2. Align red mark on the connector with the red mark on the cable

   b. Flip up the receptacle cover and insert the connector. An audible click indicates when the cable engages properly.



   c. Gently pull on the connector to verify the cable is fully seated.



Note: The protective metal caps attached to each system cable should be installed on cable ends at all times when not connected to the system.

4. If the Patient Cart has a system fiber strain relief, insert the strain relief ball into the strain relief socket.



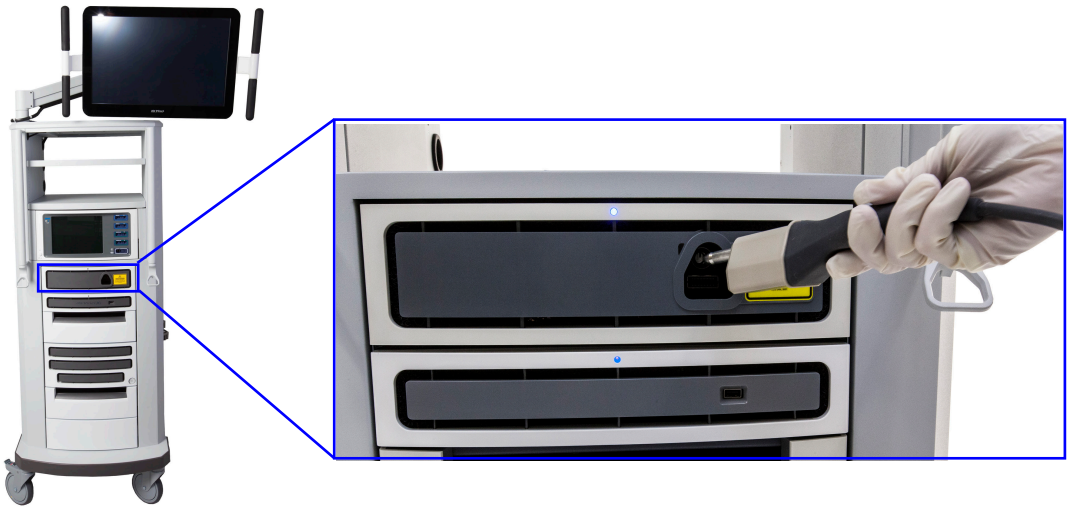
4.3 Connect Endoscope Cable

Note: Do not route the endoscope cable in any pinch points.

WARNING: The surface beneath the endoscope connector cover is non-sterile (see Figure 7.2). Contacting the endoscope connector to a sterile component could cause a breach in sterility, which may result in patient infection or immunologic reaction or infection.

The endoscope must be sterilized before each use according to the Reprocessing Instructions User Manual and handled only by a person prepared to work in the sterile field. Plug the endoscope cable into the receptacle on the Endoscope Controller (located on the Vision Cart) as shown.

Figure 4.5 Connecting the endoscope cable



Note: It is physically possible to install more than one endoscope on the arms. However, only the endoscope connected to the Endoscope Controller sends video to the 3D viewer and touchscreen monitor. If more than one endoscope is installed on the Patient Cart, a system message appears indicating that only one endoscope will send video.

The endoscope can also be used hand-held for pre-operative exploration and cannula insertion. See 7.5 Hand-held Endoscope Use on page 7-12.

For more information on vision system use, see Chapter 7 Set Up and Use Vision System on page 7-1.

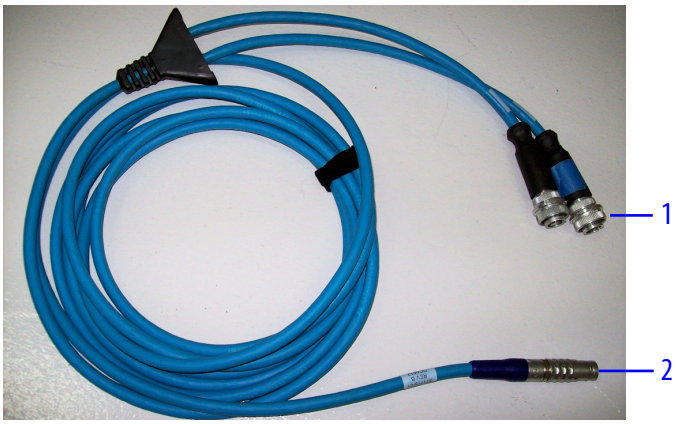
4.4 Connect Electrosurgical Unit

CAUTION: Ensure proper electrosurgical unit (ESU) cable connection. An improperly connected or disconnect cable can prevent the ESU from working.

Compatible electrosurgical units can be used after connecting the appropriate energy activation cable to any of the auxiliary connectors on the rear of the Vision Cart. Attach up to three electrosurgical units. Cables are color-coded by electrosurgical unit model. See the Instruments and Accessories User Manual for a complete list of cables and electrosurgical units compatible with the system.

Note: The system does not allow energy activation if two electrosurgical units of the same energy type are connected to the system, for example, two monopolar electrosurgical units.

Figure 4.6 Representative Energy Activation Cable



1. Connects to ESU
2. Connects to Vision Cart

WARNING: Ensure that only compatible electrosurgical units are connected to the system. Refer to the Instruments and Accessories User Manual for a complete list of compatible electrosurgical units. Performance of cables or accessories other than those specified in the Instruments and Accessories User Manual cannot be guaranteed. Any damage to the system resulting from using an incompatible electrosurgical unit will not be covered under warranty.

Connect an Electrosurgical Unit to the System

CAUTION: Follow proper procedure for connecting generators to the system, to prevent patient injury.

1. Connect the electrosurgical unit (ESU) end of the cable into the corresponding channel(s) on the electrosurgical unit. Tighten the screw lock completely to ensure that the cable is fully connected.



2. Connect the system end of the cable into any of the three energy receptacles Energy on the rear of the Vision Cart.
   Align the red dot on the cable connector with the red dot to the right of the receptacle.
   An audible click can be heard when the cable engages properly.
   Gently pull on the cable connector to verify that the cable is fully seated.
   When the ESU and system are turned on, the corresponding LED indicator will turn on.



4.5 Auxiliary Video and Audio Connections

Refer to Appendix F Video and Audio Connections on page F-1 to connect and configure auxiliary video and audio devices.

End of Section

Chapter 5 Startup

This chapter provides information on starting up the da Vinci Xi system, (referred to in this document as the system). The following subjects are covered:

Contents

5.1 Start Up the System 5-1
5.2 Startup Sequence 5-1
5.3 Power Button Color Indicators 5-2
5.4 Power Overview 5-3
5.5 Emergency Power Off 5-4
5.6 Component AC Power Switches 5-4
5.7 Guidelines on System Power 5-4

5.1 Start Up the System

1. Ensure the Vision Cart (including fiber and auxiliary cables), Patient Cart, and Surgeon Console cables are connected to each component.
2. Ensure that all components are connected to AC power.
3. Press any **Power** button ( ) to power on the entire system.

Figure 5.1 Power Buttons – Surgeon Console, Patient Cart, Vision Cart



5.2 Startup Sequence

During the startup sequence, the system performs an integrity test. The Patient Cart arms and Surgeon Console hand controls perform various movements during this integrity test. An audible beep and voice annunciated feedback (if enabled) indicates that the system is ready.

Patient Cart

The arms that are not stowed perform a self-test. The arms move and perform a short mechanical integrity test. Once the system integrity test is successfully completed, the arm LEDs (of all un-stowed arms) illuminate pulsing blue, and the Power button LEDs illuminate solid blue when powered on.

- If the system detects a mounted sterile adapter, instrument, or cannula before startup, the arms will not move *during* startup. This feature allows the system to stay connected to a patient during the startup sequence.
- If an arm bumps into something during the test, use the instrument or port clutch buttons to move the arm clear of the obstacle.

Surgeon Console

The hand controls perform a self-test. The hand controls move to their start position and must arrive there for the system to work.

- If a hand control is impeded in some way, move it by hand to free it and it will move to its start position.
- During the startup sequence, do not put anything in the 3D viewer.
- Do not activate any of the system controls, including the clutch buttons, foot pedals, etc.
  - While most button activations will be ignored during the startup sequence, some may cause a non-recoverable fault, which means that the system will have to be restarted. See Non-recoverable Faults on page B-9 for more information.
- The Emergency Stop feature is available during startup if needed. Once the system beeps, the surgeon may interact with the system controls. See Emergency Stop – Surgeon Console on page B-10 for more information.

5.3 Power Button Color Indicators

The component power buttons display specific colors depending on the mode.

Table 5.1 Power Modes — Color Indicators

Power Button Color	Definition
 Gray (not lit)	Component is not connected to AC power.
 Yellow	Component in standby (sleep) mode.
 Flashing yellow	Countdown to standby (sleep) mode. Power-up sequence.
 Blue	Component is powered on.

5.4 Power Overview

If the Vision Cart, Patient Cart, or Surgeon Console is connected to AC power and not powered on, it is defined as being in standby (sleep) mode. The component can be powered on by pressing the **Power** button.

The Vision Cart, Patient Cart, or Surgeon Console can be independently powered on when the blue system cables are disconnected. For example, the Surgeon Console is powered on – the Vision Cart and Patient Cart are off. This is defined as stand-alone mode.

To power on the Vision Cart or Surgeon Console independently:

First, ensure the Vision Cart or Surgeon Console is connected to AC power. Disconnect the blue fiber cable. Press the **Power** button to power on the Vision Cart / Surgeon Console.

To power on the Patient Cart independently:

Press the **Power** button to power on the Patient Cart. The Patient Cart does not need to be connected to AC power for this mode.

Power Guidelines

The components exhibit specific behavior when they are powered on independently. Table 5.2 describes the behavior in detail.

Table 5.2 Component Behavior – Independently Powered

Component	Independent power behavior
Vision Cart	All system functions available (video sources, illumination On/Off, white balance, brightness control, etc.)
Patient Cart	LEDs provide feedback on the arms
	System instruments do not engage
Patient Cart when not connected to the Core or AC power	Motor Drive activated
	Arm clutch buttons enabled
	Helm controls activated
Surgeon Console	Ergonomic control adjustment only

5.5 Emergency Power Off

Figure 5.2 Patient Cart EPO button



The **Emergency Power Off** (EPO) button is on the back of the Patient Cart. Press this button to completely remove power to the Patient Cart. The system classifies this a non-recoverable fault. The system must be restarted, see B.7 Restart the System on page B-7.

5.6 Component AC Power Switches

The Vision Cart, Patient Cart, and Surgeon Console each have a rear AC power switch that must be in the **ON** position (indicated by "I" near each switch) for that subsystem to power on.

Figure 5.3 AC Power Switch (Patient Cart shown)



The Endoscope Controller, Video Processor, and the Core have their own rear component power switch. Each component power switch must be in the **ON** position.

All subsystem and component power switches are intended to be left in the **ON** position. Use these power switches in special circumstances only; such as those described in B.6 System Power Issues on page B-4.

5.7 Guidelines on System Power

- The Patient Cart battery should be **adequately charged** (that is, at least 30 minutes of AC power charge). If the battery is not adequately charged and the system is powered on, an error message appears on the monitors. The error can be overridden if the Patient Cart is connected to AC power.

- Once the cables are connected, they must not be disconnected until the system has been completely powered down.
- To operate in dual console mode (using a second Surgeon Console), see 10.7 Dual Console Surgery on page 10-66. The second Surgeon Console behaves just as the first with respect to power operations.

End of Section

Chapter 6 Drape the System

This chapter provides information on draping the arms and column. The following subjects are covered:

Contents

6.1 Draping Overview 6-1
6.2 Deploy for Draping 6-3
6.3 Column Draping Procedure 6-6
6.4 Arm Draping Procedure 6-8
6.5 Sterile Stow the Draped Patient Cart (Optional) 6-18
6.6 Remove the Patient Cart Drapes 6-19

The drapes you install may look different from the images used in the draping the system instructions.

6.1 Draping Overview

Draping makes the Patient Cart sterile and suitable for surgery. Use Guided Setup to have the Patient Cart automatically position itself for draping through the Patient Cart touchpad. Optionally, manually move the arms into position.

Warnings and Cautions

WARNING: Follow proper drape installation and use of drapes, ensuring the drapes do not get contaminated against a non-sterile surface, to prevent breach of sterility.

WARNING: Drape tears due to interactions between arms and instruments could cause breach of sterility.

WARNING: DO NOT RE-STERILIZE. DO NOT RE-USE.

Reprocessing or reuse of products intended for single use may result in degraded instrument performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prionic pathogens.

CAUTION: Properly position the arms during drape application, to prevent breach in sterility.

Note: The drapes are sterile unless the package is opened or damaged. The drapes are designed for single use.

Note: Do not substitute generic drapes for Intuitive drapes with a sterile adapter. Drapes with a sterile adapter are available from Intuitive or your distributor. Each Intuitive drape with a sterile adapter has been designed to maintain sterility, provide the interface between the system arm and endoscopes/instruments, and make the draping process efficient.

Draping Supplies

Before beginning a procedure, make sure there is at least one backup of each drape to account for inadvertent contamination while setting up the system.

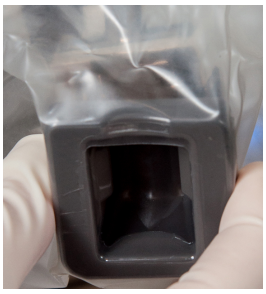
- Four arm drapes (PN 470015): each drape includes an instrument sterile adapter, cannula sterile adapter and arm clip
- One column drape (PN 470341)

Figure 6.1 Arm drape features

Instrument sterile adapter



Cannula sterile adapter



Arm clip



Draping Guidelines

- The Patient Cart should be positioned to ensure there is enough space to drape the Patient Cart outside of the sterile field.
- For speed, sterility and safety, draping should be done by a two-person team: a sterile user (scrub nurse or surgical assistant) and a non-sterile user (circulating nurse) who can handle non-sterile components.

The Patient Cart touchpad provides instructions to **deploy** the boom and arms for draping, **install** the drapes, and sterile **stow** the arms until the procedure (optional).

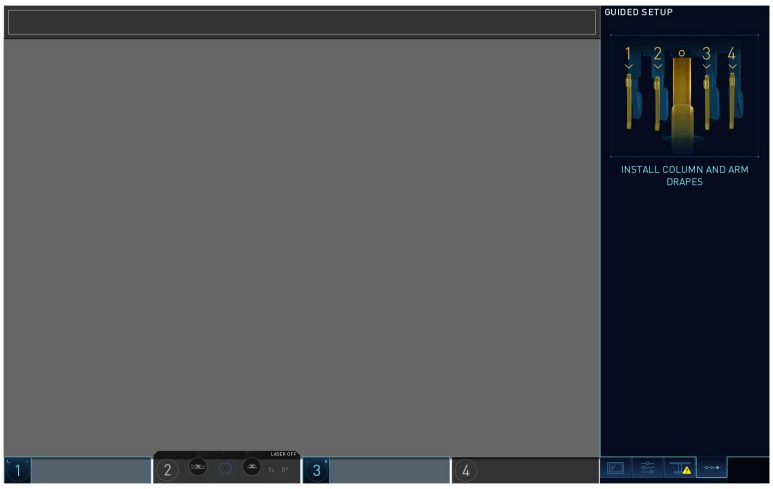
Figure 6.2 Patient Cart touchpad



1. Patient Cart touchpad

The Vision Cart touchscreen provides visual prompts to deploy the boom, select anatomy and approach, install the drapes, and sterile stow or dock the Patient Cart.

Figure 6.3 Touchscreen



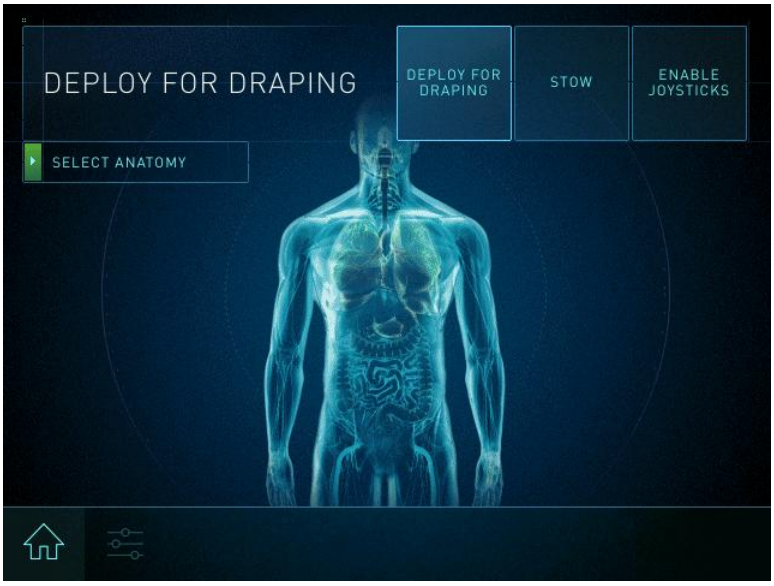
6.2 Deploy for Draping

During the deploy step, the boom is extended to allow access to the column for draping while avoiding contamination of the arm drapes. Additionally, the column raises to avoid contamination of the drapes in the sterile field.

There are two ways to deploy the boom for draping: automated and manual.

Automated Deploy for Draping - Guided Setup

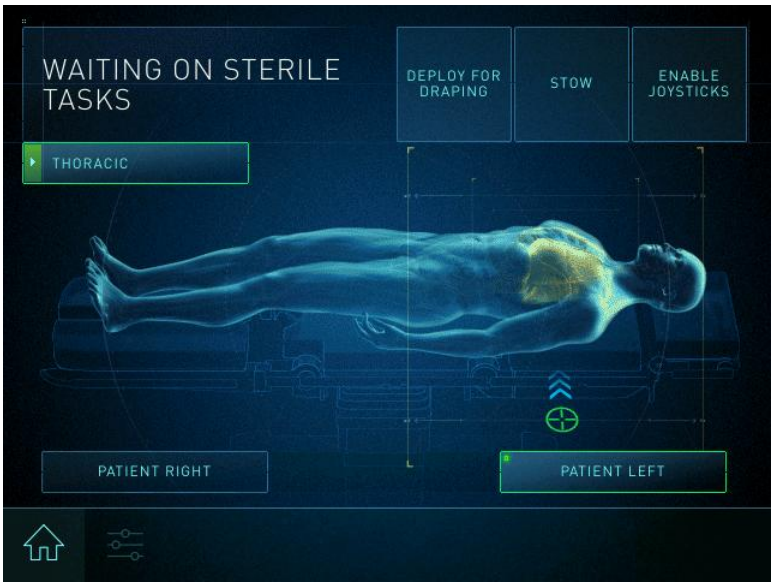
1. **Circulating Nurse:** On the Patient Cart touchpad, press and hold **Deploy for Draping**.



The system deploys the boom and adjusts the arms to prepare the Patient Cart for draping.



2. If known, select the anatomy and approach on the Patient Cart touchpad. Once these are selected, the Waiting on Sterile Tasks screen appears. This screen displays until the arms are draped and positioned beyond the green laser line.



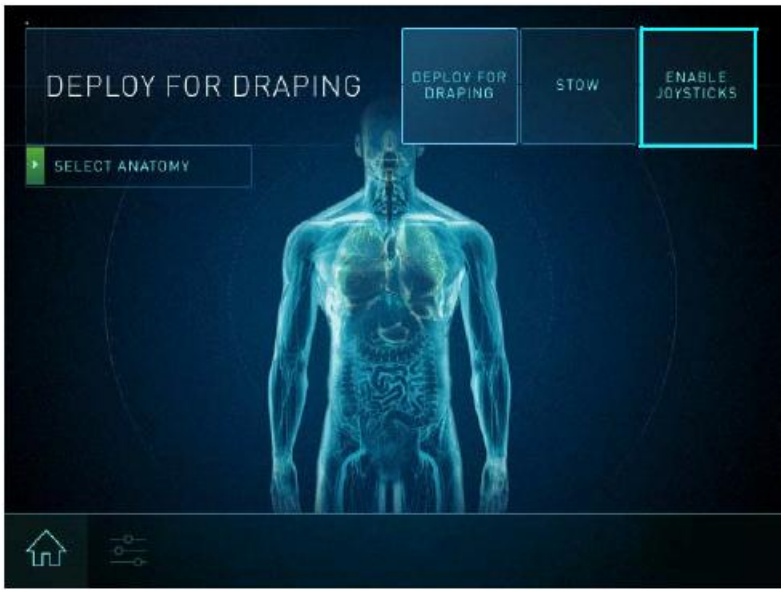
3. **Scrub Nurse:** Drape the column and arms, following the steps in 6.3 Column Draping Procedure on page 6-6 and 6.4 Arm Draping Procedure on page 6-8.

Manual Deploy for Draping

WARNING: Be sure to understand the function of the Patient Cart joystick and the use of the setup controls to prevent patient injury.

Use the Patient Cart joysticks and clutch buttons on the arms to use the manual method to deploy the boom for draping.

1. **Circulating Nurse:** To position the Patient Cart manually, press and hold **Enable Joysticks**.



2. Use the joysticks to raise and deploy the boom and extend the arms outward, leaving adequate space to avoid contamination of the arms and column while draping. See 9.3 Manually Adjusting the Patient Cart Arms on page 9-25 for more information on moving the arms manually.
3. **Scrub Nurse:** Drape the column and arms, following the steps in section 6.3 Column Draping Procedure on page 6-6 and section 6.4 Arm Draping Procedure on page 6-8.

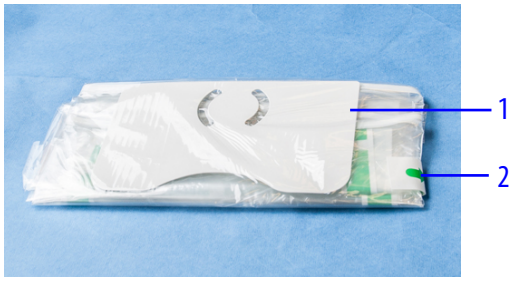
6.3 Column Draping Procedure

WARNING: Drape the Patient Cart column, to prevent a critical patient infection.

Note: The color band on the drape indicates the sterility barrier. If a non-sterile person is assisting in installation of the drape, he/she must not grasp the drape anywhere below the color band.

Drape the Patient Cart column to protect from cross-contamination in the event that an arm contacts the column.

1. Circulating Nurse: Deliver the column drape to the scrub nurse in sterile fashion, with the drape card facing the ceiling.

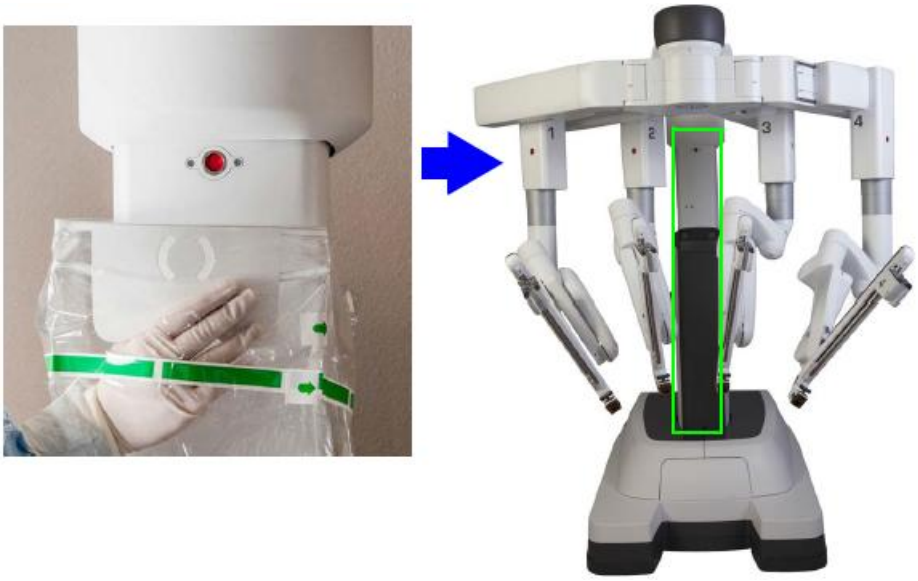


1. Drape card
2. Tear-away tab

2. Scrub Nurse: Release the first tear-away tab and partially unfold the drape on a sterile table. Open so the both sides of the flex-strips are positioned at approximately 90 degrees.



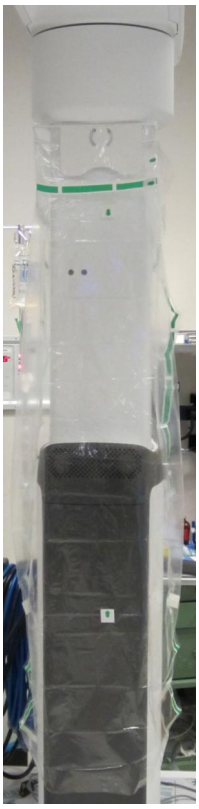
3. Pick up the drape: Hold the drape card within the drape cuff and move towards the center column, being careful to prevent cross-contamination.



4. Attach the metal disc on the drape card to the magnetic socket on the column.



5. Snap the tear-away tabs and unroll the remainder of the drape. Adjust the drape around the column as needed.



6.4 Arm Draping Procedure

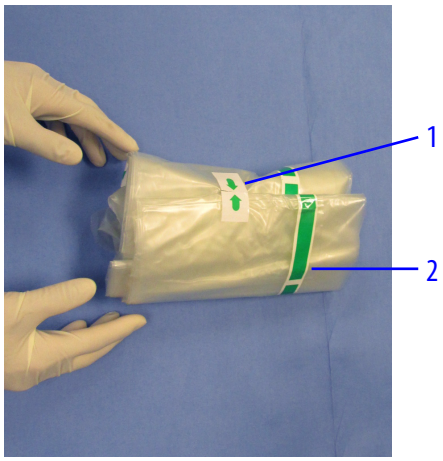
Note: To move the arms using the instrument clutch and port clutch buttons, see 9.3 Manually Adjusting the Patient Cart Arms on page 9-25.

Note: While draping the arm, ensure that the drape pouch attached to the sterile adapter does not become pinched between the sterile adapter and the instrument carriage. If this occurs, remove the sterile adapter, straighten the drape pouch, and re-seat the sterile adapter.

Note: The color band on the drape indicates the sterility barrier. If a non-sterile person is assisting in installation of the drape, he/she must not grasp the drape anywhere below the color band.

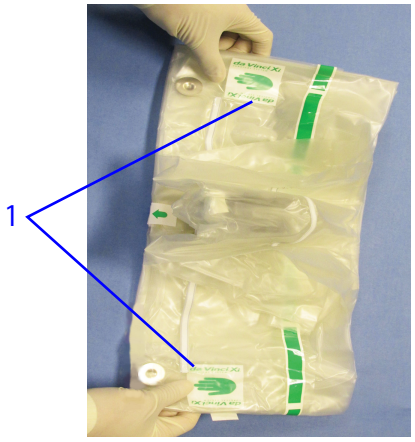
1. **Circulating Nurse:** Move each arm as needed to make sure there is enough space to maneuver between each arm to maintain sterility while draping. Manually adjust the boom height as needed using the boom height control joystick on the Patient Cart Helm.

   Deliver the arm drape to the scrub nurse in sterile fashion. Orient the drape with the tear-away tab facing the ceiling and the sterility band up.



1. Tear-away tab or drape band
2. Sterility band

2. **Scrub Nurse:** Unfold the drape.
   a. Partially unfold the drape on the sterile table so the hand symbols face the ceiling.



1. Hand symbols

   b. Position the excess drape material to show the arm clip.



   c. Flip the drape over so the instrument sterile adapter faces the ceiling (the hand symbols no longer show).



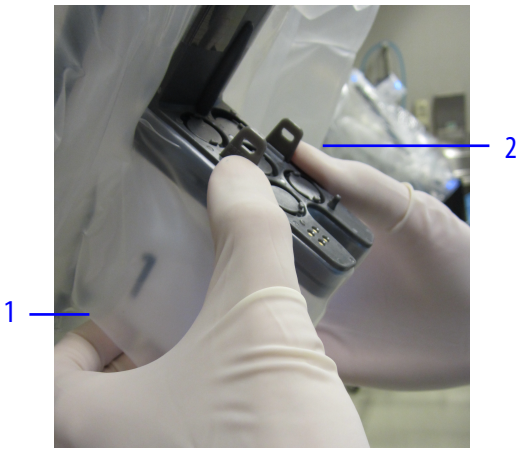
3. Grab (do not break) the tear-away tabs located on opposite ends along the fold of the drape cuff and spread apart to expose the center opening for the arm.



4. If needed, extend the arm using the grab and move feature to prevent contamination when installing the drape.
5. Tent the opening of the drape and hold the section with the sterile adapter with the front of the drape cuff in one hand, and hold the distal end of the drape with the other hand. Carefully lower the drape over the arm.



6. Attach the instrument sterile adapter:
   a. Place your hands on the bottom of the instrument carriage to stabilize it, and use both thumbs to press the sterile adapter into the instrument carriage until it clicks into place.
   b. The discs at the top of the sterile adapter spin, and an audible signal will be heard, indicating that the system recognizes the sterile adapter. If the sterile adapter does not engage, remove and re-seat the adapter.



1. Support bottom of instrument carriage
2. Press sterile adapter into place

7. Place your hands inside the drape cuff with your fingers behind the metal discs and the flex-strips facing you (we recommend orienting your hands in a 6 o'clock and 12 o'clock position). Move the drape along the Patient Cart arm towards the center column.

WARNING: Non-sterile personnel aiding the draping process must only touch the non-sterile portions of the drape. Touching the sterile portions of the drape by non-sterile personnel may result in patient infection.

Note: If needed, the non-sterile user can assist with this step by holding onto the outside of the drape anywhere behind the color sterility barrier.

a. The color band on the drape indicates the sterility barrier. Keep hands inside the cuff to maintain sterility.



1. Sterile area
2. Non-sterile area behind color band
3. Flex strip

8. Attach both metal discs on the inside of the drape cuff into the magnetic sockets on the arm. The dimple of the disc in the drape should face towards the arm. Ensure there is no excess drape material or twisting that can block the disc-to-socket connection. To prevent twisting, make sure the flex-strip faces towards you (wraps around the front of the arm).

WARNING: Properly attach the metal drape discs to the arm magnets so that the flex-strip faces inwards, towards you. Failing to do so may cause the drape to become disconnected and fall, compromising the sterile field, which may lead to a critical patient infection.

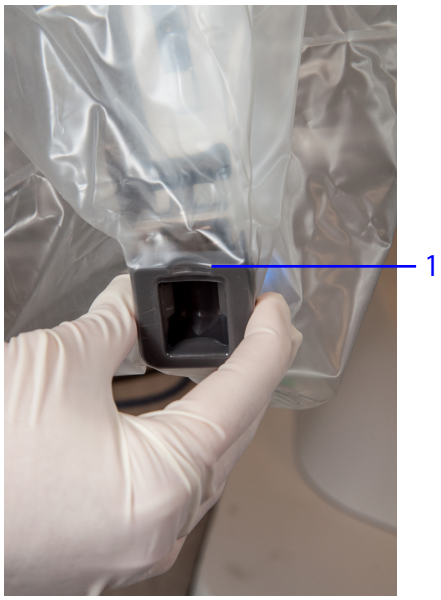


1. Flex-strip wraps around front of arm

9. If needed, gather the excess drape material and move it towards the back of the arm.

10. Align the cannula sterile adapter to the cannula mount such that the top of the sterile adapter (identified by a slight indent on the top lip) aligns with the top of the cannula mount. Ensure there is no excess drape material between the cannula mount and cannula sterile adapter that can block the connection. Press the cannula sterile adapter straight into the cannula mount to engage.

WARNING: Properly orient the cannula sterile adapter before attaching it to the cannula mount. Failing to do so may tear the drape and cause breach in sterility, which may lead to a critical patient infection.



1. Indent identifies top of sterile adapter

11. Snap to release the tear away tab located near the arm clip on the back of the drape.



12. Carefully slide excess drape material away from the gray handle as you prepare to attach the arm clip to the back of the arm. If needed, fold the excess drape material to the back of the instrument carriage.
13. Stabilize the gray handle to prevent inadvertent arm movement when snapping the arm clip into place. Using care not to pinch excess drape material, attach the arm clip to the back of the arm.

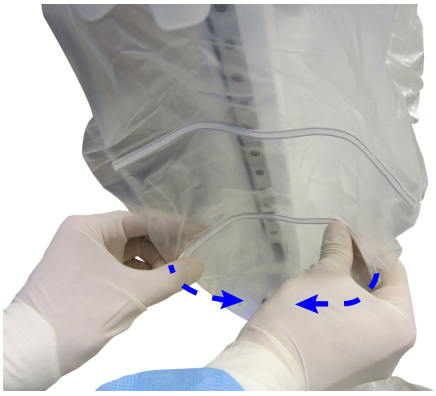
WARNING: Install the arm clip to prevent a patient infection or procedure delay.





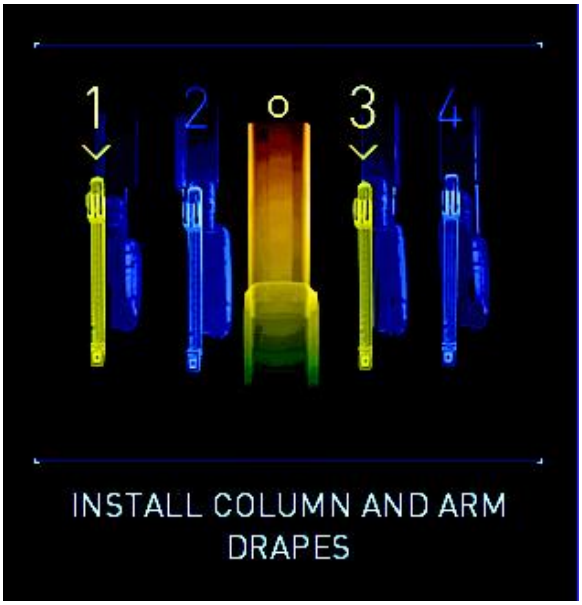
14. Bend the flex-strips inward such that the ends of the strips are towards you (similar to a “U” shape) to create a clear instrument insertion path along the arm.

WARNING: When bending the arm drape flex-strips on the instrument arm, follow the provided instructions to ensure that the drapes do not block the instrument insertion path. Failing to do so could puncture the drape and cause critical patient infection.

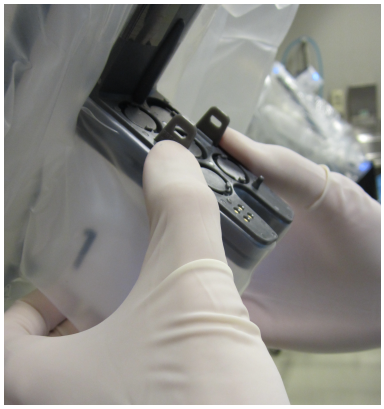


15. Move the draped arm away from the undraped arms to avoid cross-contamination.
16. **Circulating Nurse:** Move the next undraped Patient Cart arm into position.
17. **Scrub Nurse:** Drape the remaining arms in the same fashion.

    During Guided Setup, the touchscreen image indicates when each arm and the column is successfully draped. The following example shows arm 1, arm 3, and the column are not draped.



The positioning laser illuminates after the last instrument sterile adapter is attached.



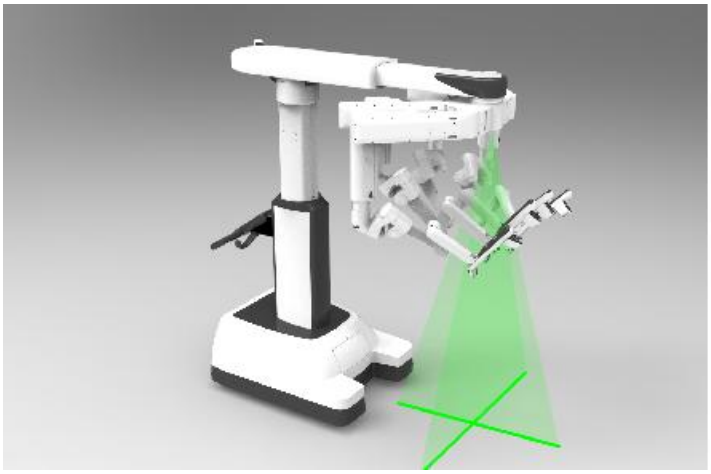
x4

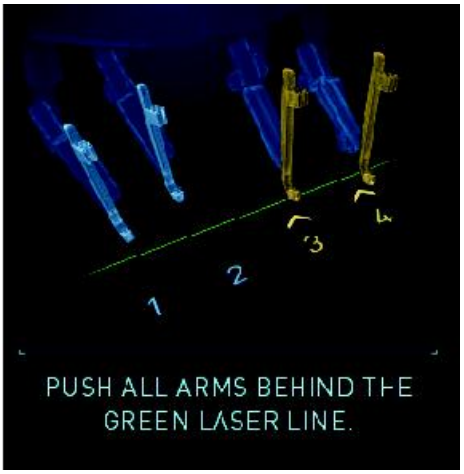


18. After draping the last Patient Cart arm and the column, follow prompts to position all of the arms behind the green laser line. This ensures the laser line is visible while docking the arms to the patient.

> **Note:** The laser line turns off after a period of time to prevent dimming. If the laser line turns off before the arms are pushed behind it, press any clutch button to turn it back on.

Once the Patient Cart is draped the Patient Cart may be stowed until the procedure, or proceed to docking. The following example show arms 1 and 2 are behind the laser line.



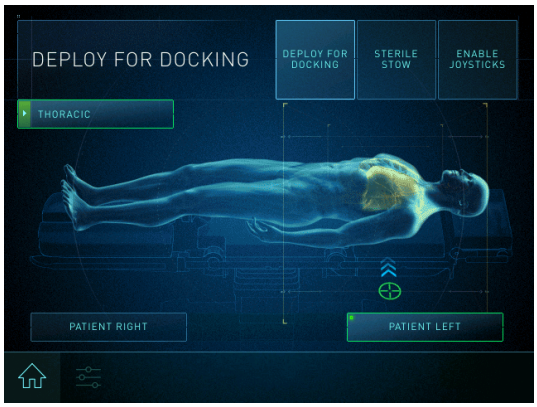


- To sterile stow: See 6.5 Sterile Stow the Draped Patient Cart (Optional) on page 6-18.
- To proceed to Docking: See 9.5 Dual Docking on page 9-33.

6.5 Sterile Stow the Draped Patient Cart (Optional)

The draped Patient Cart may be sterile stowed so that it is out of the way until needed for the surgical procedure.

1. **Sterile Stow:** On the Patient Cart touchpad, press and hold **Sterile Stow**. The Patient Cart moves to the sterile stow position where the arms are folded out of the way with enough space from the column to ensure that sterility is not breached.





Example of arms sterile stowed

2. Cover the arms in sterile fashion (for example, with sterile central supply room wrap) until the system is ready for docking to the patient.

6.6 Remove the Patient Cart Drapes

After the procedure, remove and dispose of all drapes. Ensure to fully remove the sterile adapters, clips, and metal discs. See 11.2 Remove the Patient Cart Drapes on page 11-1 for more information.

End of Section

Chapter 7 Set Up and Use Vision System

This chapter explains the setup and use of the da Vinci Xi Vision System (referred to as vision system). The following subjects are covered:

Contents

7.1 Vision System Components 7-1
7.2 Endoscope Features 7-3
7.3 Connect the Endoscope to the Vision Cart 7-8
7.4 Endoscope Settings 7-11
7.5 Hand-held Endoscope Use 7-12
7.6 Endoscope Installation and Removal 7-14
7.7 Endoscope Fogging and Intraoperative Cleaning 7-18
7.8 Vision Cart Touchscreen 7-19
7.9 Troubleshooting Image Quality 7-29

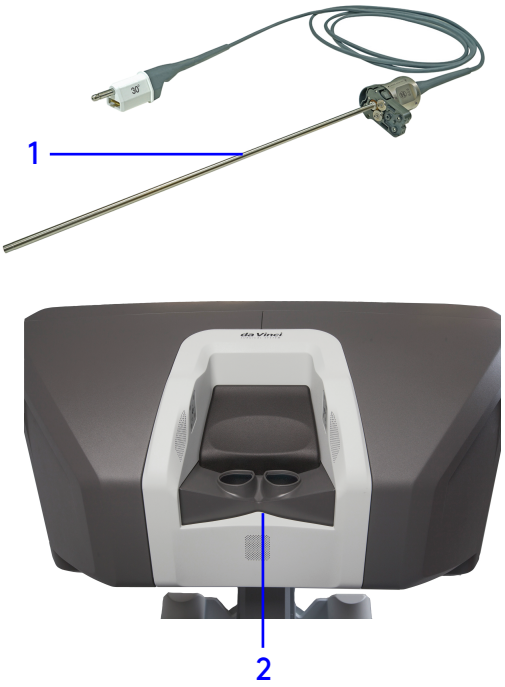
⚠ **CAUTION:** Be sure to follow all instructions to safely and effectively use of vision system and its adjustment capabilities, to prevent deviation in workflow.

7.1 Vision System Components

For a general overview of the Vision Cart, see 2.4 Vision Cart on page 2-6.

Figure 7.1 Vision system components

Surgeon Console



Vision Cart



1. **Endoscope:** The da Vinci Xi endoscope produces high definition (HD) visible light (VIS). Endoscopes are available with either a 0 degree or 30 degree tip.
2. **3D viewer:** The 3D viewer is a pair of high definition screens that provide the surgical video to the surgeon.
3. **Touchscreen:** The touchscreen monitor provides a view of the surgical site from the patient-side and a set of controls for endoscope and video configurations.
4. **Endoscope Controller (Illuminator):** Contains a high-intensity light source to illuminate the surgical site and the electronics for initial processing of endoscopic video.
5. **VIO dV:** The ERBE VIO dV (VIO dV) is an integrated Electrosurgical Unit (ESU) that can be used with da Vinci and laparoscopic instruments.
6. **Video Processor:** Provides additional processing of endoscopic video and allows the recording of still images onto a USB flash drive.
7. **System electronics (Core):** Contains the electronics for advanced processing of the video image, system control algorithms, and control of electrosurgical unit when the surgeon uses the instrument function pedals.

Note: Only use Intuitive approved or supplied endoscopes, accessories, and image processing equipment with the da Vinci system. This requirement ensures optimal image quality and da Vinci system performance.

7.2 Endoscope Features

The endoscope acquires three-dimensional (3D) video from the surgical site in high definition (HD). The HD video is processed by the system electronics in the Vision Cart and displayed on the Surgeon Console 3D viewer and Vision Cart touchscreen.

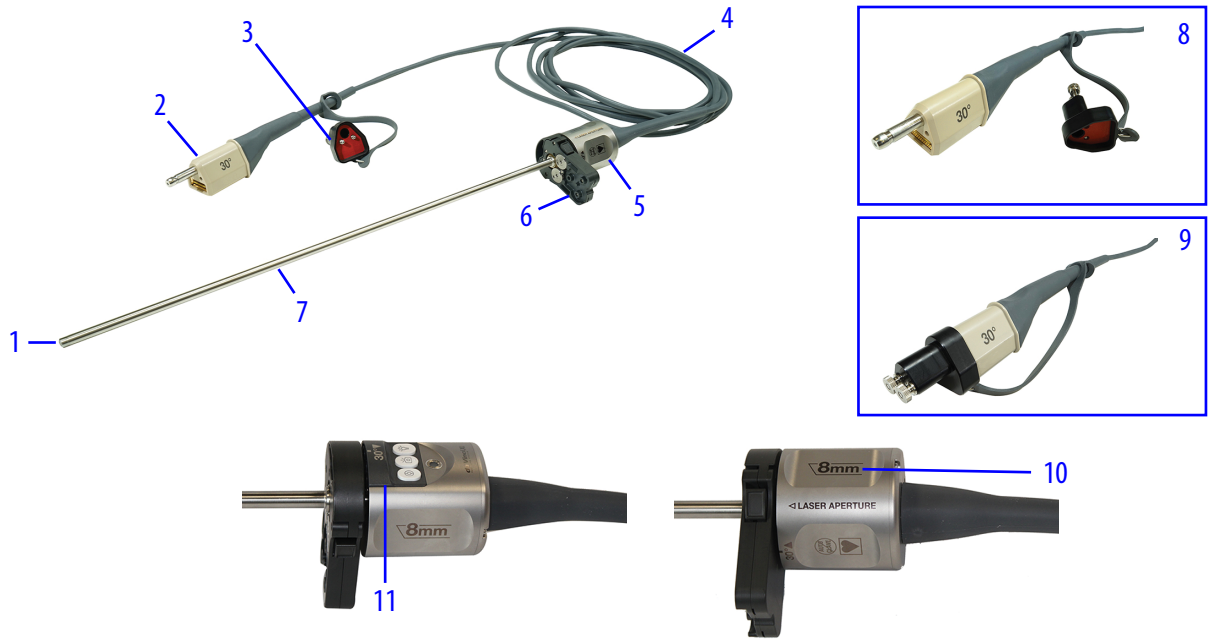
The 8 mm endoscope is available with either a straight (0°) or angled (30°) tip. For 30° endoscopes, the Surgeon Console touchpad and the Vision Cart touchscreen provide the ability to change between an up or down angle orientation without removing the endoscope from the patient. See Endoscope Orientation on page 7-15 for more information.

The endoscope consists of the tip, shaft, base, housing, cable, and connector. Some endoscopes are supplied with a connector cover. If a connector cover is present, it must be removed before the procedure and re-attached before reprocessing. Refer to the Reprocessing Instructions User Manual for detailed reprocessing instructions.



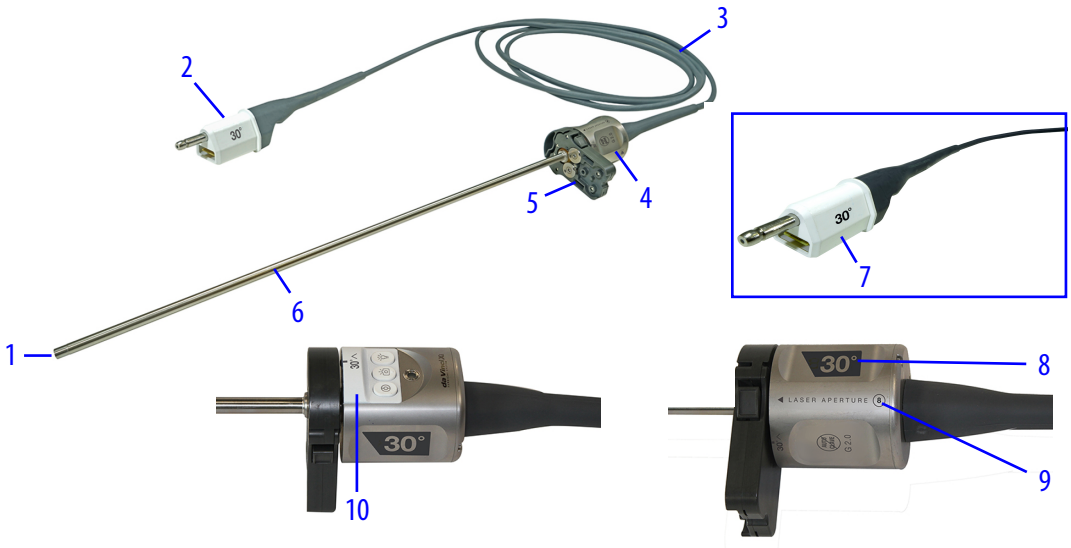
WARNING: The surface beneath the endoscope connector cap is non-sterile. Contacting the endoscope connector with the sterile filed could cause a breach in sterility, which may result in patient infection of immunologic reaction.

Figure 7.2 Endoscope supplied with connector cover



1. Tip
2. Beige connector
3. Connector cover
4. Long cable
5. Housing
6. Base
7. Shaft
8. Connector cover off
9. Connector cover on
10. 8 mm marking
11. Gray label

Figure 7.3 Endoscope supplied without connector cover



1. Tip
2. White connector
3. Short cable
4. Housing
5. Base
6. Shaft
7. No connector cover
8. Angle marking
9. 8 mm marking
10. White label

The endoscope has two release levers on the sides of the base for removing the endoscope from the Patient Cart arm.

Figure 7.4 Endoscope housing



1. Base
2. Release lever (one on each side)
3. Buttons
4. Endoscope LED

The light guide and endoscope communication signals are integrated into a single cable, permanently attached to the endoscope. The endoscope cable connects directly to the Endoscope Controller on the Vision Cart to provide communication and illumination to the endoscope.

Figure 7.5 Endoscope cable and Vision Cart



Vision System Light Apertures

WARNING: Be aware of potential exposure from the light apertures to prevent eye injury.

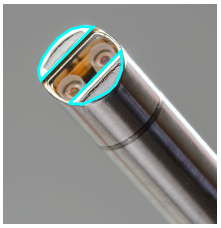
There are three light apertures (openings that emit light) in the vision system. The first aperture is on the Endoscope Controller. When an endoscope is removed from the Endoscope Controller, a shutter in the Endoscope Controller closes and blocks the light output. The other apertures are located at the tip of the endoscope.

Figure 7.6 Vision system light apertures

Light aperture on the Endoscope Controller



Light apertures on the endoscope



Endoscope Guidelines

WARNING: Be careful when the endoscope is connected to the system and emitting light. Direct eye exposure to emitted light can cause permanent eye injury.

WARNING: While Class 1 laser products are considered to be "eye safe" without the need for additional protection, when working around the circuit boards, the following general safety guidelines should be observed to reduce the risk of eye injury:

- Do not look or stare at optical fiber ports or optical fibers that are connected to a light source.
- Do not examine with optical instruments optical fiber ports or optical fibers that are connected to a source. The use of optical instruments (for example, a magnifying glass) may increase eye hazard.
- Adjustments and settings, maintenance, operational parameters and procedures other than those specified and allowed herein and on the rating plate of the da Vinci system may result in increased eye hazard.
- Do not attempt to perform any repair or maintenance on optical communications components. Repairs and maintenance outside that which is allowed herein must be performed only by an authorized repair facility.

Do not use an optical instrument (magnifying glass or similar) to examine the optical fibers at the tip of the endoscope when it is connected to the Endoscope Controller. If the light becomes activated, permanent eye injury can occur.

WARNING: Surgery should only be performed when the vision system provides sufficient visualization, to prevent possible tissue injury or the inability to perform surgical tasks.

WARNING: Turn the illuminator off when the endoscope is removed from the arm, to prevent a breach of sterility or thermal injury to the patient or user.

WARNING: Do not place endoscopes on the patient or patient drapes, to prevent a breach of sterility, or thermal injury to patient or user.

WARNING: To avoid excessive heating of the cannula, do not leave the endoscope tip (that is, the distal 25 mm) inside a cannula for a prolonged period of time while the Endoscope Controller is on. The components can get hot and lead to burn injuries.

WARNING: Use the system with a compatible endoscopes only, to prevent injury to the eye.

CAUTION: For endoscopes supplied with a connector cover, ensure that the cover is properly affixed prior to the start of reprocessing. Failure to ensure properly installed cover may result in fluid ingress and damage to the endoscope.

- The endoscope must be cleaned and sterilized before each procedure and does not require sterile draping during surgical use. Refer to the Reprocessing Instructions User Manual for reprocessing methods and parameters.

Note: Do not leave the endoscope tip inside the cannula for prolonged time while the Endoscope Controller is on.

Calibration and White Balance

The endoscope is calibrated and white balanced at the factory. If white balance requires adjustment, see Image Too Bright or Dark on page 7-29 for instructions.

Confirm Live Image in 3D Viewer

Each time an endoscope is installed, and after changing view modes or settings during a procedure, look in the 3D viewer to confirm a live image is present and has the desired orientation. Adjust endoscope orientation as necessary.

Inspect the Endoscope

WARNING: Use proper handling, cleaning, and sterilization of components within the sterile field to prevent breach of sterility.

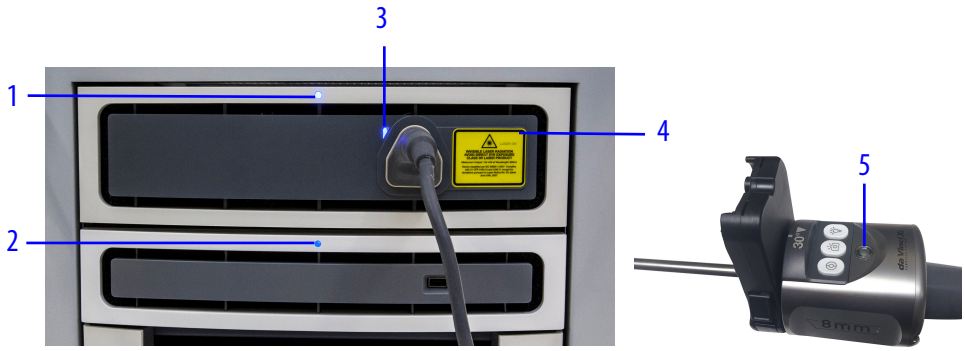
WARNING: Failure to adhere to approved operating practices may result in damage to the endoscope. For example, dropping equipment, collisions, and improper cleaning and sterilization techniques can cause damage. A damaged endoscope may result in fragments falling into the patient.

7.3 Connect the Endoscope to the Vision Cart

WARNING: Avoid direct interaction with the illuminator to prevent burn injury or IR radiation injury to the user.

To use the endoscope, its integrated cable must be connected to the Endoscope Controller. When the system detects that the endoscope has been connected, the LED next to the connector is lit, indicating a proper connection.

Figure 7.7 Vision system LED locations



1. Endoscope Controller LED
2. Video Processor LED
3. Endoscope cable connection LED
4. Label: Laser On indicator
5. Endoscope LED

Table 7.1, Table 7.2, and Table 7.3 provide vision system LED quick reference.

Table 7.1 Endoscope Controller

Endoscope Controller LED	Status
Off	No Power
Red	Failure

(continues on next page)

Table 7.1 Endoscope Controller (continued)

Endoscope Controller LED	Status
Blue, Flashing	Powering up
Blue, Steady	Powered and ready

Table 7.2 Endoscope cable connection

Endoscope Cable Connection LED	Status
Off	Not connected
Blue, Steady	Connected and ready

Table 7.3 Endoscope

Endoscope LED	Status
Off	Not connected
Green, Flashing	Connected and loading data
Green, Steady	Connected and data is fully loaded

Connect the Endoscope to the Endoscope Controller

Note: When the endoscope is powered on and outside of the body, the tip emits a purple tinted light. This illumination is expected and normal, and it will not impact the surgeon's view of the surgical image.

Note: Some endoscopes are supplied with a connector cover, and some endoscopes are supplied without a connector cover.

1. If not already done, remove the cover from the connector.

2. Plug the connector into the Endoscope Controller.



When the cable is fully connected, the LED next to the connector illuminates (Figure 7.7).

Note: The endoscope produces a usable image during calibration, but the system may make visible corrections to the image while the data is loading. It is not necessary to wait until the endoscope finishes calibrating to begin using it.

Dynamic Illumination

The system automatically determines and adjusts the amount of light output based on the surgical scene. As the endoscope is positioned closer to tissue, less light is needed to maintain a bright image and the system will reduce the light output. This reduces the ability of the light to affect tissue at close working distances.

Endoscope Buttons

WARNING: Be sure to understand the function of each endoscope button to prevent patient tissue injury from unintentionally turning off the endoscope during a procedure.

Figure 7.8 Endoscope buttons



1. Left/Right eye swap and Targeting
2. Take Photo
3. Illumination On/Off

Table 7.4 Endoscope buttons

Button	Adjustment	Description
	**Left/Right eye Swap**	Press to toggle the view on the Vision Cart touchscreen to the left or right endoscope image.
	Targeting	Press and hold to activate the targeting feature.
	**Take Photo**	Press to capture an image from the endoscope view. The system saves the image to a USB flash drive connected to the Video Processor on the Vision Cart. The system records the left or right image based on which image is currently displayed on the touchscreen.
	**Illumination On/ Off**	Press and hold to turn illumination on or off.

7.4 Endoscope Settings

Focus-free Endoscope

The endoscope optics are designed to keep the surgical image in focus over relevant working distances. There is no need to adjust the focus of the endoscope.

Digital Zoom

The digital zoom setting increases the magnification of the image. The normal endoscope zoom setting is 1x magnification but 2x and 4x are also available. When 2x or 4x digital zoom is active, the image resolution decreases, which may impact image quality. The 1x setting provides the maximum resolution. When the surgeon enters digital zoom, the Vision Cart touchscreen continues to display the 1x view.

To change digital zoom settings:

1. From the Surgeon Console touchpad Settings tab, tap **Display**.
2. Select **1x**, **2x**, or **4x**.
   - Alternatively, activate Haptic Zoom and toggle through the digital zoom settings. See Image on page 10-33.

Working Distance

The working distance setting enhances the surgeon's ability to see a fused 3D image when working very close to tissue. The system defaults to Normal working distance. To enable Close-up working distance:

1. From the Surgeon Console touchpad Settings tab, tap **Display**.
2. Tap **Close-up**. Tap **Normal** to enable Normal working distance.

Targeting

WARNING: Be sure to understand the function of the targeting feature, including supporting the cannula while targeting, to prevent patient or user injury.

The targeting button is used to orient and align the Patient Cart to the center of the surgical workspace boundary. For additional information, guidelines and steps, see Targeting on page 9-20.

7.5 Hand-held Endoscope Use

The endoscope can be used hand-held for any non-robotic or laparoscopic portions of the procedure, such as port placement. The endoscopic image displays on the Vision Cart touchscreen to aid with visualizing during hand-held use. After hand-held use, the Patient Cart is docked to the patient, and the endoscope is attached to a Patient Cart arm.

0° Endoscope

Hold the endoscope with buttons (and the base) facing up so the image appears upright on the monitor.

Figure 7.9 Endoscope buttons and base facing up

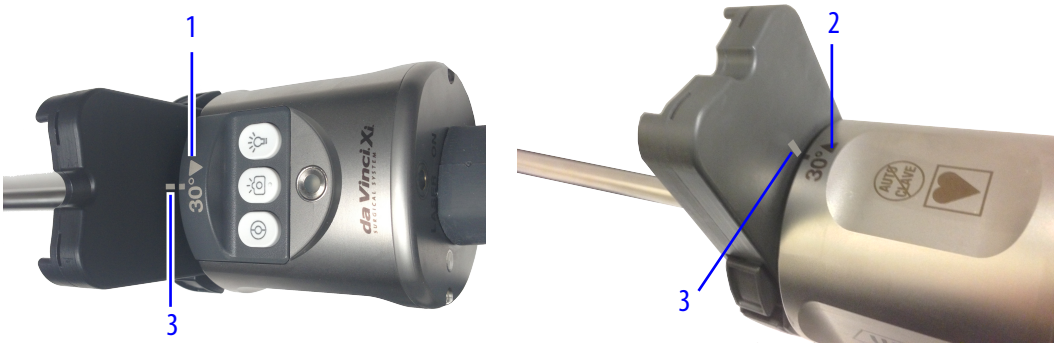


30° Endoscope

The 30 degree (30°) endoscope has two tip orientations: **up** and **down**.

The 30° endoscope has a marking on the base that aligns with the 30° down (on top) or up (on bottom) arrow on the endoscope. The endoscope senses when the base is pointed up or down and flips the video accordingly. If the tip of the endoscope and the base are both pointing down, the displayed image will be upside-down.

Figure 7.10 30° endoscope base



1. 30° down arrow
2. 30° up arrow
3. Hash mark

To select the 30° **down** orientation, hold the endoscope housing with the buttons facing **up** and base pointing up (the endoscope tip will point down). A hash mark on the base aligns with the 30° down marking on the housing.

Figure 7.11 Endoscope in down orientation



To select the 30° **up** orientation, hold the endoscope housing with the buttons facing **down** and the base pointing up (the endoscope tip will point up). A hash mark on the base aligns with the 30° up marking on the housing.

Figure 7.12 Endoscope in up orientation



When the 30° endoscope is installed on an arm, the up and down orientations can be selected from the Vision Cart Touchscreen or the Surgeon Console touchpad Instrument tab. In response, the system rotates the endoscope 180° and adjusts the left and right eye view. This enables the surgeon to change between the up and down orientations without patient-side assistance.

WARNING: Avoid contact with the endoscope tip when it is outside the cannula and exercise caution when handling the endoscope due to temperature, to prevent burns.

WARNING: The distal tip of the endoscope may reach high temperatures during use. Avoid contact with skin, tissue, and clothing when the Endoscope Controller is turned on, as damage may occur. Do not attempt to clean the tip of the endoscope by wiping with tissue. The tissue can be damaged because of the heat, and the tip of the endoscope may develop tissue deposits that can decrease light output.

7.6 Endoscope Installation and Removal

WARNING: During surgery, avoid endoscope contact with tissue to prevent tissue damage due to excessive heat.

Note: The endoscope produces a usable image during calibration, but the system may make visible corrections to the image while the data is loading. It is not necessary to wait until the endoscope finishes calibrating to begin using it.

Endoscope Cable Management

WARNING: Ensure the endoscope and instrument cables are properly managed (for example, the cables are not placed on the Patient Cart arms, not positioned such that they are a tripping hazard, etc.). Failing to do so could lead to patient harm resulting from inadvertent movement of the endoscope or instruments, loss of instrument control, or loss of camera visualization.

For improved cable management throughout the procedure, place the cable between the endoscope shaft and the arm before inserting the endoscope into the cannula. This minimizes the length of cable that is free to swing around during the procedure. Do not hang the endoscope cable over the arm as it may get caught or damaged and limit the arm's range of motion.

Figure 7.13 Cable management

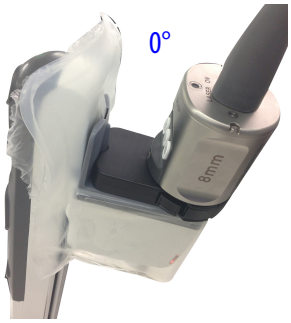


Endoscope Orientation

0° endoscope

The **0°** endoscope is typically installed with the buttons facing the arm.

Figure 7.14 0° orientation



30° endoscope

The 30° endoscope is typically installed with the buttons facing the arm (facing in) for the **down** orientation, and the buttons facing away from the arm (facing out) for the **up** orientation.

Figure 7.15 30° down and up orientation

30° down



30° up



Endoscope Port Hopping Overview

WARNING: Be careful to correctly identify which instrument is associated with each hand controller when the endoscope is port hopped, to prevent inadvertent instrument movement or removal, which could lead to tissue injury.

The endoscope can be used on any Patient Cart arm (where cannula diameters permit). The ability to install the endoscope on any of the arms is referred to as Port Hopping. When interchanging an endoscope with an instrument on any arm, Guided Tool Change is canceled. The arm status pods adjust to display the arm on which the endoscope and instruments are installed. Moving the endoscope between any arm does not change the left and right hand control assignments: arms 1 and 2 are controlled by the left hand; arms 3 and 4 are controlled by the right hand. Therefore, if the endoscope moves from arm 3 to arm 2, the instrument that went from left hand control on arm 2 changes to the right hand control on arm 3.

Endoscope Installation

Note: Althouogh the endoscope may be installed on any of the arms and more than one endoscope may be used, only one endoscope may be used on the system at one time.

Before installing the endoscope to an arm or Port Hopping to a different arm during the procedure, make sure the surgeon is ready and knows which arm will house the endoscope. Also, ensure that the arm is draped and the drape sterile adapter is attached.

1. Inspect the endoscope for broken, cracked, chipped, or worn parts. Do not use an endoscope if it is damaged.
2. Insert the endoscope tip into the cannula and press the base into the sterile adapter. Audible completion beeps signal that the endoscope is engaged.

3. Use the instrument clutch button to manually advance the endoscope. Position the endoscope to view the target anatomy before inserting instruments.

Figure 7.16 Inserting the endoscope into the cannula and sterile adapter



Remove and Change Endoscope

When a surgeon wishes to change from one endoscope to another (for example, 0° and 30°), it is necessary to disconnect one endoscope from the Endoscope Controller and then connect the other endoscope. To protect the endoscope connectors during this exchange, there are two holders on the Vision Cart.

Figure 7.17 Vision Cart holders



To remove the endoscope, or change endoscopes during a procedure:

1. Remove the endoscope from the Patient Cart arm by squeezing both release levers on the endoscope base and pulling the endoscope up and away from the arm.



2. Unplug endoscope cable from the Endoscope Controller.
3. When switching endoscopes:
   a. Place the removed endoscope cable connector in the holder on the Vision Cart (Figure 7.17), and place the endoscope on the sterile table.
   b. Connect the new endoscope cable to the Endoscope Controller.
   c. Attach the new endoscope to the Patient Cart arm.
4. If applicable, after the procedure, attach the cover onto the connector and tighten the screws. Place the endoscope into a validated sterilization tray before reprocessing. Refer to the Reprocessing Instructions User Manual for detailed reprocessing instructions.

7.7 Endoscope Fogging and Intraoperative Cleaning

Endoscope Fogging

WARNING: When the endoscope is connected to the Endoscope Controller, do not use endoscope warming methods that apply elevated temperatures for extended periods of time. This can result in overheating and damage to the endoscope. The electronics in the distal tip of the endoscope generate heat, which should reduce fogging.

Endoscope fogging occurs when there is a difference between the temperature of the endoscope tip and the pneumoperitoneum. The da Vinci Xi endoscope is designed to keep the tip of the endoscope warm, which reduces the likelihood of fogging. If fogging does occur, use the following guidelines:

- Use heated insufflation.
- When possible, avoid connecting insufflation or smoke evacuation to the endoscope cannula.
- Connect the endoscope to the Endoscope Controller 30 minutes prior to the start of a procedure. The light does not need to be “on” since the heat from the distal internal electronics will warm the tip.
- Before reinserting the endoscope after intraoperative cleaning, briefly (less than 15 seconds) submerge the tip of the endoscope in warm water (less than 131 °F [55 °C]).
- When the endoscope is outside the patient and waiting to be used, it should be placed in a scope warming device. Do not use warming devices that apply temperatures greater than 131 °F (55 °C).
- Clean any remnant sterilization detergent.
- Use anti-fogging solution.
- Set insufflator to maximum flow rate (that is, speed of CO_2 inflow, not pressure).
- Activate smoke evacuator prior to activating energy. Deactivate after use.

Intraoperative Endoscope Cleaning

WARNING: Clean the lens of the endoscope during a procedure by first removing the endoscope from the arm and wiping the lens with moistened gauze, to prevent patient injury.

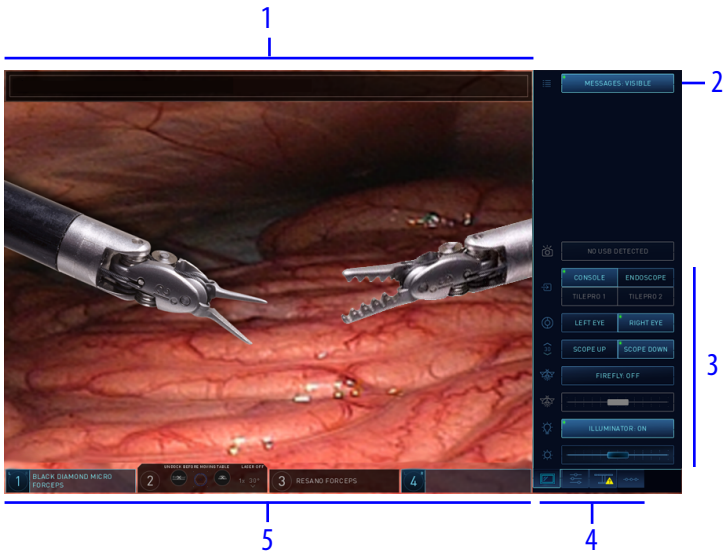
As necessary due to fogging or smudging of the tip, remove the endoscope and wipe the tip with moistened sterile gauze.

1. Remove the endoscope from the arm.
2. Carefully wipe the tip of the endoscope with moistened sterile gauze.
3. To further reduce the likelihood of fogging, briefly submerge the endoscope into a container of warm water and wipe dry with sterile gauze (optional).
4. Reinstall the endoscope onto the arm.
5. Advance the endoscope into the patient.

7.8 Vision Cart Touchscreen

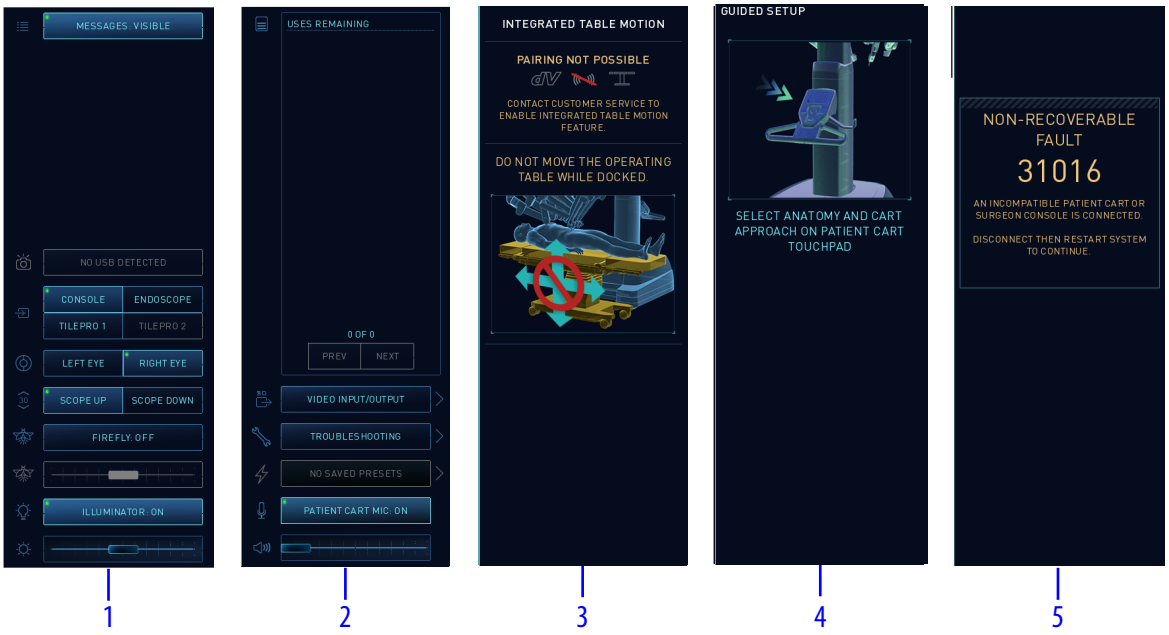
The touchscreen image duplicates the entire surgical image seen in the Surgeon Console 3D viewer, including video output display (such as TilePro) and digital zoom settings, as applicable. The right side of the touchscreen provides a menu for settings.

Figure 7.18 Vision Cart touchscreen (Display tab selected)



1. System status message area
2. Messages (visible/hidden)
3. Options
4. Menu tabs (Display tab selected)
5. Arm, instrument, and endoscope status area

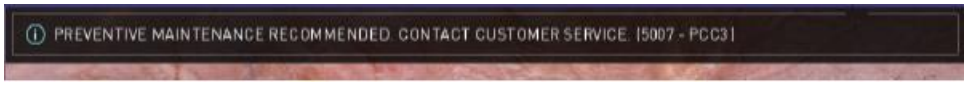
Figure 7.19 Vision Cart touchscreen (example Display, Settings, Table[1], Guided Setup, and Fault tabs selected)



1. Display
2. Settings
3. Table
4. Guided Setup
5. Fault

System status messages appear in the upper corner of the surgical image.

Figure 7.20 Touchscreen with system status message



The touchscreen main menu includes a Display tab, a Settings tab, and a Table tab. When applicable, the menu includes a Guided Setup and Fault tab. When a tab is highlighted, it is active. A grayed out tab is not active. In Figure 7.19, the Display tab is selected (active). In Figure 7.21, the Fault tab is selected (active).

Figure 7.21 Touchscreen all tabs showing, Fault tab selected



1. Display
2. Settings
3. Table
4. Guided Setup
5. Fault

1. Not all technologies may have regulatory approval or may be commercially available in all geographies. For availability in your country, check with your local representative.

Note: When Guided Setup is activated from the Patient Cart Helm, the accompanying messages and images display on a third tab, next to Settings, in the Vision Cart touchscreen. See Guided Setup on page 9-9.

Table 7.5 Touchscreen Display tab

Control	Adjustment	Description
	**Messages Visible / Hidden**	Tap to hide or show system messages.
	**Take Photo**	Tap to capture an image from the endoscope view. The system saves the image to a USB flash drive connected to the Video Processor on the Vision Cart. The system records the left or right image based on which eye is being displayed on the touchscreen.
	**Console / Endoscope/ TilePro 1 / TilePro 2**	Tap **Console** to display the Surgeon Console view. Tap **Endoscope** to display the endoscope view. **Note:** If the Surgeon Console view displays TilePro, the endoscope view will not display TilePro. Tap **TilePro 1** or **TilePro 2** to display auxiliary input 1 or auxiliary input 2 in full screen.
	**Left Eye / Right Eye**	Tap to display the left or right eye video image.
	**Scope Up / Scope Down**	Tap to orient the endoscope angle up or down.
	**Firefly On / Off**	Tap to turn Firefly[a,b] on or off. If Firefly is already on, then the button will turn off Firefly.
	**Firefly Intensity Slider**	Move slider to change the visibility of the green fluorescing tissue relative to the non-fluorescing tissue.
	**Turn Illumination On / Off**	Turn on or off the illumination from the touchscreen.
	**Brightness**	Drag the slider to adjust the brightness of the surgical image.

(continues on next page)

Table 7.5 Touchscreen Display tab (continued)

Control	Adjustment	Description
	**Erase Telestration**	Tap to erase telestration marks.
Notes a. Not all technologies may have regulatory approval or may be commercially available in all geographies. For availability in your country, check with your local representative. b. For more information on Firefly use, see the *da Vinci Xi Firefly Imaging System User Manual Addendum*.		

Table 7.6 Touchscreen Settings tab

Control	Adjustment	Description
	**Uses Remaining**	Provides an inventory overview of the instruments used during the procedure.
	**Video Input/Output**	Tap Video Input/Output to specify video output format. See Appendix F Video and Audio Connections on page F-1 for more information.
	**Troubleshooting**	Displays the system software version and provides access to event logs, color bars for vision troubleshooting, color balance adjustment, factory default vision settings, and manual 3D alignment if needed.
	**Presets**	Provides information on energy presets. For more information, see VIO dV 2.0 Energy Presets on page 10-56. Energy presets are only available with VIO 2.0.
	**Patient Cart Mic On /Off**	Tap to mute or unmute the Patient Cart microphone.
	**Volume**	Drag the slider to adjust the Patient Cart speaker volume.

Table 7.7 Touchscreen Settings tab, Troubleshooting Button

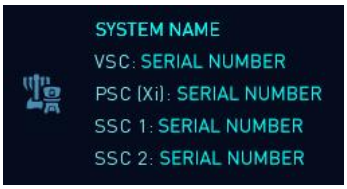
Control	Adjustment	Description
	**3D Calibration**	Controls for performing manual 3D calibration of the endoscopic camera. Not normally required - used for troubleshooting only.
	**White Balance**	Controls for performing manual white balance of the endoscopic camera. Not normally required - used for troubleshooting only.
	**Color Balance**	Slider control for adjusting the color balance of the endoscopic image. Moving the slider to the left increases the red tones in the image. Moving it to the right increases the blue tones in the image.
	**Color Bars**	Displays a color bar image in either the left or right eye of the endoscope view. Used only for troubleshooting.
	**Restore Video Defaults**	Restores the following settings to factory default values: • Brightness: 50% (of full slider value) • Color Balance: 15% (of full slider value) • Dynamic Contrast: 0% (of full slider value) • Firefly Intensity: 50% (of full slider value) • Firefly Background Brightness: 50% (of full slider value) Restores user-initiated white balance.
	**Display Event Logs**	Displays the system event logs on the Vision Cart touchscreen.
	**OnSite**	The status of the network connection is shown here. The connection states are disconnected, connected, or active session in progress.
	**Software Version**	Lists the current system software version number.
	**System Identification**	Lists the system name and serial numbers for the Surgeon Console (SSC), Patient Cart (PSC), and Vision Cart (VSC).  Example

Table 7.8 Touchscreen Table, Guided Setup, and Fault tabs

Tab	Adjustment	Description
	**Table**	Displays operating table status (for example, Do Not Move Operating Table While Docked).
	**Guided Setup**	Displays Guided Setup messaging, steps, and status.
	**Fault**	Displays system status and troubleshooting information.

Arm Status from the Vision Cart Touchscreen

The arm and instrument status area displays real-time information about the endoscope and instruments installed on the Patient Cart. The arms are shown in status pods numbered 1 through 4. Instruments on arms 1 and 2 map to the left hand control and are controlled by the left set of foot pedals, and instruments on arms 3 and 4 map to the right hand control and are controlled by the right set of foot pedals. If arm 4 is on the left side, then the instruments on arms 4 and 1 map to the left hand control and the left set of foot pedals, and the instruments on arms 2 and 3 map to the right hand control and the right set of foot pedals. The status area provides arm, hand control, and the status of the instruments and endoscope in use.

Figure 7.22 Arm status pods



WARNING: Messaging displayed over an arm pod indicates the arm associated with that pod, to prevent patient injury due to confusion over messaging.

Instrument Status Indicators

- Instrument not in use: Gray instrument name and arm number
- Instrument Ready: Illuminated instrument name and arm number

Instrument Activation Status Indicators

- Activation not available: Gray
- Activation available: Associated pedal color
- Foot is hovering: Background highlight green

- Activated: Background highlight associated pedal color

Figure 7.23 Activation status indicators

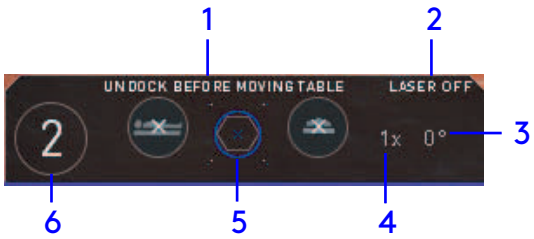


1. Arm number Instrument name and status
2. Activation status (no activation available)
3. Hovering, but no activation available
4. Activation available
5. Hovering and activation available
6. Activating associated blue pedal
7. Activating associated yellow pedal

Endoscope Status Indicators

- Endoscope not available: Gray
- Endoscope available: Highlight

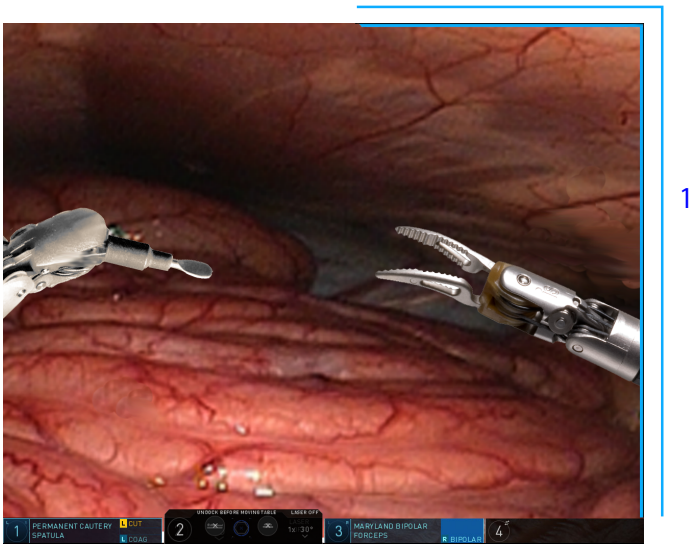
Figure 7.24 Endoscope status



1. Table
2. Firefly laser on/off
3. Endoscope type and direction
4. Digital zoom
5. Horizon
6. Arm number

A hover and activation status bar appears in the surgeon view to indicate hover (foot is over an active pedal but not pressing it) and then activation (foot pedal is pressed).

Figure 7.25 Activation status bar in surgeon view



1. Activation status bar

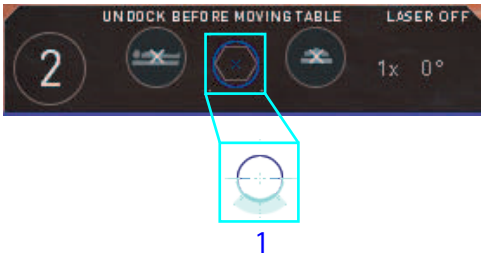
See 10.5 3D Viewer Display on page 10-47 for more information.

The status area for a specific arm pops up to display extended information or warnings. For a complete list of icons and text messages, refer to Appendix D Symbols, Icons, Audio Messages on page D-1.

Endoscope Horizon Indicator

This icon indicates the orientation of the endoscope in the surgical field. The thick part of the circle is “pulled” by gravity so it points at which direction is “down” with respect to the surgical image.

Figure 7.26 Endoscope horizon



1. Horizon

Off -Screen Indicator

CAUTION: Be aware of the off-screen indicators and their tool associations, to prevent tissue injury.

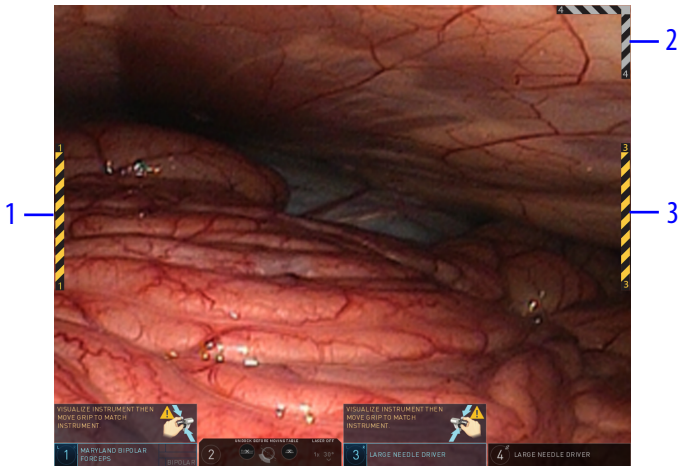
When an instrument is out of view, the off-screen indicator appears as a colored border that provides a guide for the user to point the endoscope towards the out of view instrument(s).

If the instrument out of view is active (associated), for example arm 1, the border is yellow and black with the number 1. If the instrument out of view is *not* active, for example arm 4, the border is gray and black with the number 4 (Figure 7.27).

To use the off-screen indicator:

Adjust the endoscope view so that it points towards the indicator until the instrument is in view.

Figure 7.27 Off-screen indicator example



1. Instrument arm 1 is off-screen and active
2. Instrument arm 4 is off-screen and not active
3. Instrument arm 3 is off-screen and active

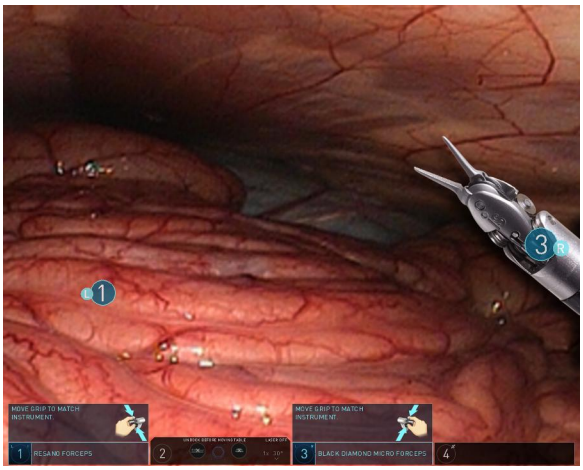
Tool Association Icons

CAUTION: Monitor the user interface cues to confirm associated instruments prior to taking control of them to prevent patient tissue damage.

The Tool Association icons provide visual cues to see which instruments are controlled from the Surgeon Console. The icons appear over or around the instrument wrist at the approximated corresponding depth in the 3D viewer (for example, when the icon is larger, the instrument is closer to the endoscope, and when the icon is smaller, the instrument is farther from the endoscope). The icons, which appear when the user is head-in the 3D viewer and prior to matching grips, provide a reference to know if an instrument is visually obstructed. For example, the icon may be visible in the 3D viewer, but the instrument tip is not, because it is behind tissue. Tool Association Icons are not available for da Vinci Xi Single-Site[2].

2. Not all technologies may have regulatory approval or may be commercially available in all geographies. For availability in your country, check with your local representative.

Figure 7.28 Tool Association icon examples (left instrument is behind tissue)



Take Photo

This feature enables the user to capture a still image of the endoscope view. The system saves the image to a USB flash drive connected to the Video Processor on the Vision Cart. The system records the left or right image based on which eye is being displayed on the touchscreen.

Note: External USB hard drives are not supported and are not recognized by the da Vinci system.

Vision Cart Photo

1. Insert a USB flash drive into the Video Processor.

   The Take Photo icon appears once the USB flash drive is recognized. This may take several seconds.

2. From the Display tab, tap **Take Photo** to capture the image.
3. The Saving Image message appears on the touchscreen while the image is being saved.

Endoscope Photo

1. Insert a USB flash drive into the Video Processor.
2. Press the **Take Photo** button on the endoscope to capture the image.

Wait a few seconds for the image to save before pressing the **Take Photo** button again to capture another image. An error beep sounds if the **Take Photo** button is pressed while an image is being saved.

Surgeon Console Touchpad Photo

1. Insert a USB flash drive into the Video Processor.
2. From the Instrument tab, tap the **Take Photo** quick-setting to capture the image.

The Take Photo icon has various states. It is grayed out for a few seconds while the image saves, it also indicates whether or not a scope is installed, a USB is detected, a USB is full or not recognized, and if there is a save error.

Telestration

The touchscreen also has a telestration feature that permits using a finger to draw a colored line over the video image. Telestration can be performed on the video image from the main surgical field or from an optional video input. To telestrate, press and drag a finger on the monitor to draw a colored line on the video image. The telestration drawn also appears in the Surgeon Console viewer, overlaid on whichever video channel (left or right) is being used at the touchscreen. The surgeon cannot block the appearance of telestration, but can remove the line(s) by pressing the endoscope foot pedal.

Telestration can be erased in two ways:

- The surgeon pressing the endoscope control pedal.
- The non-sterile user tapping the **Erase Telestration** button  located above the right most status pod on the touchscreen.

7.9 Troubleshooting Image Quality

Image Too Bright or Dark

Correct an Overly Bright Image

Use the brightness slider on the touchscreen or touchpad to decrease the brightness to the desired level.

Correct a Dark Image

1. Use the brightness slider on the touchscreen or touchpad to increase the overall brightness to the desired level, or use the Dynamic Contrast slider to increase the localized brightness.
2. When clinically feasible, check the tip of the endoscope for smudges or soiling, and clean the tip if necessary. Blood or other protein may have accumulated on the tip, diminishing light throughput.
3. Try another endoscope and contact Intuitive for a replacement.
4. If the problem persists contact Intuitive Customer Service.

Correct Flickering Image

1. Check for cautery interference.

   If flickering only happens during cautery, move any external ESUs away from the Vision Cart and move all of the cautery cords away from the Vision Cart cables.

2. Try another endoscope and contact Intuitive for a replacement.
3. Replace the ESU.
4. Restart the system.
   a. Power down the system.
   b. Power up the system.
5. If the problem persists contact Intuitive Customer Service.

Correct Blurry Image

1. Adjust the digital zoom setting:

   On the touchpad, select **1x**.

2. When clinically feasible, check the tip of the endoscope for smudges or soiling, and wipe the tip with sterile gauze if necessary. Blood or other protein may have accumulated on the tip, diminishing light throughput.
3. Try another endoscope and contact Intuitive for a replacement.
4. If the problem persists contact Intuitive Customer Service.

White Balance the Endoscope

Typically, the endoscope will not need to be white balanced; this is set automatically by the system. If for any reason white balancing is needed, follow these steps:

1. If not already done, connect the endoscope cable to the Endoscope Controller on the Vision Cart.
2. From the Vision Cart touchscreen or Surgeon Console touchpad, restore the Factory Defaults:
   a. On the touchscreen: On the Settings tab tap **Troubleshooting > Restore Video Defaults**.
   b. On the touchpad: On the Settings tab tap **Image > Restore Image To Factory Defaults**.
3. Point the distal tip of the endoscope about 4 in. (10 cm) away from a white object (such as sterile paper) so the object covers the entire field of view.
4. Tap the **White Balance** button on the touchscreen. The system sounds audible beeps when white balance is complete.

End of Section

Chapter 8 Prepare Patient and Place Ports

This chapter provides patient preparation and port placement information. The following subjects are covered:

Contents

8.1 Position the Patient 8-1
8.2 Place Ports and Insert Cannulas 8-1

8.1 Position the Patient

Patient positioning is procedure-specific and is at the discretion of the surgeon. arms should be arranged to avoid contact with the patient or equipment.

Note: The patient should be positioned before docking. Table movements are most easily performed before driving the Patient Cart into position. It is good practice to lower the table height before positioning the Patient Cart for docking.

Note: Once the da Vinci System is connected to the patient, the operating table MUST NOT BE MOVED in any way. Serious injury could result. If intraoperative OR table movement is necessary, remove all instruments and the endoscope, undock the da Vinci System, move the OR table, and re-dock the system.

8.2 Place Ports and Insert Cannulas

WARNING: Check the port sites throughout surgery for forces on the patient at the remote center, to prevent patient harm.

CAUTION: Consider instrument length when placing ports to prevent inability to access target anatomy.

Note: The initial port placed can be used to provide hand-held endoscope visualization for placement of the other cannulae. All port placement should be done under endoscopic vision. The obturator tips should remain in view at all times during cannula insertion (under endoscopic visualization).

Port Placement Guidelines

- Port placement varies by procedure and patient and should be thoroughly discussed with an experienced surgeon.
- Anatomical restriction may necessitate an alternate setup.
- For specialty-specific port placements, see published Intuitive Specialty Guides. Contact your Intuitive representative for available Specialty Guides.

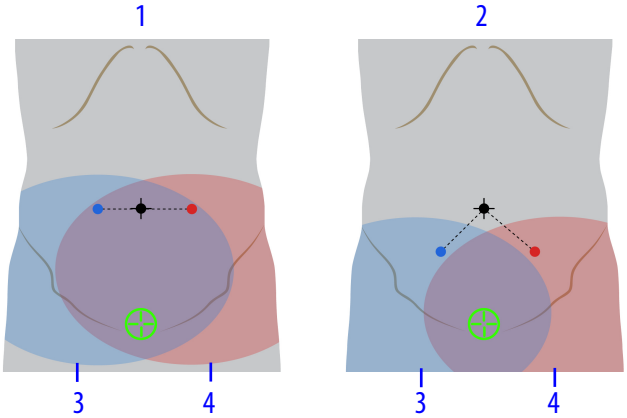
Key Terms:

- **Surgical workspace:** The area within the patient that the instruments must reach to complete all surgical tasks throughout the procedure.
- **Target anatomy:** The center of the surgical workspace boundary.

Note: The target anatomy is the center of the surgical workspace boundary, not necessarily the location of the pathology.

Straight line port placement allows arms to work in parallel, maximizing surgical workspace and minimizing arm interference. This is important if instrument reach behind the ports or in line with the ports is required. Triangulated port placement may also be used.

Figure 8.1 Examples of straight line ports and triangulated ports



1. Straight line
2. Triangulated
3. Blue oval: instrument reach area for blue port
4. Red oval: instrument reach area for red port

WARNING: Check cannulas for dents visually and with the Intuitive application-specific gauge pin prior to each use, to prevent damage to the instrument resulting in fragments in the patient.



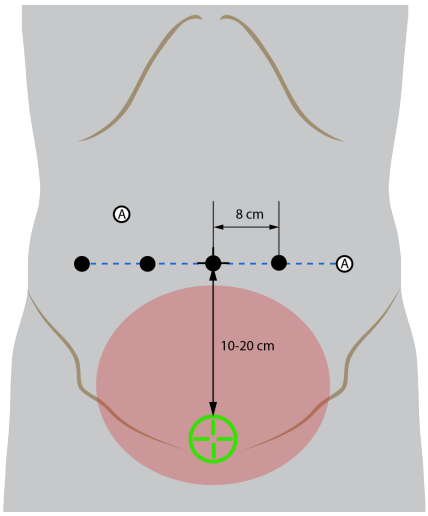
Note: Follow the instructions in the Instruments and Accessories User Manual to inspect cannulae and obturators before use, including use of a gage pin for 8 mm cannulae.

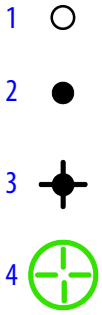
1. Insufflate the abdomen before measuring port placement. Following insufflation, mark the locations of instrument and accessory ports.

2. Identify the surgical workspace:
   - If two quadrants or less, place the target in center of the surgical workspace boundary.
   - If greater than two quadrants, consider dual docking (see 9.5 Dual Docking on page 9-33).
3. Place the initial endoscope port 10-20 cm from the target anatomy.
   - Place da Vinci Xi (robotic) ports using the compatible obturator.
   - Ensure adequate visualization and instrument reach to the surgical workspace.
   - Place the initial endoscope port at the edge, or beyond the edge, of the surgical workspace. This avoids losing perspective over the surgical workspace.
     – If more than 20 cm from the target anatomy, consider dual docking (see 9.5 Dual Docking on page 9-33).
4. Place remaining ports 6-10 cm apart (8 cm recommended) in a perpendicular line relative to the target anatomy.
   - Before placing ports, visually confirm target anatomy with initial endoscope port.
   - If space is limited, minimize distance between ports to 6 cm.
     – Ports can be a minimum of 4 cm apart in certain cases (for example, small surgical workspace requiring minimal outer arm motion such as mitral valve repair).
   - If space is not limited, distance between ports can be up to 10 cm.
   - Maintain 2 cm or more between ports and bony prominences.
   - Do not place ports between another port and the target anatomy.
   - Consider Port Hopping potential when placing ports (see Endoscope Port Hopping Overview on page 7-16).
     – Consider placing four ports to switch between two right hands and two left hands.
     – Consider placing five ports to switch between two left and two right hands, and maintain vantage point.

5. Place assistant ports as needed, as far away as possible (at least 7 cm) from robotic ports.
   - Place in line with or triangulated between robotic ports to maximize access and minimize Patient Cart arm interference.
   - Do not place an assistant port between a robotic port and the target anatomy.
   - Consider what the assistant needs to do or access. Consider which side of the patient the assistant will be on. Ensure the assistant is facing the target anatomy and can access the arms for instrument exchanges and intraoperative endoscope cleaning.
   - Consider using longer length laparoscopic instruments to add distance between the assistant and the arms.

   The following example shows port placement guidelines.





1. Assistant port
2. Robotic port
3. Initial endoscope port
4. Targeting (center of the surgical workspace boundary)

Once cannulae are inserted and the patient is positioned, a non-sterile person uses the Patient Cart drive to move the Patient Cart into the sterile field for docking.

Docking is the process of moving the Patient Cart to the OR table and connecting the arms to the cannulas. To dock the da Vinci system, follow the steps in Position the Patient Cart on page 9-15.

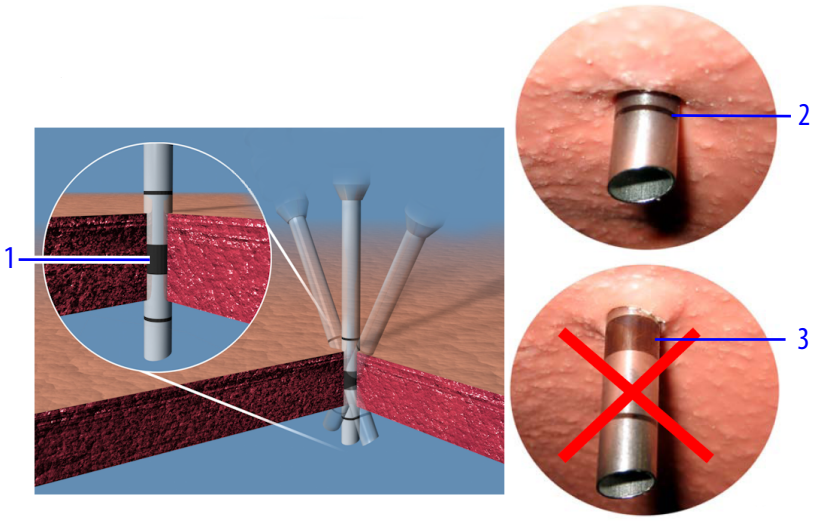
Specific applications may warrant placement of the cannula while connected to the Patient Cart arm (for example, Cardiac and Thoracic procedures). In specific applications, the Patient Cart needs to be positioned before cannula insertion.

Remote Center

The da Vinci system uses remote center technology. The remote center is the pivot point around which the da Vinci system moves the arms. Remote center technology enables the system to precisely maneuver instruments in the surgical site while exerting minimal force on the patient's body wall. When the cannula remote center is placed correctly in the patient’s body wall, moving the arms exerts minimal pull and tug at the port site, and ensures the best performance of the instrument motion.

The remote center is indicated by the thick, center black band on the cannula.

Figure 8.2 Proper placement of instrument cannula remote center



1. Correct placement allows instruments to pivot through the incision with less friction and greater precision. To correctly place the remote center, the thick black line on the da Vinci cannula should be inserted within the patient's body wall.
2. Correct placement of the cannula should be verified by looking at the cannula tip with the endoscope. Only the first thin line at the distal cannula tip should be visible, indicating that the remote center is placed correctly within the boundaries of the patient's body wall.
3. If the thick black line on the cannula is seen in the endoscopic view, the remote center is inserted too deeply. Moving the arms with the remote center placed incorrectly increases friction, reduces precision, and increases tissue trauma at the port site.

The Surgeon Console operator cannot move the remote center. The patient-side assistant can adjust the remote center by repositioning the arm using the port clutch button. It is recommended to check the position of the arms throughout surgery to ensure there is no tension on the port sites. For instructions to release tension see Port Clutch on page 9-28.

End of Section

Chapter 9 Patient Cart Use

This chapter provides information on the Patient Cart. The following subjects are covered:

Contents

9.1 Patient Cart Overview 9-1
9.2 Patient Cart Positioning and Docking Overview 9-9
9.3 Manually Adjusting the Patient Cart Arms 9-25
9.4 Three-Arm Procedure 9-32
9.5 Dual Docking 9-33
9.6 EndoWrist Instruments 9-35
9.7 Instrument Installation 9-36
9.8 Intraoperative Arm Management 9-39
9.9 Instrument Removal 9-45
9.10 Intraoperative Instrument Maintenance 9-48
9.11 Manage Instrument Inventory 9-49
9.12 Fluid Leakage Precautions 9-50
9.13 Stow the Patient Cart 9-50
9.14 Patient Cart Troubleshooting Quick-reference 9-52

9.1 Patient Cart Overview

The Patient Cart is the operative component of the da Vinci Xi system and its primary function is to move the instruments and endoscope using four arms under the control of the Surgeon Console operator (surgeon). A patient-side assistant in the sterile field helps the surgeon by exchanging instruments and endoscopes on the arms. To help ensure patient safety the Patient Cart operator actions take precedence over Surgeon Console operator actions. For full descriptions of Patient Cart components, see 2.3 Patient Cart on page 2-3.

Laser Indicators

The Patient Cart has laser indicators that provide users information about the positioning of the Patient Cart during transportation and positioning to the patient.

The laser indicators are activated when:

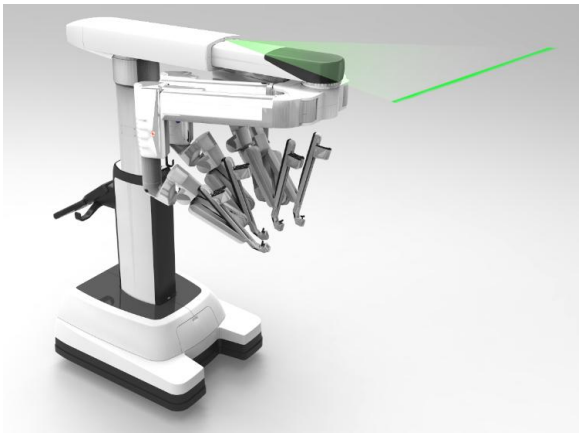
- The boom is deployed and cart drive is enabled.

- The boom is being moved by any user control.

Horizontal Laser

The horizontal laser is mounted just below the highest point of the system. The horizontal laser projects a horizontal line in front of the Patient Cart, highlighting possible collisions during powered Patient Cart movement.

Figure 9.1 Horizontal laser

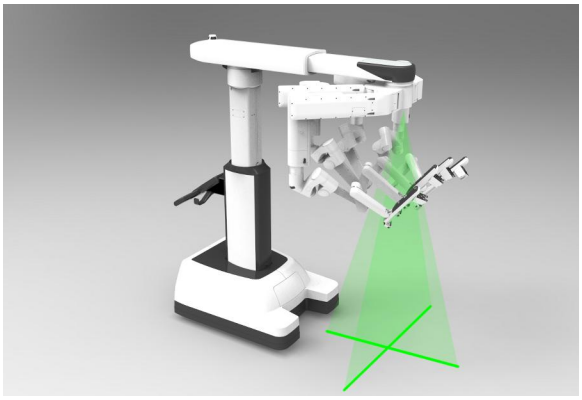


Positioning Laser

WARNING: Be sure to safely and effectively use the system lasers to prevent eye injury.

The positioning laser is mounted at the center of the boom and projects downward to assist positioning the Patient Cart at the patient. Additionally, the positioning laser activates during draping, when it is helpful to have a reference line for adjusting arm position (see Chapter 6 Drape the System on page 6-1).

Figure 9.2 Positioning laser



Patient Cart Helm

Figure 9.3 Patient Cart Helm



1. Touchpad
2. Emergency Stop button
3. Cart drive enable switches
4. Boom position control
5. Battery LED indicator
6. Power button
7. Cable holder
8. Boom height control
9. Handlebars

WARNING: Avoid collisions during any user-initiated powered motions of the Patient Cart, to prevent damage to equipment or harm to the user or patient.

WARNING: Always use caution when moving the Surgeon Console, Vision Cart, or Patient Cart to prevent injury to the user or patient.

WARNING: Undock the instrument arms prior to moving the patient, table, or Patient Cart to prevent patient harm.

WARNING: Be sure to understand the function of the Patient Cart joystick and the use of the setup controls to prevent patient injury.

Note: To move (drive) the Patient Cart, press the cart drive enable switches on the handlebars. The cart drive enable switches adjust the motion speed according to the amount of force applied by your hands.

Note: The boom control joysticks adjust the speed according to the button limit. That is, pressing the joystick to its furthest limit results in the fastest speed.

To enable the adjustments below, press and hold Enable Joysticks on the Patient Cart touchpad.

- **Raise/Lower the boom:** Push the boom height control button up to raise the boom. Push down to lower the boom.
- **Extend/Retract:** Push the boom position control up to extend the boom. Push down to retract the boom.
- **Rotate boom:** Rotate the boom position control to rotate the boom.
- **Move boom left/right:** Push the boom position control left or right to move the boom to the left or to the right.

To stop system operation at any time, press the red **Emergency Stop** button. Emergency Stop initiates a recoverable fault, which can be overridden by tapping **Resume Use** on the touchpad.

Patient Cart Touchpad

The touchpad, located on the Patient Cart Helm, provides features for Patient Cart activities such as preparing the cart for draping or docking, stowing the cart for transport, or stowing after draping to help the user minimize the space it uses in the OR. The touchpad also provides a means for system fault notification and recovery.

Figure 9.4 Patient Cart touchpad Home tab and Settings tab



1. Home
2. Settings

Home Tab

The Patient Cart touchpad includes a Guided Setup feature on the home tab that provides a series of context sensitive prompts and controls to prepare the Patient Cart for draping, stowing, and docking (see Guided Setup on page 9-9).

Settings Tab

Voice Feedback:

Access the voice feedback controls from the Patient Cart touchpad, touch **Settings**.

- **All** plays all voice prompts. This is the default behavior.
- **Reduced** turns off tutorial voice prompts. If Reduced is selected, a message appears informing that tutorial voice prompts are turned off.
- **Patient Cart volume slider** adjusts the Patient Cart volume.

System Height Limit

The system height limit feature aids the use of the Patient Cart in environments with low overhead clearance. The system height limit prevents users from inadvertently raising the boom to heights that may interfere with ceiling-mounted OR equipment.

There are two possible settings for System Height limit: On and Off. To make a selection, navigate to the Patient Cart touchpad **Settings** tab, and under System Height Limit select the desired option (summarized in Table 9.1, below):

Table 9.1 System Height Limit Settings

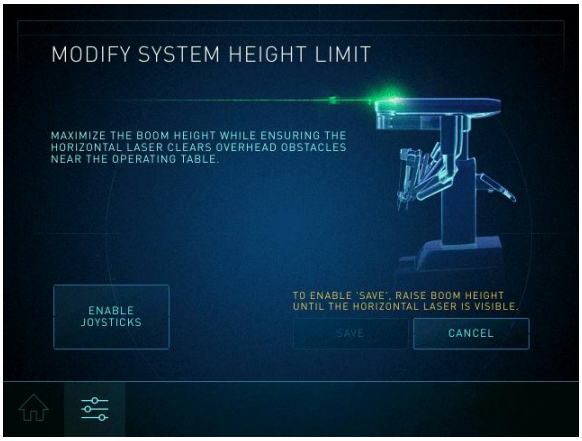
System Height Limit	
On (default)	Selecting On restricts the maximum height of the system to minimize the likelihood of colliding with ceiling-mounted objects, such as OR lights.
Off	Selecting Off allows the system to extend to its full height, which may be necessary in some circumstances, such as with very large patients. • The system height limit is automatically re-enabled upon system startup if a valid height limit has been set.
Modify	Selecting Modify provides controls for the user to manually set the system height limit, so that it can be set appropriately for the relevant operating room(s).

Modify System Height Limit

The system height limit is set for its maximum setting by default, so that vertical motion of the boom is unrestricted. However, trained personnel can set or modify this limit as needed, which will persist across uses of the Patient Cart.

1. Tap **Modify** from the Settings tab on the Patient Cart touchpad.
2. Point the Patient Cart near where it will be used for surgery but not directly underneath a low ceiling obstacle.
3. Press and hold **Enable Joysticks** and use the boom height control joystick to raise or lower the boom. The horizontal laser will illuminate and can be used as a guide to identify potential overhead obstacles.
4. Adjust the boom height so the horizontal laser illuminates the lowest point on any obstacle(s) near, or in the path to, the operating table, and then adjust the laser so it is below the obstacle(s).
5. Tap **Save**.

The system height limit can be cleared by raising the boom to its range of motion limit and pressing **Save**.



LED Status Indicators

The arms and boom have LEDs to communicate system status and conditions. Corresponding icons and graphics depicting system status appear simultaneously on the Vision Cart touchscreen and 3D viewer.

Figure 9.5 Patient Cart arm LED indicator locations



The meanings of the arm LED indicators are defined in Table 9.2.

Table 9.2 Arm LED status indicators

LED Status	Meaning
Off	The arm is unpowered, disabled, or stowed.
Blue / Solid	The system is operating properly.

(continues on next page)

Table 9.2 Arm LED status indicators (continued)

LED Status	Meaning
Blue / Blinking	• Instrument clutch or port clutch is in progress. • Patient clearance should be considered to improve instrument reach.
Blue / Pulsing	• The arm is performing an activity which requires the user to wait for a brief period, for example, instrument engagement. • The user is adjusting the patient clearance of the arm.
Green / Blinking	Guided Tool Change is in progress.
Yellow / Solid	Recoverable fault
Yellow / Blinking	Arm-related issue that the user normally can resolve, including issues associated with instruments, for example, during a homing failed message.
Red / Solid	Non-recoverable fault

The Boom LEDs are located on the underside surface of the boom, as shown.

Figure 9.6 Patient Cart boom LED indicators



The meanings of the boom LED indicators are defined in Table 9.3.

Table 9.3 Patient Cart Boom LED status indicators

LED Status	Meaning
Off	Unpowered or disabled
Blue / Solid	The system is operating normally.
Blue / Pulsing	Patient Cart boom is moving and positioning laser is not active.
Green / Pulsing	Patient Cart boom is moving and positioning laser is active.
Yellow / Solid	Recoverable error
Red / Solid	Non-recoverable error

Patient Cart battery LED indicators are located on the Helm. The battery LED indicator meanings are defined in Table 9.4.

Table 9.4 Patient Cart Battery LED Indicator (not connected to AC power)

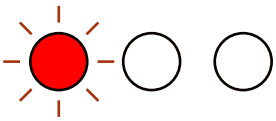
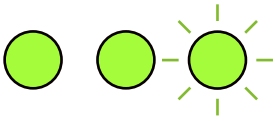
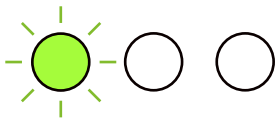
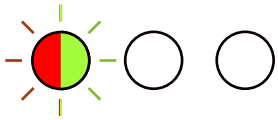
LED Status	Meaning
Three Green / Solid 	The battery is fully charged.
Two Green / Solid 	The battery is 50 percent charged (approximately).
One Green / Solid 	The battery is 25 percent charged (approximately).
One Red / Solid 	The battery is 10 percent charged (approximately).
One Red / Flashing 	The battery is less than 10 percent charged (or battery status not known).

Table 9.5 Patient Cart Battery LED Indicator (connected to power)

LED Status	Meaning
Three Green / Solid 	The battery is fully charged.
Two Green / Solid, One Green / Flashing 	The battery is 75 percent charged (approximately).
One Green / Solid, One Green / Flashing 	The battery is 50 percent charged (approximately).

(continues on next page)

Table 9.5 Patient Cart Battery LED Indicator (connected to power) (continued)

LED Status	Meaning
One Green / Flashing 	The battery is 10 percent charged (approximately).
One half Red / Green Flashing 	The battery is less than 10 percent charged (approximately).
One Red / Flashing, One Green / Flashing 	The battery status not known (disabled).

9.2 Patient Cart Positioning and Docking Overview

To position the Patient Cart for docking, deploy the boom, adjust the arms, and position the Patient Cart next to the OR table in preparation for surgery. Patient Cart movements are performed using either of two methods: Guided Setup (see Guided Setup on page 9-9) or manual control (see 9.3 Manually Adjusting the Patient Cart Arms on page 9-25). The boom is adjustable in height, extension (closer or further from the base), and rotation. The arms flex (a joint that allows spacing of the arms from each other) and can be extended and adjusted for appropriate placement and range of motion for surgery.

Guided Setup

Guided Setup and targeting simplifies preparing, positioning, and docking the Patient Cart for intraoperative use. Figure 9.7 shows Patient Cart movement areas for Guided Setup and targeting. For full descriptions of Patient Cart components, see 2.3 Patient Cart on page 2-3.

Figure 9.7 Guided Setup and targeting movement areas



1. Column
2. Boom pivot
3. Boom
4. Boom rotation
5. Flex joint
6. Patient clearance

Settings for draping and stowing the Patient Cart are also available. For information regarding draping the system, see Chapter 6 Drape the System on page 6-1. For information regarding stowing, see 11.3 Stow the Patient Cart on page 11-2.

Guided Setup Guidelines

- Operating rooms may have overhead obstacles. Consider positioning the patient such that these obstacles are out of the way.
- Room restrictions may require an alternate setup.
- For specialty-specific Patient Cart anatomy and approach selections, see published Intuitive Specialty Guides. Contact your local Intuitive representative for available Specialty Guides.

During Guided Setup, the da Vinci system deploys to a preset position for docking based on the anatomy and cart location selections made from the Patient Cart touchpad.

Make selections from the Patient Cart touchpad based on:

- the Patient Cart location for draping, sterile stow, and intraoperative use,
- the anatomical region of the target anatomy to be used for the surgery, and
- access to the patient with consideration for how much room the patient-side assistant may need for comfortable ergonomics.

While deploying, the Patient Cart adjusts the following simultaneously:

- rises to a preset height, facilitating patient clearance,
- extends the boom outward from the column to ensure sufficient reach over the patient,
- pivots the boom from the center of the column, as needed, to create enough room for a patient-side assistant to work on the same side as the base,

- rotates the boom to generally orient the arms towards the intended target anatomy, and
- adjusts the patient clearance joints to preset positions facilitating patient clearance.
- Once positioned further manual adjustment of the arms is required to maximize overall reach and minimize potential interference.

Using Guided Setup, there are three basic Patient Cart positions, each based on the boom pivot angle and the rotation of the arms: straight, toward the head, or toward the feet.

Figure 9.8 Deployment examples

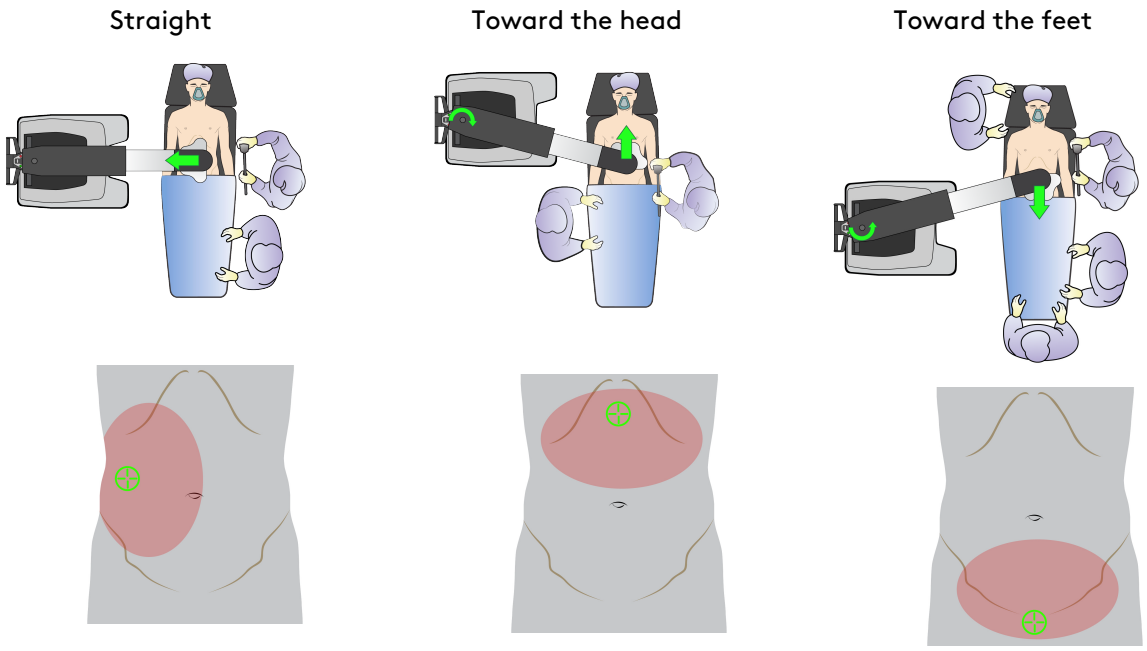


Table 9.6 outlines deployment positions based on the selected anatomy and approach from the Patient Cart touchpad. The boom may need further adjustment once docked.

Table 9.6 Patient Cart Deployment Settings

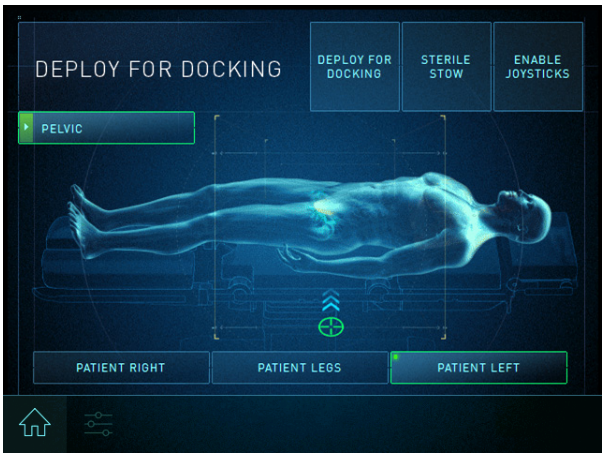
	Selected Cart Location (Approach)		
Selected Anatomy	**Patient Right**	**Patient Left**	**Patient Feet (Between the legs)**
Thoracic	Toward the head	Toward the head	N/A
Cardiac	Straight	Straight	N/A
Upper Abdominal	Toward the head	Toward the head	N/A
Lower Abdominal	Straight	Straight	N/A
Renal	Straight	Straight	N/A
Pelvic	Toward the feet	Toward the feet	Straight

After draping, once cannulae are inserted in the patient, a non-sterile person moves the Patient Cart into the sterile field to prepare for docking.

Manual Positioning: While Guided Setup is the simplest and most accurate way to position the Patient Cart, if Guided Setup does not achieve the desired positioning, the manual controls can be used. See 9.3 Manually Adjusting the Patient Cart Arms on page 9-25.

The Patient Cart touchpad provides Guided Setup instructions for the non-sterile Patient Cart operator through positioning and docking. The Vision Cart touchscreen provides images and text to assist the sterile assistant at the OR table with the completion of each step.

Figure 9.9 Guided Setup



Patient Cart touchpad



Vision Cart touchscreen

- During Guided Setup, the Patient Cart touchpad displays text indicating the next step.
- The Vision Cart touchscreen provides images and text to assist the sterile person at the OR table to complete each task.
- The Patient Cart touchpad Home tab can be used to return to the Guided Setup instructions any time before all arms are docked.

For further instructions see the following sections of this manual:

- Chapter 6 Drape the System on page 6-1
- 9.5 Dual Docking on page 9-33
- Chapter 10 Surgeon Console Use on page 10-1

Prepare for Positioning

WARNING: To avoid an electrical hazard, do not touch the patient and undraped surfaces of the Patient Cart at the same time.

- A non-sterile person operates the Patient Cart drive and moves the Patient Cart into the sterile field.
- Communication is critical when moving and docking the Patient Cart. Only one person should give directions to the Patient Cart operator about potential collisions and for positioning when approaching the patient.
- When moving to the OR table, the person providing directions should use anatomical or room references (such as “toward the head,” or “away from the Vision Cart”) to direct the Patient Cart movements. The person providing directions should avoid using relative terms such as “left” or “right”.

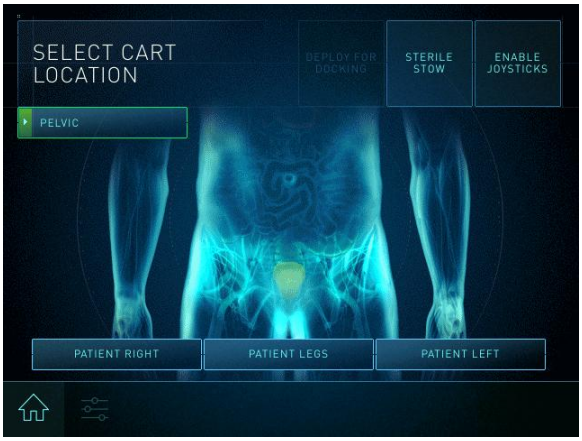
Deploy

Once the Patient Cart is fully draped (as described in Chapter 6 Drape the System on page 6-1), follow these steps to continue with Guided Setup:

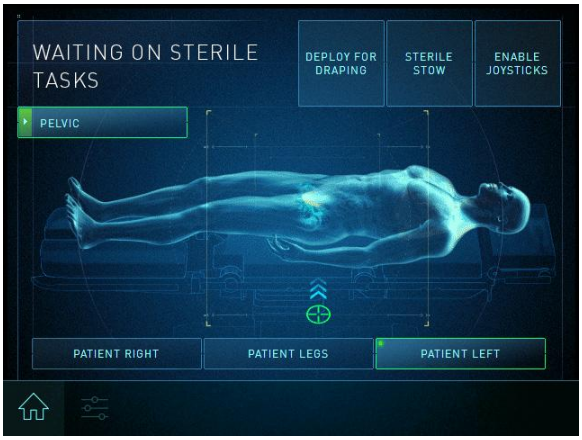
1. Select the desired anatomical region from the **Select Anatomy** screen on the Patient Cart touchpad.



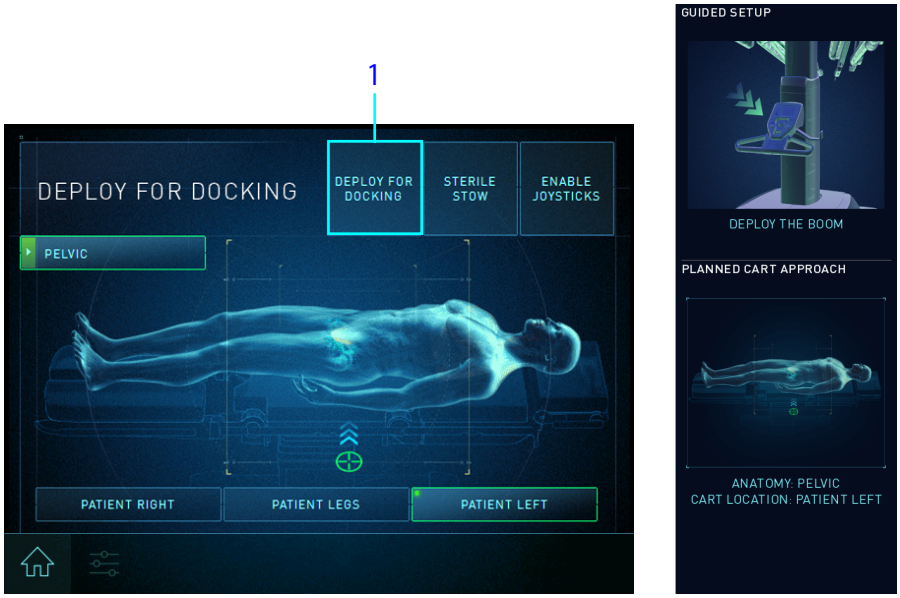
2. Select the desired cart location (the side of the patient where the Patient Cart will be positioned) from the **Select Cart Location** screen on the Patient Cart touchpad.



3. If not already done, confirm all of the arms are positioned behind the green laser line. The Waiting on Sterile tasks screen appears until sterile tasks are complete.



4. When ready to move towards the patient: From the Patient Cart touchpad, press and hold **Deploy for Docking**. The boom rises, extends, and rotates. The arms move to the proper orientation for the selected approach.



1. Press and hold

Note: Be aware of potential collisions within the OR. Move any overhead lights, booms, and equipment.

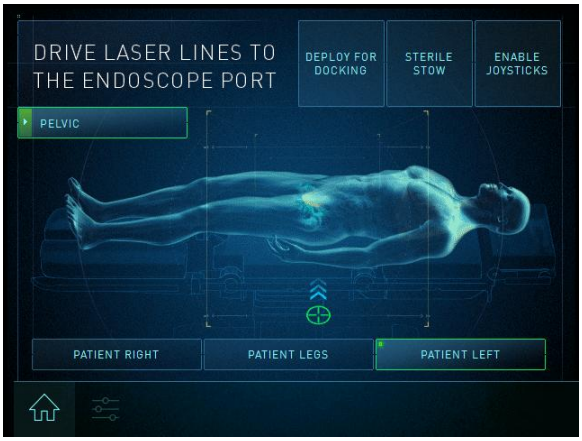
Note: If Guided Setup does not provide the required system configuration, it is possible to position the boom using manual controls as described in 9.3 Manually Adjusting the Patient Cart Arms on page 9-25.

Note: The setup may be changed as needed by selecting a new anatomy and cart location and pressing and holding Deploy for Docking again.

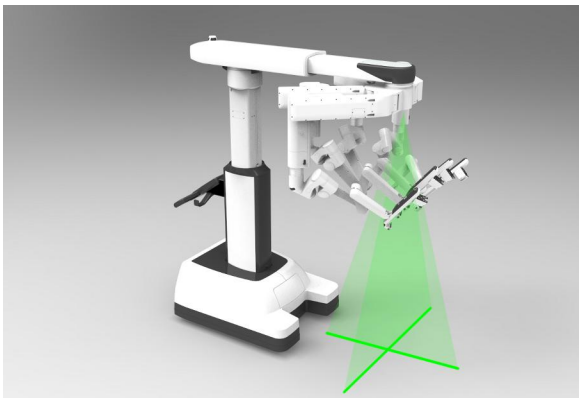
Position the Patient Cart

Once deployed, drive the Patient Cart to the operating room (OR) table.

Figure 9.10 Drive Laser Lines (touchpad)



1. Squeeze one or both of the cart drive enable switches on the Patient Cart Helm to start the cart drive. A green positioning laser is projected from the boom toward the floor. It may be necessary to adjust the arms to see the laser and/or avoid collisions.
2. Confirm that the positioning laser is visible on the floor before positioning the Patient Cart. If the laser is not visible, push all arms behind the laser lines.



3. Slowly drive the Patient Cart to the OR table. Position the Patient Cart base next to the OR table where patient-side access is not required.

4. Watch for potential collisions with the non-sterile field. Ensure there is sufficient clearance between the patient and the lowest point of the arms.

   The following adjustments can be made during Patient Cart positioning to increase patient clearance and avoid contamination:

   - A sterile staff member can use the *grab and move* feature (see 9.3 Manually Adjusting the Patient Cart Arms on page 9-25) to reposition the arms individually.
   - A sterile staff member can use *extended port clutch* to raise the entire boom (see 9.3 Manually Adjusting the Patient Cart Arms on page 9-25).
   - A non-sterile staff member can adjust boom height and position using the joysticks at the Patient Cart Helm (see 9.3 Manually Adjusting the Patient Cart Arms on page 9-25).

5. Slowly drive the Patient Cart to position the laser lines within 5 cm of the initial endoscope port. The orientation of the Patient Cart with respect to the OR table is not critical. Make further adjustments using the manual controls on the Patient Cart Helm (see 9.3 Manually Adjusting the Patient Cart Arms on page 9-25).

   Note: Before moving the Patient Cart towards the OR table, make sure there is enough clearance between patient and lowest point of arms. Raise the arms, if needed, using the port clutch button.

Docking

Docking is the process of moving the Patient Cart to the OR table and connecting the arms to the cannulae. Once cannulae are inserted in the patient, a non-sterile person moves the Patient Cart into the sterile field.

When moving the Patient Cart towards or away from the OR table, the person providing directions should use anatomical or room references (such as “toward the head,” or “away from the Vision Cart”) to direct the Patient Cart movements. The person providing directions should avoid using relative terms such as “left” or “right”.

WARNING: Use the Lock/Unlock button to lock and unlock an arm’s position to prevent tissue injury.

WARNING: Avoid instrument contact or collisions (including endoscopes) inside the patient to prevent tissue injury or damage to the instrument resulting in fragments in the patient.

CAUTION: Ensure proper setup of the cannula, seal, and any attachments to these, to prevent tissue injury.

CAUTION: Avoid collisions or contact between the endoscope arm and instrument arms to prevent patient tissue damage.

CAUTION: Avoid external collisions during any motion of the arms, including when using the Grab and Move feature, to avoid collisions that could result in user or patient harm.

CAUTION: Instrument arm spacing (for example, flex functionality) performance is different when in a normal state versus a faulted state, to prevent patient harm.

CAUTION: Unexpected motion can occur when instruments collide. Ensure there is adequate room for instruments to move inside the patient to prevent tissue injury.

Note: Pay special attention to avoid collisions to prevent patient tissue damage.

Note: If, while operating, you move the hand controls and no instrument motion occurs, there may be interference between instruments or arms, or between an arm and the patient. Resolve the interference before proceeding with the surgery.

Note: If collisions between the arms occur, it may be possible to slightly adjust the position of setup joints using the port clutch button to create more space between arms. Remove the instruments before pressing the port clutch button and use care to prevent sliding of the cannula out of the port site while you adjust the arm positions.

Note: If collisions between the arms occur, ensure that the instruments are still fully engaged on the arm.

Once the Patient Cart is in place (see Position the Patient Cart on page 9-15), the arms and boom must be positioned to connect (dock) to the cannulae.

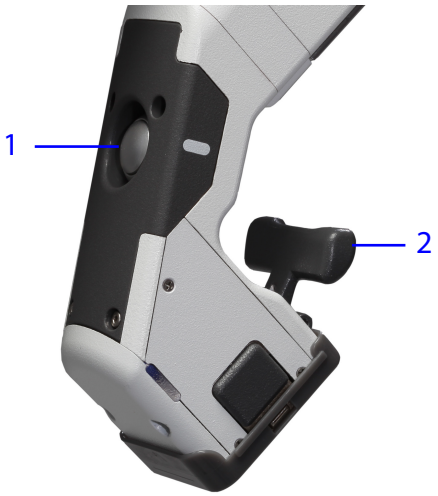
Figure 9.11 Dock initial endoscope arm (Vision Cart touchscreen)



1. If needed, use the instrument clutch and port clutch buttons to manually adjust the position of the arm that will hold the endoscope. Dock that arm's cannula first.

   Note: Arms that are not docked to a cannula can be positioned by grabbing the arm and moving as desired (grab and move feature).

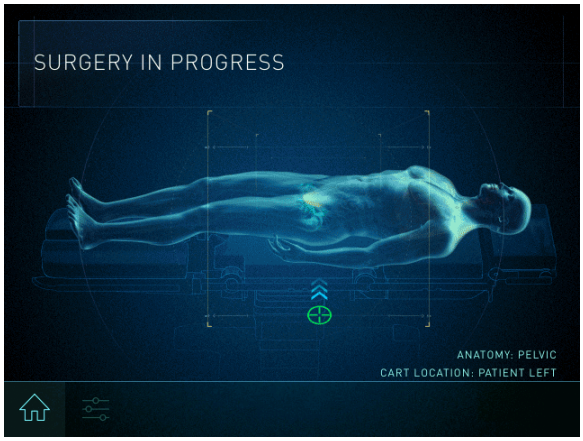
   Note: To ease connection of the cannula to the cannula mount, simultaneously press the port clutch button and the cannula mount lever.



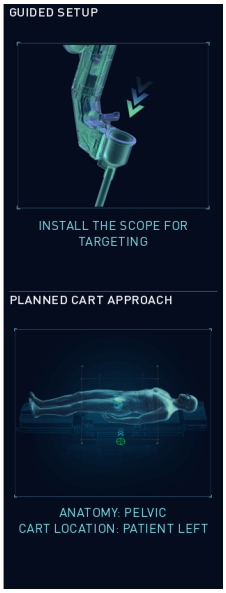
1. Port clutch
2. Cannula mount lever

2. Make sure the cannula sterile adapter on the drape is properly aligned with the cannula mount.
3. Press and hold the cannula mount lever and insert the cannula fin. Release the lever. An audible tone indicates a properly docked cannula. Once a cannula is docked, the Surgery in Progress screen appears on the Patient Cart touchpad. Prompts to install the endoscope for targeting appear on the Vision Cart touchscreen.

Patient Cart touchpad



Vision Cart touchscreen



4. Install the endoscope on the arm by inserting the endoscope tip into the cannula and pressing the endoscope onto the sterile adapter until it clicks into place.
5. Use the instrument clutch button and manually advance the endoscope. Position the endoscope to view the target anatomy, using the targeting icon as a guide.

   Perform Targeting: See Step 4 on page 9-21.

Targeting

WARNING: Be sure to understand the function of the targeting feature, including supporting the cannula while targeting, to prevent patient or user injury.

Once the Patient Cart is deployed and the initial endoscope arm is docked, perform targeting. While the da Vinci system can be positioned manually, targeting ensures the system is oriented and aligned to the center of the surgical workspace boundary established during port placement.

Targeting aligns the Patient Cart boom over the surgical workspace to:

- Ensure that all arms can dock to the cannulas.
- Orient the arms towards the target anatomy.
- Maximize the setup joint range of motion.
- Maintain sterility with the undraped boom.

Note: While the boom is moving, watch all undocked arms to ensure they do not contact objects in the environment (sterile or non-sterile). The undocked arms may enter a state similar to port clutch (to soften potential collisions with the patient or environment) and may drift.

Note: Hold the cannula with one hand to support it during motion and hold the Targeting button with the other hand.

Note: Targeting generally orients the boom. Targeting does not change the position of the flex joints, patient clearance joints (except for da Vinci Single-Site[1]), or the arms. To optimize setup, manually adjust the arms once targeting is complete.

Note: The positioning laser remains on after targeting is complete so it can be used as a guide to align the initial endoscope arm. The positioning laser turns off after a brief period of time, or when a second cannula is installed on the system (whichever occurs first).

What Targeting Does

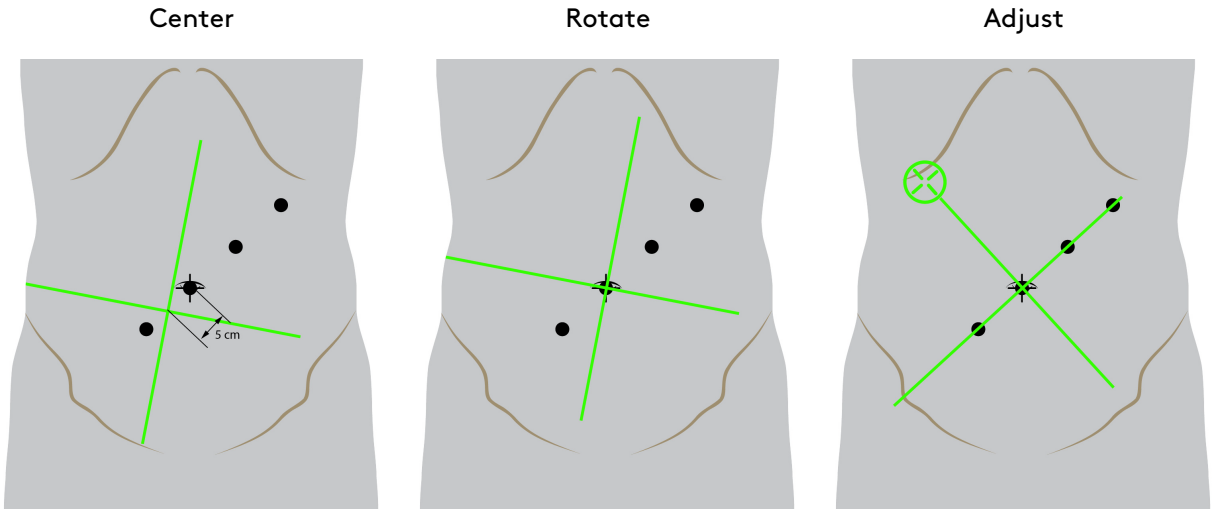
During targeting, the da Vinci system makes the following adjustments simultaneously:

- Center the boom over the remote center of the initial endoscope port (occurs only if arms 2 and 3 are docked).
- Rotate the boom to point toward the target anatomy.

1. Not all technologies may have regulatory approval or may be commercially available in all geographies. For availability in your country, check with your local representative.

- Adjust the system height to maximize sterility between the boom and the arms, while ensuring reach to low, lateral ports (that is, there is enough space between the docked arm remote center and the underside of the boom to maintain sterility).

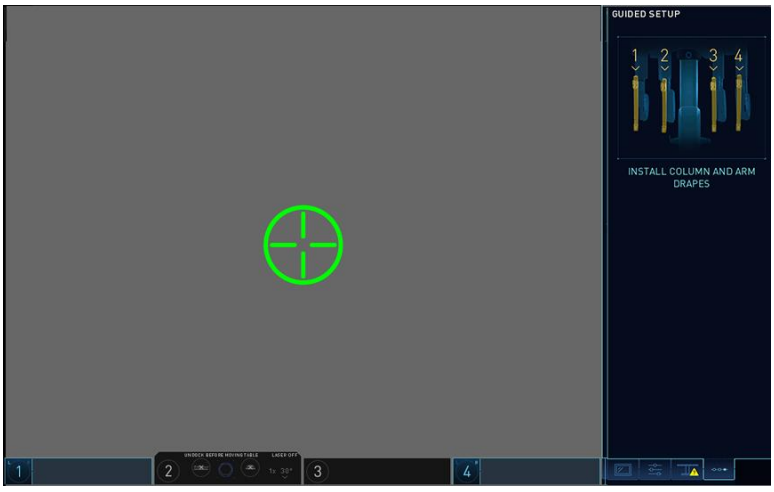
Figure 9.12 What happens in targeting



Perform Targeting

1. Dock the initial endoscope port.
2. Ensure the remote center is appropriately placed within the body wall.
3. Install the endoscope, and use the instrument clutch button to point the target icon lines (that appear on the touchscreen) at the target anatomy.

> **Note:** The target anatomy is the center of the surgical workspace boundary, not necessarily the location of the pathology.



4. Support the cannula with one hand, and use the other hand to press and hold the targeting button on the endoscope. Continue holding until the audible signal completes and motion stops.

5. After targeting completes, confirm target anatomy placement.
   - If ports are placed in a line perpendicular to the target anatomy, the positioning laser should transect the line of ports.
6. If targeting does not complete, confirm boom placement and rotation with respect to the target anatomy. If the following requirements are met, continue without completing targeting:
   - Ensure all arms can dock.
     - If unable to dock all arms, remove the endoscope, undock all arms, and adjust the column height.
   - Ensure there is sterile clearance between the boom and the arms.
   - Ensure the boom is rotated toward the target anatomy.
     - If the target anatomy is not centered in the surgical image, undock all arms, and adjust the boom rotation.

If any of the above requirements are not met, follow the instructions on the touchscreen, or contact Intuitive Customer Support.

Docking and Arm Alignment after Targeting

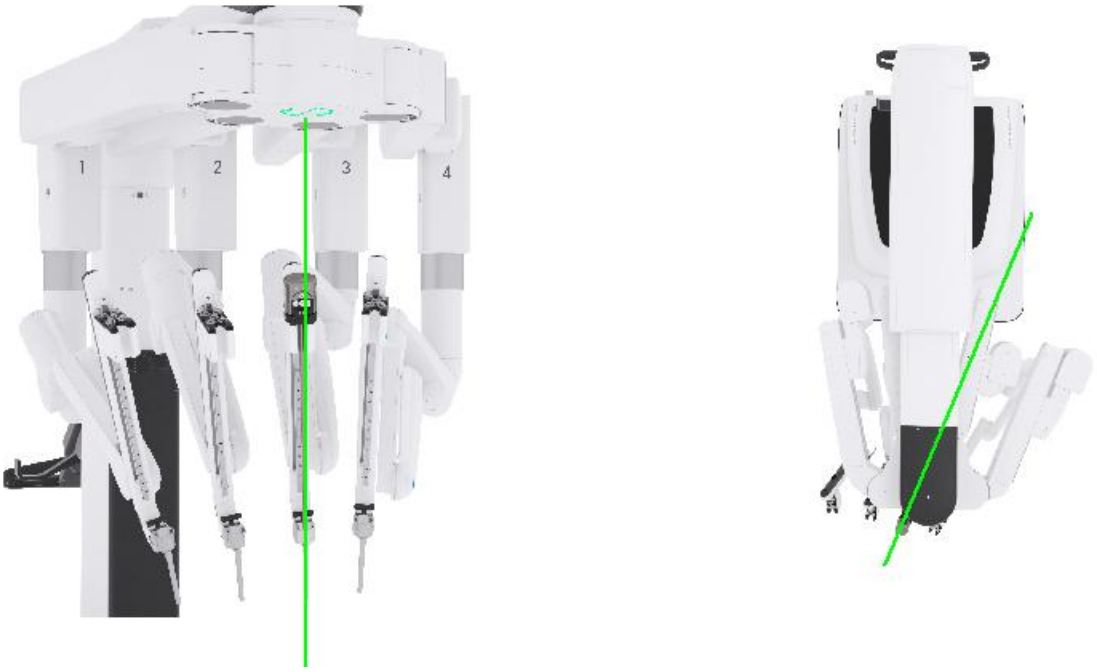
⚠ **CAUTION:** Adjusting a Patient Cart arm may result in the instrument or cannula tip moving, which may lead to patient harm.

Once targeting is complete, or the requirements in step 6 (above) are met, follow these guidelines to complete docking:

1. Use the port clutch button to adjust the flex joint of the initial endoscope arm to be in line with the target anatomy. This centers that arm so the rest of the arms can be adjusted.
   - Ensure the flex joint is not at a range of motion limit.

   Note: The positioning laser remains on after targeting is complete so it can be used as a guide to align the initial endoscope arm. The positioning laser turns off after a brief period of time, or when a second cannula is installed on the system (whichever occurs first).

   The following example shows the initial endoscope on arm 3 and the positioning laser in line with target anatomy.



2. Dock the remaining arms: align each cannula mount to a cannula and connect.

   If needed, use the port clutch button to space the arms (about a fist's spacing). This helps resolve and avoid potential arm collisions during a procedure. It is recommended to position the arms as close together as possible while still allowing each axis to move without interference.

   If needed, use the **patient clearance** button on each arm to adjust the arm angle. Adjust the angle "up" for increased patient clearance, or "down" for increased instrument access.

3. Starting with the arms closest to the initial endoscope arm, use the port clutch and flex joints to bring arms together, using one hand to measure about a fist's space between the arms. This ensures sufficient space for the arms to work in parallel, and for patient clearance adjustment.



- The flex joint range of motion varies depending on the boom rotation (target anatomy). The flex label indicates the range of motion for each arm, but it is not meant for setting up or arranging the arms.



4. After the arms are spaced, lower the patient clearance joints with about a fist's space to the patient or other sterile obstacles. This ensures maximum instrument reach.

Note: Patient clearance adjustment is optional. Consider patient access and instrument reach needs and adjust patient clearance joints accordingly.

Note: The relative position of each patient clearance joint can vary from arm to arm.

Note: Patient clearance and flex joint adjustment may result in cannula and/or instrument tip movement.

The following example shows the patient clearance adjustment using a fist's spacing.



9.3 Manually Adjusting the Patient Cart Arms

Under normal circumstances, Guided Setup on page 9-9, is the easiest and most accurate way to position the Patient Cart, If Guided Setup does not achieve the desired positioning, the manual controls can be used.

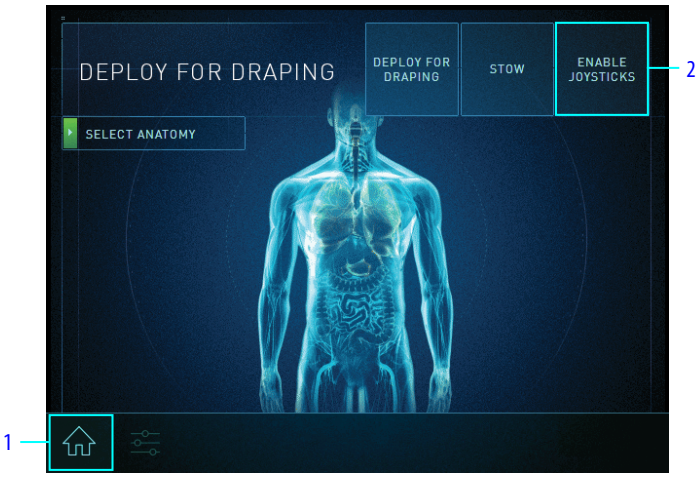
WARNING: Check for clearance between the patient and the arms. Prolonged pressure on the patient could result in serious injury.

Note: When moving the arms or instruments, keep fingers clear of the joints located on the arms to avoid injury.

Manual Positioning Overview

The Patient Cart operator can use manual controls on the helm to deploy, dock, and stow the Patient Cart. First, navigate to the Patient Cart touchpad Home screen. Then, press and hold the **Enable Joysticks** button while simultaneously manipulating the **boom height control** or **boom position control** joysticks to move the boom.

Figure 9.13 Patient Cart touchpad



1. Home
2. Enable Joysticks

The arms include a series of clutch buttons, links and joints, which allow the user to connect the arms to the cannulae during setup. The arms are locked in position unless specifically moved from the patient-side or as controlled by the Surgeon Console.

Grab and move feature: Prior to docking to a cannula, the arm can be positioned by grabbing the arm by its gray handle and moving as desired. The entire length of the arm is free to move.

Figure 9.14 Grab arm on gray handle and move as desired



Arm control buttons: The Patient Cart is equipped with controls as shown in Figure 9.15. The types of motions allowed by pressing arm control buttons changes as the cannulae are attached to the arms.

When any cannula is installed, the Patient Cart operator can no longer rotate the boom. When more than one cannula is installed, only instrument clutch, patient clearance, and port clutch options are available.

In addition to the controls available on all of the arms, the outer two arms (1 and 4) are equipped with boom rotation buttons.

Figure 9.15 Buttons on Patient Cart arms to initiate movement



1. Instrument clutch
2. Patient clearance
3. Port clutch
4. Boom rotation

Instrument Clutch and Port Clutch

The instrument clutch (Figure 9.15 **1**) and port clutch (Figure 9.15 **3**) buttons allow users to reposition arms at the Patient Cart.

WARNING: Be sure to understand the function of the port clutch and instrument clutch buttons to prevent patient injury.

CAUTION: Be familiar with the location of all system buttons and understand their expected behavior across system modes, to prevent patient or user harm, or confusion due to unanticipated mode change.

CAUTION: Hold the port clutch button with one hand and support the cannula with the other to prevent increased forces on the body wall that could lead to tissue injury.

Note: When the port clutch button is used, use care to prevent sliding the cannula out of the port site.

Instrument Clutch

- User initiated movements of the arm about the remote center.
- User initiated movements to advance or retract the endoscope or instrument tip within the surgical site.

To use instrument clutch:

- Press and hold or press and release for On, then press for Off.

Figure 9.16 Instrument clutch movement examples



Port Clutch

When no cannulae are installed:

- Reposition the arm (for example, bring the arm to cannula for docking, or stow the arm for a 3-arm procedure). See 9.4 Three-Arm Procedure on page 9-32.
- Raise or lower the boom.

When cannulae are installed (and inside body wall):

- Space the arms together or apart.
- Resolve and avoid potential arm collisions during the procedure.
- Reposition the remote center to release tension at the port site.

To use port clutch:

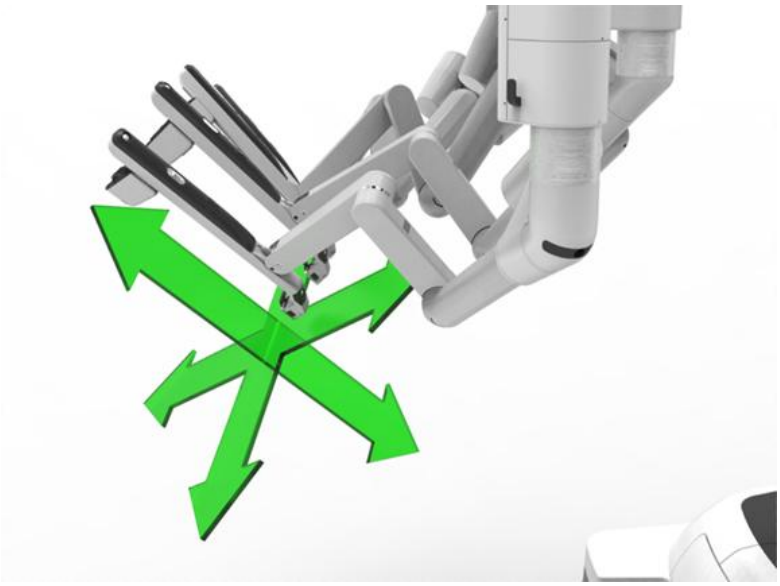
With no cannulae installed:

- Press and hold to reposition the arm.
- Press and hold to raise/lower the boom: press and hold the port clutch and adjust the arm vertically to its upper or lower limit of travel. Continue to hold the port clutch while the system begins a 3-second countdown accompanied by audio indications. Hold the arm at the limit of travel to the end of the countdown, and the system enters an extended mode: when the arm is raised, the boom rises, and when the arm is lowered, the boom descends.

With cannulae installed (and inside body wall):

- Press and hold to space the back-end of the arms together or apart, like a fan.
- Press and hold to reposition the remote center in small motions (up-down or side-to-side) to release tension at the port site.

Figure 9.17 Port clutch movements



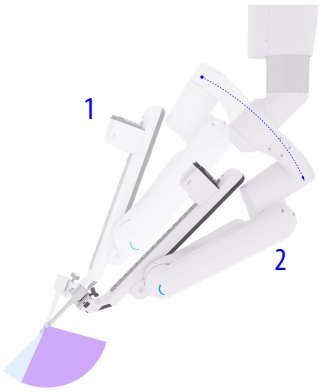
Patient Clearance

WARNING: Be sure to understand the function of the patient clearance buttons to prevent patient or user injury.

Patient clearance is a pair of buttons that allows users to adjust the arm to a steep or shallow angle.

Steep angles are used to make more room under the arm (patient clearance), whereas shallow angles are used to achieve the maximum working range of motion (instrument reach).

Figure 9.18 Examples of shallow and steep angles



1. Steep angle
2. Shallow angle

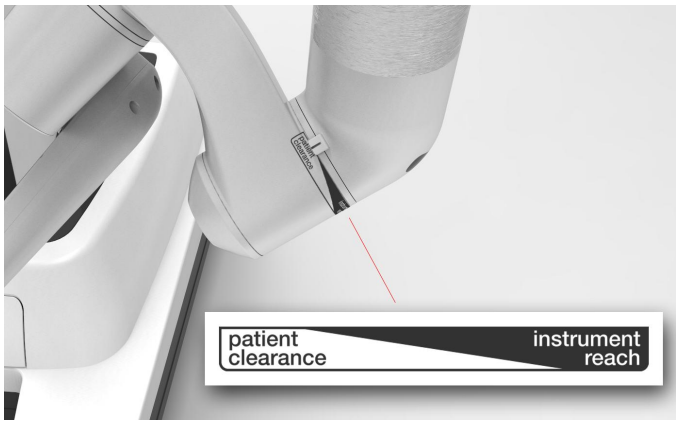
What Patient Clearance Does:

- Adjust the arm angle.
  - The remote center does not move.

To use patient clearance:

- Press and hold the up or down arrow to adjust the angle “up” for improved patient clearance, or “down” for improved instrument access (for example, to sites behind the location of the cannula).

Figure 9.19 Patient clearance/instrument reach label



Boom Rotation

The outer two arms (1 and 4) have a boom rotation button that allows the user to rotate the boom clockwise or counter-clockwise.

Note: The boom can also be rotated by pressing and holding the Targeting button on the endoscope. See Targeting on page 7-12.

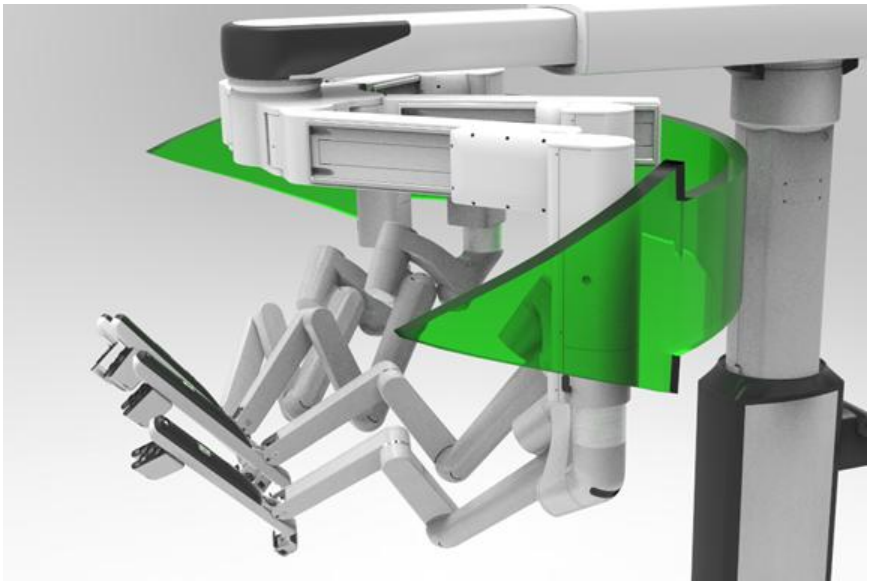
What boom rotation does:

- Rotate the boom
  - Located on arms 1 and 4 only.
  - The boom can be ONLY be rotated when there are no cannulae installed.

To use boom rotation:

- Press and hold the boom rotation button on arms 1 or 4 (or press the targeting button on the endoscope) while rotating the boom in the desired direction.

Figure 9.20 Boom rotation movements



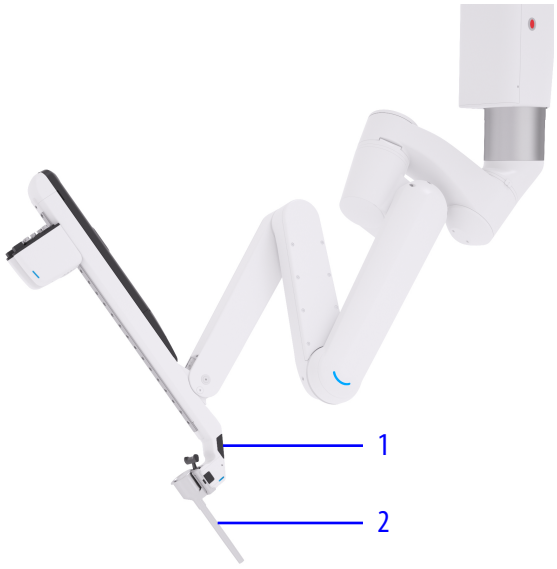
Flex Joint

The arms flex and can be extended and adjusted for appropriate remote center placement and arm position management during surgery. If adjustment of the flex joint is desired, and instruments are installed on the system:

1. Ensure that the instruments are not grasping tissue.
2. Remove all instruments.
3. With one hand, support the arm and cannula while the flex joint is adjusted.

4. With the other hand, press the port clutch button, and carefully move the flex joint closer to or further from the adjacent arm.

Figure 9.21 Example where to support the arm to adjust flex



1. Port clutch
2. Cannula

9.4 Three-Arm Procedure

WARNING: Drape all four arms for every procedure to prevent a critical patient infection.

To stow an arm not required for use in surgery:

Note: It is recommended to stow an outer arm. If an inner arm needs to be stowed, perform Step 4 (below) before docking.

1. Drape the arm to stow when draping all other arms, see 6.4 Arm Draping Procedure on page 6-8.
2. Dock the arms to be used for the procedure, see 9.5 Dual Docking on page 9-33.
3. Once the arms that will be used are docked, collapse the stow arm onto itself using the instrument clutch button.

4. Use the port clutch button to fully rotate and move the arm up and away from the surgical field.

   For the system to recognize an arm as “stowed”, the arm must be at its rotation limit, that is, moved up and all the way clockwise or all the way counter-clockwise.

> ⚠ **CAUTION:** The system will detect the position of the stowed arm during any boom motions; however, it is up to the Patient Cart operator to ensure that the arm is placed out of the way of the other arms during surgery.

Figure 9.22 Example of stowed arm



9.5 Dual Docking

Dual docking is the process of undocking the arms, rotating the boom to a new target anatomy, and re-docking.

- Dual docking use varies by procedure and patient and should be thoroughly discussed with an experienced surgeon.
- For specialty-specific port placements, see published Intuitive Specialty Guides. Contact an Intuitive representative for available Specialty Guides.

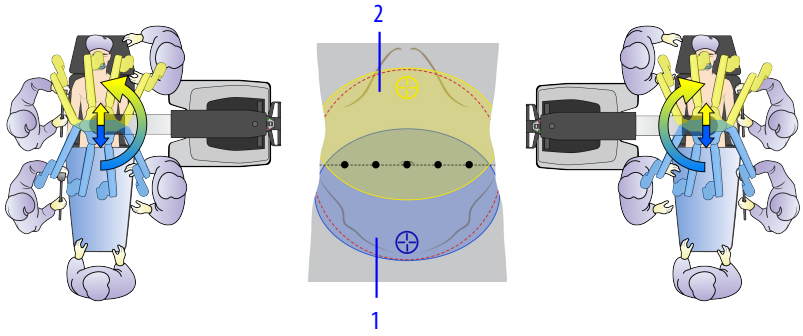
Dual docking can be used in procedures requiring a surgical workspace larger than two quadrants (for example, if the initial endoscope port can not be placed 10-20 cm from the target anatomy, and two targets are necessary), and when working beyond the level of the ports does not provide enough instrument reach.

If it is determined that dual docking is needed after initial port placement, skip to step 6.

1. Identify the surgical workspace. If larger than two quadrants, or if the initial endoscope port cannot be placed 10–20 cm from the target anatomy, split the surgical workspace in half.
2. Identify a target anatomy in each half.
3. Place the initial endoscope port at equal distance between the two target anatomies (approximately 10–20 cm from each target).

4. Place remaining ports in a line between the two target anatomies.
   - Consider placing five ports in a line, allowing two right-hands or two left-hands in either set-up. The lateral port (not docked to an arm) can be used as an assistant port.
   - The surgical workspace that is in line with the ports is the most difficult to access. This may affect how the surgical workspace is divided and what target anatomies are identified.
5. Using the guidelines for targeting and docking, set up the system for the first target anatomy (see Targeting on page 9-20 and Docking and Arm Alignment after Targeting on page 9-22).
   - It is recommended to select a straight deployment setting (see Deploy on page 9-13). This allows the most access to the patient.
6. When ready to dual dock (for example, access the second target anatomy or additional workspace), remove all instruments and undock all arms.
   - While the boom and the arms require re-adjustment, the Patient Cart location does not.
7. Position the boom to reach the target anatomy. Rotate the boom towards the column, this avoids a range of motion limit.
   - Reposition the patient as necessary.
8. Dock the initial endoscope port and perform targeting and docking following the guidelines in 9.5 Dual Docking on page 9-33.

   The following example show dual docking with left and right approaches.



1. First surgical workspace
2. Second surgical workspace

9.6 EndoWrist Instruments

EndoWrist Instruments Overview

The EndoWrist instruments have an articulating design at their distal tips that mimics the human wrist. Each instrument is used to perform a specific surgical task such as grasping, suturing, or tissue manipulation.

Figure 9.23 EndoWrist instrument



1. **Flush ports:** Two flush ports are used for instrument reprocessing.
2. **Instrument housing:** The instrument housing engages with the instrument sterile adapter.
3. **Release buttons:** The two release buttons, one on each side of the housing, are used to disengage the instrument from the arm sterile adapter for removal.
4. **Discs:** The discs connect to the instrument wrist and translate the movements of the master hand controls from the Surgeon Console.
5. **Tip:** The instrument's end effector (for example, graspers, cautery hooks, blades).
6. **Wrist:** The articulating wrist provides a wide range of movements (Figure 9.23).
7. **Shaft:** The shaft inserts through the cannula and rotates as controlled by the movements of the master hand controls.
8. **Maximum use indicator:** Indicates when the instrument has reached its maximum uses.
9. **Grip release socket:** Mechanism for manual grip release.

WARNING: Leakage currents from other endoscopic instruments may be additive. To ensure maximum safety for the patient and to prevent patient harm, only Type CF endoscopic accessories should be used with the system.

WARNING: Use care when manually opening the instrument jaws when the system is functioning normally, to prevent tissue injury.

WARNING: Open the instrument jaws using the Surgeon Console hand controls when the system is functioning normally (not in a faulted or unpowered state), to prevent patient injury.

WARNING: Do not use instruments repaired, refurbished, reconditioned, or serviced by a third-party, because the instrument may be damaged or its operation affected, and could cause injury to the patient or staff.

CAUTION: Do not press the release buttons once an instrument is installed, unless removing an instrument. Pressing the release buttons once an instrument is installed can lead to unintended consequences such as disengagement of the instrument from the arm to prevent tissue injury.

Note: The discs can be rotated by hand (when not attached to the sterile adapter) to verify the cable functionality or align the wrist for tool insertion.

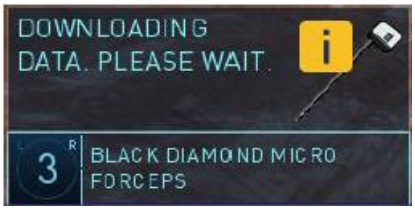
Refer to the Instruments and Accessories User Manual for more information on the various da Vinci instruments, accessories, and components. Refer to the Reprocessing Instructions User Manual for cleaning and sterilization instructions.

WARNING: To prevent patient harm, use only the instruments and accessories approved by Intuitive. System compatibility with non-approved instrumentation cannot be guaranteed. The warranty does not cover damage to the system that occurs as a result of using non-approved instruments and accessories.

Plug and Play

Newly released instruments may need to download their new parameters to the da Vinci Xi system. This process is only required once for each new type of instrument, and can take up to 15 seconds. During this download period, the arm LED pulses blue and a message displays. If an error occurs during plug and play, re-install the instrument.

Figure 9.24 Plug and play message



9.7 Instrument Installation

Note: Some instruments require use of the Instrument Introducer (PN 342562) during installation. See the Instruments and Accessories User Manual for more information on proper use of the Instrument Introducer.

Note: Do not use unapproved or incompatible third-party accessories with the da Vinci system.

1. Straighten the instrument wrist and close the jaws to ensure easy insertion into the cannula and prevent damage to the instrument.

2. Insert the instrument tip into the cannula and press the instrument housing into the sterile adapter. Audible completion beeps signal that the instrument is engaged.

   Once the system recognizes the instrument installed on the arm, it can be inserted manually or by using the Guided Tool Change, described next.

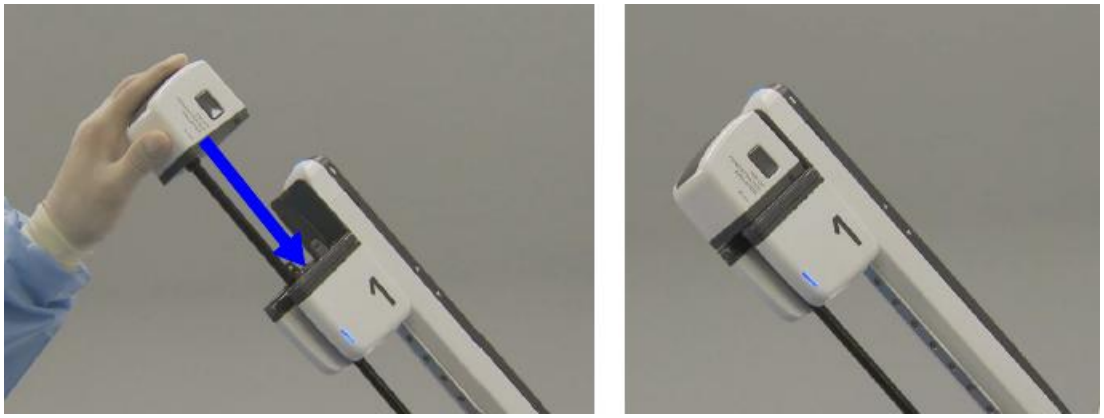
WARNING: Close the instrument jaws prior to insertion into a cannula, to prevent damage to instrument, resulting in potential patient harm.

WARNING: Unlock the instrument before installing the instrument onto an arm after intraoperative cleaning, to prevent damage to instrument, which may result in instrument fragments in the patient, or tearing of the cannula seal, which may result in loss of insufflation and instrument fragments in patient.

WARNING: Make sure the Surgeon Console operator is ready to resume control of the instrument before inserting an instrument into the sterile field to prevent tissue injury.

CAUTION: When inserting the instrument tip into the cannula, be careful not to puncture the arm drape with the tip of the instrument.

Figure 9.25 Inserting the instrument into the cannula and sterile adapter



Manually Insert an Instrument

WARNING: When inserting an instrument into the patient, follow standard surgical practice (in minimally invasive surgery) of retracting and pointing the endoscope tip toward the instrument port to prevent patient tissue injury.

WARNING: Do not manipulate instruments that are outside the surgeon's field of view, because doing so may cause patient tissue damage.

WARNING: Insert and exchange instruments under vision to prevent tissue injury.

WARNING: After inserting, ensure all installed instruments are visible in the Surgeon Console view before proceeding. This visual check prevents inadvertent harm to the patient.

The first instrument installed on each arm during a procedure must be manually inserted.

1. Use the instrument clutch button to manually insert the instrument. The Surgeon Console operator cannot control the instrument until the tip is moved out of the cannula.

   The LEDs blink blue when the button is clutched. The Surgeon Console operator cannot control the instrument until it is moved out of the cannula and is no longer clutched. Note that if the clutch button is pressed and released (instead of holding it down continuously while inserting the instrument), the clutch button must be pressed and released again after insertion through the cannula, to give control of the instrument to the surgeon.

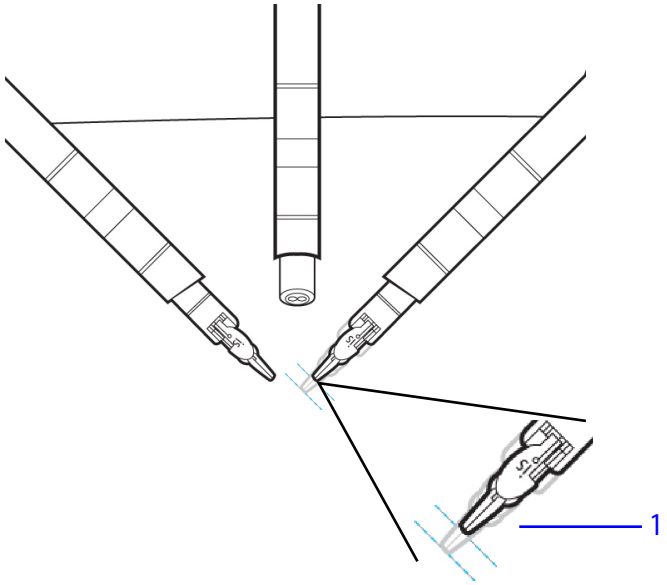
   See 9.3 Manually Adjusting the Patient Cart Arms on page 9-25 for details on using the instrument clutch button.

Guided Tool Change

Guided Tool Change Overview

To provide an efficient and safe method for instrument exchange or reinsertion, the system can assist the Patient Cart operator by guiding an instrument into the patient. Guided Tool Change helps guide the instrument tip to a location just short of the last position of the previously installed instrument or endoscope tip.

Figure 9.26 Guided Tool Change



1. Guide Tool Change

Using Guided Tool Change

- If Guided Tool Change is enabled, the LED on the instrument carriage and on the top of the arm blinks green. The system also displays a message to advance the instrument or endoscope to return to the previous location.
- If Guided Tool Change is not enabled, the LED does not blink green. The system also displays an icon and message instructing the user to insert the instrument past the cannula tip and advance.

These actions disable Guided Tool Change:

- Pressing a port clutch or instrument clutch button.
- Changing the endoscope arm.
- Any detected system errors.
- Instrument tip too close to cannula.

To install an instrument using the Guided Tool Change feature:

1. Straighten the instrument wrist and close the jaws.
2. Insert the instrument tip into the cannula and press the instrument housing into the sterile adapter.
3. Wait for the blinking green LED near the sterile adapter.
4. Gently slide the instrument into the surgical field by pressing on the housing until there is resistance and the LEDs turn blue. The instrument is now ready for surgeon control.

WARNING: During Guided Tool Change, do not use excessive force while inserting an instrument, to prevent patient tissue damage.

WARNING: When inserting an instrument into the patient, follow standard surgical practice (in minimally invasive surgery) of retracting and pointing the endoscope tip toward the instrument port to prevent patient tissue injury.

WARNING: During an instrument exchange, including using Guided Tool Change, ensure that instruments are visualized during insertion and exchanges to prevent tissue injury.

CAUTION: Do not let go of the hand controls while the surgeon's head is still in the viewer, because doing so may cause patient tissue damage.

Note: If Guided Tool Change is disabled or does not initiate, use the arm clutch button to insert the instrument manually, as described in Manually Insert an Instrument on page 9-37.

9.8 Intraoperative Arm Management

The following are guidelines for intraoperative arm management:

- Arm management varies by procedure and patient. Anatomical restrictions may require alternate adjustments or 9.5 Dual Docking on page 9-33.
- For specialty-specific Patient Cart approaches, see published Intuitive Specialty Guides. Contact an Intuitive representative for available Specialty Guides.

To ensure maximum reach and minimum arm-to-arm interference, set up the arms in parallel (using the flex joints) and lower the patient clearance joints, if space is available to do so.

Note: When adjusting or repositioning the instrument arms, use a port clutch button to avoid collision of cannula bowls during a surgical procedure.

Note: To avoid external collisions during a surgical procedure, ensure that there is adequate room or spacing between instrument arms.

Work Behind Ports

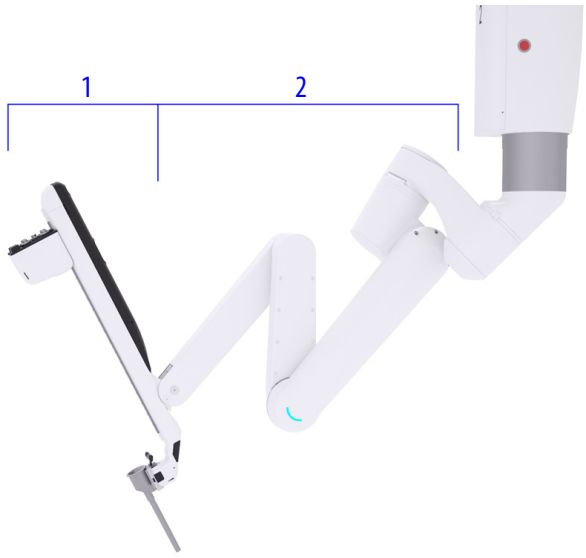
WARNING: Be careful to correctly identify which instrument is associated with each hand control when the endoscope is port hopped or manually rotated 180 degrees. Failing to do so may result in inadvertent instrument movement or removal, which may lead to tissue injury.

If the endoscope is rolled 180° to enable working behind the level of the ports (reaching anatomy beyond the normal leveled view), manually associate the right and left hand controls with the respective arms for intuitive motion: Go to the Surgeon Console touchpad **Settings > Controls** tab and tap **Configure** next to Hand Control Assignments. Note that although the arm containing the endoscope is not controlled by a hand, it will need to be reassigned, as no more than two arms can be assigned to any one hand control.

For additional information and suggested steps for working behind ports, see Increase Instrument Reach on page 9-42.

Arm-to-arm Interference

1. Identify the interference (for example, on the front end or back end of the arm).



1. Front end
2. Back end

2. If the interference is on the front end of the arm (near the instrument):
   - Use the flex joints to bring the arm close to the adjacent arm. This allows the arms to work in parallel, minimizing interference.



Interference



No interference

3. If the interference is on the back end of the arm (near the patient clearance joint):
   - Use the **patient clearance** button to adjust the arms away from each other (up or down). This increases the space between the joints and minimizes interference.



Interference



No interference

Identifying and Resolving Instrument Collisions

If resistance is felt at the hand controls, or non-intuitive motion is observed, there may be an external arm collision or an internal instrument collision. To resolve collisions, do the following:

1. Check for collisions by inspecting the arms or by asking the bedside assistant.
2. Identify whether the collision is external (between the arms).
3. If the collision is not external, identify whether the collision is internal (inside the patient).
   a. Return to the Surgeon Console and inspect for internal instrument collisions. Do not take control or move instruments to prevent further interference.
   b. Safely retract the endoscope and survey the surgical field to check for internal instrument collisions.

4. Resolve the collision.

Resolving External Instrument Collisions

1. Remove the instruments from the arms.
2. Adjust the setup joints by stabilizing the cannula and using the port clutch button to create more space between arms.
3. Move the patient clearance joints, if needed to free the arms from collisions.

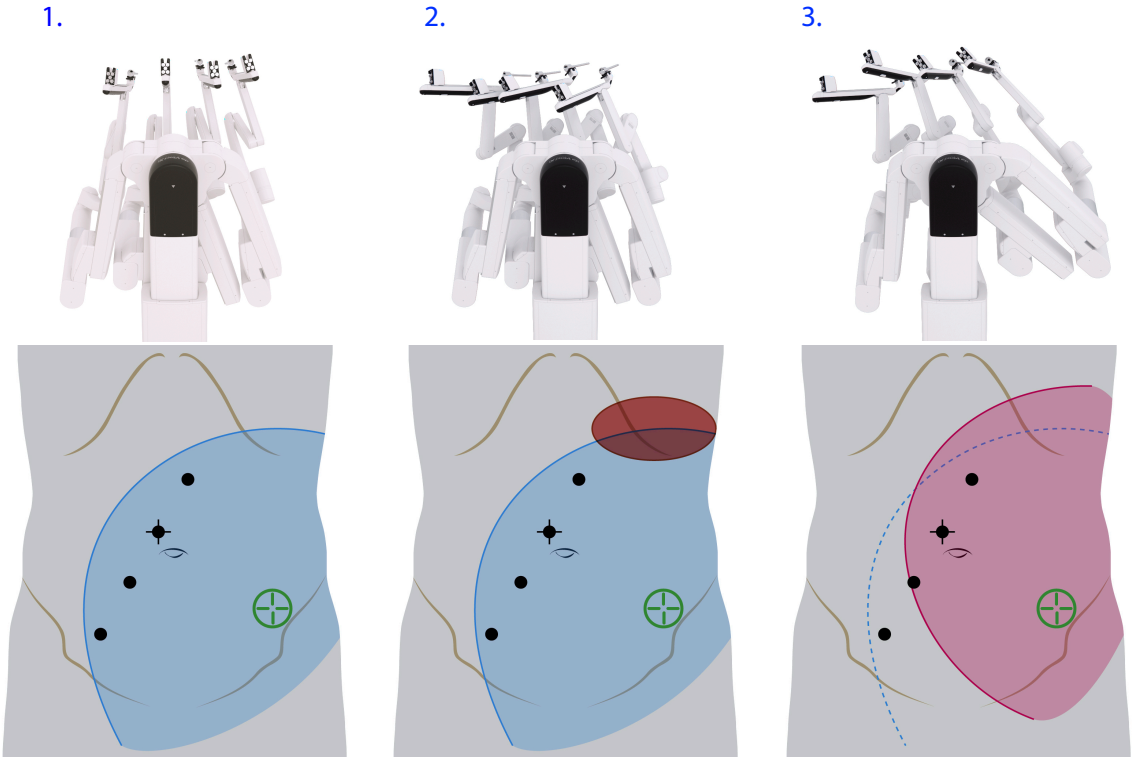
Resolving Internal Instrument Collisions

1. Determine which instrument can be safely moved to resolve the collision.
2. Carefully move the instrument out of the way while keeping the instrument tip in view.

Increase Instrument Reach

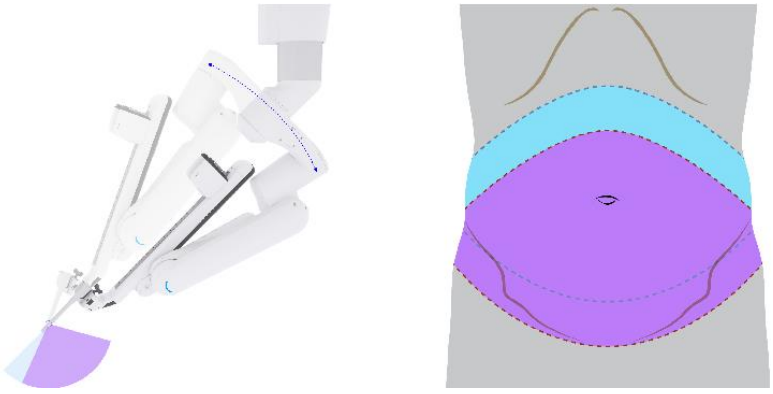
1. Identify where reach is needed (for example, in line with or beyond the level of the ports).

2. When increasing the surgical workspace in line with the ports:
   - Use the flex joints: Starting with the arm closest to the desired area of reach (near the boundary of the surgical workspace), adjust all arms towards the direction where reach is desired.
     – As you work away from this boundary, consider moving the flex joints back towards the center of the total surgical workspace.



1. Arms nominal,
2. Arms reaching ports (no flex adjustment),
3. Arms reaching ports (with flex adjustment)

3. When increasing the surgical workspace beyond the level of the ports:
   - Consider lowering the patient clearance joint where available.



   - When working at or behind the level of the ports (arms pitched back), the surgical image may appear upside-down (that is, the anterior body wall is on the bottom of the surgical view). To re-orient the surgical image and maintain intuitive instrument motion, consider the following:
     - Ensure all instruments remain in view.
     - Roll the endoscope 180 degrees, such that the image is right-side up. This may be done by the surgeon using the hand controls, or by the patient side assistant using the port clutch button.



   - Manually associate the right and left hand control assignments with the respective arms for intuitive motion.
     - If the arms reach a range of motion limit, adjust the patient clearance joint to provide additional reach.
   - To straighten back out, there are two options:
     - Keeping instruments in view, move the endoscope towards the initial target anatomy. Rotate the endoscope the opposite way (to avoid a range of motion limit) and re-associate the hand controls (go to the Surgeon Console touchpad **Settings** tab > **Hand Controls** and tap **Configure** next to Hand Control Assignments), or
     - Remove the instruments, rotate the arms back to their normal orientation, and reinsert the instruments under direct vision. Re-associate the hand controls.

9.9 Instrument Removal

Before removing an instrument, make sure the surgeon is ready.

WARNING: Use proper instrument removal techniques (for example, straightening instrument wrist, freeing instrument jaws of patient anatomy) to avoid damaging tissue or the instrument upon removal.

WARNING: Use proper instrument removal techniques to prevent procedure delay and patient harm.

WARNING: Be aware of the risk of damaging the drapes during instrument removal, to prevent a critical patient infection.

WARNING: Properly use Instrument Release Kit to release instrument jaws from tissue during system faults or power losses, to prevent patient injury.

WARNING: When extracting the instrument from the patient, straighten the wrist, and pull the instrument straight out until it is completely clear of the cannula. Any lateral pressure on the instrument during removal may damage, break, disconnect the tip, or bend the shaft, which could result in patient injury.

WARNING: Removing instruments during a procedure should be performed very carefully and only when the Surgeon Console operator is informed of the removal and has the instrument in full view. Do not remove the instrument if it is not in view to prevent tissue damage.

Prior to removing the instrument, the Surgeon Console operator should:

1. Ensure the instrument is free and clear of any patient anatomy.
2. Straighten the instrument wrist.
3. Clearly communicate to the Patient Cart operator which instrument to remove. Identify the name of the instrument and the number of the arm (1, 2, 3, 4).

To remove the instrument:

1. Ensure the instrument is positioned for removal.

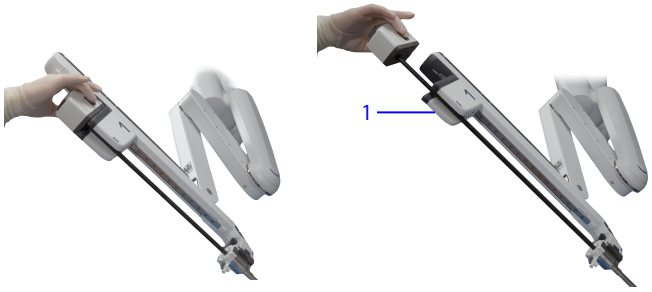
2. Squeeze the instrument release buttons and slide the instrument up and out through the cannula.

Note: The Patient Cart automatically retracts the instrument carriage when the instrument is disconnected. If the instrument is not removed in time, the sterile adapter may re-engage the instrument during the retraction. If the instrument re-engages, repeat the instrument removal steps.

Note: To avoid damage to the arm drapes, use care not to scrape instruments against arms during instrument removal.

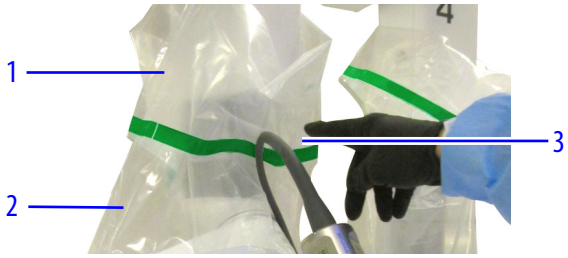
Note: Use care not to inadvertently breach the sterility barrier when removing an instrument or endoscope from the draped Patient Cart arm (see Figure 9.28 for example of breached sterility barrier). If needed, clutch the arm to adjust its angle such that the instrument or endoscope clears the sterility barrier upon removal.

Figure 9.27 Instrument removal



1. Instrument carriage

Figure 9.28 Sterility barrier (and example of breached sterility barrier)



1. Non-sterile area behind band color
2. Sterile area
3. Example of breached sterility barrier

Manual Grip Release

For additional information regarding the Emergency Stop button, see Emergency Stop – Surgeon Console on page B-10 and Emergency Stop – Patient Cart Helm on page B-10.

WARNING: Improper use of the Instrument Release Kit may cause injury to the patient or tissue.

WARNING: Properly use the Instrument Release Kit to release instrument jaws from tissue during system faults or power losses, to prevent patient injury.

WARNING: The long end (rather than the short end) of the grip release wrench should be used to manually open the instrument jaws. Using the incorrect end could result in patient injury.

WARNING: Manually open the instrument jaws when an Instrument Release Kit is not available, to prevent patient tissue injury.

WARNING: To prevent injury, use the translated instructions that instruct how to manually open instrument jaws to release tissue.

WARNING: In case of system failure while the instrument is grasping tissue, the grips (jaws) can be opened manually by inserting the long end of the grip release wrench from the Instrument Release Kit into the socket and following the grip release instructions. Use visualization of the surgical site when inserting the grip release wrench, opening jaws, clearing tissue from jaws, and removing instruments from the system. Failure to follow the grip release instructions may result in tissue injury.

WARNING: Keep the Instrument Release Kit individually sterile-wrapped, labeled, and available for use (for example, in Vision Cart drawer) during a procedure to prevent patient injury from a closed and unresponsive instrument jaw on vital tissue prior to instrument removal.

WARNING: Follow the Instrument Release Kit instructions to manually open the instrument jaws when the system is in a faulted or unpowered state, to prevent patient injury.

WARNING: The grip release should only be used after pressing E-stop (on a non-faulted system) and while visualizing the surgical site to prevent patient injury.

Note: Press the E-stop button during manual instrument grip release, to prevent patient injury from lack or delay in visualization.

Note: Whenever possible, use robotic, Surgeon Console control to release the instrument grips. The grip release mechanism facilitates removal of an instrument in the event of a system fault, or when Surgeon Console control of the instrument is not practical. If the instrument tips are holding tissue, the grip release wrench contained on the Instrument Release Kit (PN 381216) allows the patient-side operator to manually release the grips.

Note: It is recommended that the Instrument Release Kit (PN 381216) be individually sterile-wrapped, labeled, and placed in the Vision Cart drawer. Surgeon and OR staff should always know where the sterile-wrapped Instrument Release Kit is located in case it is needed to manually release an instrument.

Figure 9.29 Instrument Release Kit



To release the instrument grips manually, perform these steps while visualizing the surgical site:

1. Locate the Instrument Release Kit.
2. Press the **Emergency Stop** button on the right-side of the Surgeon Console.
3. Insert the straight, long end of the wrench into the grip release socket on the instrument housing. Push to be sure the wrench engages with the socket. Once engaged, a slight resistance will be felt when gently rotating the wrench.

   WARNING: To prevent patient injury, when using the Instrument Release Kit, be sure to hold the Patient Cart arm and instrument steady while inserting and turning the grip release wrench.

4. Turn the wrench ***counter-clockwise*** (approximately 1/4 turn), to open the instrument grips. Support the instrument carriage to prevent accidental advancement of the instrument.
5. Under endoscopic or direct vision, verify the grips are not grasping tissue.
6. Once the tissue is released from the grips, remove the wrench from the instrument.
7. Squeeze the release buttons on the sides of the instrument housing and remove the instrument.
8. Recover the fault on the touchscreen or touchpad, or restart the system as necessary. Do not reuse the instrument.

   WARNING: Do not re-use an instrument that has had its grip released with the Instrument Release Kit. Re-using an instrument after use of the Instrument Release Kit could result in critical failure of the instrument and injury to the patient.

   After use of the Instrument Release Kit, return the affected instrument to Intuitive by contacting Customer Service.

9.10 Intraoperative Instrument Maintenance

To ensure the EndoWrist instruments are kept at their highest level of functionality:

- Clean the tips of instruments between instrument exchanges.
- Do not use instruments to clean other instruments while inside the body.

9.11 Manage Instrument Inventory

EndoWrist instruments are programmed for a predetermined number of uses. This feature ensures reliable and consistent performance throughout the EndoWrist instrument life. The system decrements one use from an instrument the first time it is installed and taken into following mode during a procedure. Once an installed instrument is controlled from the Surgeon Console, the system counts down one use for that instrument. If an installed instrument does not become surgeon controlled, it may be removed without reducing the number of uses remaining.

When an instrument that is on its last use is used during a procedure the system displays the message, **"Instrument will expire after procedure."** The instrument may be used during the current procedure, but not for a new procedure. A maximum use indicator on the instrument housing changes color when the instrument has reached its maximum uses.

Figure 9.30 Maximum use indicator on expired instrument



1. Maximum user indicator: instrument is expired

While most instruments are designed to be used for a predetermined number of procedures, a few (such as the Clip Appliers) are to be used for a predetermined number of activations.

Note: When an instrument use is based on activations, it usually has a relatively large number of activations compared to instruments that have uses based on the number of procedures. For these instruments, the system decrements one use from the instrument each time it is installed on the system and goes into following mode.

View Uses Remaining

The number of uses left (expiration information) for all instruments used during the current procedure can be viewed on the system. Additionally, each instrument has an indicator on the housing that changes to red when the instrument has reached its maximum uses.

1. On the Vision Cart touchscreen, tap the **Settings** tab. The Uses Remaining summary appears.

Expiration and Disposal

When instruments expire, they are automatically inactivated and can no longer be used. Expired instruments must be properly disposed of following all applicable national and local laws and guidelines.

9.12 Fluid Leakage Precautions

The EndoWrist instruments are designed so that they may be positioned horizontally or inclined upwards during surgery according to the requirements of the procedure. As with any laparoscopic instrument, these positions can allow blood or other fluids to migrate through the instrument shaft towards its proximal end. The EndoWrist instruments are designed to resist fluid migration of this nature and minimize fluid leakage from the proximal end. However, in the event that blood or other fluid is noticed leaking out of the instrument and onto the arm drapes or sterile adapter during the surgery, take following actions:

1. Remove the instrument from the arm and hold it vertically (tip down) to drain any fluids.
2. Thoroughly wipe any fluid off the sterile adapter and drape before inserting any other instrument.
3. After surgery, thoroughly clean the instrument following the cleaning instructions in the Reprocessing Instructions User Manual before reuse.

   In addition, if any blood or other fluid is observed on the inside of the drapes (on the Patient Cart arm), contact Intuitive Customer Service as soon as possible and before any future use. Intuitive personnel will provide guidance in adequately cleaning the arm.

9.13 Stow the Patient Cart

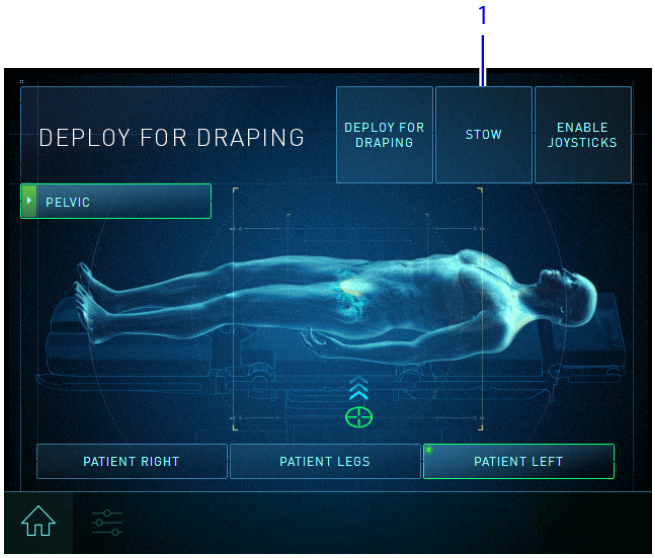
Stowing retracts the boom and arms from their current positions to a predefined default stow or sterile stow position. The Patient Cart is stowed when the structure is in its most compact state. For more information, see 6.5 Sterile Stow the Draped Patient Cart (Optional) on page 6-18.

The Patient Cart has two stow positions depending upon on whether Patient Cart sterile adapters are installed. The system automatically detects the stow and sterile stow positions.

Stow

If the sterile adapters are not installed, the Patient Cart automatically provides the option of the stow position. Stow the Patient Cart for transporting through the hospital or within the operating room (OR) and for storage when not in use.

1. After all drapes have been removed, press and hold **Stow** on the Patient Cart touchpad. The LED on the boom pulses.



1. Stow

2. The Patient Cart automatically retracts until the vertical column and boom are both extended less than 12 inches from their most compact state.
3. The stow feature achieves a compact stow position, however the user may still need to use the port clutch buttons to get the system compact enough to fit comfortably through a doorway.

Sterile Stow

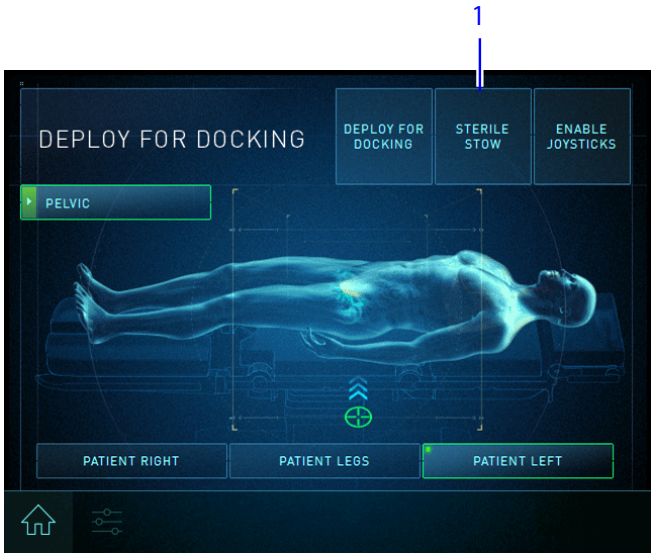
WARNING: When the Patient Cart is draped, avoid contact with non-sterile items during any user-initiated powered motions of the Patient Cart, to prevent breach in sterility.

If one or more sterile adapters are installed, the Patient Cart automatically provides the option to move the arms into a sterile stow position to maintain sterility. This sterile stow position compacts the Patient Cart with the drapes installed in order to minimize potential contact and contamination of the patient-side assistant with the sterile draped system while preparing the patient.

Note: Ensure that the column drape is installed before stowing the system for surgery, as stowing without this drape installed can compromise sterility.

1. On the Patient Cart touchpad, press and hold **Sterile Stow** . The Patient Cart moves into the sterile stow position: the boom moves to a sterile stow position where the arms are folded out of the way; with enough space away from the column to ensure that sterility is not breached.

2. Release the button when audible beeps indicate Sterile Stow is complete.



1. Sterile Stow

9.14 Patient Cart Troubleshooting Quick-reference

- Appendix B.1 Customer Service on page B-1
- Appendix B.2 Convert to Open Surgery or Obtain Immediate Access to the Patient on page B-1
- Appendix B.3 Access the Event Logs on page B-2
- Appendix B.4 Troubleshooting the Patient Cart Drive on page B-2
- Appendix B.6 System Power Issues on page B-4
- Appendix B.7 Restart the System on page B-7
- Appendix B.8 System Faults, Recoverable Faults, and Non-recoverable Faults on page B-7
  - Battery Backup on page B-11
  - Battery Low Condition on page B-11
  - Troubleshoot a Non-responsive System on page B-11

End of Section

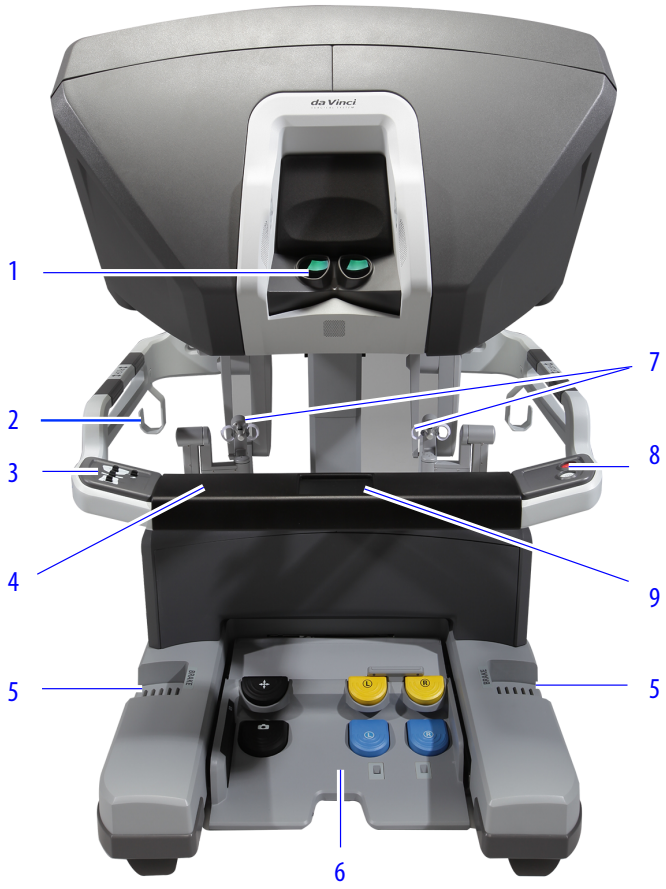
Chapter 10 Surgeon Console Use

This chapter explains use of the Surgeon Console during surgery. The following subjects are covered:

Contents

10.1 Surgeon Console Overview 10-2
10.2 Set Up the Surgeon Console 10-5
10.3 Surgeon Console Touchpad Controls 10-7
10.4 Surgical Controls 10-42
10.5 3D Viewer Display 10-47
10.6 Integrated ERBE VIO dV 1.0 and VIO dV 2.0 Overview 10-51
10.7 Dual Console Surgery 10-66

Figure 10.1 Surgeon Console



1. 3D viewer
2. Cable holder (one on each side)
3. Ergonomic controls
4. Armrest
5. Brakes
6. Footswitch panel
7. Hand controls
8. Power button and Emergency Stop button
9. Touchpad

10.1 Surgeon Console Overview

Hand Controls

The hand controls are positioned below the magnified, three-dimensional image of the surgical site. The surgeon grasps the hand controls while viewing the surgical site. The instrument tips, as seen in the 3D viewer, appear aligned with the surgeon's hands at the controls.

Figure 10.2 Hand controls (motion scaling example: fine)





⚠ **CAUTION:** If instruments cannot be manipulated in a precise and controlled manner, contact Intuitive Customer Service. If instrument motion appears to be non-intuitive, contact Intuitive Customer Service immediately to prevent tissue injury.

For more information on use of the hand controls, see Match Grips on page 10-42, Finger Clutch on page 10-44, and 10.4 Surgical Controls on page 10-42.

3D Viewer

The 3D viewer is a high-resolution screen that provides the video image to the Surgeon Console operator, the surgeon. Icons and text messages are overlaid on the video to provide extended information to the surgeon. With their head in the viewer, the surgeon can view the 3D image in full-screen mode, change digital zoom settings, and swap to TilePro mode, which displays the 3D image along with up to two auxiliary images. Changes to view settings take place globally in dual console mode. For example, when one surgeon applies digital zoom or TilePro in their 3D viewer, the exact image shows on the other surgeon's 3D viewer. TilePro viewing options for the Vision Cart touchscreen can be independently controlled by the OR staff.

Surgeon Console Audio Communication

The system provides two-way audio communications with the Patient Cart operator by a microphone located on the Surgeon Console 3D viewer and a pair of speakers located in the head rest.

Figure 10.3 3D viewer



1. Speaker
2. Microphone

Armrest

The armrest contains a touchpad user interface, controls for adjusting the ergonomics of the Surgeon Console, and Power and Emergency Stop buttons.

Touchpad

The touchpad is the main control interface of the Surgeon Console.

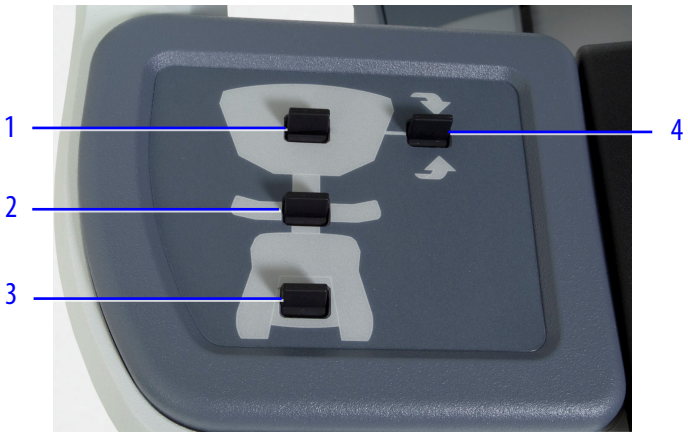
Figure 10.4 Touchpad (Instrument screen)



For more information on use of the touchpad, see Instrument Tab on page 10-30.

Left-Side Pod – Ergonomic Controls

The left-side pod provides the ergonomic adjustment controls for the Surgeon Console, as indicated below.

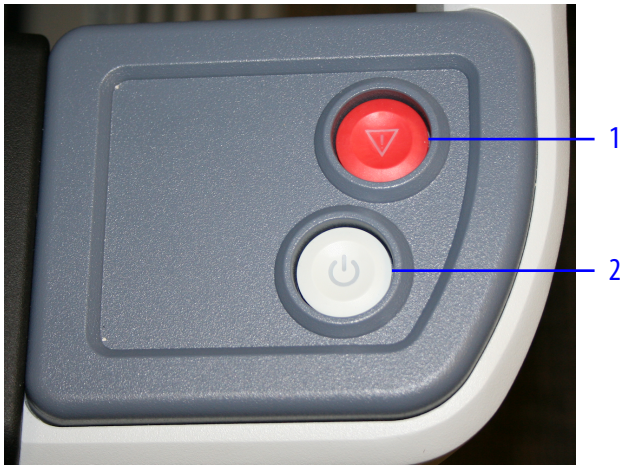


1. 3D viewer height
2. Armrest height
3. Footswitch panel depth
4. 3D viewer tilt

For more detail on ergonomic adjustments, see Manual Ergonomic Setup on page 10-5.

Right-Side Pod – Power and Emergency Stop

The right-side pod provides Power and Emergency Stop buttons.



1. Emergency Stop
2. Power

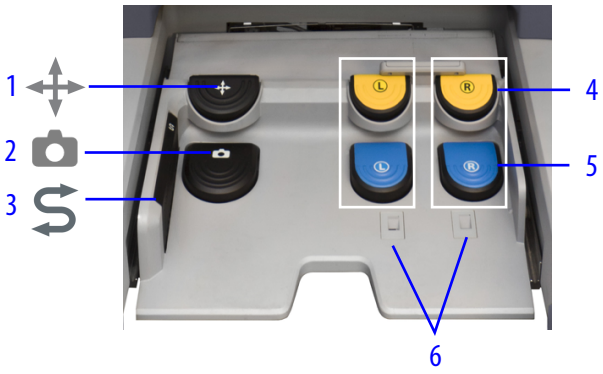
To stop system operation at any time, press the red **Emergency Stop** button. The Emergency Stop button ceases robotic control of the instruments and endoscope. The instruments and endoscope stay in their last commanded position.

If the instrument grips are closed when the Emergency Stop button is pressed, the grips remain closed. However, the gripping force may decrease.

Pressing the Emergency Stop button initiates a recoverable fault, which can be overridden by tapping **Resume Use** on the touchscreen or touchpad. The Emergency Stop button illuminates when pressed and remains illuminated until Resume Use is tapped. See Appendix B System Troubleshooting on page B-1 for more details.

Footswitch Panel

The footswitch panel allows the surgeon to control the endoscope, instruments, and instrument functions (such as electrocautery) without removing their head from the 3D viewer.



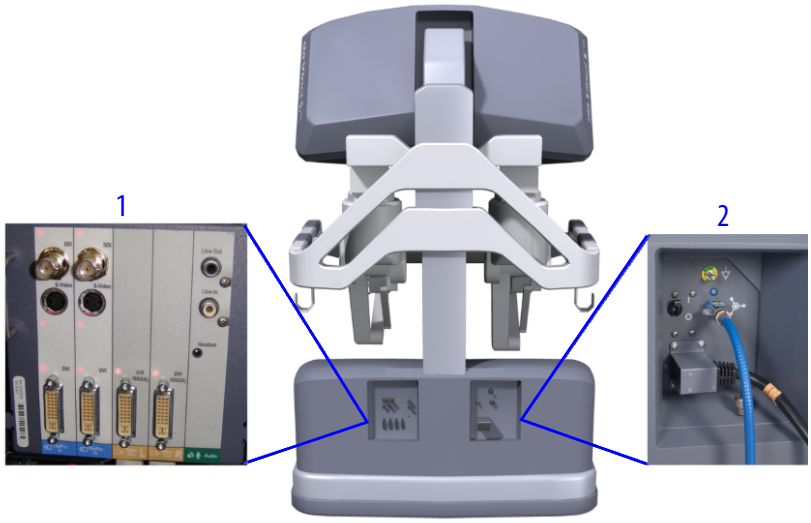
1. Master clutch
2. Endoscope control
3. Swap
4. Secondary yellow foot pedals
5. Primary blue foot pedals
6. Foot sensors

For instructions to use the footswitch panel, see Footswitch Panel Use on page 10-44.

Rear Panels

The Surgeon Console rear panels provide various connections as shown.

Figure 10.5 Rear panel connections



1. Video and audio connections
2. Power and fiber connections

For more information on these rear panels, refer to the following sections of the manual: F.1 Video and Audio Connections on page F-1 and Connect System Cables on page 4-4.

10.2 Set Up the Surgeon Console

This section explains how to set up the Surgeon Console for use.

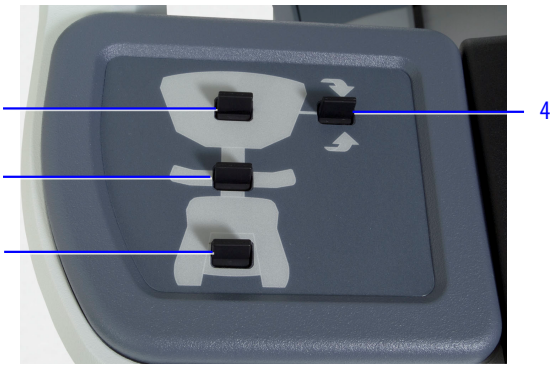
Manual Ergonomic Setup

To adjust the Surgeon Console ergonomics at any time, perform the following steps:

1. Set the chair backrest to vertical or slightly tilted forward. Adjust the chair height so your hips are higher than your knees, with feet flat on the floor.
2. Adjust the armrest height so the so the angle between your forearm and upper arm is about 90°.
3. Adjust the 3D viewer height so you can easily access the viewer while slightly leaning forward.
4. Adjust the 3D viewer tilt to minimize hunching your back and shoulders.
5. Adjust the footswitch panel so your lower legs are almost vertical and your heels rest just in front of the pedals.

Figure 10.6 Left-side ergonomic adjustments

1. Adjust the 3D viewer height
2. Adjust the armrest height
3. Adjust the foot-switch panel



4. Adjust the 3D viewer tilt

10.3 Surgeon Console Touchpad Controls

The touchpad is designed for use only when the hand controls are not actively controlling the instruments. To prevent inadvertently touching controls on the screen while maneuvering the hand controls, the touchpad controls are locked out. If the touchpad controls are unlocked by the user, any motions of the hand controls and the instruments they are controlling are immediately stopped.

System Startup

Tap the **Start** button to begin using the Surgeon Console touchpad controls.



Unlock Touchpad

When the surgeon takes instruments into their control (surgeon control mode), the touchpad automatically locks, to prevent inadvertent actions. Tap **Unlock** to access the touchpad again.

Figure 10.7 Touchpad locked



Information Icons

Information icons indicate that more information is available for reference. Tap the icon next to an item on the screen to view further information about that topic, and then tap **Close**.

Figure 10.8 Information icons example



Login, Settings, and User Accounts

The login feature allows surgeons to save and restore user-adjustable settings to and from a user account, such as ergonomic settings.

There are two types of user accounts, Intuitive accounts and Console-only accounts:

- **Intuitive account:** At login, the Surgeon Console synchronizes to the user's Intuitive account (when there is an available network connection, all users are logged out, and all cannulas are undocked from the system). Logging in also allows case reports to be generated for procedures, which can be in the My Intuitive app. Surgeons can restore their preferences on any Surgeon Console with their Intuitive account[1].

  When available, Intuitive recommends that users log in using their Intuitive account each time they use the Surgeon Console to synchronize case metrics, procedure data, and settings.

  Requirements to enable Intuitive account login from the Surgeon Console:

  - Internet access for the da Vinci system
  - OnSite is enabled and on
  - Completion of Intuitive account setup, including PIN code and hospital affiliation verification in the My Intuitive app — contact your Intuitive representative for your Intuitive account setup

- **Console-only account:** These accounts are created and stored on an individual Surgeon Console. Account preference changes are only saved to that console.

Log into the applicable user account to use.

- **Intuitive account:** Use this login if the surgeon has an Intuitive account.
- **Console-only account:** Use this login if the surgeon does not have an Intuitive account, but has a Console-only account.

1. This feature may not be available in all geographies. Contact your Intuitive sales representative with questions regarding availability.

WARNING: Ensure that you select the intended account. All accounts are saved independently, and therefore may differ, leading to unanticipated system settings. For example, unintentional use of an account with a saved motion scaling setting of Quick (1.5:1) could lead to faster-than-expected instrument movement.

CAUTION: Properly use the PIN code enabled advanced imaging modes to prevent user confusion and procedure delay from improper access or loss of access of advanced imaging.

Login Overview for Intuitive Account

1. Tap the **Account** tab.
2. Tap the **Start** button.
3. Select **Intuitive Accounts**.
4. Select the account to use.
5. Enter the account PIN code.
6. Import saved user settings (this is automatically prompted during first-time login).
7. Set up ergonomics.
8. Select one or more procedures to perform.
9. Select the energy presets.
10. Review the overview of selected settings for this procedure.

Login Overview for Console-only Account

- **Returning user login**
  1. Tap the **Account** tab.
  2. Tap the **Start** button.
  3. Select **Console-only Accounts**.
  4. Select the account to use.
  5. Set up ergonomics.
  6. Select the energy presets.
  7. Review the overview of selected settings for this procedure.
- **New user login**
  1. Tap the **Account** tab.
  2. Tap the **Start** button.
  3. Select **Console-only Accounts**.

     (This button is only available when the user has an Intuitive account, but is logging in to a Console-only account.)
  4. Create an account.
  5. Import settings from another account (this is automatically prompted during first-time login).
  6. Set up ergonomics.
  7. Select the energy presets.

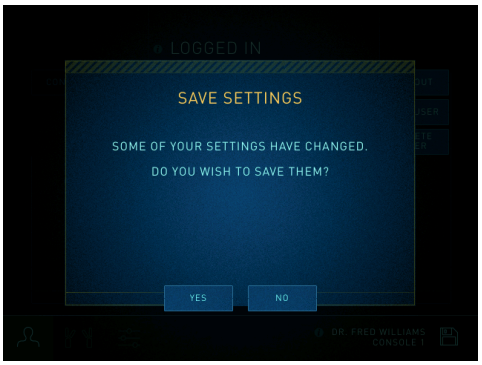
Save Button

After login, a Save button appears on the touchpad. The Save button illuminates when there are changes to certain user-savable settings. Pressing it saves these changes.

The Save button saves the following settings. In dual console mode with two users logged in, only the settings marked with an asterisk (*) are saved.

- Energy presets
- Ergonomic settings*
- Surgeon Console microphone mute*
- Surgeon Console speaker volume*
- Sharpness
- Color mode
- Color balance
- Dynamic contrast
- Haptic zoom*
- Video recording
- Telestration eye
- TilePro (off/on)
- TilePro QuickClick*
- Firefly fingerswitch*
- Scaling*
- Finger clutch*

Before logging out, a message prompts to save any unsaved changes to user-savable settings. Tap **Yes** to save settings or tap **No** to log out without saving.





1. Save button

Intuitive recommends that users log in with their user name each time they use the Surgeon Console.

Account Tab

Tap the **Account** tab to log in, edit, create, or delete a user.

Figure 10.9 Account tab



Logging in to an Intuitive Account

Use the Account tab to log in to an Intuitive account. In dual console mode, one surgeon will log in on console 1 or 2 and the other surgeon will log in on the other console.

1. Tap the **Account** tab.

2. Tap **Start**.
3. Tap **Intuitive Accounts** to view available Intuitive accounts.



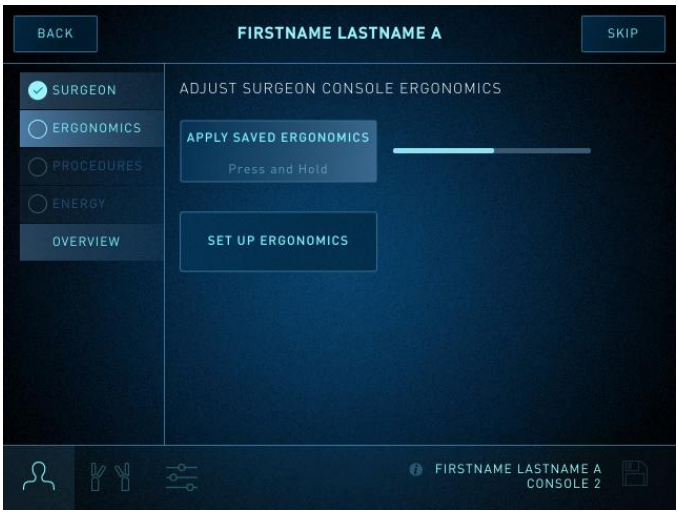
4. Select the surgeon's account from the list of accounts.
5. Enter the surgeon's PIN code to authenticate the account.



1. Back space
2. Delete

6. If this is the first time logging into your Intuitive account, go to Importing Settings on page 10-27 to import settings from another account. If not, continue to the next step.

7. Set up ergonomics.
   a. Make sure persons and objects are clear of the Surgeon Console.
   b. Set up ergonomics by applying a user's saved ergonomic settings or use the ergonomic set up wizard.



- **To apply saved ergonomic settings:** Press and hold the **Apply Saved Ergonomics** button to restore ergonomic settings.

  Note: A progress bar indicates movement as the Surgeon Console applies the last saved ergonomic settings for the selected user. Releasing the button stops movement of the Surgeon Console and the progress bar. Press and hold the button again to resume movement. When ergonomic settings are fully restored, the next step appears.

- **To use the ergonomic set up wizard:** Tap **Set Up Ergonomics** and follow the setup wizard onscreen prompts.

8. Select one or more procedures to perform, or tap **Skip** to go to the next step.

Note: Procedures displays a selectable list of procedure types that indicate which procedures you will be performing. The procedure types are categorized under Surgical Specialties. My Cases displays procedure types most commonly performed by the Intuitive account.

Note: In dual console mode, selected procedures attribute to both surgeons and display in both My Intuitive Case Reports.



a. Tap **My Cases** or one of the listed specialties.

b. Select one or more procedures from the list by tapping the procedure. After making selections, you can tap **Clear** to remove all procedure selections.

- When selecting multiple procedures, the first selected procedure becomes the primary procedure. You can change this primary procedure selection later from **Overview**.
- Procedures listed farther down the list can be accessed by scrolling the list.

c. Tap **Next** to go to the next step.

9. Select the energy presets.

Note: The Energy tab displays saved energy presets from a user's account (for returning users). If no energy presets are found for an account (for example, a new account), then the current generator settings will be applied. Energy presets can be created using the Energy controls in the Instrument tab. For more information, see VIO dV Settings on page 10-51.

Note: If the generator power is off, the Energy tab will not display. Make sure that the generator power is on prior to selecting energy presets.



a. Use the displayed energy settings or use the energy controls on the Instrument tab to select the settings to use for the procedure.

b. Tap **Next** to go to the next step.

The Overview screen displays a summary of the login process settings.



The Case Overview tab appears to provide more detail on Primary designation when selecting more than one procedure or logging in more than one surgeon into the same case. The designated Primary Surgeon and the Primary Procedure can be changed here. See Changing the Primary Surgeon on page 10-16 and Changing the Primary Procedure on page 10-15.

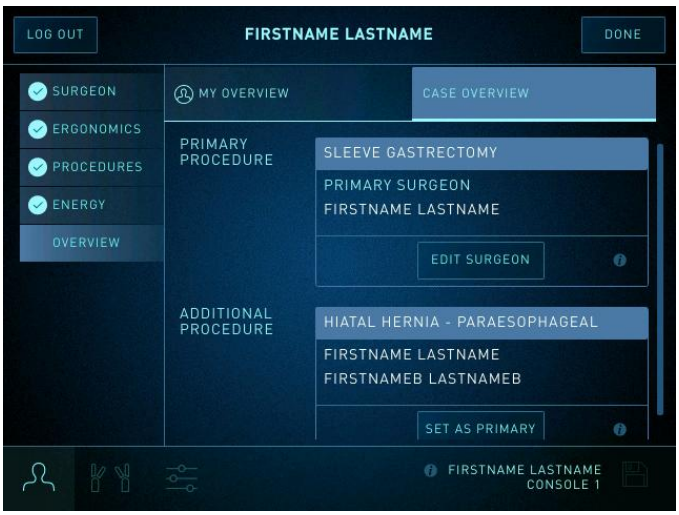


10. When you are finished with your login settings, tap **Done**. The system returns to the Instrument tab.

Changing the Primary Procedure

When there are more than one selected procedures displaying in the Overview tab, you can change which one is the primary procedure.

1. When logging in to the system as an Intuitive account surgeon after having selected more than one procedure from the Procedure list, tap **Overview**.
2. Tap **Case Overview**.



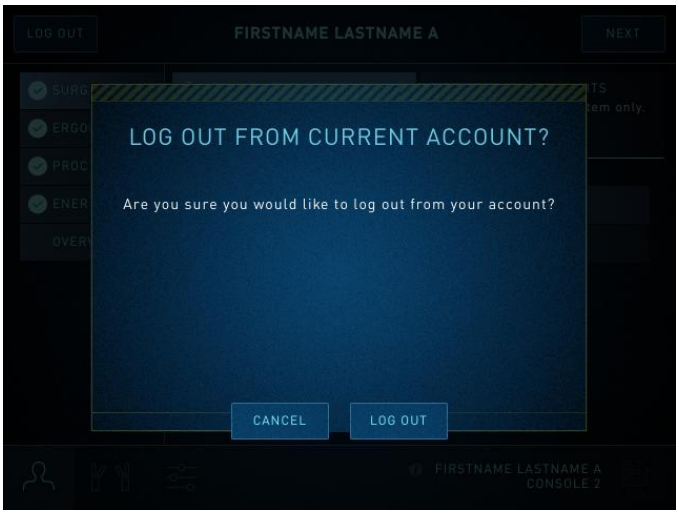
3. In the Additional Procedure list, select the procedure that you want to be primary then tap **Set as Primary**. You may need to scroll the screen to see the button.
4. Confirm that your selection appears as the Primary Procedure.

5. When you are finished with your login settings, tap **Done**. The system returns to the Instrument tab.

Changing the Primary Surgeon

When more than one Intuitive account surgeon logs in during the same case, you can change which surgeon is set as the primary surgeon for the primary procedure.

1. Completely log in an Intuitive account surgeon, selecting at least one procedure.
2. After the first surgeon is logged in, completely log in a second Intuitive account surgeon.
   a. When prompted, tap **Log Out**, to confirm the log out of the first surgeon to log in the second surgeon.

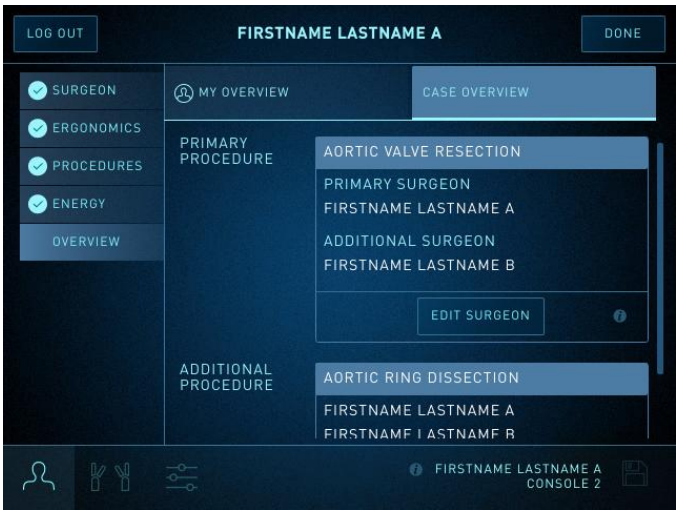


   b. Complete the log in process for the second surgeon, selecting the same primary procedure as the first surgeon account login, and then any other procedure if needed. The first procedure selection is the default primary procedure.

> **Note:** After entering the second surgeon's PIN, if prompted to Select Previous Procedure, tap **Yes**.

3. On the Overview screen, tap **Case Overview**.

4. Verify for the Primary Procedure that there is an Additional Surgeon name listed. If it is missing, you must go back to the Procedure tab and change the primary procedure setting for the second surgeon. It must match the primary surgeon's primary procedure login setting.



5. In the Primary Procedures section, tap **Edit Surgeon**.

   The Edit Surgeon dialog displays the currently selected primary surgeon for the selected primary procedure.

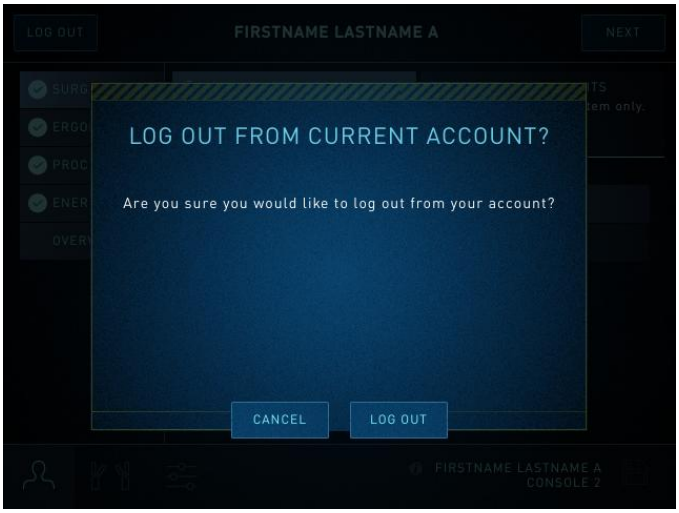


6. Tap the surgeon name without the check mark to change the selection, then tap **Done**.
7. Confirm that your selection appears as the Primary Surgeon for the Primary Procedure.
8. When you are finished with your login settings, tap **Done**. The system returns to the Instrument tab.

Managing Procedures With Another Surgeon Logged in to the Same Case

When you log in after another surgeon logs into a system during the same case, you, as another surgeon, can join the case without changing procedures, and you can change, add, or remove procedures.

1. After a first surgeon completes logging in and selecting at least one procedure, log in as a second Intuitive account.
2. When prompted, tap **Log Out**, to confirm the log out of the first surgeon to log in the second surgeon.



3. Continue following the log in process to the Procedures screen.

   A dialog appears displaying the currently selected procedure chosen by the previously logged in surgeon for you to change or confirm use.



4. Specify how you want to continue.
   a. To return to the procedure list and select different procedures, tap **No**, then select one or more procedures from the list by tapping the procedure.
   b. To continue with the same procedure as the other logged in surgeon, tap **Yes**.
5. Tap **Next** to continue the log in process.
6. When you are finished with your login settings, tap **Done**. The system returns to the Instrument tab.

Changing Surgeons During a Case

The Current Case Surgeons screen is a shortcut to use when multiple surgeons have already logged in to a case and you want to change from the currently logged in surgeon to a different previously logged in surgeon. Access this screen with the Case tab.

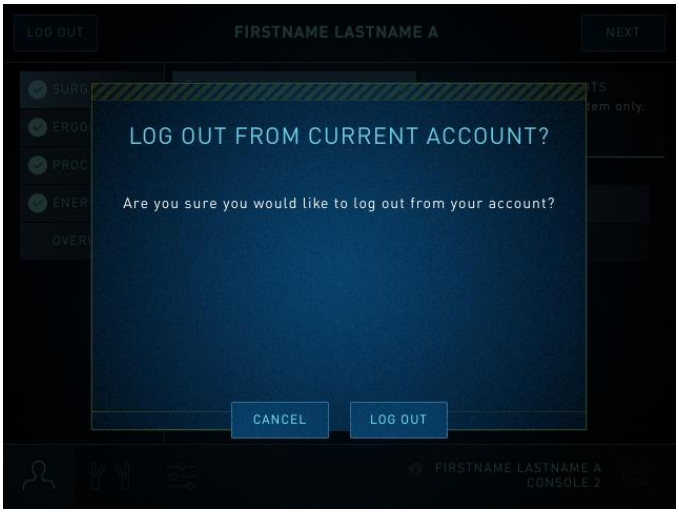
1. When a surgeon is currently logged in, tap the **Account** tab.
2. Tap **Surgeon**.
3. If not already visible, tap **Case**.

   The Current Case Surgeons screen displays a list of all the surgeons who have previously logged in for this case.

   Note: There is no limit to the number of surgeons who can log in during a case.



4. Tap the name of the next surgeon to log in. Only one surgeon at a time can be logged in to a Surgeon Console.
5. When prompted, tap **Log Out** to confirm the log out of the currently logged in surgeon.



6. Complete the log in process.
7. When you are finished with the login settings, tap **Done**. The system returns to the Instrument tab.

Logging in to a Console-only Account as a Returning User

Console-only accounts save settings to this system only.

1. Tap the **Account** tab to select an account.
2. Tap **Start**.
3. When visible, tap **Console-Only Accounts** to view available console-only accounts.

   If necessary, move to a different section of the list by tapping the alphabetical buttons on the touchpad (for example, R-Z).

Account selection screen — no available Intuitive accounts (example)



Account selection screen — available Intuitive accounts (example)



4. Tap a user name to log in.

5. Set up ergonomics.
   a. Make sure persons and objects are clear of the Surgeon Console and then apply saved ergonomic settings or use the ergonomic setup wizard.

      Once settings have been fully applied, the screen progresses to the next step.

   b. Apply saved ergonomic settings or use the ergonomic setup wizard.

      - **To apply saved ergonomic settings:** In the Ergonomics screen, Press and hold the **Apply Saved Ergonomics** button. A progress bar indicates movement as the Surgeon Console applies the last saved ergonomic settings for the selected user. Releasing the button, stops movement of the Surgeon Console and the progress bar. Press and hold the desired button again to resume movement. Once settings have been fully applied, the screen progresses to the next step.
      - **To use the ergonomic setup wizard:** Tap the **Set Up Ergonomics** button and follow the setup wizard prompts.



6. Select the energy presets.

Note: If the generator power is off, the Energy tab will not display. Make sure that the generator power is on prior to selecting energy presets.



a. Use the displayed energy settings or use the Energy controls to select the settings to use for the procedure.

b. Tap **Next**.

Note: The Energy tab displays saved energy presets from a user's account (for returning users). If no energy presets are found for an account (for example, a new account), then the current generator settings will be applied. Energy presets can be created using the Energy controls in the Instrument tab. For more information, see VIO dV Settings on page 10-51.

7. The Overview screen appears after completing setup of the surgeon, ergonomics, and energy settings. Review the surgeon's settings, delete the account, or edit the account name.



   - To edit the account name:
     a. Tap **Edit Name**.
     b. In the dialog that displays, edit the surgeon account name.
     c. Tap **Done** to save the changes to the account.
   - To delete the account:
     a. Tap **Delete Account**.
     b. In the dialog that displays, tap **Delete Account** to delete the account. The system returns to the Account tab Start screen.

8. When you are finished with your login settings, except after deleting an account, tap **Done**. The system returns to the Instrument tab.

Logging in to a Console-only Account as a New User

Note: With Console-only accounts, ergonomics, and other preferences will not be synchronized across other da Vinci systems. Console-only accounts save settings to that system only.

When creating a new Console-only account, setup the surgeon's information, ergonomic settings, and energy settings. The panel on the left side of the screen shows the setup progress.

1. Using the touchpad (on the Surgeon Console), tap the **Account** tab.
2. Tap **Start**.

3. When visible, tap **Console-Only Accounts**.

Account selection screen — no available Intuitive accounts (example)



Account selection screen — available Intuitive accounts (example)



4. Tap the **New Account** button.
5. On the Create a Console-only account screen, tap **Continue**.
6. On the New Console-only account screen, enter the surgeon's name using the touchpad keyboard and tap **Done**.



7. In the screen that opens, tap **Continue** to select an account from which to import settings or tap **Skip** to configure the surgeon's settings manually.

   A new account does not have any saved settings and is created using default settings. The first time a user logs in to their console-only account the user will be prompted to import settings.

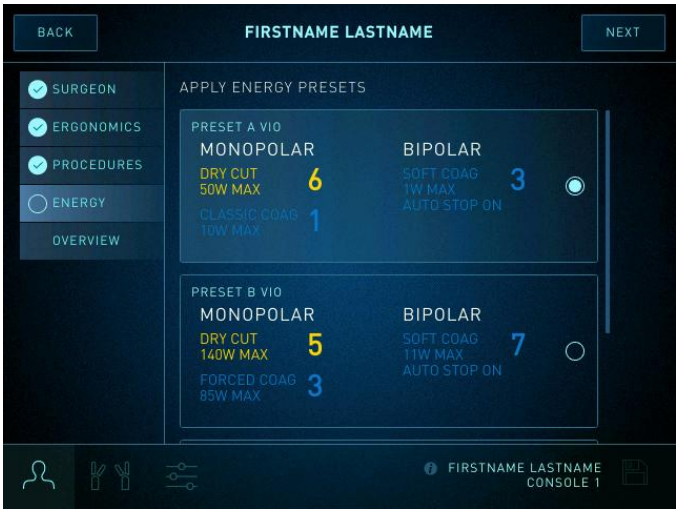
   For instructions to import settings, go to Importing Settings on page 10-27.

8. The system provides guidance through ergonomic setup. Follow the instructions on the succession of Ergonomics screens and tap **Next** when each task is complete. After completing the last ergonomic setup step (footswitch panel), tap **Done**. The settings automatically save and the Energy screen opens.

   Optionally, tap **Skip** to perform the Ergonomics setup at another time and proceed to the energy setup. For more information to skip import settings, see Skip Import Settings on page 10-27.

9. Select the energy presets and tap **Next**, or when no presets are available, tap **Skip**.

   Note: If no energy presets are found for a user account, current generator settings will be applied. Energy presets can be created using the Energy controls in the Instrument tab. For more information, see VIO dV Settings on page 10-51.



10. The Overview screen appears after completing setup of the surgeon, ergonomics, and energy settings. Review the surgeon's settings, delete the account, or edit the account name.



- To edit the account name:
  a. Tap **Edit Name**.
  b. In the dialog that displays, edit the surgeon account name.
  c. Tap **Done** to save the changes to the account.

- To delete the account:
  a. Tap **Delete Account**.
  b. In the dialog that displays, tap **Delete Account** to delete the account. The system returns to the Account tab Start screen.

11. When you are finished with your login settings, except after deleting an account, tap **Done**. The system returns to the Instrument tab.

Importing Settings

The first time a user logs into an account, the user has default settings, but no saved settings. The system will prompt the user to import settings. Use the import settings feature to import previously-save settings from another account.



- Go to Skip Import Settings on page 10-27 to skip importing settings.

1. Tap **Continue**.
2. Tap **Intuitive Account** or **Console-only Accounts**, and then select the account from which to import settings.



3. In the screen that opens, tap **Import** to import settings from that account or **Back** to select another account.

Skip Import Settings

Manually enter the ergonomic, procedure, and energy settings.

1. The Ergonomics screen opens, tap **Begin** and follow the onscreen prompts to complete the ergonomic setup manually. After completing the ergonomic setup, tap **Done**.

   Note: Selecting Skip applies the current ergonomic settings.

2. In the Select Procedures screen, select the procedure category and procedure to use.
3. In the Energy Presets screen, tap **Next**. The current generator settings will be applied.

   Note: You can create energy presets using the energy controls on the Instrument tab.

Cloud Synchronization

For Intuitive accounts, changes are saved to the Surgeon Console for later synchronization to the Cloud. Synchronization occurs when the system is powered on and when a user logs out of the Surgeon Console. The system will synchronize to the Cloud only when there is an available network connection, all users are logged out, and all cannulas are undocked from the system.

OnSite

To synchronize to the Cloud, OnSite must be enabled and on. For more information regarding OnSite and its use, see the applicable da Vinci system user manual.

Manual and Automatic Logout

1. To log out manually, go to the Login tab and tap **Logout**.
2. Before logging out, a message prompts to save any unsaved changes to user-savable settings. Tap **Yes** to save the settings and log out or **No** to log out without saving.



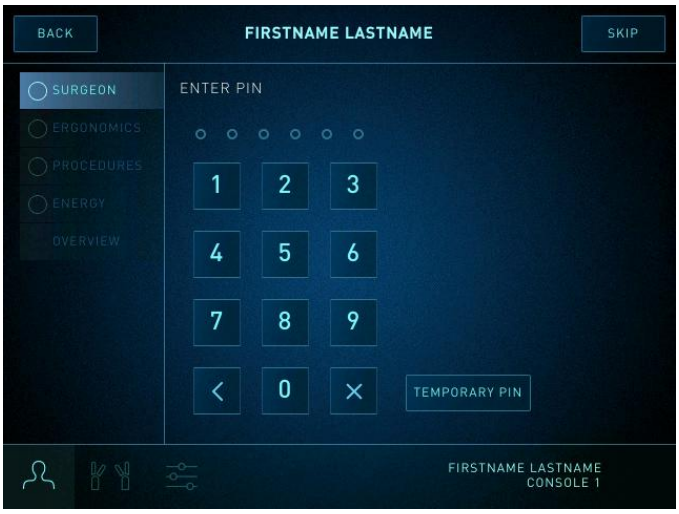
Automatic logout occurs when the system recognizes the end of a procedure. If the system automatically logs out, changes to settings are not saved, and any unsaved changes to user-savable settings are lost.

Login Help

Temporary PIN

If you forget your PIN you can obtain a temporary PIN to log in to your account.

1. Tap the **Temporary PIN** button.



2. In the Temporary PIN screen, tap **Temporary PIN**.

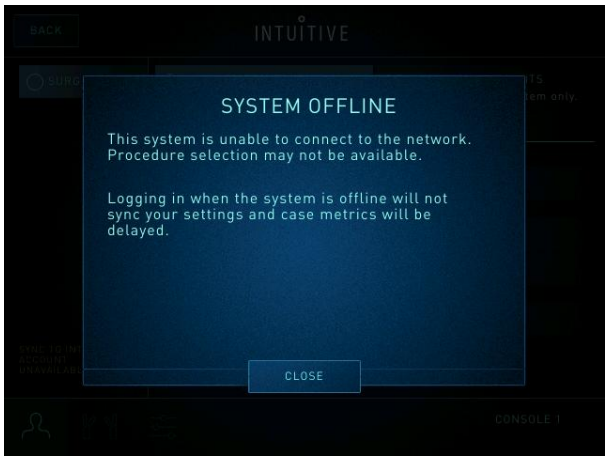
   A message appears on the Temporary PIN screen notifying the user that a temporary PIN has been sent to the phone number and email associated with the account.

Unable to Connect to the Network

Figure 10.10 Sync to Intuitive account unavailable screen



Figure 10.11 System offline screen



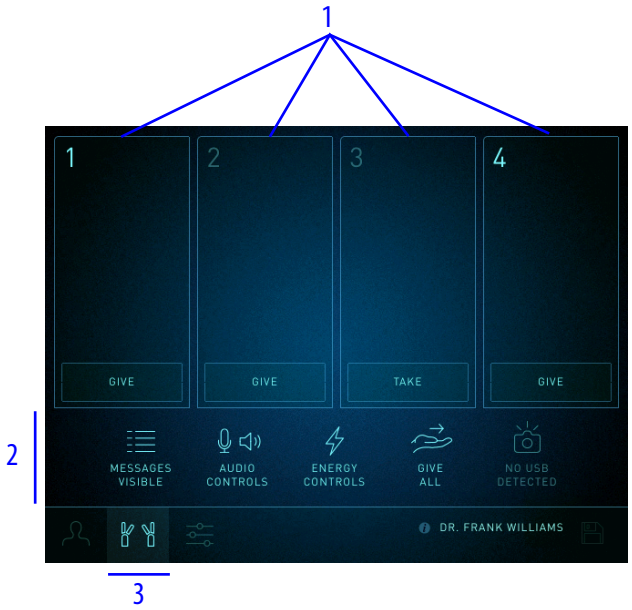
Customer Service

If you are unable to connect to the Cloud, contact Intuitive Customer Service.

Instrument Tab

The Instrument tab provides status for all arms and enables quick adjustment of video and audio. In dual console mode, it also enables surgeons to give or take control of the arms (see 10.7 Dual Console Surgery on page 10-66). The status and controls associated with each of the arms is displayed on the Instrument tab as arm status pods arranged horizontally across the screen.

Figure 10.12 Touchpad Instrument tab



1. Arm status pods
2. Quick settings
3. Instrument tab

Arm Status Pods

The information and controls that appear on each pod vary depending on whether the associated Patient Cart arm is holding an instrument or an endoscope.

Figure 10.13 Example of arm with endoscope and instrument



1. Endoscope
2. Instrument

Quick-settings Bar

Provides fast access to select controls. Tap a quick-setting to select, toggle, or modify it. Some features may require additional setup to display, such as TilePro.

Figure 10.14 Quick-settings example





- **Messages:** Non-critical system messages and status can be toggled between Messages Visible and Messages Hidden.



- **Audio:** Open the dialog to turn the Surgeon Console microphone On or Off, and adjust the speaker volume.

- **Headset:** If a headset (with microphone) is connected to the headset port on the rear of the Surgeon Console:
  - All voice audio is routed to the headset instead of the Surgeon Console speakers. System annunciation tones are played in both the headset and the Surgeon Console speakers.
  - The Surgeon Console microphone is deactivated and the surgeon's voice is routed through the headset microphone.
  - The On and Off control applies to the headset microphone and the touchpad indicates that a headset is connected.
  - The Volume control applies to the headset speakers.

Figure 10.15 Headset connected example





- **Energy Controls:** Opens the VIO dV control panel, and provides troubleshooting information.



- **Give All and Take All (Dual Console):** Toggle to assign control (that is, Give or Take) of all instruments from one Surgeon Console to another.



- **Take Photo:** Captures a still image of the endoscope view to a USB flash drive connected to the front of the Vision Cart. The icon indicates if a USB flash drive is detected, and provides other troubleshooting information.



- **TilePro:** Toggle to show or hide the TilePro image.

Arm Pod Quick-settings



- **Brightness:** Open the panel to adjust visible light or Firefly mode background brightness (not illumination) in the 3D viewer. Dragging the slider up increases brightness.

Figure 10.16 Brightness adjustment





- **Give/Take (Dual Console):** Toggle between Give on the console that has control and Take on the console that does not have control. Either surgeon can Give or Take control of a specific arm by tapping its **Give** or **Take** button. When control is transferred by tapping **Give** or **Take**, the instrument goes out of following until the surgeon assuming control matches grips in the usual way.



- **Scope Angle:** When the endoscope is installed on the arm, the system detects and displays the endoscope angle, 30° up, 30° down, or 0° for straight endoscopes. When an angled endoscope is installed, tap the **30° Down** or **30° Up buttons**, which has the effect of rotating the endoscope and the live video 180°.



- **VIO dV Settings:** Access to the Energy button and settings panel to adjust VIO dV settings or view messages. For more information, see VIO dV Settings on page 10-51.

Settings Tab

Figure 10.17 Settings tab



The Settings tab allows surgeons to configure a variety of system settings. The available settings are grouped in the following sections:

- Image
- Display
- TilePro
- Firefly[2]
- Hand Controls
- Account

Tap the **Settings** tab to access the Image, Display, TilePro, Firefly, Hand Controls, and Account sections.

Image

Tap the **Image** button or scroll to view the Image section by swiping up or down on the touchpad.

- **Restore Image to Factory Defaults:** Restores the following settings to factory default values:
  - Brightness (visible light mode): 50% (of full slider value)
  - Color Balance: 15% (of full slider value)
  - Dynamic Contrast: 0% (of full slider value)
- **Brightness:** Drag the slider right to increase the visible light mode brightness of the 3D viewer image. This does not change the actual light output of the Endoscope Controller. The Brightness slider in the Image section is enabled while in visible light mode.
- **Color Balance:** Drag the slider to adjust color balance of the endoscopic image. Moving the slider to the left increases the red tones in the image. Moving it to the right increases the blue tones in the image. Color Balance is enabled while in visible light mode.
- **Dynamic Contrast:** Drag the slider to adjust the contrast of the image. As dynamic contrast is increased, darker regions of the image are brightened, and brighter regions are darkened. Dynamic Contrast is enabled while in visible light mode.

Display

Tap the **Display** button or scroll to view the Display section.

- **Digital Zoom:** Zoom in on the image without changing the position of the endoscope tip. Zoom has three settings (1x, 2x, 4x). The current setting appears below the endoscope status icon on the touchpad.

  When the digital zoom setting is changed, a navigation screen appears in the bottom right corner of the Surgeon Console image. The navigation screen represents the 1x image.

2. Not all technologies may have regulatory approval or may be commercially available in all geographies. For availability in your country, check with your local representative.

- **Haptic Zoom:** Turns haptic zoom on or off. Off by default, haptic zoom is a method to apply digital zoom using the hand controls in endoscope control mode. Digital zoom does not move the endoscope tip.

  To use haptic zoom, press the endoscope control pedal to enter endoscope control mode and:

  – Push the hand controls closer together to zoom in (digitally).

  – Pull the hand controls further apart to zoom out (digitally).

  Note: A slight detent (pushback) may be felt on the hand controls as the levels are adjusted.

- **Working Distance:** Enhances the ability to see a fused 3D image at Normal or Close Up distances.
- **Telestration Eye:** Toggles display of telestration overlay between the left-eye (Left) and right-eye (Right) image.
- **Viewer Mode:** Toggles the 3D viewer between 2D and 3D mode.

TilePro

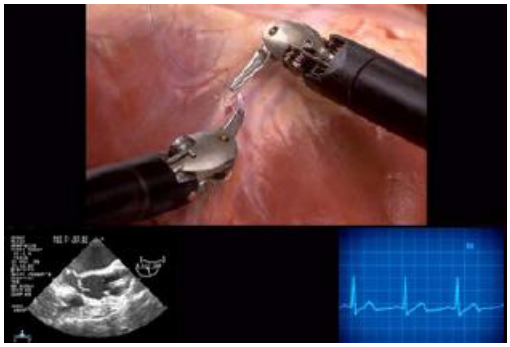
Use TilePro to view auxiliary video sources in the Surgeon Console viewer, below the endoscopic image. Examples of auxiliary video sources include Digital Imaging and Communications in Medicine (DICOM) viewer, ultrasound, endoscope, and room camera. TilePro video input connections are located on the Surgeon Console and the Vision Cart.

TilePro Controls

- Tap the **TilePro** button or scroll to view the TilePro section.
- **TilePro (On/Off):** Turns TilePro display on or off.
- **TilePro QuickClick:** Turns TilePro QuickClick on or off. When TilePro QuickClick is enabled, the surgeon can switch to TilePro mode with a quick press of the endoscope pedal.
- **TilePro Viewer Mode:** To display a 3D TilePro video source in the viewer, simultaneously connect a compatible stereo video source to both the TilePro left (L) and right (R) connectors and tap **3D** on the touchpad.

> **Note:** TilePro is disabled unless auxiliary video sources are connected to the system. TilePro sources connected to the Vision Cart take precedence over TilePro sources connected to the Surgeon Console.

Figure 10.18 Sample TilePro layout



- **TilePro Size:** Scales the TilePro image using the buttons.

Figure 10.19 Sample TilePro touchpad settings



To Use TilePro

1. Connect the video source to the Surgeon Console or the Vision Cart TilePro input connections (L or R).
   - When one video source is connected to an input, the video is centered in the display.
   - When two video sources are connected, the videos display side-by-side.
   - To change which side the videos are displayed, switch the video input connections.
   - To display a video on the left side of the screen, connect the video source to the left (L) TilePro input connector. To display a video on the right side of the screen, connect the video source to the right (R) TilePro input connector.
2. Turn on TilePro from the touchpad.

Note: In dual console mode, the console must be assigned all active instruments in order to make TilePro size changes. If a console that is not assigned all active instruments attempts to make a TilePro size change, a system message appears.

To Use 3D TilePro

1. Connect the stereo video source to the Vision Cart TilePro left and right input connections.
2. Turn on TilePro from the touchpad.
3. Select TilePro Viewer Mode '3D' to merge the two video sources.

   The merged image may look incorrect if the left and right connectors are switched.

Firefly

Tap the **Firefly** button or scroll to view the Firefly section.

For more information on Firefly use, see the *Firefly Imaging System User Manual Addendum for da Vinci Xi and da Vinci X Systems*[3].

Hand Controls

Tap the **Hand Controls** button or scroll to view the Hand Controls section.

- **Scaling:** Scales the sensitivity of the hand controls in relation to the instruments. Quick (1.5:1), Normal (2:1) and Fine (3:1) ratios.
- **Finger Clutch:** Turns finger clutching off or on. The finger clutch buttons on the hand controls are on by default when no one is logged in to the Surgeon Console. However, the previously saved setting is applied automatically upon login.
- **Hand Control Assignments:** Tap to open the Hand Control Assignments screen, which enables the surgeon to manually associate either hand control with any arm.

  Tap **Auto** to apply Hand Control Assignments automatically, or tap **Manual** and then tap **Save** to manually switch assignments by arm. When arms are reassigned, the system takes the instrument arms out of following, and prompts the user to press the **Arm Swap** pedal to take control of the arm.

  The system does not allow association of more than two arms with one hand control.

Note: In dual console mode, either surgeon can use the Hand Control Assignments screen to reassign instruments to different hand controls, even while the other surgeon has control of the instruments. The new instrument assignment applies on both consoles and persists when instruments are swapped. The system notifies the surgeons when reassignment occurs.

Account

Tap the **Account** button or scroll to view the Account section.

- **Restore Saved Settings:** Tap **Restore Saved Settings** to return settings to user-saved values. To restore ergonomic settings, go to the Login tab and press and hold the **Apply Saved Ergonomics** button. The Apply Saved Ergonomics button is available when a user is logged in to the Surgeon Console.

  The following user-saved settings are restored. For dual consoles with two users logged in, the settings marked with an asterisk are restored.

  - Energy presets
  - Ergonomic settings
  - Surgeon Console microphone*
  - Surgeon Console speaker volume*
  - Color Balance
  - Dynamic Contrast
  - Haptic Zoom*
  - Telestration Eye
  - TilePro (On/Off)
  - TilePro QuickClick*
  - Firefly Fingerswitch*
  - Scaling*
  - Finger Clutch*
- **Restore Factory Defaults:** Restores the following settings to factory defaults:
  - Surgeon Console microphone: Enabled

3. Not all technologies may have regulatory approval or may be commercially available in all geographies. For availability in your country check with your local representative.

  - Surgeon Console speaker volume: 50% (of full slider value)
  - Brightness (visible light mode): 50% (of full slider value)
  - Color Balance: 15% (of full slider value)
  - Dynamic Contrast: 0% (of full slider value)
  - Digital Zoom: 1X
  - Haptic Zoom: Off
  - Working Distance: Normal
  - Telestration Eye: Right
  - Viewer Mode: 3D
  - TilePro (On/Off): Off
  - TilePro QuickClick: Off
  - TilePro Viewer Mode: 2D
  - Firefly Fingerswitch: Off
  - Firefly Intensity: 50% (of full slider value)
  - Firefly Background Brightness: 50% (of full slider value)
  - Scaling: Fine (3:1)
  - Finger Clutch: On

- **Import Settings:** Allows a user who is logged in to the Surgeon Console to import settings (including ergonomics) from another user profile. Tap **View List** to view the list of users, and then tap a user name, and confirm the settings. Additionally, press and hold the **Restore Ergonomic Settings** button to apply the imported ergonomic settings.

Da Vinci Update Tool

The Download tab is displayed on the Surgeon Console touchpad when a new software update is available. Additionally, when surgery is not occurring (all cannulas, drapes, and instruments are removed), the Vision Cart touchscreen will display a message that an update is available.

To perform the software update, follow the onscreen instructions listed for each download step.



1. Download steps
2. Download tab

Note: The software update process will display the time required to complete the update. The system will be unavailable for the duration of the update.

Note: To download a software update, OnSite must be enabled. For more information regarding OnSite, see the applicable system user manual.

Note: Do not begin an update before a planned surgical procedure. It is recommended that updates are only performed when the system is done being used for the day. All cannulae, drapes, and instruments must be removed before the update will start.

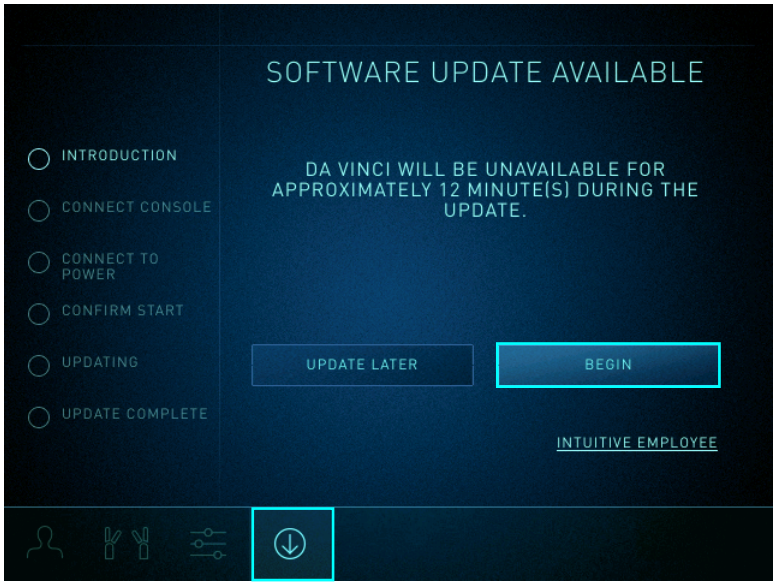
Using the da Vinci Update Tool

Note: The Intuitive Employee button is not for customer use. The button is for Intuitive Sales representative or Field Service Engineer use only.

Note: The software update cannot be performed using battery power.

Note: Initiating the software update disables the power buttons during the update process, and tabs cannot be selected.

1. Tap the **Download** tab.



The Download tab changes to blue.

2. Tap the **Begin** button and follow the onscreen instructions.
3. Follow the onscreen prompts in the Introduction screen.

4. Connect the Surgeon Console, Vision Cart, and Patient Cart (system components) blue fiber cables.



The system will prompt the user to connect a second Surgeon Console if they have one.

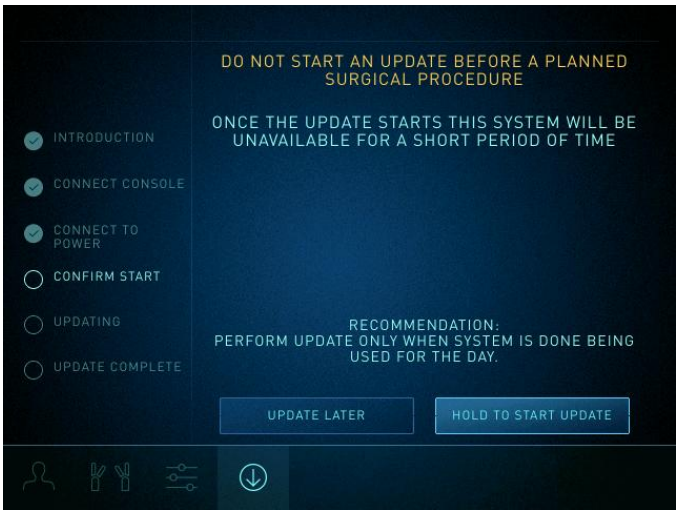
If this is a dual console system, connect the second console blue fiber cable.

5. Tap **Next** to continue to the Connect to Power screen.

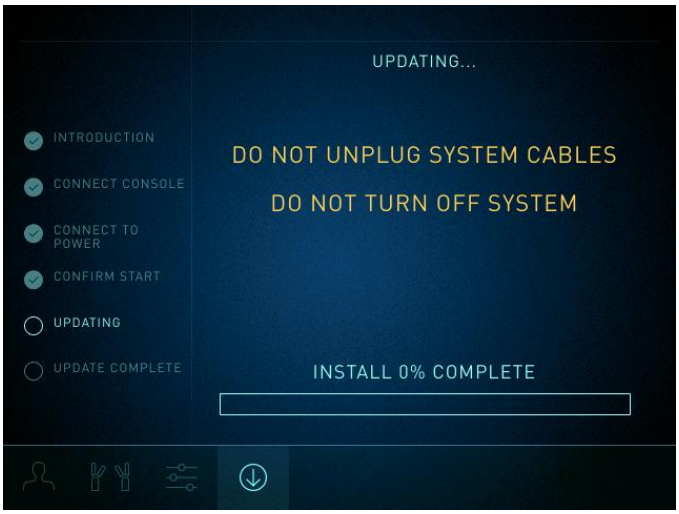


6. Ensure that the Patient Cart is connected to its dedicated power outlet.
7. Tap **Next**.

8. Press and hold the **Hold to Start Update** button to initiate the software update. To cancel, release the button before the timer reaches zero.



During the update process, do not unplug any cables or attempt to turn off the system. The system will automatically restart when the update is complete.



The system will restart and then display an update confirmation screen. The software version installed is displayed on this screen.

9. Tap the **Close** button to return to the Surgeon Console touchpad Instrument screen. If the update was successful, the Download tab will no longer be visible on the screen.

Troubleshooting

If there is a problem during the update process, the system displays further instructions.

1. Power cycle the system and perform the update steps again, or contact customer service.



OnSite is Not Enabled

To download a software update, OnSite must be enabled. For more information regarding OnSite and its use, see the applicable system user manual.

10.4 Surgical Controls

This section describes the interface for controlling the instruments, endoscope, and 3D viewer display using the hand controls and footswitch panel.

Head-in Requirement

To begin using the hand controls, the surgeon must first put their head in the 3D viewer. The 3D viewer uses a pair of infrared head sensors to determine whether the system is in use or not. If the surgeon's head is out of the viewer, he or she cannot take control of the instruments or endoscope.

⚠ **CAUTION:** The infrared head sensors perform a safety function by preventing movement of the arms when the surgeon's head is not in the viewer. Do not defeat this safety feature by intentionally blocking the sensors.

Match Grips

Before taking control of instruments, the surgeon must first match grips. Matching grips is a safety feature designed to prevent inadvertent activation of instruments. It also ensures that items being held by inactive instruments are not accidentally dropped when activated.

The surgeon cannot match grips until the instrument tip moves past the cannula tip. When the instrument is ready to match grips, an icon and text message prompts to match grips.

Figure 10.20 Match grips icon example



Two Requirements To Match Grips:

1. Satisfy intended motion:
   - Use the hand controls to partially close or open the grips.
   - For instruments like the Clip Appliers, where opening or closing the grips would fire the instrument, use the hand control to slightly rotate the grips.
2. Match the hand control grip angle to the instrument grip angle.

The surgeon can now control the instruments. Maintain a light grip on the hand controls when taking or re-taking control (for example, when a new instrument is installed, when the Patient Cart operator moves the Instrument or endoscope arms, after arm swapping, etc.). This allows the system to align the hand controls relative to the tips of the instruments in the 3D viewer.

WARNING: For patient safety, the surgeon *must not* match grips for instruments whose tips are not visible in the 3D viewer. Do not move instruments if the tips are not visible in the 3D viewer. Failure to observe this warning can cause serious harm to the patient.

WARNING: Be careful to use the system electrical components safely and effectively to prevent electrical shock.

WARNING: To avoid an electrical hazard, the Surgeon Console operator must not touch the patient while using the hand controls.

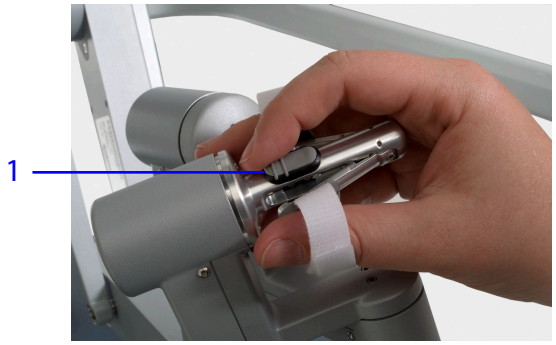
CAUTION: Do not let go of the hand controls while the surgeon's head is still in the viewer, because doing so may cause patient tissue damage.

Note: Clip Appliers must match grips and be open more than 90% before they will be allowed to close.

Note: To ensure patient safety, the Patient Cart operator's actions take precedence over Surgeon Console control. Any movement of the arms by the Patient Cart operator takes all instruments out of surgeon control.

Finger Clutch

CAUTION: Fully understand the finger clutch capability to avoid unintentional instrument movement and prevent patient tissue damage.



1. Finger clutch

Slide the finger clutch to decouple the hand control from instrument control.

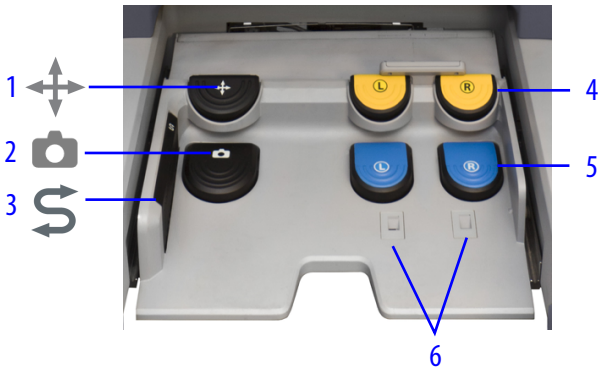
- While holding the finger clutch, the surgeon can move the hand control and the instrument does not move. Applying the finger clutch enables the surgeon to reposition the hand controls for comfort, and to reclaim space to maneuver when the hand control reaches its limits.
- Unlike the master clutch foot pedal, the finger clutch applies only to its own hand. So when the surgeon applies the right-hand finger clutch, the instrument assigned to the left hand remains in surgeon control.
- To resume instrument control, release the finger clutch and match grips as usual (see Match Grips on page 10-42).
- The surgeon can turn off finger clutching using the **Hand Controls** section on the touchpad (see Hand Controls on page 10-37).

Footswitch Panel Use

WARNING: Activation of the incorrect instrument activation pedal could result in unintended instrument function, causing tissue injury.

The footswitch panel features two groups of foot pedals. The three pedals on the left control system functions (master clutch, endoscope control, and swap). The four pedals on the right control instrument activation. The instrument activation pedals are arranged as a left pair of pedals and a right pair of pedals, see Instrument Activation Pedals on page 10-46.

Figure 10.21 Footswitch panel controls



1. Master clutch
2. Endoscope control
3. Swap
4. Secondary yellow foot pedals
5. Primary blue foot pedals
6. Foot sensors



- **Endoscope Control:** Press and hold the endoscope pedal to switch the hand controls from instrument control to endoscope control. In endoscope control mode, the surgeon's movement of both hand controls together – such as moving in or out, side to side, or rotating – translates into endoscope movements.

  Hold down the endoscope pedal while performing these actions:

  - To move the endoscope closer to the target anatomy, pull both hand controls toward your eyes. Push both hand controls away to move the endoscope farther away from the target anatomy. To rotate the endoscope clockwise, rotate the two hand controls together clockwise, like a steering wheel.

  Note: Pressing the endoscope pedal takes all instruments out of surgeon control and also stops firing of energy instruments on the other console when operating in dual console mode (see 10.7 Dual Console Surgery on page 10-66). Releasing the endoscope pedal resumes control of the instruments.



- **Master Clutch:** Pressing the master clutch decouples both hands from the instrument movement and enables the surgeon to adjust the hand controls while all instruments remain immobile. (The master clutch cannot be used to decouple hands independently.) Pressing the master clutch pedal allows the surgeon to reposition their hands for ergonomic comfort, and to reclaim space to maneuver the hand controls when they run out of workspace. All instruments remain immobile until the surgeon resumes control by releasing the pedal and then matching grips as usual (see Match Grips on page 10-42).



- **Swap pedal (left kick-plate):** Pressing the swap pedal allows the surgeon to select which of the instruments is actively controlled by the hand controls.

WARNING: When swapping instruments, the surgeon must always visualize the tip of the instrument to ensure it is in view before moving the instrument to prevent tissue injury.

Instrument Activation Pedals

SmartPedal Technology

WARNING: Improper use of instruments with advanced functionality, or lack of familiarity with messaging or audio indications during activation could lead to tissue injury.

The instrument activation pedals include two pairs of pedals, left and right, for activating the special instrument functions (for example, electrocautery energy delivery) of the instruments being controlled by the hand controls.

The da Vinci system uses SmartPedal Technology, a simple association of pedals with instruments. The left pair of pedals activate the instrument associated with the left hand control; likewise, the right pair of pedals activate the instrument associated with the right hand control. These automatic associations for pedals cannot be changed.

Along the bottom of the 3D viewer, the system displays information about the instrument on each arm. In the scenario below, the surgeon presses the associated blue pedal to activate the Permanent Cautery Spatula's primary energy mode (**Coag**). The surgeon presses the associated yellow pedal to activate the Permanent Cautery Spatula's secondary energy mode (**Cut**).

Figure 10.22 Instrument activation pedals



Instrument Activation Pedal Functions

Each pair has a blue pedal below for primary activation, and a yellow pedal above for secondary activation.



- **Left Primary Pedal (blue):** Activates the primary instrument function on the instrument controlled by the left hand control (for example, **Coag** for monopolar instruments).
- **Right Primary Pedal (blue):** Activates the primary instrument function on the instrument controlled by the right hand control (for example, **Coag** for monopolar instruments).
- **Left Secondary Pedal (yellow):** Activates the secondary instrument function on the instrument controlled by the left hand control (for example, **Cut** for monopolar instruments).
- **Right Secondary Pedal (yellow):** Activates the secondary instrument function on the instrument controlled by the right hand control (for example, **Cut** for monopolar instruments).

For information about the user interface associated with pedal activation, see Instrument Activation Pedals on page 10-46 and 10.5 3D Viewer Display on page 10-47.

10.5 3D Viewer Display

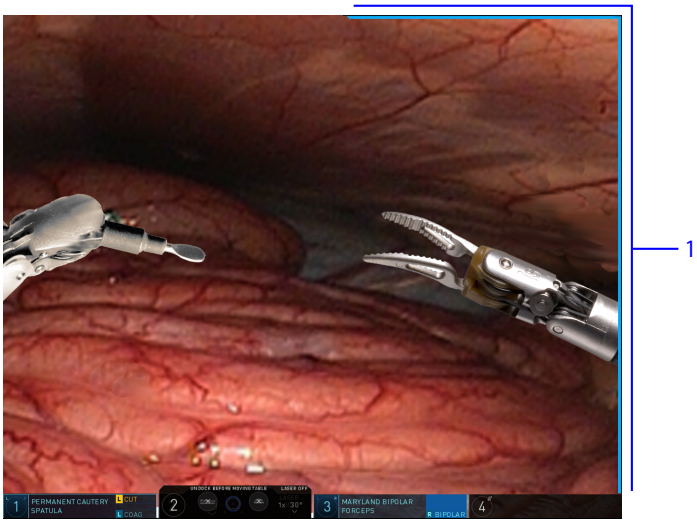
The 3D viewer displays the surgical site and provides extended system information using icons and text messages. For a general list of icons and text messages, refer to Appendix D Symbols, Icons, Audio Messages on page D-1.

Foot Pedal Activation Status Bar

WARNING: Improper setup or inadvertent activation of energy instruments could lead to patient harm.

A hover and activation status bar appears in the surgeon view to indicate hover (foot is over an active pedal but not pressing it) and then activation (foot pedal is pressed). The foot pedal activation status bar has two fields. The left field displays the left bank foot pedals. The right field displays the right bank of foot pedals.

Figure 10.23 Foot pedal activation status bar



1. Activation status bar

The status bars change color depending on the primary (blue) or secondary (yellow) foot pedal states (hover, activation, no actuation).

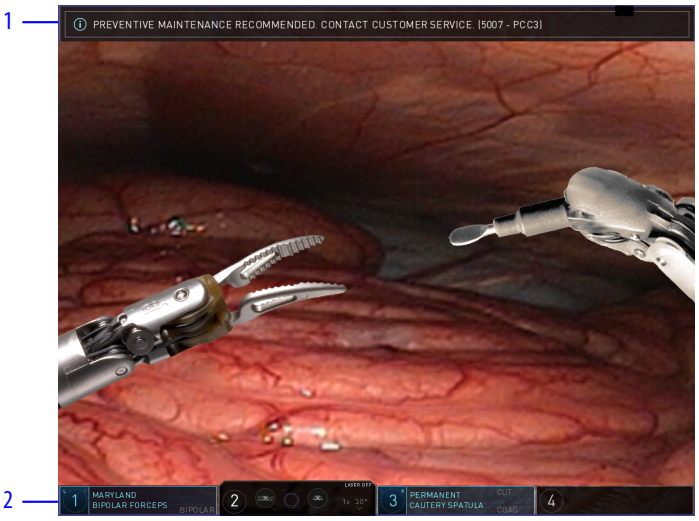
- No hover and no pedal actuation detected - Black
- Hover detected, but no pedal actuation detected - Highlight green
- Activation of feature assigned to primary pedal detected - Associated pedal color
- Activation of feature assigned to secondary pedal detected - Associated pedal color

3D Viewer Messages

Arm and Instrument Information Area: Displays messages pertaining to arms, instruments, or the endoscope.

System Status Information Area: Displays basic system status and information.

Figure 10.24 3D viewer messages



1. System status information area
2. Arm and instrument information area

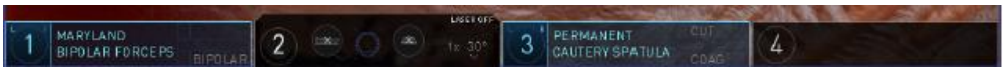
Icons indicate that the feature is active. Any additional system-related information is displayed on a message screen below this field. This field does not display arm or instrument information.

Arm, Instrument, and Endoscope Information

WARNING: Be aware that the messaging over pods indicates the arm associated with that pod; this is to prevent patient injury due to user confusion.

When one Surgeon Console is in use, the 3D viewer shows hand control, instrument, and endoscope status.

Figure 10.25 Arm and instrument / endoscope status



The arm and status pod provides information on the arms and associated instruments and the endoscope. If an installed instrument provides a special function (for example cautery), such functions are shown on the right edge of that arm pod.

1. Non-function Status – Just the name of the instrument appears; for instruments with no special functions.
2. Function Status – Special functions available are shown at right edge of its field, such as BIPOLAR, CUT, and COAG.
3. Endoscope Status – Shows the endoscope type (angle), rotation angle indicator, digital zoom indicator, and endoscope up or down indicator.

Arm and Instrument Status

WARNING: Be careful to correctly identify which instrument is associated with each hand control when the endoscope is port hopped or manually rotated 180 degrees. Failing to do so may result in inadvertent instrument movement or removal, which may lead to tissue injury.

Provides arm, hand control, and instrument status for consoles in use.

Figure 10.26 Arm status



1. Arm status and hand control association
2. Activation status
3. Instrument name

The hand control association indicator appears as an “L” or an “R” in the upper left and upper right of the arm number. An “L” indicates that the instrument is assigned to the left hand control, and an “R” indicates that the instrument is assigned to the right hand control.

The arm number icon provides additional status information described in the table below:

Table 10.1 Arm number status indicators

Example	Description
	Arm 1 is assigned to the left hand control.
	Arm 3 is assigned to the right hand control.
	The arm is paused, for example, because the user is actively moving the endoscope.
	The hand control assigned to the arm is being clutched by the user at the Surgeon Console.
	The arm has experienced a fault. Note that in this case, the status indicator supplements the information provided in the 3D viewer message areas, and on the touchscreen and touchpad.
	The swap pedal can be pressed to change hand control assignment.

When operating in dual console mode, all controlled arms appear in color on the touchscreen display. In the surgeon view, arms appear in color when controlled by the local console, and arms appear gray when controlled by the second console.

Arm Pop-up Information

In the event that an action is required by the Surgeon Console operator to control an arm, including handling an arm-specific error or fault condition, the system generates a pop-up message with information about the required action. When the action is complete, the pop-up message disappears.

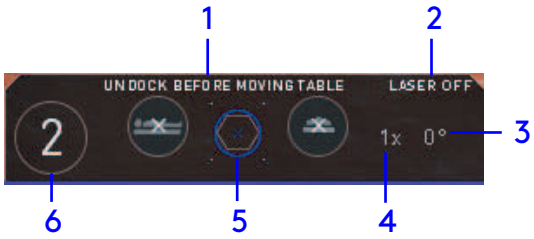
Figure 10.27 Pop-up message



Endoscope Status

Displays all of the associated endoscope information including arm number, endoscope type, endoscope direction, endoscope horizon, and digital zoom.

Figure 10.28 Endoscope status



1. **Table:** Displays operating table status (for example, undock before moving table).
2. **Firefly Laser On/Off:** Displays status of Firefly laser (Firefly mode)[4]. When Firefly mode is off, normal endoscope light is referred to as visible (white) light mode.
3. **Endoscope type and direction:** Displays the endoscope type and direction (for example, 0°, 30° up, or 30° down).
4. **Digital Zoom:** Shows current zoom level of 3D Viewer (1x, 2x, 4x).
5. **Endoscope Horizon Indicator:** Provides information regarding the rotation of the endoscope relative to ground. This feature is useful for understanding the frame of reference of the video relative to the anatomy.
6. **Arm Number:** The arm number with the endoscope installed.

Second Console Instrument Status Area

While in dual console mode, the 3D viewer provides:

4. Not all technologies may have regulatory approval or may be commercially available in all geographies. For availability in your country, check with your local representative.

- The instrument status for the *other* console.
- The associated instrument name, arm number, and energy status.

10.6 Integrated ERBE VIO dV 1.0 and VIO dV 2.0 Overview

WARNING: Do not activate two energy instruments at the same time to prevent tissue injury due to possible simultaneous energy delivery.

CAUTION: Ensure the compatibility of instruments with generator, to prevent burns to unintended tissue structures.

The ERBE VIO dV (VIO dV) is an integrated Electrosurgical Unit (ESU) that can be used with da Vinci Xi and laparoscopic instruments. This section provides general information specific to use with the da Vinci Xi system and the da Vinci X system and instruments. Two versions of the generator are available, VIO dV 1.0 and VIO dV 2.0. For further information, see the Instruments and Accessories User Manual.

VIO dV 1.0	VIO dV 2.0
Looks like 	Looks like 

Note: Follow the instructions specific to the generator version used in your facility. Instructions that do not specify a VIO dV version apply to both versions.

VIO dV Settings

WARNING: Verify the generator presets and settings before activating energy to avoid tissue damage.

The **Energy** button for energy messages and VIO dV settings (Mode and Effect) is on the Surgeon Console touchpad Instrument tab, in each applicable arm pod. Settings or messages appear in the **Energy** button if a monopolar or bipolar instrument is installed on the arm and connected to the generator.

The surgeon can tap the **Energy** button to:

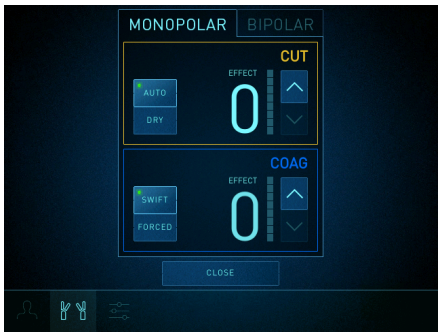
- Access the VIO dV Settings panel to adjust VIO dV settings.
- Get more information on an energy message.

Figure 10.29 Touchpad Energy button and VIO dV Settings panel examples

Energy button



VIO dV Setting panel



If VIO dV settings are at “0” (that is, off), the effect value flashes.

Dual Console Use

CAUTION: Simultaneous energy setting adjustment is possible when dual consoles are present. Verify energy settings before activating energy to prevent patient tissue damage.

Adjust VIO dV 1.0 Settings on the Surgeon Console Touchpad

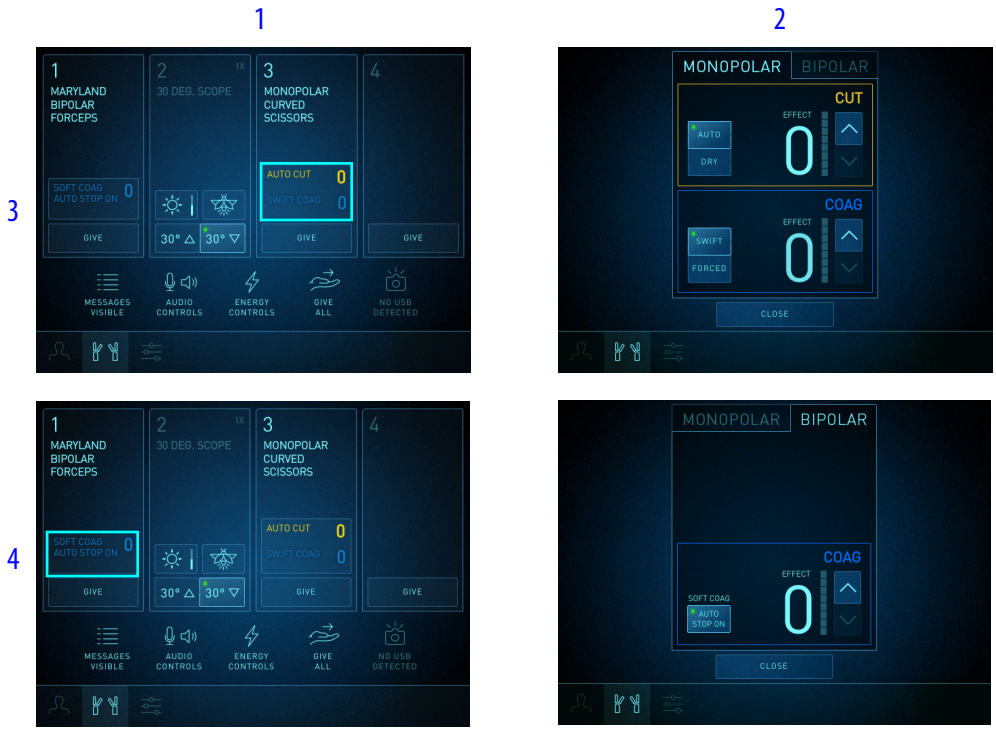
Note: Settings cannot be changed from the Surgeon Console(s) or the VIO dV touchscreen while energy is activating.

Note: When a setting is adjusted, the change happens immediately. For best results, confirm setting levels before activating instruments.

Follow these steps to adjust the VIO dV settings from the Surgeon Console touchpad:

1. Tap the **Energy** button or the Energy Controls quick-setting to access the VIO dV Settings panel.
2. Tap the **Mode** button to select the mode. Tap the Effect up or down arrow to adjust the effect.

3. Tap **Close**.



1. Energy buttons
2. Settings panel
3. Monopolar example
4. Bipolar example

If a message other than settings adjustment displays, tap the **Energy** button to see additional information to resolve the issue. See Troubleshooting on page 10-64 for more information.

Using Two Instruments of Same Energy Type

Even though there are two monopolar and two bipolar ports on the VIO dV, there is only one set of monopolar settings and only one set of bipolar settings.

CAUTION: Using the Surgeon Console to change settings on one monopolar instrument changes settings for all connected monopolar instruments. Changing settings on one bipolar instrument changes settings for all connected bipolar instruments. This can result in an unintended energy level being delivered to the patient, causing tissue damage.

A message displays when two instruments of the same energy type are connected to the VIO dV (for example, two monopolar or two bipolar instruments). The message must be acknowledged by tapping **OK** before VIO dV settings can be adjusted from a Surgeon Console.

VIO dV Display Troubleshooting

If there is a connection problem with the VIO dV or an installed energy instrument, settings cannot be adjusted from the Surgeon Console. The touchpad arm pod **Energy** button shows information in flashing color messages.

Tap the arm pod **Energy** button to see detailed messages to resolve each issue.

Adjust VIO dV 2.0 Settings on the Surgeon Console Touchpad

In addition to adjustments on the generator control panel, energy settings (mode, effect, power limit, and auto stop) for instruments connected to the VIO dV can be adjusted on the Surgeon Console touchpad Instrument tab.

For instructions on da Vinci Xi monopolar and bipolar energy instruments, see the Instruments and Accessories User Manual.

Open the VIO dV Control Panel

The VIO dV control panel can be opened by either of two ways:

- On the arm pod, tap the **Energy** button.
- On the quick-settings bar, tap the **Energy** quick-setting button.

Note: On the quick-settings bar, the Energy quick-setting button text changes depending on the generators that are connected and whether or not an energy preset is applied.

Note: Settings cannot be changed from the Surgeon Console(s) or the VIO dV touchscreen while energy is being activated.

Note: When a setting is adjusted, the change is applied immediately. For best results, confirm setting levels before activating instruments.

Adjusting Energy Settings

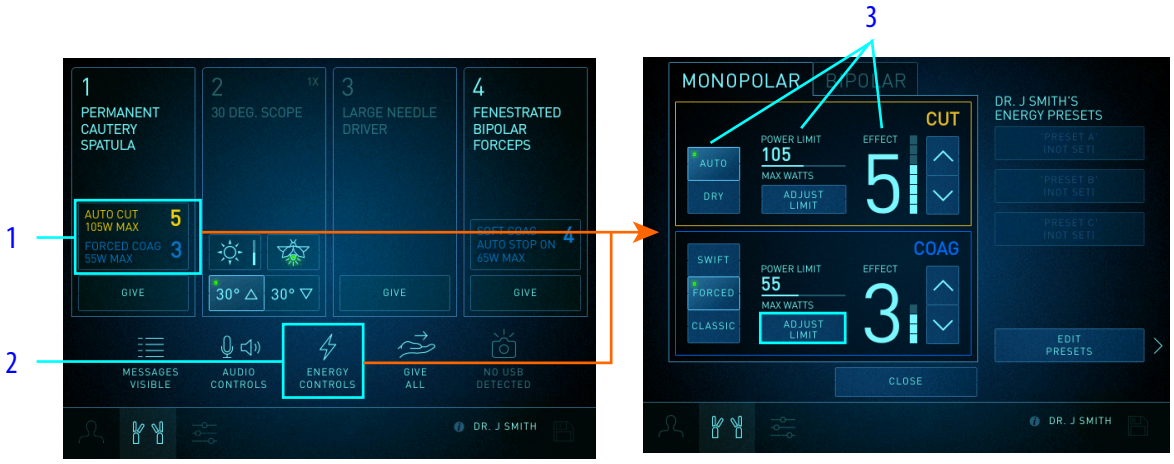
The VIO dV control panel has two tabs to switch between monopolar and bipolar settings without closing the panel.

1. On the VIO dV control panel, select the tab of the energy type (monopolar or bipolar) to be adjusted.
2. Adjust the settings:
   - For monopolar energy:
     - Tap the **Mode** button to select the mode.
     - Tap the **Effect** up/down arrows to adjust the effect.
     - Tap the **Adjust Limit** button to adjust the power limit settings.
   - For bipolar energy:
     - There is one mode, Soft Coag, which has an Auto Stop setting. Toggle the **Auto Stop** button to select whether or not to end activation automatically.
     - Tap the **Effect** up/down arrows to adjust the effect.
     - Tap the **Adjust Limit** button to adjust the power limit settings.

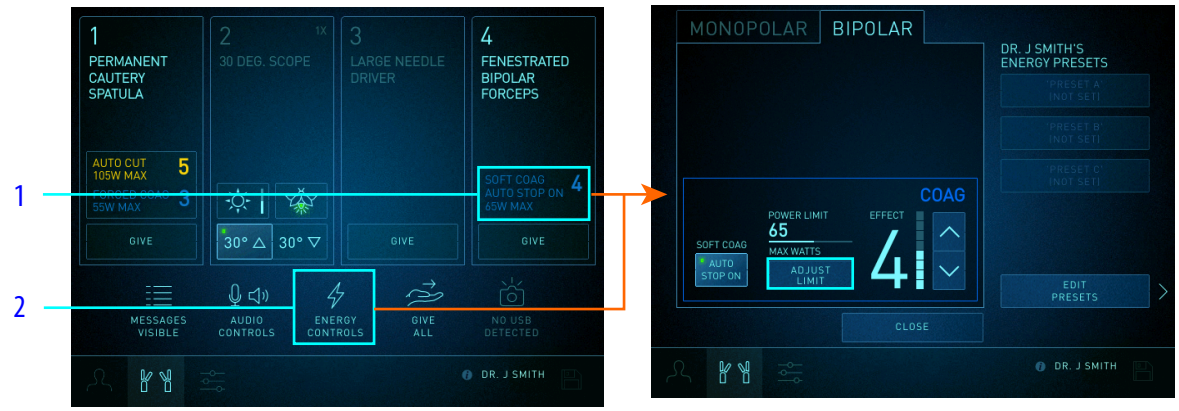
   For instructions on adjusting power limits, see Adjust Power Limit Settings on the Surgeon Console Touchpad on page 10-55.

   The new settings are applied to the VIO dV immediately.

3. Tap **Close** to hide the VIO dV control panel and return to the Instrument tab main screen.



1. Monopolar Energy button on arm pod
2. Energy quick-setting button
3. Monopolar VIO dV control panel - Mode/Power Limit/Effect settings



1. Bipolar Energy button on arm pod
2. Energy quick-setting button

VIO dV 2.0 Power Limit Settings Overview

In addition to adjusting mode and effect settings, users can set and adjust power limit settings from the Surgeon Console touchpad. Power limit settings enable users to adjust the limit on the maximum power delivered for fine-tuned control over tissue effect in each energy mode. Decreasing power limits reduces the potential range of power fluctuation.

For details on monopolar and bipolar modes and their associated power limit settings on the VIO dV 2.0, see the *ERBE VIO dV User Manual*.

Adjust Power Limit Settings on the Surgeon Console Touchpad

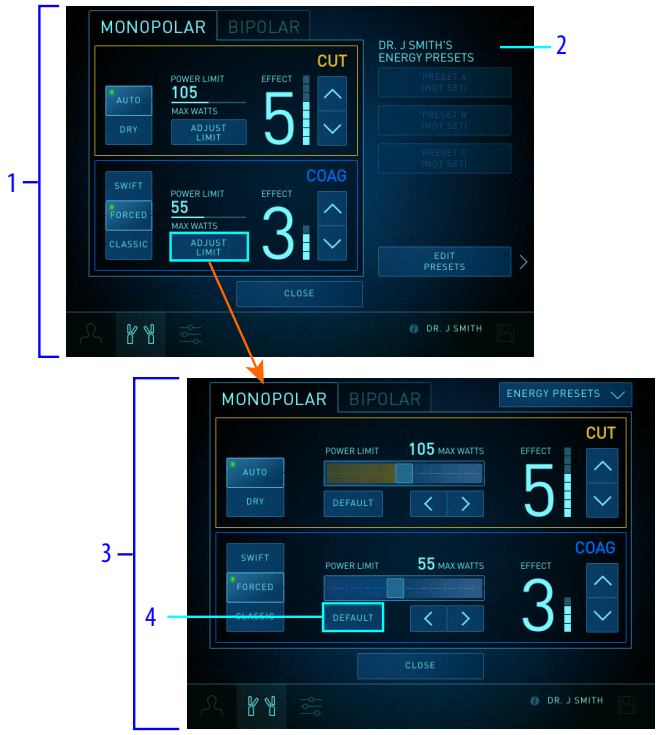
1. On the VIO dV control panel, select the mode for which the power limit is to be adjusted.
2. Tap **Adjust Limit**.

   The power limit settings and controls are displayed.

3. Adjust the power limit settings:
   - Drag the slider to make large adjustments. Moving the slider to the right increases the power limit.
   - Tap the left/right arrows to make incremental adjustments. Tapping the right arrow increases the power limit by increments of one.
   - Tap **Default** to reset the mode to its factory default power limit. If the mode is already set to the default power limit, the **Default** button is inactive.

     The new power limit settings are applied to the VIO dV immediately.
4. Tap **Close** to hide the VIO dV control panel and return to the Instrument tab main screen.

   After a power limit is set, it is displayed in the VIO dV control panel and in the instrument arm pod **Energy** button.



1. VIO dV control panel — with Preset controls
2. Preset controls
3. VIO dV control panel — with Power Limit controls
4. Default button

VIO dV 2.0 Energy Presets

If a VIO dV 2.0 is connected to the system, up to three preferred sets of energy settings (presets) can be saved to a user account. Presets can be given custom names, and can be assigned to be applied by default at login.

Each preset includes:

- effect and power limit settings associated with each mode,
- a default selected mode for monopolar COAG,
- a default selected mode for monopolar CUT, and
- a bipolar COAG Auto Stop setting.

Presets can be edited, saved, and applied to the VIO dV from the VIO dV control panel on the Surgeon Console touchpad. They can be applied to the VIO dV (but not edited or saved) on the Vision Cart touchscreen.

Edit Energy Presets on the Surgeon Console Touchpad

CAUTION: Adjusting energy settings on the touchpad always adjusts the energy settings on the VIO dV immediately.

Note: Users must be logged in to the system to edit energy presets. For instructions on logging in, see the applicable system user manual.

For details on adjusting settings on the touchpad, see Adjust VIO dV 2.0 Settings on the Surgeon Console Touchpad on page 10-54. For details on adjusting power limit settings, see Adjust Power Limit Settings on the Surgeon Console Touchpad on page 10-55.

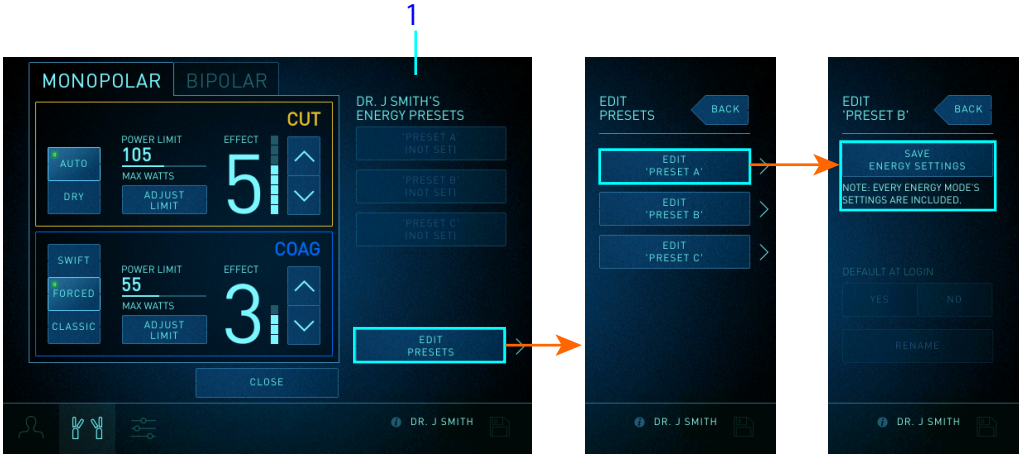
Editing Presets

1. On the arm pod, tap the **Energy** button, or, on the Quick-settings bar, tap the **Energy** Quick-setting button to open the VIO dV control panel.
2. On the VIO dV control panel, adjust the settings to the desired values.

   If power limits have been adjusted, tapping the **Energy Presets** button collapses the power limit controls and displays the preset controls.
3. Tap **Edit Presets**.
4. Tap the button of the preset to be edited.

5. Tap **Save Energy Settings**.

   The settings are saved to the preset immediately and the preset is selected. The selected preset is indicated in the VIO dV control panel preset list and in the Energy quick-setting button text.



1. Preset list



1. VIO dV control panel with Preset controls
2. Preset controls
3. VIO dV control panel with Power Limit controls
4. Energy Presets button, returns the user to the VIO dV control panel screen

6. Rename the preset if a new name is desired (optional).
   a. Tap **Rename**.
   b. In the Rename Presets screen, use the keypad to enter the new name for the preset.
   c. Tap **Save Name**.

      The new preset name is displayed in the VIO dV control panel.
7. To create or modify another preset, tap **Back** (optional).
8. Tap **Close** to hide the VIO dV control panel and return to the Instrument tab main screen.

Applying Presets to the VIO dV

Presets can be applied by the surgeon on the Surgeon Console touchpad or by the operating room staff on the Vision Cart touchscreen. When a preset is applied from either the touchpad or the touchscreen, it becomes the selected preset immediately.

Whenever a preset is applied, whether from the Surgeon Console touchpad or the Vision Cart touchscreen, the system closes any Apply Preset confirmation screens that are showing on the Surgeon Console touchpad(s).

Note: Users must be logged in to the system in order to apply energy presets. For instructions on logging in, see the applicable system user manual.

Note: Applying presets on the touchpad or on the touchscreen is not allowed during energy activation.

Note: Users can apply and edit presets only when the VIO dV is turned on.

Applying Energy Presets from the Surgeon Console

1. On the Instrument tab, open the VIO dV control panel.
2. In the list of presets, tap a preset button.
3. On the Apply Energy Preset confirmation screen, tap **Apply**.



The settings are applied to the generator immediately. A message indicating that the preset has been applied is displayed in the surgical view.

Using Default at Login Presets in Single and Dual Console Setups

In single console or dual console setup:

- Only one preset for an account can be applied by default at login.
- If the user has saved a preset to be applied by default at login:
  - If the VIO dV is already turned on when they log in, the Apply Energy Preset confirmation screen prompts them to apply the preset.
  - If the VIO dV is not turned on when they log in, the Apply Energy Preset confirmation screen prompts them to apply the preset after the VIO dV is turned on and detected by the system.

In dual console setup:

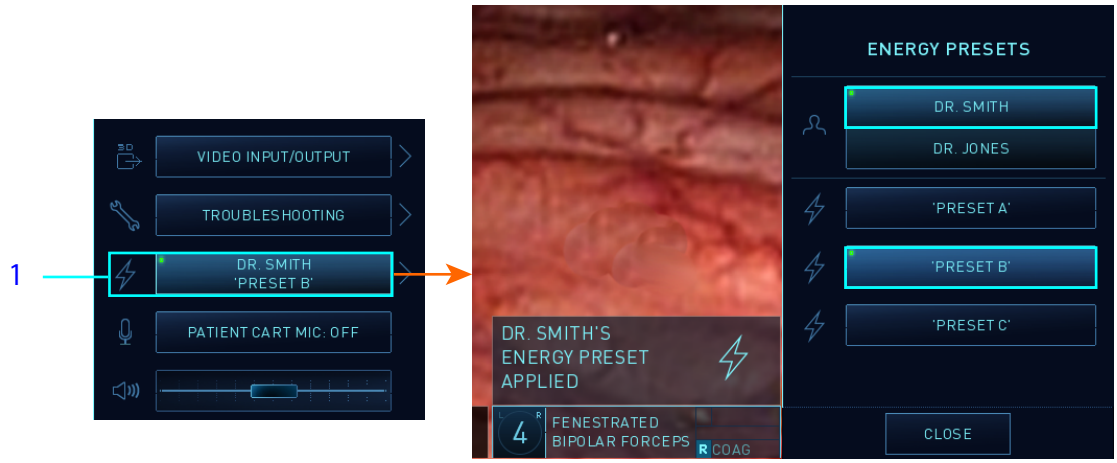
Even if users have a default at login preset, they are not automatically prompted by the Apply Energy Preset confirmation screen if a preset is currently applied on the other console.

Applying Energy Presets from the Vision Cart

1. On the Settings tab, tap the **Energy Presets** button to open the energy presets menu.
2. In the energy presets menu:
   - For single console setups, tap a preset button.
   - For dual console setups, tap a user's name to display that user's presets, then tap a preset button.

   The settings are applied to the generator immediately. A message indicating that the preset has been applied is displayed in the surgical view.
3. Tap **Close** to hide the energy presets menu.

Figure 10.30 Selecting presets on the touchscreen, dual console example



1. Energy Presets button

Dual Generator Use

Overview

The ERBE VIO dV (VIO dV) can be connected to up to two instruments of the same energy type, but with only one set of settings for both instruments. The ForceTriad can only be used with one instrument of a given energy type.

There are instances when users require multiple instruments of the same energy type to have different, independent energy settings.

The Dual Generator capability of the da Vinci system enables this behavior. To allow independent energy settings, one instrument is connected to the VIO dV and the other is connected to the ForceTriad.

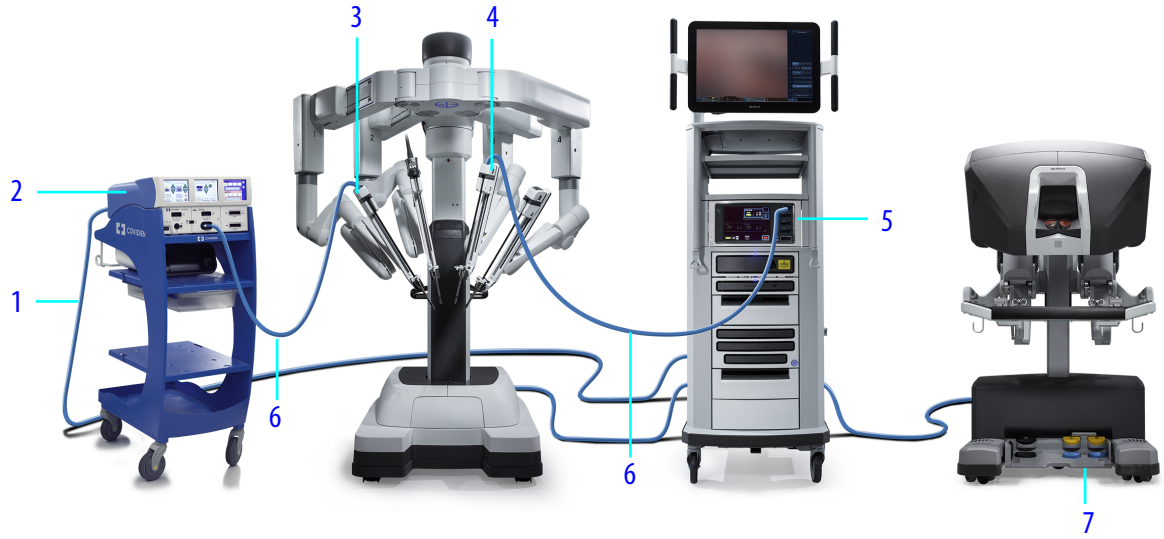
Note: When one monopolar instrument is connected to the VIO dV and the other monopolar instrument is connected to the ForceTriad, two patient neutral pads must be used.

Dual Generator Setup

As an example, in a Dual Generator configuration (Figure 10.31):

- An integrated VIO dV and a non-integrated ForceTriad are simultaneously connected to the system, each providing independent energy settings. The ForceTriad is connected to the Vision Cart core with an Energy Activation Cable.
- As they are both connected to the system, both generators can be activated by using the system's instrument activation pedals.
- One instrument is connected to the VIO dV and the other is connected to the ForceTriad.

Figure 10.31 Dual Generator configuration - two bipolar instruments example



1. Energy activation cable
2. ForceTriad non-integrated generator
3. Arm 1 bipolar instrument
4. Arm 3 bipolar instrument
5. VIO dV integrated generator
6. Bipolar cord
7. Instrument activation pedals (arms 1 and 3)

Connecting Generators

WARNING: Do not connect the generator PMED cable in any configuration other than instructed because doing so may cause patient injury.

CAUTION: Ensure that the energy is delivered from the intended generator to the intended instrument, to prevent patient or user injury.

1. Ensure that the VIO dV is powered on.

2. Connect the ForceTriad to the Vision Cart core with an Energy Activation Cable (PN 371716).

   For details, see the Instruments and Accessories User Manual.

3. Ensure that the ForceTriad is powered on.

Connecting Instruments

1. Connect the instrument(s) to the VIO dV.
2. Connect another instrument to the ForceTriad.

   The arm pod Energy button indicates when the ForceTriad is associated with an instrument. Tapping the button displays detailed information about configuring instrument connections.

Figure 10.32 VIO dV and ForceTriad connected - two bipolar instruments (example)



Adjusting Energy Settings

The Surgeon Console touchpad arm pod Energy buttons display the energy settings for each instrument connected to VIO dV.

- VIO dV settings can adjusted on the touchpad or the generator. For instructions on using the touchpad to adjust VIO dV 1.0 settings, see Adjust VIO dV 1.0 Settings on the Surgeon Console Touchpad on page 10-52. For VIO dV 2.0 settings on the touchpad, see Adjust VIO dV 2.0 Settings on the Surgeon Console Touchpad on page 10-54. For details on VIO dV settings, see the *ERBE VIO dV User Manual* that was supplied with the generator.
- The ForceTriad is a third-party generator, manufactured by ValleyLab and is compatible with the da Vinci system. The generator is designed to provide RF energy for monopolar and bipolar surgical and tissue-fusion applications. ForceTriad settings are adjusted directly on the ForceTriad generator. For details on adjusting ForceTriad settings, see the ForceTriad user manual and follow the adjustment guidelines in the Instruments and Accessories User Manual. Read all warnings, cautions and instructions provided with the ForceTriad before use. Additional information regarding instrument compatibility and use are provided in the Instrument and Accessories User Manual.

Troubleshooting

Swapping Instrument Connections from VIO dV to ForceTriad

There may be situations in which the initial configuration is not as intended. For example, an instrument may be connected to the VIO dV, and it is decided that it should be connected to the ForceTriad instead.

Although the system can detect when an instrument is properly connected to the VIO dV, this is not always the case for connections to the ForceTriad. If an instrument was previously connected to the VIO dV, and then the connection is switched to the ForceTriad, users must *manually* confirm ForceTriad as the intended generator before they can activate energy on that instrument. In this scenario, follow these steps:

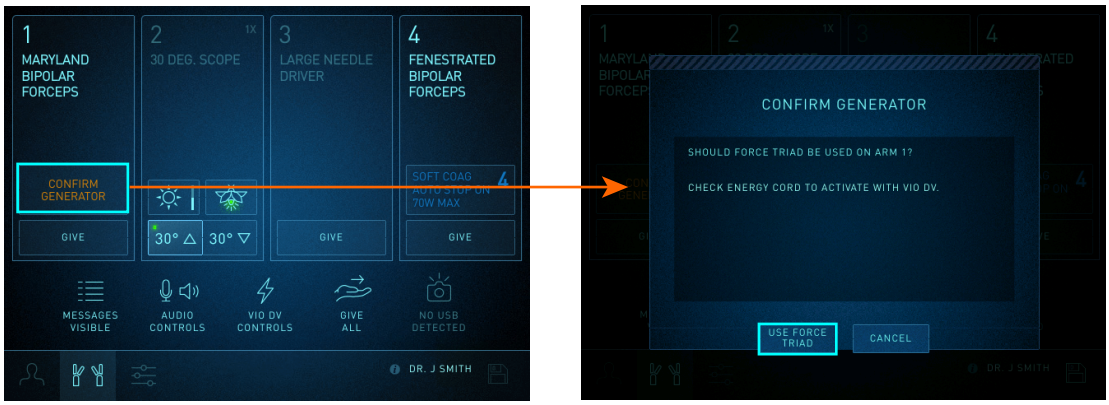
1. Disconnect the instrument from the VIO dV.
2. Connect the instrument to the ForceTriad.

   The touchpad arm pod Energy buttons display messages for each instrument:

   - For the instrument connected to the VIO dV, the energy settings are shown.
   - For the instrument that is now connected to the ForceTriad, the Confirm Generator message is displayed.
3. On the touchpad, tap **Confirm Generator**.
4. In the Confirm Generator screen, tap **Use Force Triad**.

   The arm pod Energy button for that instrument then indicates that the ForceTriad is connected.

Figure 10.33 After instrument swap, manually confirm connection to ForceTriad, example



Other Troubleshooting

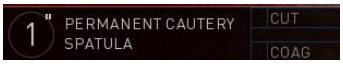
Table 10.2 Other dual generator troubleshooting scenarios

Issue	Solution
Cord accidentally unplugs from the VIO dV.	Plug the cord back in. Do not use the Confirm Generator screen.
Instrument loses communication with VIO dV due to electrical interference from another instrument being activated.	Wait for the interference to stop or untangle the energy cords.

Activation Status in the 3D Viewer

For installed energy instruments, the 3D viewer names the function associated with each pedal, and indicates activation status using highlighting colors. A gray instrument name indicates that an instrument is not associated with a hand control or not ready to activate.

Figure 10.34 Instrument not associated



A non-gray instrument name indicates that the instrument is associated with a hand control (that is, the instrument is in the surgeon's control). Pedal function names are highlighted the associated pedal color (yellow or blue) when activation is available. If the pedal function names are gray, or the associated pedal colors are desaturated, activation is not available.

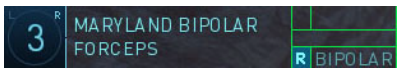
Figure 10.35 Instrument and activation control



1. Instrument control associated, arm 1
2. Activation unavailable
3. Activation available

When the surgeon's foot hovers (is close to or touching) a pedal pair that is ready to activate, a green highlight appears around pedal function names.

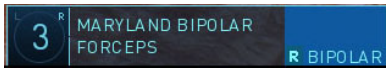
Figure 10.36 Surgeon's foot hovering over pedal



1. Foot over pedal (hover)

When the surgeon presses an activation pedal, the background changes to a solid associated pedal color. The surgeon is activating a bipolar instrument in the example below.

Figure 10.37 Surgeon activating energy



1. Activating

Pedal Activation Behavior

- The system can activate only one instrument at a time: pressing a second pedal on a single console makes the first stop firing, and neither can fire until both pedals are released.
- In dual console mode, if each surgeon controls an activation instrument, the first press of a pedal activates the associated instrument, and other presses are locked out until the first is ended. When the first press ends, a blocked press must be released and re-applied before it is effective.
- In dual console mode, if a surgeon is activating an instrument from one console, a surgeon at the other console can stop all energy by pushing the endoscope control pedal.
- The system beeps if the surgeon presses a pedal while the instrument cannot be activated.

Troubleshooting Activation Not Available

Activation is disabled in any of the following situations:

- The associated electrosurgical unit is not connected to the da Vinci system, or not powered on.
- If not using the VIO dV, two energy instruments of the same type are installed on the system, for example, two bipolar instruments.
- The foot pedals are disabled.

Activation is limited in the following situation(s):

- If the VIO dV and a validated non-integrated ESU are connected to the system and each powered on, the VIO dV supports use of the Vessel Sealer instrument only. In this scenario, the non-integrated ESU must be used for all monopolar and bipolar instrument functions.

10.7 Dual Console Surgery

This section describes the interface for working with two Surgeon Consoles.

Dual Console Connection and Startup

To operate in dual console mode (using a second Surgeon Console), connect the second console's fiber cable in one of the available rear Vision Cart fiber ports (see Connect System Cables on page 4-4 for more information) and connect the second console to a dedicated AC power outlet (see 4.1 Power Connections on page 4-1 for more information). The second Surgeon Console behaves just as the first with respect to power operations, as described in Chapter 5 Startup on page 5-1.

Comparison Between Consoles

This section describes the relationships between the touchpads, 3D viewers, and instrument controls when using two Surgeon Consoles.

Touchpads

Except for the availability of the **Give** and **Take** buttons, TilePro and digital zoom settings, the arm status area functions the same as usual, reporting arm status to both consoles. Each surgeon controls the touchpad settings that affect their console independently, and viewer globally. For example, when a surgeon applies digital zoom and TilePro in their viewer, the other surgeon's viewer also changes. Each surgeon can use the **Save** button to save the touchpad settings that affect their Surgeon Console independently. For more information on what is saved in single versus dual console use, see Save Button on page 10-10.

3D Viewers

The 3D viewers act independently except that they share the endoscopic video source and its associated video settings for view of the surgical field, and the overlays associated with shared elements like the endoscope (for example, the endoscope rotation indicator). Each 3D viewer presents the overlays for instruments that the surgeon controls in the usual places, and shows information about the instruments the other surgeon controls in the 3D viewer. Changes to view settings take place globally. For example, when one surgeon applies digital zoom or TilePro in their 3D viewer, the exact image shows the other surgeon's 3D viewer (and also on the Vision Cart touchscreen). See Second Console Instrument Status Area on page 10-50 for additional details on what surgeons can see about the instrument status of the other console.

Instrument Control

The instrument control settings, in particular motion scaling (also referred to as scaling), operate independently for each Surgeon Console. When instrument control is transferred, the surgeon assuming control matches grips in the usual way (see Match Grips on page 10-42). When a surgeon takes control, they use the control settings selected at their console.

Hand Control Assignments

The system gives both surgeons the ability to reassign instruments to different hand controls, and this feature continues to operate in dual console mode. The new instrument assignment applies on both consoles and persists when instruments are given or taken. For details, see Hand Controls on page 10-37.

Dual Console Instrument Control Settings

WARNING: Be careful to correctly recognize arm associations and instrument control for each console while using dual console mode, because inadvertent instrument motion could lead to tissue injury.

When the system detects two Surgeon Consoles in use, the **Give/Take** buttons on the touchpad Instrument screen appear.

Figure 10.38 Dual console Instrument screen example



Either surgeon can give or take control of a specific arm by tapping the respective **Give** or **Take** button. For each arm, the touchpad button shows "Give" on the Surgeon Console that has control of the arm and "Take" on the touchpad that does not have control.

Give or Take: This button says "Give" when the console has control and "Take" when the console does not have control. Either surgeon can give or take control of a specific arm by tapping its **Give** or **Take** button. When control is transferred by tapping **Give** or **Take**, the instrument goes out of following until the surgeon assuming control matches grips in the usual way.

Instruments that are not under control of any hand control may be freely "given" or "taken", but the action of taking an arm that is being controlled by one of the hand controls on the other console requires the user to respond to a confirmation dialog box.

Figure 10.39 Instrument control message



When control is transferred by tapping **Give** or **Take**, the associated instrument is decoupled from the hand control that is controlling it and it is locked in place until the receiving surgeon satisfies the normal conditions for taking control of an instrument (see Match Grips on page 10-42).

Note: During dual console surgery, the surgeon can give or take a locked arm using the Give/Take button on the touchpad. Arms remain locked when transferred until unlocked at the touchpad in the usual way.

When the actions of a surgeon at one Surgeon Console causes the hand control assignments to change at the other Surgeon Console, the surgeon whose hand control assignments are affected receives a notification (Figure 10.40) and is not allowed to move any instruments until acknowledging the notification (by pressing the arm swap pedal).

Figure 10.40 Arm swap message



Give All and Take All: Either surgeon can change control of all arms (with instruments installed) by tapping **Give All** or **Take All**. Activation control follows the arm. All instruments go out of surgeon control until the surgeon assuming control matches grips as usual (see Match Grips on page 10-42).

This feature affects all arms with instruments installed (not the endoscope). However, if Surgeon A controls no arms before the swap, Surgeon A can control only up to two arms when matching grips after the swap. He or she must first match grips on the two instruments that were in control with the other surgeon before the swap; the third arm will remain out of surgeon control as it was. To take control of the third instrument, he or she must press the swap pedal (left kick-plate).

When instruments are reassigned, the system takes the instruments out of surgeon control, notifies and prompts the surgeon with an icon and associated message: "Press 'Arm Swap' pedal to activate arm".

Endoscope Control

Either surgeon can take control of the endoscope by pressing the endoscope pedal as usual; the first one to do so has endoscope control and, as usual, all arms go out of surgeon control while the endoscope arm is under control, and energy instruments on the other Surgeon Console will stop firing.

Video Control

While in dual console mode, video settings are shared between the two Surgeon Consoles as well as the touchscreen monitor on the Vision Cart. Video settings cannot be saved while in dual console mode.

TilePro Control

When in dual console mode, the console must be assigned all active instruments in order to make TilePro size changes. If a console that is not assigned all active instruments attempts to make a TilePro size change, a system message appears.

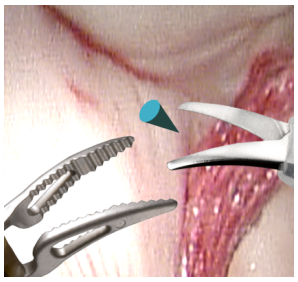
Virtual Pointer (Dual Console Teaching Aid)



The virtual pointer is a software tool designed as an instructional aid, typically for use during dual console surgery. The pointer is a three-dimensional (3D) graphical object, light blue and conical in shape, which appears overlaid on the live video image when activated. It enables a surgeon to point and refer to specific anatomical features on the live video image intraoperatively. The surgeon can activate and control one pointer with each hand control that is not associated with an arm.

Typical Usage Scenario

Figure 10.41 Typical Dual Console Usage for Proctoring



Dual console, 1 pointer

One Pointer Controlled at Each Console

In this scenario, one surgeon would have control of two arms associated with the same hand control, and the other surgeon would have control of the other arm, so that one hand control on each console is not associated with an arm.

Virtual Pointer

Close and hold the grips of a hand control that is not associated with an arm to activate a virtual pointer, then move the hand control as usual to move the pointer. Clutching is available as usual to reclaim space when using a virtual pointer.

Use Characteristics

The virtual pointer has the following use characteristics:

- By closing the grips of an unassociated hand control, the surgeon activates a virtual pointer. Its initial position is centered and slightly offset right or left to correspond with the hand control used. At a console having neither hand control associated with an arm, the surgeon can activate two pointers simultaneously by closing the grips of both hand controls.
- While a pointer is activated, the hand controlling it has free movement. The surgeon manipulates the position and orientation of the pointer using the hand control while holding the grips closed. The pointer's tip corresponds to the fingertips closing the grips.
  - As part of the 3D effect, the pointer is shaded as if the light comes from where the surgeon is looking, it gets smaller as the surgeon moves it away, and larger as the surgeon moves it back. It has vanishing points left and right, near and far, past which the surgeon can bring it back on screen if the surgeon does not release the grips. If the grips are released while past a vanishing point, the pointer reappears in its default position when the surgeon closes the grips again.
- If telestration marks are on screen, they are erased when the pointer is activated, and telestration is not available while the pointer is activated.
- The surgeon can clutch the hand control while the pointer is active to reposition the hand control without moving the pointer.
- The pointer disappears when the surgeon releases the grips and while a surgeon presses the endoscope pedal (during endoscope control mode). The hand control that moved the pointer is not free to move when the pointer is not present, except by clutching the hand control as usual.
- On subsequent activations, the pointer appears in its last position, unless that position is such that it would be off screen. In that case, it reappears in its initial position.

End of Section

Chapter 11 Shut Down and Store the System

Contents

11.1 Prepare to Shut Down the System 11-1
11.2 Remove the Patient Cart Drapes 11-1
11.3 Stow the Patient Cart 11-2
11.4 Stow the Vision Cart 11-2
11.5 Shut Down the System 11-2
11.6 Store the System 11-3

11.1 Prepare to Shut Down the System

1. Remove the instruments and endoscope from the Patient Cart. See 9.9 Instrument Removal on page 9-45, and Remove and Change Endoscope on page 7-17.
2. Disconnect (undock) the cannulae from the arms. Hold the cannula and press the cannula mount lever to release the cannula.

   WARNING: Ensure the Patient Cart arms are undocked (detached) from the cannulas before moving the arms away from the patient. Failing to do so may result in injury to the patient.

3. Use the port clutch buttons to move the arms away from the patient. Find port clutch instructions in 9.3 Manually Adjusting the Patient Cart Arms on page 9-25.
4. Move the Patient Cart away from the OR table.
5. Remove all sterile system accessories for cleaning.

   For instructions on cleaning system components, see 12.1 Clean the System on page 12-1.

   Note: Discard single use product per institution biohazard protocol.

11.2 Remove the Patient Cart Drapes

1. Start at the front of the arm and release the instrument sterile adapter.
2. Release the cannula sterile adapter.
3. Release the arm clip at the back of the arm.
4. Release the metal discs at the back of the arm.
5. From the back of the arm, invert the drape towards the front of the arm.
6. Dispose of the drape in a biohazard bin.
7. With clean gloves (or with the assistance from a second person with clean gloves), move the undraped arm out of the way.
8. Release the metal disc at the top of the column drape.
9. Discard the drapes per institution biohazard protocol.

11.3 Stow the Patient Cart

1. Compact the arms.
2. Stow the arms, using the **Stow** button on the Patient Cart touchscreen.

   For more information see 6.5 Sterile Stow the Draped Patient Cart (Optional) on page 6-18 and 9.13 Stow the Patient Cart on page 9-50.

11.4 Stow the Vision Cart

See 3.4 Position Vision Cart on page 3-8.

11.5 Shut Down the System

Follow these steps to shut down the system:

1. Press any system **Power** button. The system will begin the ten second shutdown process and displays the following message:

   `Preparing to shutdown`

   `Shutting Down in X Seconds, Press Power Button to Cancel`

   Note: If the system is not restarted within ten minutes after power down, the system will view any restart as a new procedure and instrument uses will be decremented accordingly.

   Note: Cooling fans on the Patient Cart and the Core (Vision Cart) run continually when either is connected to AC power. This behavior is normal.

   Note: Do not use the Patient Cart Emergency Power Off button to turn off the cooling fans. This action prevents the Patient Cart battery from charging.

2. It is now safe to disconnect all blue system cables, although we recommend that they remain connected to minimize exposure of the connectors to contaminants.

   Note: If possible, the blue system cables should be left connected to minimize exposure to contaminants.

Detaching the Blue System Cables

Should there be a need to detach the blue system cables, follow these steps:

1. Remove non-system connections as necessary (such as auxiliary video and audio cables, electrosurgical units, insufflators, etc.).
2. If the Patient Cart has a system fiber strain relief, remove the strain relief ball from the strain relief socket.
3. Disconnect the blue system cables from the Surgeon Console and Patient Cart by twisting counter-clockwise and pulling back on the metal collar.

   Note: Immediately attach the protective cap to protect the connectors from contamination and physical damage.

4. Store the blue system cables on the side of the Vision Cart.

11.6 Store the System

Follow these steps to store the da Vinci system:

1. Ensure the storage room meets the following specifications:
   - Room temperature between -20 to 60 °C (-4 to 140 °F).
   - Relative humidity between 5 to 90% non-condensing.
2. Place the Patient Cart near a wall outlet and connect it to AC power.

Note: To maintain battery backup charge, it is important to keep the Patient Cart plugged into AC power while stored. Failure to do so will drain the batteries. The Surgeon Console and Vision Cart do not need to be plugged into AC power while stored.

Note: The Patient Cart cooling fan runs continually when it is connected to AC power. Do not use the Patient Cart Emergency Power Off button to turn off the cooling fan. This action prevents the Patient Cart battery from charging.

End of Section

Chapter 12 System Maintenance

Contents

12.1 Clean the System 12-1
12.2 Clean the Touchscreen Display 12-1
12.3 Preventive Maintenance 12-1

12.1 Clean the System

Use a soft, lint-free cloth and a surface disinfectant product (or a pre-moistened disinfectant wipe product) to wipe the exterior surfaces of the system components and cabling at the frequency required by individual hospital policy. Examples of these products include Envirocide®, CaviCide® and 70% isopropyl alcohol or the corresponding pre-moistened disinfectant wipe product. Allow components to dry before use. If any liquids—including bodily fluids—get inside the system, contact Intuitive Surgical Customer Service (1.800.876.1310 in the U.S.).

WARNING: Properly clean the system to prevent patient infection.

WARNING: Equipment on the Surgeon Console, Patient Cart, and Vision Cart is not designed for exposure to liquids. Do not spray liquids while disinfecting the Surgeon Console, Patient Cart, and Vision Cart. Care should be taken to ensure liquids do not contact electronic equipment on the system components.

Note: The blue system cables and their receptacles contain fiber-optics. Only when requested by Intuitive personnel, clean both cable and receptacles by blowing the fiber ends with a generic dry and oil-free canned air duster.

Note: Pay particular attention to areas where the Surgeon Console operator comes into contact with the system (such as the hand controls, the 3D viewer, and the armrest).

12.2 Clean the Touchscreen Display

Follow hospital protocol for the handling of blood and body fluids. Clean the display with a diluted mixture of mild detergent and water. Use a soft towel or swab. Use of certain cleaning agents may cause degradation to the labels and plastic components of the product. Consult cleanser manufacturer to see if their agent is compatible with it. Do not allow liquid to enter the display.

12.3 Preventive Maintenance

Preventive maintenance is required and must be performed by an authorized Intuitive Service representative. There are no user-serviceable parts on the main system components, with the exception of system accessories.

For Customer Service

If the system requires maintenance or service, call Intuitive Customer Service. In the U.S., call 1.800.876.1310, where phones are staffed 24 hours a day, seven days a week.

End of Section

Appendix A OnSite for da Vinci Xi System

Contents

A.1 General Information A-1
A.2 Introduction A-2
A.3 OnSite System Requirements and Connections A-2
A.4 Automatic Status and System Log Retrieval A-5
A.5 OnSite Servicing and Diagnostics A-6
A.6 Wireless Connectivity Option A-7
A.7 IT Requirements A-13
A.8 Electromagnetic Compatibility A-15
A.9 Wireless Bridge Data A-20
A.10 End-of-Service Deprovisioning A-25

A.1 General Information

General Precautions, Warnings, and Contraindications

WARNING: Be sure to read and understand all information, particularly the caution and warning information, found in the applicable user manuals before using these products. Failure to properly follow all instructions, including those supplied with accessory devices such as electrosurgical units, may lead to injury and result in improper functioning of the device.

WARNING: Be aware of hazards related to wireless interference to prevent erroneous system behavior or potential patient harm. For information to restart the system, see B.7 Restart the System on page B-7.

WARNING: Be careful to use the system electrical components safely and effectively to prevent electrical shock.

WARNING: Leakage current from interconnected electrical equipment may exceed safe levels. To maintain the safety of patients and users, interconnect only with devices in compliance with IEC 60601-1. It is the user's responsibility to ensure that any interconnected equipment not supplied by Intuitive maintains compliance with IEC 60601-1. If current leaks, patient or user harm can result.

WARNING: Ensure proper and safe use of remote access to prevent any potential data corruption that could impact system behavior.

Note: Ethernet networks (both wired and wireless) are subject to losses of connectivity that could disrupt use of OnSite or make data unreliable when it is received at a remote location. Such disruptions, if they occur, have no effect on the performance or functionality of the da Vinci system.

Device Description

OnSite is an accessory indicated for use by trained Intuitive Technical Support to: (1) obtain system information for the purpose of diagnosing faults, (2) remotely enable or disable features including configuration updates through either a wired or wireless Ethernet connection between the da Vinci system and the hospital's Internet Protocol (IP) infrastructure.

Network Connections

OnSite requires a wired RJ45 Ethernet 10bT/100bT/1000bT and/or optional wireless 802.11b/g/n network connection with Internet access where the da Vinci system (referred to in this document as the system) will be used.

Transmitter Module Label

When the optional wireless bridge is installed, the following Federal Communications Commission (FCC) identification label is affixed to the Vision Cart.

Figure A.1 Transmitter Module Label



Contains Transmitter Module FCC ID: SWX-M2L

A.2 Introduction

OnSite provides connectivity that enables Intuitive Technical Support to remotely service the system operatively. It enables the following capabilities:

- Automated log retrieval, where the system uploads logs to an Intuitive server when idle
- Remote system status monitoring
- Remote diagnostics and servicing
- Remote configuration changes
- Enable or disable device features
- Da Vinci Update Tool (DUT), formerly Remote Software Update (RSU).

The monitoring capability may enable a faster response time from Intuitive Technical Support for problem resolution, real-time diagnosis, and increased diagnostic accuracy.

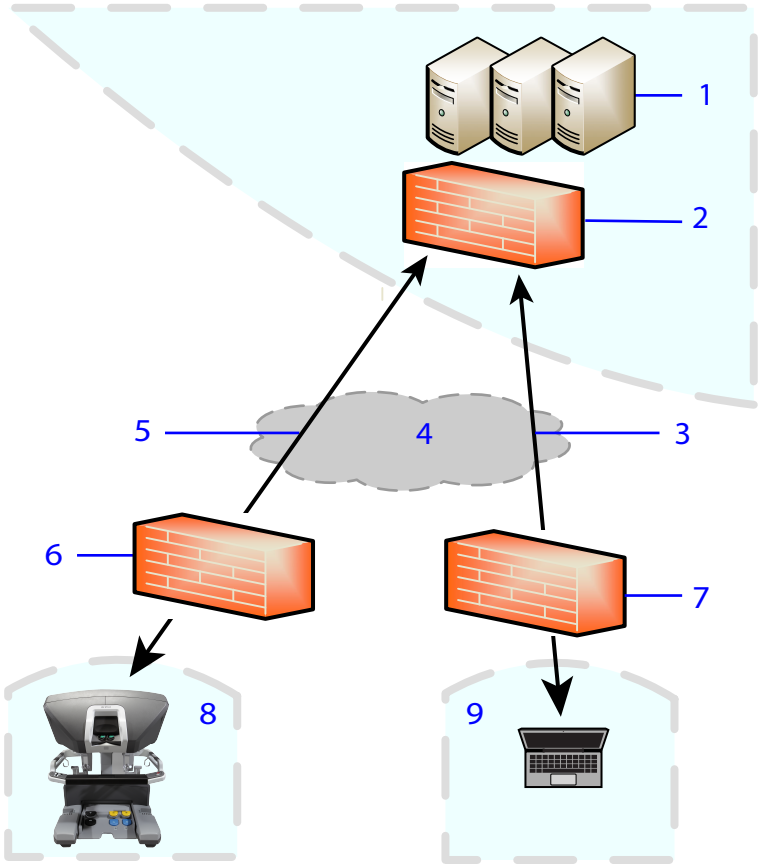
To implement remote service capabilities, the system must have access to the Internet. OnSite is designed to accomplish this using existing hospital networks.

A.3 OnSite System Requirements and Connections

The remote servicing features of OnSite are designed to be highly secure and to function transparently. The system communicates with an Intuitive OnSite server via outgoing network connections to enable Intuitive Technical Support to remotely monitor and service the system while in use.

In summary, OnSite consists of three major components, the system with installed networking components, the Intuitive server, and the remote user (Intuitive Technical Support). The block diagram below illustrates the OnSite networking infrastructure.

Figure A.2 OnSite Networking Infrastructure



1. Servers
2. Intuitive server firewall
3. TCP 443 (TLS 1.2 outbound)
4. Internet
5. TCP 443 (TLS 1.2 outbound)
6. Hospital firewall
7. Intuitive firewall
8. Hospital
9. Intuitive Technical Support

Note: Network connections are not required for the surgical usage of the system. However, to take advantage of the full potential of OnSite, it is recommended for the system to remain connected to the Internet.

Wired Network Connection

Intuitive Technical Support install a network security device inside the system, along with necessary cables and panels to enable a wired network connection for OnSite.

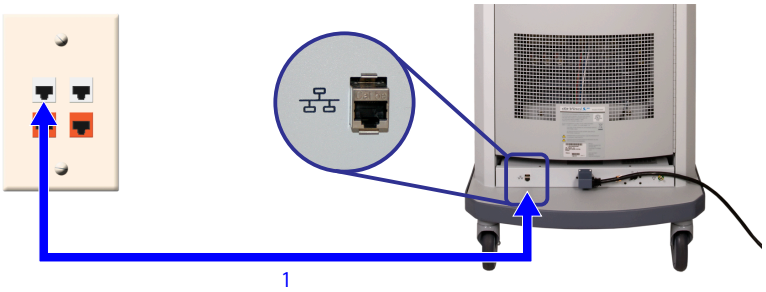
Figure A.3 Network Security Device



To establish a wired connection:

Connect the da Vinci Ethernet connection to the hospital network (wall plate) using a CAT5e network cable.

Figure A.4 Network Cable Connections (da Vinci system)



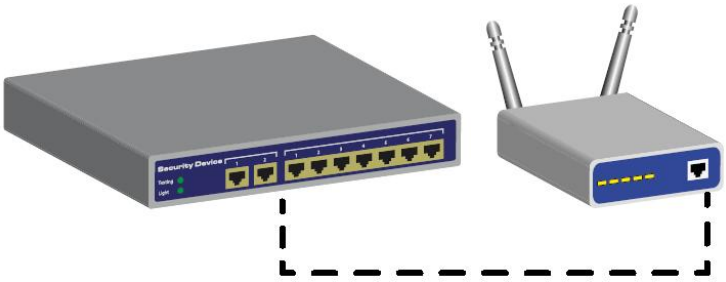
1. Ethernet to hospital network (wall) Connects system to network

Optional Wireless Connection

There is an optional wireless connection[1] available using the Network Security device and a Wireless Bridge. See A.6 Wireless Connectivity Option on page A-7 for details on wireless connectivity.

1. Not all technologies may have regulatory approval or may be commercially available in all geographies. For availability in your country, check with your local representative.

Figure A.5 Network Security Device with Wireless Bridge



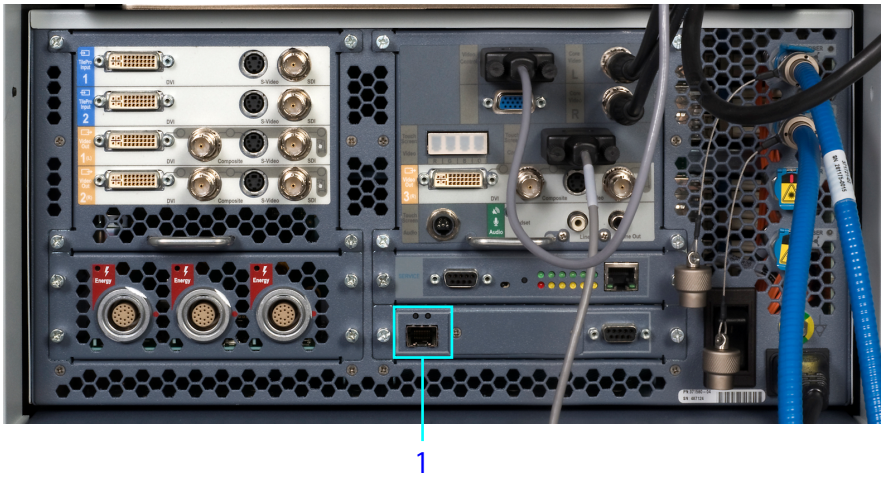
Note: External network connections are not required for the essential clinical performance of the system.

Disable All Network Connectivity

This section describes the procedures necessary to disable all network connectivity for the system.

If there is a need to disable all network connectivity for the system, open the back of the Vision Cart and disconnect the RJ-45 (Ethernet) connector at bottom center of the Core, indicated below.

Figure A.6 RJ-45 Connector – Core



1. Disconnect to disable networking

Note: This action disables all network connectivity for the system, but it does not power off the wired or wireless networking equipment.

Note: To re-establish network connectivity, re-connect the indicated RJ-45 connector on the back of the Core.

A.4 Automatic Status and System Log Retrieval

OnSite provides real-time system status monitoring and post-procedure upload of system logs, for the support team to service the system. When Intuitive Technical Support enables the OnSite functionality, the system can:

1. Connect to an Intuitive server for these purposes:
   - Provide status updates indicating that the system is functioning, at 10-second intervals
   - Upload all system logs to the Intuitive server after each procedure
2. Connect to field service diagnostic applications running on a remote laptop.

A.5 OnSite Servicing and Diagnostics

OnSite enables the technician to troubleshoot remotely, using a proprietary service application. Through a remote OnSite connection, the technician can interact with the system in either Normal mode or Maintenance mode.

Normal Mode

In Normal mode, OnSite can only enable remote monitoring of system status. This allows Intuitive Technical Support to passively monitor information transmitted, with no ability to perform any activity that impacts the safety or performance of the surgical system.

In Normal mode, Intuitive Technical Support can:

- Read system logs
- Check the configuration of the system

Normal Mode – OnSite Mode Indications

While in Normal mode, the system indicates the status of the network connection on the Vision Cart touchscreen.

Figure A.7 OnSite Connection Status Indicators



Da Vinci network offline



Da Vinci network online



OnSite session in progress

Note: Once the Ethernet cable is connected, it can take up to two minutes to detect the da Vinci network and update the status on the touchscreen.

Standby Mode

Standby mode is state where the system is receiving power and minimal or low-level services are running; such as battery charging and basic OnSite network services.

Maintenance Mode

Maintenance mode is a state where Intuitive Technical Support can perform diagnostic and troubleshooting operations.

When in Maintenance mode, the system ***is not for human use.***

Put the System into Maintenance Mode

To put the system into standby mode, make sure the following conditions are met:

- All system components are connected to AC power
- Surgeon Console and Patient Cart system cables are connected to the Core

Someone physically present at the system is required to place the system in Standby Mode before the system can be placed in Maintenance mode.

During an OnSite session in Maintenance mode, the system displays:

`Maintenance Mode – Not for Human Use`

`Remote Session in Progress`

System Service and Diagnostics

An example of an OnSite servicing capability that requires assistance and feedback from hospital personnel is when remotely testing the control and motion of the manipulators and robotic arms.

The following list shows several diagnostic capabilities that an Intuitive Technical Support can execute remotely when connected in Maintenance mode via OnSite:

- Test joints, internal sensors, and positioning potentiometers
- Check condition of system switches and buttons
- Check synchronization of system configuration
- Modify system configurations
- Perform arm motion and other diagnostic tests
- Verify surgical instrument functionality
- Check usage hour meter data

A.6 Wireless Connectivity Option

Wireless Overview

A wireless bridge is installed on the system to enable the Wireless Connectivity Option. A hospital-supplied Wireless Access Point with Internet access is required to establish wireless connectivity.

Wireless Network Requirements

Intuitive Technical Support will install and configure the Wireless Connectivity Option. Below are the details of a suitable wireless network to support da Vinci wireless applications.

WiFi Specifications

- The Wireless Connectivity Option uses the IEEE 802.11b/g/n wireless standard used on the 2.4 GHz Industrial, Scientific, and Medical (ISM) band.
- The Wireless Bridge operates as a client to the hospital-supplied Wireless Access Point, transmitting data back and forth between the hospital network and the system.
- The Wireless Access Point must be located within 75 feet of the system.
- The Wireless Bridge supports 20 MHz channels by default.
- The wireless modulation used is:
  - DSSS (Direct Sequence Spread Spectrum) for 802.11.b.
  - OFDM (Orthogonal Frequency Division Multiplexing) for 802.11g and 802.11n.
- The max output power (EIRP) is 20 dBm.

WiFi Security

- Wireless Network Infrastructure
  - Intuitive has tested the Wireless Connectivity Option in WPA2 pre-shared key mode with AES encryption, and recommends that the Wireless Connectivity Option is integrated into the hospital network using this security configuration.
- OnSite Software Application
  - The OnSite Software Application uses a Transport Layer Security (TLS) v.1.2 or newer session based on unique certificates on the system and the OnSite server.
  - Data being transmitted from the system to the server is 256-bit encrypted.

WiFi Quality of Service

- Wireless Bridge
  - Maximum latency of 50 ms between the Wireless Bridge and the hospital-supplied Wireless Access Point
  - Wireless Channel that has 20% or less utilization
- Overall Network
  - Maximum end-to-end packet loss of less than 10%
  - Network latency should not exceed 300 ms

Once successfully installed and configured, Intuitive Technical Support will conduct an end-to-end functional test to ensure that OnSite functions as expected.

Note: After installation, Intuitive recommends that the hospital routinely monitor to ensure that the Wireless Channel does not exceed 20% utilization, and the latency between the Wireless Access Point and the Wireless Bridge does not exceed 50 ms. If either exceeds the specified levels, contact Intuitive Technical Support.

It is possible that the wireless network conditions might degrade over time or experience periods of disturbance; da Vinci applications have been designed to be robust to typical network disturbances, but if an issue persists, contact Technical Support for assistance to resolve the issue.

Note: Intuitive recommends that an active wired port be available when using the Wireless Connectivity Option. The configuration for the Wireless Connectivity Option provides a wired backup that the router automatically activates when plugged in. Refer to A.7 IT Requirements on page A-13 for details on how to establish a wired connection.

Note: It is important to note that if the hospital wireless network is modified or updated after the Wireless Connectivity Option is installed, its suitability to support the wireless applications should be re-assessed. In particular, contact Technical Support if any of the following changes are planned or have occurred:

- If the Wireless Access Point or system is moved from the location where it resided during installation
- If the Wireless Access Point is replaced with a new make or model

Wireless Coexistence

Wireless coexistence with other devices that transmit in the 2.4 GHz range is a concern since it can impact the reliability of the wireless link. This section summarizes testing conducted by Intuitive in an environment with other wireless devices representative of a typical operating room to demonstrate that the Wireless Connectivity Option functioned as expected. The test setup represented the worst case system setup, and the position of the common wireless devices was defined to ensure that they were located near the Wireless Connectivity Option or the Wireless Access Point, and the path between the transmitter and receiver for most paired devices passed through the signal path between the Wireless Connectivity Option and the Wireless Access Point.

Testing was conducted with a wireless network that satisfied the characteristics identified in Wireless Overview on page A-7.

The Wireless Access Point used during the testing was the Ubiquiti NanoStation Series. The Ubiquiti NanoStation Series was configured to operate as a typical Access Point, and therefore Wireless Access Points from other vendors should result in the same performance. Note that the characteristics for a suitable wireless network are summarized in Wireless Overview on page A-7, and Intuitive Technical Support will confirm the wireless network is functioning as expected after installation. A complete list of the common wireless devices used during the testing (along with details on position, orientation, and type of data transmission) is summarized in the table in Common Wireless Devices Tested on page A-10.

Note: If different types of wireless devices will be used in the operating room, or if the wireless devices are used in different locations than what is described below, then Intuitive recommends that performance is tested with the wireless devices active, before use. If issues occur while using the Wireless Connectivity Option in the presence of other wireless devices in the operating room, contact Intuitive Technical Support.

Note: The wireless coexistence testing conducted by Intuitive does not cover use in the presence of MRI or diathermy machines. The Wireless Connectivity Option should not be used in the vicinity of these devices.

Common Wireless Devices Tested

Common Wireless Devices	Disturbance Details	Test Setup
Wireless Monitor	IOGear Model: GUW2015V (receiver) GUWA200 (transmitter) 3.1 – 4.8 GHz Certified wireless USB RF Modulation: QPSK/DCM; Data Rate: 480 Mbps	Transmitter attached to a desktop PC located 50 inches away from the wireless bridge, and receiver attached to a monitor on the boom. Desktop PC oriented so the transmitter has clear line of sight to the receiver attached to the monitor, and PC configured so it is streaming 720p video.
Smart Phone and Bluetooth Speaker	iPhone 5 (4G and 2.4 GHz wireless)	One iPhone 5 sitting on the armrest of the Surgeon Console paired with a Bluetooth speaker streaming music. The iPhone should also be connected to the WAP.
Laptops with wireless	802.11b; 2.4 GHz	Two Dell laptops connected to the WAP on the same channel as the Wireless Bridge, with one laptop streaming a video over the network from YouTube. The laptops are approximately 90 inches away from the Wireless Bridge.
Laptop and Bluetooth wireless keyboard and mouse	Microsoft Wireless Desktop – Keyboard and Mouse 7000: 2.4 GHz range (2,400 – 2,483.5 MHz) FCC IDs C3K1345, C3K1142 and C3K1123	Wireless keyboard and mouse interfaced with one of the desktop computers, and physically sitting on the Surgeon Console.
Bluetooth keyboard	Microsoft Bluetooth Mobile Keyboard 6000 2.4 GHz range (2,400 – 2,483.5 MHz) FCC ID C3K1390	Keyboard interfaced with one of the desktop computers, and physically sitting on the Surgeon Side Console.
Microwave Oven	MagicChef Model MCD11E3W Output Frequency 2450 MHz; FCC ID C5F7NF1AMO100N	In the coexistence test, the microwave is placed in the signal path between the Wireless Bridge and the WAP, 20 feet away from the WAP. The Wireless Bridge and WAP are operating at maximum distance in this test. In the isolated test with the microwave, it is placed in the signal path between the Wireless Bridge and the WAP at a distance where no impact is observed, and then the Wireless Bridge is moved closer until the connection is dropped. Wired connection is then established. In both test cases, the microwave is oriented such that the seams in the door are pointing toward the Wireless Bridge and the Wireless Access Point.

Common Wireless Devices	Disturbance Details	Test Setup
Electrosur-gical Unit	Covidien (formerly ValleyLab) Force FX (GSTElectro02) 390 kHz	Located in the Vision Cart, with the energy cable wrapped around the instrument carriage.
RFID HF (13.56MHz) Reader	Reader: Socket Antimocrobial hand-held SoMo 655Rx RFID Reader SoMo 655 CF RFID Reader Card ^E, 13.56 MHz	RFID was tested by placing the Reader on the side of the USM closest to the RFID reader. A spectrum analyzer is used to verify constant communication at the 13.56 MHz frequency range.
RFID (2.4 GHz) Reader and Tags	Reader: TagMaster LR-3 Pro (PN 154400) 1.435 – 2.465 GHz range ID-Tags: TagMaster S1255 MarkTag and S1240 MarkTag MeM 2.435 – 2.465 GHz range	RFID was tested by placing the Reader and the ID-tags on each side of the signal path, between the Wireless Bridge and the Wireless Access Point. In the coexistence test case, the tags and reader were 30 inches apart. During the isolated test with the RFID setup, they were 36 inches apart in the worst case configuration.
XI Skills Simulator Test Unit ACCS **PN: 373065-01**	TrendNet 802.11b; 2.4 GHz USB adapter	Simulator test unit connect to WAP and main-taining a consistent connection to OnSite.

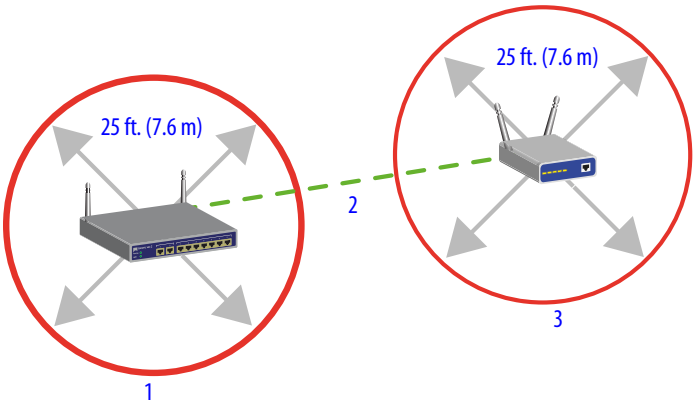
Devices Known to Interfere

Microwave Oven

Testing conducted by Intuitive determined that microwave ovens can disrupt wireless communication in certain configurations:

- Intuitive recommends keeping microwave ovens (1000 Watt) at least 25 feet (7.6 m) from the Wireless Bridge or Wireless Access Point, especially if it is located in the signal path. Higher wattage microwaves should be placed at larger distances.
- If a microwave oven causes interference, use the wired backup to correct the problem.

Placement boundaries for microwave ovens



1. Wireless bridge
2. Signal path
3. Wireless access point

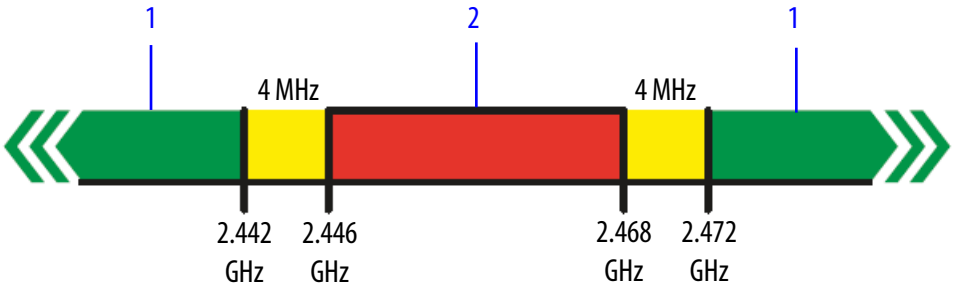
RFID Reader (2.4 GHz)

Testing conducted by Intuitive determined that RFID readers operating in frequency hopping mode, or configured to operate at a frequency that overlaps the channel being used by the wireless bridge and the WAP, will cause minor network disturbances.

To eliminate the interference, Intuitive recommends the following:

- The RFID reader not operate in frequency hopping mode if it is being used in the same room as the Wireless Connectivity Option.
- A separation of a least 4 MHz exists between the frequency range of the channel being used by the wireless bridge/WAP and the operating frequency of the RFID reader. For example, a wireless bridge/WAP operating on channel 10 spans 2.446 – 2.468 GHz; therefore, to avoid disturbances from the RFID reader, its operating frequency should be less than or equal to 2.442 GHz or greater than or equal to 2.472 GHz.

Figure A.8 Valid RFID Reader Operating Frequencies



1. Valid RFID reader operating frequencies
2. Wireless Connectivity option frequency range

Note that RFID devices can operate outside the frequency range of what was included in the testing summarized above. If RFID devices operating outside the range shown above exist in the operating room, Intuitive recommends that performance is tested with the RFID device active, before use.

Wireless Connectivity Problems

If connectivity problems occur while using the Wireless Connectivity Option, Intuitive recommends doing the following:

- Determine if a device transmitting in the 2.4 GHz range is in the room, and if so, disable the device to see if it resolves the connectivity problems.
- If several disconnections occur, and the above step did not resolve the issue, or if the interfering device must be used, then establish a wired network connection with the system (see Wired Network Connection on page A-4 for more information).

A.7 IT Requirements

Internet Access

The network security device that will be integrated into the system requires Internet access to contact servers at Intuitive.

Intuitive requires a wired RJ45 Ethernet 10bT/100bT/1000bT network drop and/or a wireless 802.11b/g/n network with Internet access in the OR where the facility's system is used. If the system is used in multiple locations, then Intuitive requests that Internet access be made available in each location.

OnSite is compatible with both DHCP and static networking addresses.

Proxy Server

OnSite is compatible with basic unencrypted HTTP proxy servers, and supports basic authentication over plaintext (deprecated). Due to client certificate authentication, OnSite is not compatible with TLS decryption/encryption (MITM) network policy devices such as BlueCoat. In these instances, a bypass network configuration may be required.

Firewall Requirements

OnSite requires outbound port TCP:443 (TLS) to be open outbound to the OnSite servers. There are no requirements to allow inbound traffic at the edge firewall.

Network Topology

OnSite requires a minimum amount of bandwidth to post log files (generally less than 50 MiB per surgery).

Physical Security

The system is a complex medical device and physical tampering with the system hardware or software may void the warranty and result in suboptimal performance. The customer should use sufficient physical security precautions.

IT Secure Deployment

The system has been tested to perform on a customer network with a customer firewall isolating the medical device from the general internet. To increase uptime and reduce chances of network based Denial of Service attacks, the system should be placed on a trusted and protected network segment that is capable of meeting the firewall requirements above.

IP Addressing

The system currently only supports IPv4 addressing. DHCP is enabled by default on the router/gateway device, but static IPv4 addressing is supported when needed.

DNS Resolution

The system does not currently require DNS services.

OnSite Not Enabled

There is no need to plug in an Ethernet cable when OnSite is not enabled.

Note: The RJ45 Ethernet port on the bottom left of the Vision Cart and the router/gateway device are powered by default when the cart has power. When the optional OnSite feature is not enabled, the router/gateway will still attempt to obtain a DHCP address when the Ethernet cable is plugged in, but the system will not send any data. Customers may request that field service manually disable the router/gateway power connection. Wi-Fi connectivity is generally only provisioned on customer request at the time OnSite is enabled, it is not present by default.

OnSite Enabled

Once enabled, OnSite will connect to the Intuitive servers whenever the network connection is available and the system has power.

Anomalous Network Behavior and Detection

The system does not generate any network traffic when OnSite is not enabled.

The system will connect to the IPv4 anycast IP address of the OnSite server infrastructure when OnSite is enabled. Currently the system does not connect to any infrastructure on the hospital network, unless the optional HTTP proxy feature is enabled. For all use cases, the only outbound connections will be TCP:443 to the OnSite server address.

As such, the detection of traffic originating from the system to devices on the hospital network, or to internet-based infrastructure would be considered anomalous when, for example, any of the following protocols or services were detected:

- SMB/CIFS
- NFS
- Network scanning
- SSH/telnet
- RDP
- Connections to known database ports
- Active Directory services
- POP3/IMAP/SMTP
- FTP
- Public Cloud endpoints

Contact Intuitive Technical Support if you suspect anomalous behavior is originating from the system. You may immediately disable all network traffic by disconnecting the network cable.

Note: Technical Support may connect to the system during service and some network traffic could be generated during service for testing and troubleshooting.

Note: Other Intuitive applications and services may connect to the system and generate other specific network traffic and would be documented in the relevant product documentation.

Audit Logging

The system produces data relative to the performance of the hardware and software, user inputs, and errors detected. These logs are binary in composition and require Intuitive proprietary software to interpret the data. Contact Intuitive Technical Support for assistance.

A.8 Electromagnetic Compatibility

The essential performance for da Vinci Wireless Connectivity during EMC testing was defined as follows during any of the required tests:

- No component failures
- Video quality exceeded pre-defined metric demonstrating that the video quality was not impacted
- Audio script test passed demonstrating that the audio link was not impacted
- No changes in programmable parameters
- No resets to factory defaults
- No change in operating mode

- No false alarms
- No initiation of any unintended operation
- No cessation or interruption of any intended operation

Exception: For Voltage Dips and Interrupts, acceptance criteria is no component failures and is restorable to the pre-test state with operator intervention. For Radiated Immunity in the band 2.0 - 2.5GHz, acceptance criteria is no component failures and is restorable to the pre-test state with operator intervention, and restorable during test with a hard-wired connection.

The system complies with IEC 60601-1-2:2014, General Requirements for safety – Collateral standard: Electromagnetic compatibility. Special precautions and installation information for the system for electromagnetic compatibility (EMC) are provided in the following section.

Use only Intuitive-branded interconnection cables and accessories. Performance of cables or accessories other than those specified by Intuitive as replacement parts for internal components cannot be guaranteed. Any resulting damage to the system will not be covered under warranty.

Equipment in the operating room, including the system and other portable or mobile communications equipment, can produce Electromagnetic Interference (EMI), which may affect the function of these devices. Such effects are prevented by use of equipment with EMI characteristics proven below recognized limits, as identified in the below tables.

In the event of suspected interference from other equipment, which prevents the proper functioning of the system, contact Intuitive and/or discontinue use of the system until the problem can be remedied.

The following Tables contain the Manufacturer's declaration and additional information required by IEC 60601-1-2:2014.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at their own expense.

Table 1: Manufacturer's Declaration – Electromagnetic Emissions
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic environment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 2: Manufacturer's Declaration – Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	• ±2 kV for power supply lines • ±1 kV for input/ output lines	• ±2 kV for power supply lines • ±1 kV for input/ output lines	Mains power quality should be that of a U.S. commercial or hospital environment with highly reliable service.
Surge IEC 61000-4-5	• ±1 kV differential mode • ±2 kV common mode	• ±1 kV differential mode • ±2 kV common mode	Mains power quality should be that of a U.S. commercial or hospital environment with highly reliable service.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	• <5% UT (>95% dip in UT) for 0.5 cycle • 40% UT (60% dip in UT) for 5 cycles • 70% UT (30% dip in UT) for 25 cycles • <5% UT (>95% dip in UT) for 5 sec.	• <5% UT (>95% dip in UT) for 0.5 cycle • 40% UT (60% dip in UT) for 5 cycles • 70% UT (30% dip in UT) for 25 cycles • <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a U.S. commercial or hospital environment with highly reliable service. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptedly power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the AC mains voltage before application of the test level.

Table 3: Manufacturer's Declaration – Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	• 3 Vrms 150 kHz to 80 MHz • 3 V/m 80 MHz to 2.5 GHz	• 3 Vrms • 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz – 800 MHz $d = 2.3\sqrt{P}$ 800 MHz – 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Notes

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the system.

b. Over the frequency range 150 kHz – 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the system

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz – 80 MHz $d = 1.2\sqrt{P}$	80 MHz – 800 MHz $d = 1.2\sqrt{P}$	800 MHz – 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz – 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

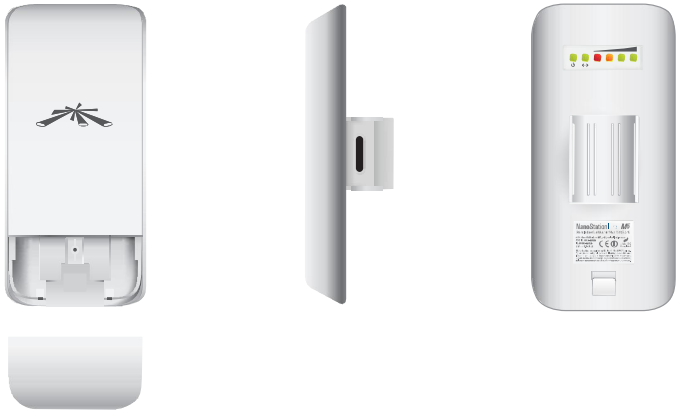
Compliance Information	
Network Router:	CAN/CSA-C22.2 No 60950-1-03 ANSI/UL Std No 60950-1 1st Ed.
Wireless Bridge[a]: Wireless Data Rate:	802.11b/g: 2.4-2.4835 GHz 802.11b/g: 2.4-2.4835 GHz

Notes

a. See A.9 Wireless Bridge Data on page A-20 for more information.

A.9 Wireless Bridge Data

Refer to the LocoM2 model for wireless bridge data.



NanoStation™ loco M

Model	Frequency	Gain
locoM2	2.4 GHz	8 dBi
locoM5	5 GHz	13 dBi

Specifications

System Information			
Model	NanoStationM	locoM5/M2	locoM9
Processor Specs	Atheros MIPS 24KC, 400 MHz	Atheros MIPS 24KC, 400 MHz	Atheros MIPS 24KC, 400 MHz
Memory	32 MB SDRAM, 8 MB Flash	32 MB SDRAM, 8 MB Flash	64 MB SDRAM, 8 MB Flash
Networking Interface	(2) 10/100 Ethernet Ports	(1) 10/100 Ethernet Port	(1) 10/100 Ethernet Port

Regulatory/Compliance Information				
Model	NSM5/NSM2/locoM5/locoM2	NSM3	NSM365	locoM9
Wireless Approvals	FCC Part 15.247, IC RS210, CE	-	FCC Part 90Z	FCC Part 15.247, IC RS210
RoHS Compliance	Yes	Yes	Yes	Yes

Physical/Electrical/Environmental						
Model	NSM5	NSM3/365	NSM2	locoM5	locoM2	locoM9
Dimensions (mm)	294 x 31 x 80	294 x 31 x 80	294 x 31 x 80	163 x 31 x 80	163 x 31 x 80	164 x 72 x 199
Weight	0.4 kg	0.5 kg	0.4 kg	0.18 kg	0.18 kg	0.9 kg
Power Supply (PoE)	24V, 0.5A	24V, 1A	24V, 0.5A	24V, 0.5A	24V, 0.5A	24V, 0.5A
Max. Power Consumption	8 W	8 W	8 W	5.5 W	5.5 W	6.5 W
Gain	16 dBi	13.7 dBi	11 dBi	13 dBi	8 dBi	8 dBi
RF Connector	-	-	-	-	-	External RP-SMA
Polarization	Dual Linear					
Enclosure Characteristics	Outdoor UV Stabilized Plastic					
Mounting	Pole Mounting Kit Included					
Power Method	Passive Power over Ethernet (pairs 4, 5+; 7, 8 return)					
Operating Temperature	-30 to 75° C					
Operating Humidity	5 to 95% Condensing					
Shock & Vibration	ETSI300-019-1.4					

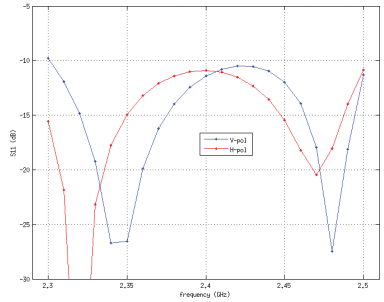
Operating Frequency Summary (MHz)					
Model	NSM5/locoM5	NSM365	NSM3	NSM2/locoM2	locoM9
Worldwide	5170 - 5875	3650-3675	3400-3700	2412-2462	902-928
USA	5725 - 5850				
USA DFS	5250 - 5850	-	-	-	-

NanoStationlocoM2 Specifications

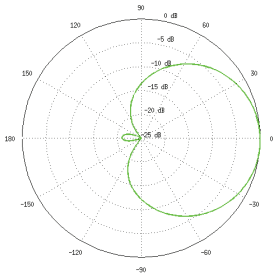
Output Power: 23 dBm							
2.4 GHz TX POWER SPECIFICATIONS				2.4 GHz RX POWER SPECIFICATIONS			
	Data Rate/MCS	Avg. TX	Tolerance		Data Rate/MCS	Sensitivity	Tolerance
11b/g	1-24 Mbps	23 dBm	± 2 dB	11b/g	1-24 Mbps	-83 dBm	± 2 dB
	36 Mbps	21 dBm	± 2 dB		36 Mbps	-80 dBm	± 2 dB
	48 Mbps	19 dBm	± 2 dB		48 Mbps	-77 dBm	± 2 dB
	54 Mbps	18 dBm	± 2 dB		54 Mbps	-75 dBm	± 2 dB
airMAX	MCS0	23 dBm	± 2 dB	airMAX	MCS0	-96 dBm	± 2 dB
	MCS1	23 dBm	± 2 dB		MCS1	-95 dBm	± 2 dB
	MCS2	23 dBm	± 2 dB		MCS2	-92 dBm	± 2 dB
	MCS3	23 dBm	± 2 dB		MCS3	-90 dBm	± 2 dB
	MCS4	22 dBm	± 2 dB		MCS4	-86 dBm	± 2 dB
	MCS5	20 dBm	± 2 dB		MCS5	-83 dBm	± 2 dB
	MCS6	18 dBm	± 2 dB		MCS6	-77 dBm	± 2 dB
	MCS7	17 dBm	± 2 dB		MCS7	-74 dBm	± 2 dB
	MCS8	23 dBm	± 2 dB		MCS8	-95 dBm	± 2 dB
	MCS9	23 dBm	± 2 dB		MCS9	-93 dBm	± 2 dB
	MCS10	23 dBm	± 2 dB		MCS10	-90 dBm	± 2 dB
	MCS11	23 dBm	± 2 dB		MCS11	-87 dBm	± 2 dB
	MCS12	22 dBm	± 2 dB		MCS12	-84 dBm	± 2 dB
	MCS13	20 dBm	± 2 dB		MCS13	-79 dBm	± 2 dB
	MCS14	18 dBm	± 2 dB		MCS14	-78 dBm	± 2 dB
	MCS15	17 dBm	± 2 dB		MCS15	-75 dBm	± 2 dB

Antenna Information	
Gain	8.5 dBi
Cross-pol Isolation	20 dB Minimum
Max. VSWR	1.4:1
Beamwidth	60° (H-pol) / 60° (V-pol) / 60° (Elevation)

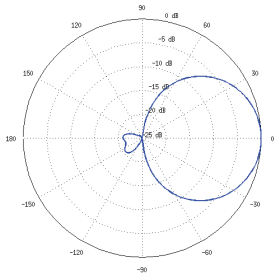
Return Loss



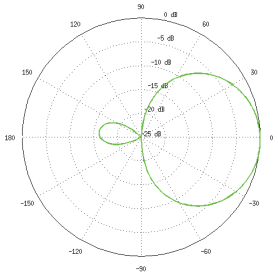
Vertical Azimuth



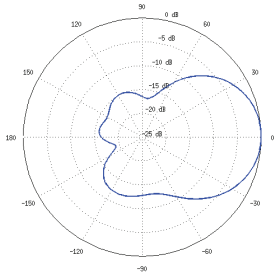
Vertical Elevation



Horizontal Azimuth



Horizontal Elevation

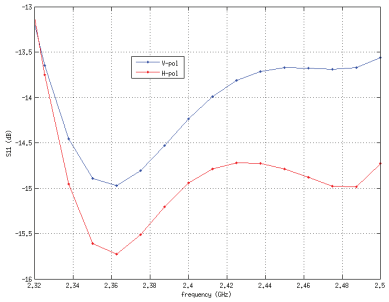


NanoStationM2 Specifications

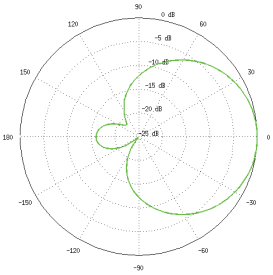
Output Power: 28 dBm							
2.4 GHz TX POWER SPECIFICATIONS				2.4 GHz RX POWER SPECIFICATIONS			
	Data Rate/MCS	Avg. TX	Tolerance		Data Rate/MCS	Sensitivity	Tolerance
11b/g	1-24 Mbps	28 dBm	± 2 dB	11b/g	1-24 Mbps	-83 dBm	± 2 dB
	36 Mbps	26 dBm	± 2 dB		36 Mbps	-80 dBm	± 2 dB
	48 Mbps	25 dBm	± 2 dB		48 Mbps	-77 dBm	± 2 dB
	54 Mbps	24 dBm	± 2 dB		54 Mbps	-75 dBm	± 2 dB
airMAX	MCS0	28 dBm	± 2 dB	airMAX	MCS0	-96 dBm	± 2 dB
	MCS1	28 dBm	± 2 dB		MCS1	-95 dBm	± 2 dB
	MCS2	28 dBm	± 2 dB		MCS2	-92 dBm	± 2 dB
	MCS3	28 dBm	± 2 dB		MCS3	-90 dBm	± 2 dB
	MCS4	27 dBm	± 2 dB		MCS4	-86 dBm	± 2 dB
	MCS5	25 dBm	± 2 dB		MCS5	-83 dBm	± 2 dB
	MCS6	23 dBm	± 2 dB		MCS6	-77 dBm	± 2 dB
	MCS7	22 dBm	± 2 dB		MCS7	-74 dBm	± 2 dB
	MCS8	28 dBm	± 2 dB		MCS8	-95 dBm	± 2 dB
	MCS9	28 dBm	± 2 dB		MCS9	-93 dBm	± 2 dB
	MCS10	28 dBm	± 2 dB		MCS10	-90 dBm	± 2 dB
	MCS11	28 dBm	± 2 dB		MCS11	-87 dBm	± 2 dB
	MCS12	27 dBm	± 2 dB		MCS12	-84 dBm	± 2 dB
	MCS13	25 dBm	± 2 dB		MCS13	-79 dBm	± 2 dB
	MCS14	23 dBm	± 2 dB		MCS14	-78 dBm	± 2 dB
	MCS15	22 dBm	± 2 dB		MCS15	-75 dBm	± 2 dB

Antenna Information	
Gain	10.4-11.2 dBi
Cross-pol Isolation	23 dB Minimum
Max. VSWR	1.6:1
Beamwidth	55° (H-pol) / 53° (V-pol) / 27° (Elevation)

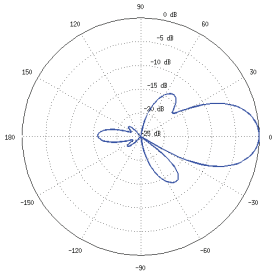
Return Loss



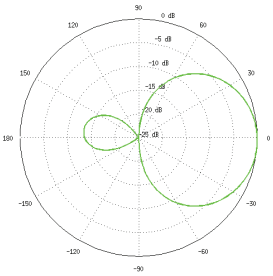
Vertical Azimuth



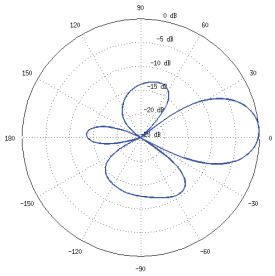
Vertical Elevation



Horizontal Azimuth



Horizontal Elevation



A.10 End-of-Service Deprovisioning

Removal of Stored Data

- The da Vinci system in normal operation may contain a list of local ergonomic profiles that include the first name and last name as entered by the surgeon or OR staff. Local profiles are created and stored individually on each specific da Vinci system.
  - To remove a single account, log into the account and tap the **Delete** button.
  - To delete all of the profiles, log into each profile sequentially to delete them.
  - Alternatively, contact Intuitive Technical Support for service.
- For da Vinci systems where the optional Surgeon Login OnSite feature for Intuitive accounts was enabled, user Intuitive profiles are protected by a PIN code. Individual profiles cannot be deleted by the user at this time, contact Intuitive Technical Support for service.
- The system will retain and store a quantity of system log data internally, including the machine data gathered during any procedures that occurred since the system was commissioned or last serviced. This data does not contain patient health information but may contain the surgeon name (ergonomic profile or cloud login) and procedure type (if cloud login was enabled). This data is not user accessible, and no user-facing mechanism to delete this data is available. Contact Intuitive Technical Support for assistance.

End of Section

Appendix B System Troubleshooting

Contents

B.1 Customer Service B-1
B.2 Convert to Open Surgery or Obtain Immediate Access to the Patient B-1
B.3 Access the Event Logs B-2
B.4 Troubleshooting the Patient Cart Drive B-2
B.5 Unexpected Motion B-4
B.6 System Power Issues B-4
B.7 Restart the System B-7
B.8 System Faults, Recoverable Faults, and Non-recoverable Faults B-7
B.9 Troubleshoot the Endoscope Controller B-12

B.1 Customer Service

If the system requires maintenance or service, call the Customer Service line. U.S. phones are staffed 24 hours a day, seven days a week.

In the U.S.

Toll free: 1.800.876.1310

B.2 Convert to Open Surgery or Obtain Immediate Access to the Patient

WARNING: Use proper methods for attaining emergency access to the patient at any time, including manual repositioning of the Patient Cart, to prevent patient harm.

If a situation arises where a conversion to open surgery or immediate access to the patient is required, perform the following steps to remove the system from the patient:

1. Remove the instruments from the patient.
   a. If needed, use robotic, Surgeon Console control to release the instrument grips.
   b. If robotic control cannot be used to release the instrument grips, see Manual Grip Release on page 9-47.
2. Remove the endoscope from the patient.
3. Disconnect the cannulae from the arms.
4. Move the arms away from the patient.

5. If necessary, move the Patient Cart away from the patient. If the Patient Cart drive is not functional, see B.4 Troubleshooting the Patient Cart Drive on page B-2.

Note: If the system is in a fault state while converting to open surgery, the Patient Cart port clutch buttons still work. If the system loses all power, the arms and setup joints can still be moved (with gentle force) as necessary.

WARNING: Do not perform grip release on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.

B.3 Access the Event Logs

To assist the Intuitive support representative in diagnosing the system, the OR staff may need to access event logs.

To access event logs from the Vision Cart touchscreen

1. On the Vision Cart touchscreen, tap the **Troubleshooting** button and tap **Display Event Logs**. The system log appears on the touchscreen. Use the navigation buttons to scroll through the log.
2. Tap **Close** to close the log.

B.4 Troubleshooting the Patient Cart Drive

There may be times (for example, power loss) when the stabilization feet need to be raised and the Patient Cart placed into manual drive. This manual drive feature lets the cart be moved without using the powered motor drive (cart drive).

Figure B.1 Cart drive failure label

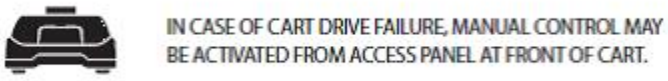


Figure B.2 Stabilization feet not deployed message



WARNING: Do not move the Patient Cart while one or more arms are docked to the patient, to prevent harm to the user or patient.

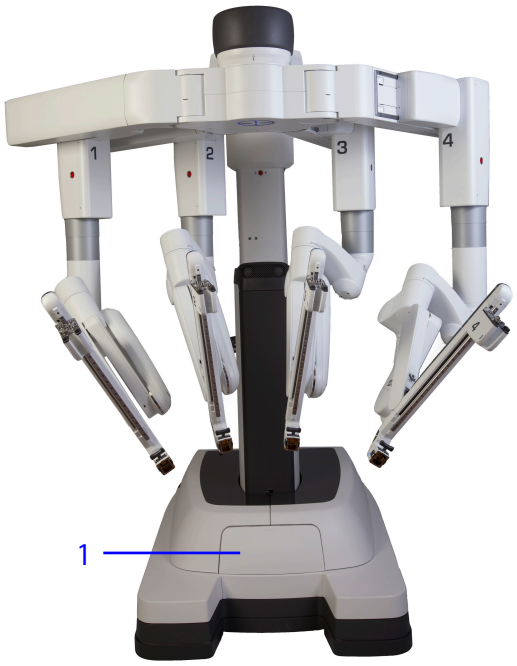
Note: We recommend using two people to manually move the Patient Cart, due to the high force required.

Note: If the Patient Cart stabilization feet are not deployed during surgery, a message displays on the touchscreen (Figure B.2). System operation is possible, but is not recommended for routine use. The instruments may vibrate in response to arm motion, and the Patient Cart may move if pushed. Use care when operating the system if the stabilization feet are not deployed.

Moving the Patient Cart Manually

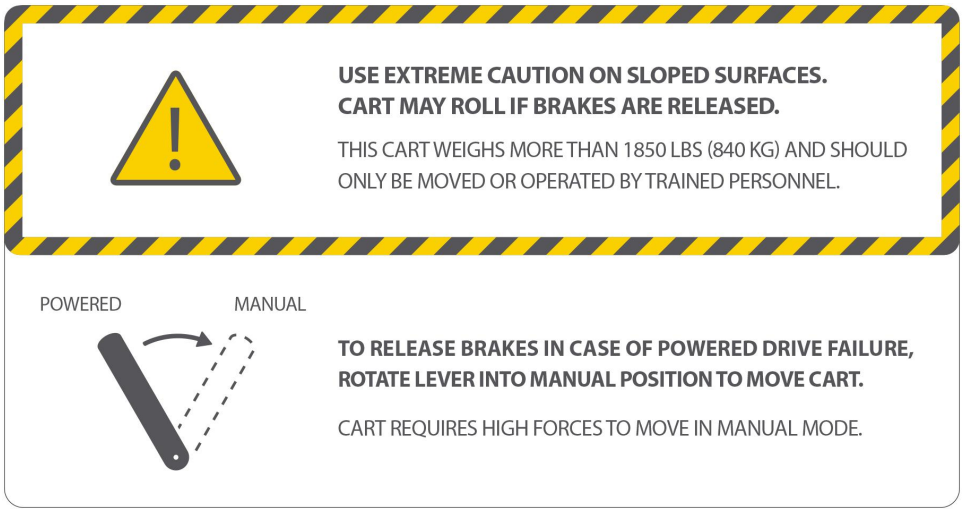
WARNING: Do not disengage the cart drive when the Patient Cart is on a slope, to prevent injury to the operator or other personnel.

1. On the base of the Patient Cart, open the access panel by pushing it inwards to unlatch, and then pull down to open the panel.



1. Access panel

2. Read the label that appears on the interior of the Patient Cart access panel. This label provides instructions on placing the Patient Cart into manual drive.



3. Move the lever into the Manual position.
4. Using two people, manually transport or position the Patient Cart.

5. To restore power to the Patient Cart drive, move the lever back to the Powered position.
6. Be sure to move the lever back to Powered position as soon as manual control is no longer needed.

B.5 Unexpected Motion

Unexpected motion occurs when the arm brakes are overpowered. Multiple factors can cause this, including excessive force on the patient and interference of Patient Cart components (arms, nearby objects). If the system detects unexpected setup joint motion, the arm LED for the associated setup joint illuminates yellow and a message appears on screen.

To clear the error, press the port clutch button for that arm. This also relieves any potential excessive force on the patient.

B.6 System Power Issues

This section provides troubleshooting information to help address system power issues.

When the da Vinci system or an individual component (Surgeon Console, Patient Cart, and Vision Cart) fails to power on normally; or, fails to undergo an automatic, controlled power-down sequence the system might experience anomalous behavior.

For instance, faulty power connections might create power on issues. Or, a system component overheating issue might cause power-down issues.

Check Connections

Check AC Power Connections

In all cases of inconsistent power behavior, first check AC power connections:

1. Confirm that the power cord for the Surgeon Console, Patient Cart, and Vision Cart is properly connected to a dedicated AC power outlet.
2. Confirm that the power switch on the Surgeon Console, Patient Cart, and Vision Cart is set to the on position (indicated by “I” near each switch). These switches are on the rear of each component.



Surgeon Console

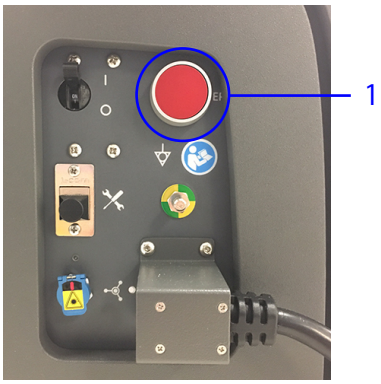


Patient Cart



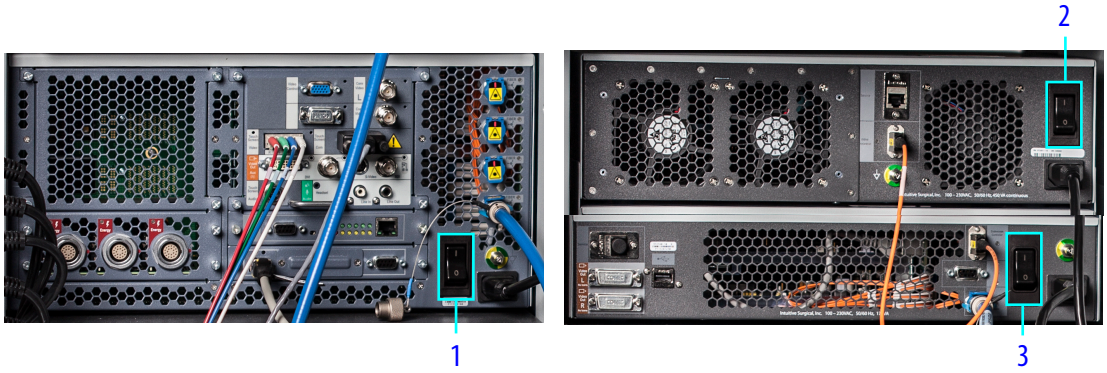
Vision Cart (at base)

3. On the Patient Cart, make sure that the Emergency Power Off (EPO) button is not pressed in. A pressed in EPO button requires a second press to reset it once it is used. (See Hard-cycle Power On System on page B-6).



1. EPO button not depressed

4. On the Vision Cart:
   - Confirm that each component (Endoscope Controller, Video Processor, Core) power switch is correctly set to the on position (indicated by "I" on the switch). These components are not intended to be turned off or disconnected at any time unless directed to do so by Intuitive Customer Service.
   - Confirm that each component (Endoscope Controller, Video Processor, Core) power cord is connected to the integrated Vision Cart power strip.



1. System electronics (Core) power switch
2. Endoscope Controller power switch
3. Video Processor power switch

Check Fiber Cable Connections

Check that the blue system cables are properly connected between the Patient Cart, Surgeon Console, and Core. See Chapter 4 Connect System on page 4-1 for more information.

Hard-cycle Power On System

Use this troubleshooting procedure, if the entire system or either the Surgeon Console, Patient Cart, or Vision Cart fail to power on normally after pressing a component Power button. All instruments can remain installed on the instrument arms.

Note: Following a system hard-cycle power on, use the manual release knob to remove the SureForm stapler, if applicable[1]. Refer to the *SureForm 45 and SureForm 60 User Manual* for instructions on stapler removal.

First, check the AC power connections as described above. If all AC power connections are sound, follow the steps below:

1. Remove AC power from the Vision Cart and Surgeon Console by switching each AC power switch to off (indicated by "O" near each switch).
2. On the Patient Cart, press the **EPO** button to remove all power; it will remain partially pressed in.
3. Wait two seconds and then press the **EPO** button to reset it; it will rebound to its fully extended ready position.



Note: The Patient Cart operates on battery power even after switching off its power switch. Using the EPO button disconnects the Patient Cart from AC power and exits the default standby (sleep) mode.

4. Switch on the Vision Cart and Surgeon Console AC power switches.
5. Verify that the Patient Cart AC power switch is in the on position (if not, switch it on). After 30 seconds, all three system components return to default standby mode. All three power buttons will be yellow ( ).
6. Power on the system normally, by pressing the Power button on either the Surgeon Console, Patient Cart, or Vision Cart.

To address anomalous power behavior when trying to power a single system component, "hard-cycle" power as described above for the applicable component.

1. Not all technologies may have regulatory approval or may be commercially available in all geographies. For availability in your country, check with your local representative.

B.7 Restart the System

Restart from Automatic High Temperature Power Down

The da Vinci system is designed to undergo an automatic, controlled power-down sequence if a component or subsystem overheats while in normal operating mode (as opposed to maintenance mode). This controlled power-down prevents system damage.
When the system detects overheating, it automatically initiates a 60-second power down sequence.

Do not interrupt the power down sequence. When complete, all three system **Power** buttons will be lit yellow (), indicating the systems are in their default standby (sleep) mode.

To restart the system from an automatic high temperature power down state:

1. Wait 5 minutes for the overheated system component to cool.
2. Address situations that may be causing the system to overheat. For instance, ensure that all vented system covers have adequate ventilation. Move system away from objects that could obstruct air flow in and out of system covers.
3. Restart the system from standby mode. Press one of the system **Power** buttons. The button flashes blue () as normal during the power-up sequence, and lights solid blue () when power-up is complete.

> **Note:** If overheating recurs, contact Intuitive Customer Service (in the U.S. 1.800.876.1310) to address the cause of overheating.

Cool Mode Restart from Individual Power

If a single component overheating issue results in automatic power-down when operating individually; press the **Power** button three times to bring that component back to normal operation. This situation is called “cool mode,” the mode in which the system component is cooling from an overheated state.

1. First Power button press has no noticeable effect.
2. Second Power button press returns the system component to standby mode. The Power button will be lit yellow ().
3. Third Power button press powers on the component normally.

This restart behavior also applies if overheating occurs when a component or system is in maintenance mode. Maintenance mode is reserved for use by Intuitive service personnel, so this situation will not normally be encountered.

B.8 System Faults, Recoverable Faults, and Non-recoverable Faults

> **CAUTION:** Use proper actions to recognize and recover from system faults, to prevent patient harm.

System Faults

When a fault occurs, the system determines whether the fault is recoverable or non-recoverable. The system behaves in the following manner when a fault occurs:

- Locks all the arms. In this state the clutch buttons function normally but the instrument is slightly harder to move and is not able to be left in clutch mode.
- Sounds a series of error beeps.
- Displays a text message on the monitors to describe the error.

Figure B.3 Fault message on touchpad (text may vary)



- If the fault is arm-specific, the system displays an error icon and the specific arm LED will be yellow or red.
- If the fault is not arm-specific, all arm LEDs will be yellow or red.

Recoverable Faults

To override an E-stop recoverable fault, tap **Resume Use**. To override all other recoverable faults, tap **Recover Fault** on the touchpads or touchscreen. The alarm silences and the system recovers after a few seconds.

Note: Using Recover Fault does not diminish the system's fault detection capability. If the fault condition remains, the system immediately faults again. If the fault condition is removed, the system is fully functional.

WARNING: Thoroughly understand the cause of the fault before using the Recover Fault button. Overriding a fault without understanding its cause may result in uncontrolled movement of the arms up to 2 cm, or uncontrolled motion of the master hand controls up to 5 cm.

Disable Patient Cart Arms, Hand Controls, or Boom

The da Vinci system can disable an arm or hand control if there is an arm-specific error. This feature lets you complete a procedure with the remaining arms.

If there is an arm-specific error, the system displays a disable arm option on the touchscreen or touchpad. Once the arms are disabled, they cannot be re-enable it until the next power cycle.

If the OR staff is unsure whether or not to disable an arm, contact Intuitive Customer Service (in the U.S. 1.800.876.1310).

After Disabling a Hand Control

The surgeon cannot control the endoscope arm from a Surgeon Console with a disabled hand control.

After Disabling an Arm

The arm clutch and port clutch buttons can still be used to move the arm out of the way.

After Disabling the Boom

If there is a boom failure, the system displays a disable boom option on the touchscreen. After disabling the boom, cart drive, targeting and boom controls will be disabled.

Non-recoverable Faults

If a fault is non-recoverable, restart the system. The following message is displayed:

```
Non-recoverable fault: XXXX

Restart System to continue.
```

Restart the System During a Procedure

If a non-recoverable fault occurs during a procedure, restart the system without having to remove instruments and endoscope from the patient.

1. Press the **Power** button on any system component to power off the system. It is not necessary to remove instruments or endoscope.

   The system takes several seconds to shut down. When complete, all system Power buttons will be lit yellow (), indicating standby mode, and readiness for restart.

2. Press the **Power** button on any system component to restart the system.

> **Note:** During system restart, video is temporarily unavailable at the Surgeon Console viewer and touchscreen monitor.

> **Note:** If the fault cannot be cleared by a system restart, contact Intuitive Customer Service.

Emergency Stop – Surgeon Console

1. Press the Surgeon Console **Emergency Stop** button if it becomes necessary to stop system operation. The system classifies this action as a recoverable fault.



1. Emergency Stop button

2. Tap **Resume Use** on the touchscreen or touchpad to override this fault.

If the Emergency Stop button is pressed while the grips are holding onto tissue, see Manual Grip Release on page 9-47.

Emergency Stop – Patient Cart Helm

1. Press the Patient Cart **Emergency Stop** button if it becomes necessary to stop system operation. The system classifies this action as a recoverable fault.



1. Emergency Stop button

2. Press **Resume Use** on the touchscreen or touchpads to override this fault.

   If the Emergency Stop button is pressed while the grips are holding onto tissue, see Manual Grip Release on page 9-47.

Emergency Power Off – Patient Cart

Press the Patient Cart Emergency Power Off (EPO) button to power off the Patient Cart. The system classifies this action as a non-recoverable fault. The system must be restarted. (See Non-recoverable Faults on page B-9).

Figure B.4 EPO Button– Patient Cart Rear



Battery Backup

Should the Patient Cart be unplugged, the system alerts that it is running on battery power and advises to plug-in the Patient Cart to avoid loss of power. System operation will be allowed to continue on reserve power.

Note: Battery backup is only intended for safe removal of the system components from the patient and is not intended for continuing a procedure.

Battery Low Condition

If the Patient Cart has insufficient battery backup power, the cart drive is disabled. Wait for the battery backup to charge before using the cart drive.

To move the cart manually, follow the instructions in section B.4 Troubleshooting the Patient Cart Drive on page B-2.

Note: The Patient Cart battery should be adequately charged. If not, an error message appears on the monitors. The error can be overridden if the Patient Cart is connected to AC power.

Note: The backup battery is not user-serviceable, and must be replaced by authorized personnel only. Contact Intuitive Customer Service for details.

Troubleshoot a Non-responsive System

If the system is non-responsive or otherwise not functioning as desired:

1. Check on-screen messages to see if the system is performing an action (for example, downloading instrument data, or performing automatic calibration of the endoscope).

2. Press the **Emergency Stop** button on the Patient Cart Helm or Surgeon Console.
3. Press **Recover Fault** on the touchpads or touchscreen, and confirm that the system is functioning normally.

If the problem persists:

- Restart the system by pressing the **Power** button on either the Vision Cart, Patient Cart, or Surgeon Console.
  - If the system fails to restart, perform a "hard-cycle" power on as described in Hard-cycle Power On System on page B-6, and then press any **Power** button to start the system normally.

B.9 Troubleshoot the Endoscope Controller

Table B.1 Troubleshooting Endoscope Controller

Symptom	Possible Problems	Remedy
No power to Endoscope Controller	Vision Cart not connected or not powered on. Internal power supply not operating. AC input power receptacle unplugged.	Connect and power on system. Contact Intuitive Customer Service.
No light emits from unit	Internal power supply not operating. Fiber-optic cable not connected.	Contact Intuitive Customer Service. Connect fiber-optic cable correctly.
Field of view is dim	Incorrect settings.	Adjust brightness controls on the endoscope.

End of Section

Appendix C Technical System Information

Contents

C.1 Manufacturer Information C-1
C.2 Compliance and Classifications C-2
C.3 System Labels C-3
C.4 Disposal Information C-7

C.1 Manufacturer Information



In the U.S.
Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086 USA
www.intuitive.com

C.2 Compliance and Classifications

Compliance and Classifications

CE
2460

The Intuitive Surgical Endoscopic Instrument Control System Model IS4000 (da Vinci Xi System) is in conformance with Regulation (EU) 2017/745 European Medical Devices Regulation (MDR).

The da Vinci Xi System is designed to be in compliance with IEC 60601-1, with the following mode of operation, and type and degree of protection against electric shock.

- **Mode of operation:** Continuous
- **Type of Protection:** Class I
- **Degree of Protection:** CF for all patient applied parts (inserted portion of instruments). Refer to the Instruments and Accessories User Manual for additional details.
- **Ingress Protection:** Ordinary, except footswitch on the Surgeon Console, which is rated IPX8.

CLASSIFIED C UL US 63MK

The da Vinci Xi System is manufactured in the USA.

The da Vinci Xi System is classified with respect to electric shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008), UL60601-1 and CAN/CSA C22.2 No. 601.1. Also classified by UL only to IEC publication(s) 60601-1, 60601-1-1, 60601-1-4, 60601-2-2 and 60601-2-18.

The da Vinci Xi System consists of a Surgeon Console Model SS4000, Patient Cart Model PS4000, and Vision Cart Model VS4000. The Vision Cart contains the Core Model CR3000; Endoscope Controller Model EC4000; and Video Processor Model VP4000. The Surgeon Console, the Patient Cart and the Vision Cart, including the Core, Endoscope Controller and Video Processor, have been evaluated for compliance with above referenced standards by a Nationally Recognized Test Laboratory (NRTL), Underwriters Laboratories, Inc. (UL). Accessories referenced in the Instruments and Accessories User Manual were not covered by the UL evaluation.

WARNING: The system is not suitable for use in the presence of a flammable anesthetic mixture of air, oxygen, and nitrous oxide.

Essential Performance of the da Vinci Xi System

The following essential performance information is in compliance with IEC 60601-1.

- The system displays a real-time image of the surgical site. If the displayed image is not live, such as when displaying a recorded image or in the event of system malfunction, it will be obvious to the user that the displayed image is not a live image.
- Insufficient endoscopic light levels, non-uniform light levels across the frequency spectrum, or other imperfections in the quality of the displayed output will be readily apparent to the operating surgeon such that they can choose whether or not to proceed with the planned surgery.
- The orientation of the displayed image is controllable by the operating surgeon or surgical staff. An indication of the image orientation is provided to the user.

- Except when clutched and under the control of the patient-side assistant, the instrument tip, shaft, and Patient Cart arm moves only in response to motions of the hand control initiated by the operating surgeon. The motions of the instrument tip are approximately proportional to the surgeon-initiated motions of the hand control and are approximately in the same direction relative to the endoscope/3D viewer frames of reference. There should be no uncontrolled or unexpected motions of the instrument tip.
- The da Vinci System includes Fault Reaction Logic (FRL) that can transition the system, or appropriate subsystem, to a safe state (motors stopped, brakes engaged as required, energy activation off). FRL will be activated upon user input (pushing one of the Emergency Stop buttons) or when real-time system health monitoring detects a potential problem that necessitates stopping all motion of the system or subsystem. Error messages will display to alert the user.
- System-connected electrosurgical generators or other energy delivery devices can only be activated by the da Vinci System when initiated, and continually commanded, by the operating surgeon.

C.3 System Labels

Note: This user manual identifies labels as they appear on systems configured for destinations in the USA. The languages supplied on labels may vary by the country or countries for which a system is configured.

The system components have individual system labels as shown below. Components with these labels include the Surgeon Console Model SS4000; Patient Cart Model PS4000; Vision Cart Model VS4000; Core Model CR3000; Endoscope Controller Model EC4000; and Video Processor Model VP4000.

Figure C.1 Surgeon Console Label (example)

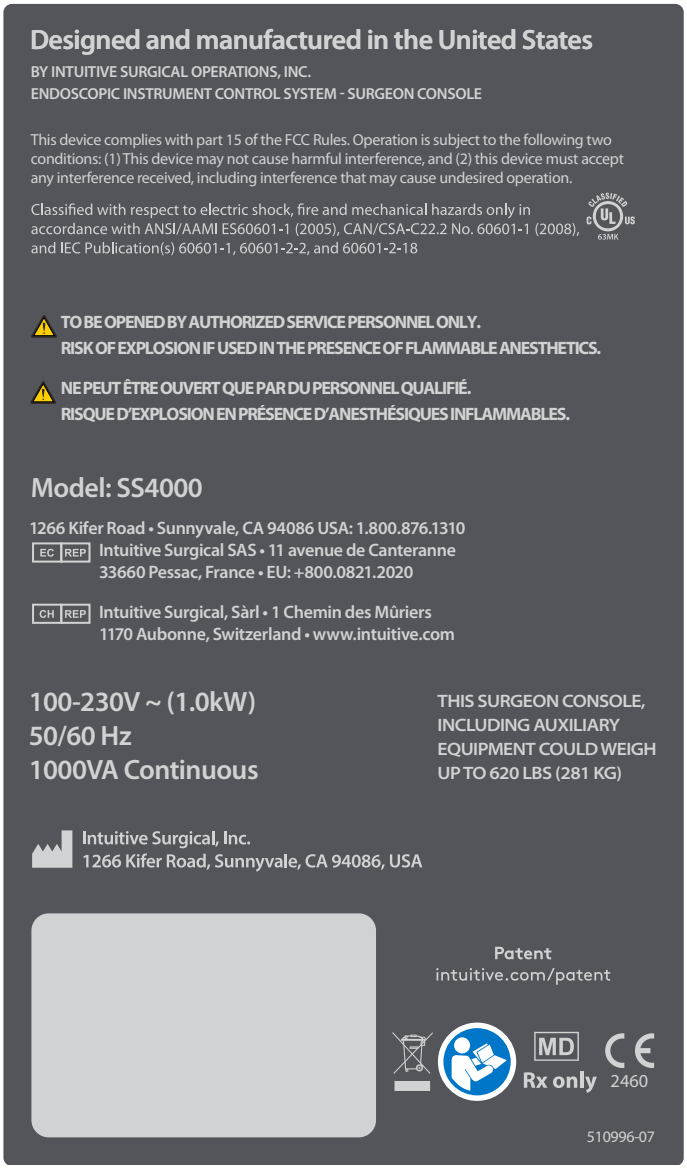


Figure C.2 Vision Cart Label (example)



Figure C.3 Patient Cart Label — da Vinci Xi (example)

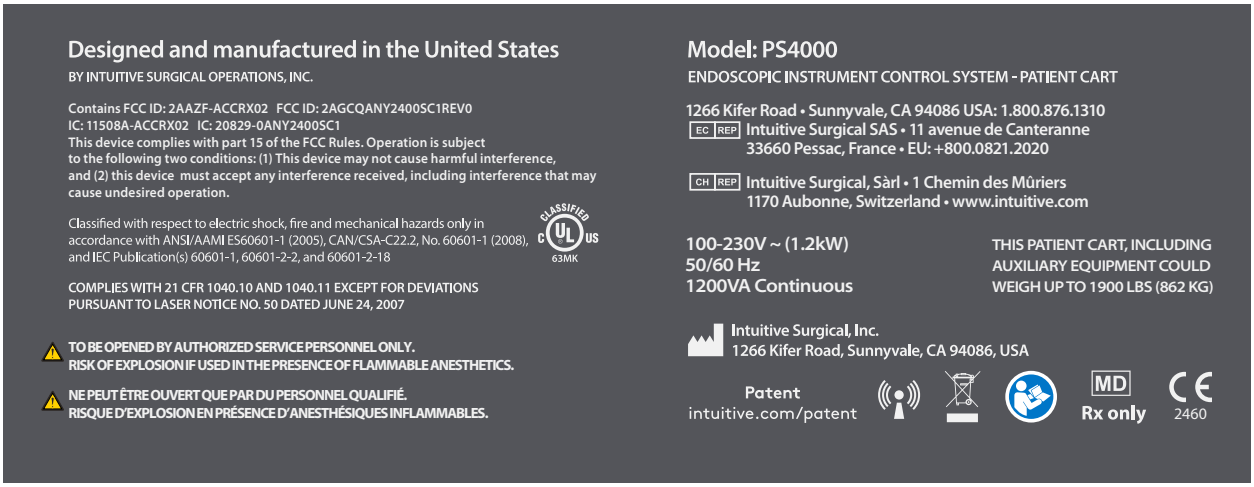


Figure C.4 Video Processor Model VP4000 (example)



Figure C.5 Core Model CR3000 (example)



Figure C.6 Endoscope Controller Model EC4000 (example)



Note: The unit identification labels include the serial number, electrical ratings, and date of manufacture. It may be necessary for the reader to be as close as 6 in. (15 cm) from the labels to read this information.

C.4 Disposal Information



Dispose of all components in accordance with local regulations. This rule particularly applies to electronic components.

Battery Disposal

The system contains one non-spillable, lead acid battery pack module and several lithium batteries that are not user serviceable. These batteries must be disposed of in accordance with local regulations. Contact your local Intuitive representative for disposal information.

Instrument Disposal

When instruments expire, they automatically inactivate and can no longer be used. See 9.11 Manage Instrument Inventory on page 9-49 for more information.

Expired instruments must be properly disposed of following all applicable national and local laws and guidelines. Contact your local Intuitive representative for disposal information.

End of Section

Appendix D Symbols, Icons, Audio Messages

Contents

D.1 Overview D-1
D.2 Symbols and Icons Reference Table D-1
D.3 Audio Messages (Voice Annunciation) D-17

D.1 Overview

This appendix provides a reference for symbols, LEDs (colored lights), icons and text messages may be seen on system components or monitors.

Symbols

Symbols appear on system components and serve these purposes:

- Identification of important system connections and functions
- Provide caution and warning information

On-Screen Icons

Icons are overlaid on the video displays to provide information regarding the status of the system. Note that non-critical messages can be hidden. Critical or work flow messages cannot be hidden. For instructions on hiding on-screen messages, see 7.8 Vision Cart Touchscreen on page 7-19 and Quick-settings Bar on page 10-30.

When messages are hidden, any new message that is generated by the system causes the message screen to automatically un-hide.

The message area provides three categories of notification:

- Warnings

  Warning messages are used when a potentially hazardous situation occurs and caution is advised.
- Alerts

  Alert messages are used when something requires attention from the user, but the hazard level is less severe than a warning.
- Information

  Information messages are used for items that may be of interest, but are unrelated to problems or hazards, and may not require any action from the user.

D.2 Symbols and Icons Reference Table

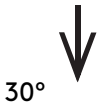
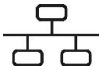
The following symbols may appear on system components or packaging labels for instruments and accessories and have the meaning indicated.

Table D.1 Symbols and Icons

Symbol or Icon	Meaning
	Attention: Consult accompanying documents
	Consult Instructions for Use
	Read the operating instructions
CE 2460	In conformance with Regulation (EU) 2017/745 European Medical Devices Regulation (MDR)
MD	Medical Device
Rx only	Prescription only
	Type CF Applied Part
	Type BF Applied Part
	MR Marking
	Protective ground
	Indicates a medical device that needs protection from direct sunlight and heat
	Flush Port
 30°	30 degrees up, indicates endoscope orientation

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	30 degrees down, indicates endoscope orientation
LASER ON	Near-infrared laser is activated
◁ LASER APERTURE	Identifies direction where the near-infrared laser will be emitted
	Non-sterile
STERILE EO	Sterilize using ethylene oxide
STERILE R	Sterilize using irradiation
	Do not re-sterilize
	Do not re-use
	Do not use if package is damaged
	Do not autoclave
	Ethernet Connection
	Alternating Current
	Equipotential Terminal It may be necessary for the reader to be as close as 6 in. (15 cm) from the equipotential terminal to view this symbol.
QTY	Quantity
	Serial Port Connection

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	Standby—found on Power buttons of Surgeon Console, Patient Cart, Vision Cart, lit yellow when in standby mode (connected to main but not powered on), blue when powered on
	Off (power: disconnection from main)
	On (power: connection to main)
DVI	DVI video port
Composite	Composite video ports
S-Video	S-Video port
SDI	SDI video port
Audio	Audio bay, green
L	Left
R	Right
Core Video	Core Video connection port
Endoscope Controller	Illumination connection port
Core	Core connection port
Video Control	Video control ports
Touchscreen Audio	Touchscreen audio connection port
Touchscreen Video	Touchscreen video connection ports
Touchscreen Com	Touchscreen communication ports
SERVICE	Service connection ports
Headset	Headset connection port
Line In	Audio line in port
Line Out	Audio line out port
Video Out	Video out bay, orange, labeled either "**Aux**" for auxiliary (on Core); **L** (left) and **R** (right) (on Surgeon Console); or **1** and **2** (optional bays on Core)

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
TilePro Input	Video in bay, blue
FIBER	Fiber cable (system cable) receptacle
BRAKE	Indicates the brakes on the Surgeon Console, applied by stepping down
	Indicates where to push the Surgeon Console
	Hand control clutch
	Arm swap
	Tip hazard during transport Stow touchscreen and close rear door before moving cart
	Do not move Surgeon Console from the back
	Move Surgeon Console using handles on side
	Dispose of in accordance with local regulations—particularly applies to electronic components
	Fiber cable (system cable) receptacle
	Caution: Laser hazard
	Video output format of associated output ports is configurable on the touchscreen Select the Video Output screen on the Settings tab

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	Energy activation cable connection port
	Video out bay, left video channel; video has no overlays A similar label appears for the right video channel
	Surgeon head-in sensor
	Pinch/Crush Hazard
EPO	Emergency Power Off
	Interference may occur in the vicinity of equipment marked with this symbol
	Speaker connection port
	Microphone connection port
	The surgeon’s instruments have been reassigned Tap ‘Swap’ pedal to acknowledge and continue
	OnSite not connected
	OnSite connected

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	OnSite Session In Progress
	Not for human use
	Home tab
	Instrument tab
	Display tab
	Settings tab
	Guided setup tab
	Fault tab
	Login tab
	Table tab
	Brightness control
	3D Calibration
	Adjust left
	Adjust right

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	Adjust up
	Adjust down
	Color bars
	Color Balance
	Troubleshooting
	Reset defaults
	Software version
	System Name (serial number)
	Video 3D input
	Video 3D output
	Video graphics output
	Video 1 output

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	Video 2 output
	Video auxiliary output
	Targeting not valid
	Targeting is valid
	Emergency Stop has been activated. Tap (press) **Resume Use** to continue.
	General information
	General alert / recoverable fault
	General warning / non-recoverable fault
	A fault has occurred on an arm
	A fault has occurred on the endoscope arm
	A recoverable fault has occurred on the left hand control

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	A recoverable fault has occurred on the right hand control
	A non-recoverable fault has occurred on the left hand control
	A non-recoverable fault has occurred on the right hand control
	Arm 1 is not mapped to any hand control
	Arm 2 is not mapped to any hand control
	Arm 3 is not mapped to any hand control
	Arm 4 is not mapped to any hand control
	Arm 1 is mapped to the left hand control
	Arm 2 is mapped to the left hand control
	Arm 3 is mapped to the left hand control
	Arm 4 is mapped to the left hand control

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	Arm 1 is mapped to the right hand control
	Arm 2 is mapped to the right hand control
	Arm 3 is mapped to the right hand control
	Arm 4 is mapped to the right hand control
	Arm 1 has been paused (for example, during camera or endoscope control)
	Arm 2 has been paused (for example, during camera or endoscope control)
	Arm 3 has been paused (for example, during camera or endoscope control)
	Arm 4 has been paused (for example, during camera or endoscope control)
	Arm 1 has been clutched
	Arm 2 has been clutched
	Arm 3 has been clutched
	Arm 4 has been clutched

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	A fault has occurred on arm 1
	A fault has occurred on arm 2
	A fault has occurred on arm 3
	A fault has occurred on arm 4
	Arm 1 can be swapped with the swap pedal
	Arm 2 can be swapped with the swap pedal
	Arm 3 can be swapped with the swap pedal
	Arm 4 can be swapped with the swap pedal
	Left primary instrument function pedal
	Left secondary instrument function pedal
	Right primary instrument function pedal
	Right secondary instrument function pedal
	The direction (30° up or down) is unknown
	A zero degree endoscope is installed
	A 30° down endoscope is installed

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	A 30° up endoscope is installed
1x	Endoscope digital magnification is 1x
2x	Endoscope digital magnification is 2x
4x	Endoscope digital magnification is 4x
	Endoscope rotation unknown
	Endoscope horizon indicator
	Match grips on left hand control by squeezing
	Match grips on right hand control by squeezing
	Match grips on left hand control by squeezing, warning indicates that instrument is currently off-screen
	Match grips on right hand control by squeezing, warning indicates that instrument is currently off-screen
	Match grips on left hand control by rotating the grip

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	Match grips on right hand control by rotating the grip
	Relax hold on the left hand control to continue
	Relax hold on the right hand control to continue
	Left hand control is not free to move
	Right hand control is not free to move
	Excessive force is being applied to an arm
	Problem with the cannula
	General information regarding an instrument or arm

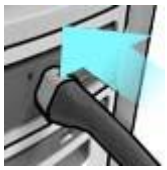
(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	Instrument is being clutched
	An instrument guided tool change is in progress
	A problem has occurred on an instrument or arm
	The instrument is in the cannula and should be advanced in order to allow the surgeon to take control
	Informative message about the instrument, for example, data is being downloaded to the instrument
	A problem has occurred involving the instrument, for example, the instrument data is invalid
	Camera is at a rotation limit
	Informative message about the scope, for example, the endoscope installed on an arm does not match the endoscope plugged in to the vision cart

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	A problem has occurred with the endoscope, for example, the camera or endoscope internal data is invalid
	The endoscope is not plugged in to the vision cart
	The user should hit the swap pedal to acknowledge the message on the screen and continue
	Close message box
	Video in
	Targeting button / Left-Right eye swap
	Swap scope up / down
	Audio volume
	Microphone unmuted
	Clear telestration marks
	Take photo
	Instrument inventory
	Illuminator on/off

(continues on next page)

Table D.1 Symbols and Icons (continued)

Symbol or Icon	Meaning
	Illumination on/off
	White balance
	Firefly fluorescence imaging
	Audio controls Variations of this icon display depending on the status of the control.
	Take photo Variations of this icon display depending on the status of the control.
	Brightness adjustment
	Hide/Show messages

D.3 Audio Messages (Voice Annunciation)

In certain situations the da Vinci system produces voice annunciation messages to help the user understand the system status and what needs to be done. Table D.2 contains a list of example audio voice annunciation messages and the situations in which they may occur.

Table D.2 Example Audio Messages

Situation	Voice Annunciation
Running on Battery	"Da Vinci is running on battery."
Running on Battery and Battery Low	"Battery Low. Plug da Vinci into a power outlet."
System ready (initialized and past self-test)	"Da Vinci is ready."
Shutdown initiated	"Da Vinci is shutting down."
During Guided Setup, when the user should make the arms compact	"Push all arms behind the green laser line."

(continues on next page)

Table D.2 Example Audio Messages (continued)

Situation	Voice Annunciation
During Guided Setup, after the first cannula has been connected	"Now install the endoscope for targeting."
During Guided setup, if the user attempts to drive the cart prior to deploying for docking	"Press the Deploy for Docking button to continue Guided Setup."
During Guided Setup, when the system is ready to be rolled into position over the patient	"Drive the laser lines to the endoscope port."
During Guided Setup, after the user has installed the endoscope and the system is ready for the targeting step	"Point the scope at the target anatomy, then press and hold the targeting button."
When the user initiates targeting, but releases the targeting button prior to completion	"Targeting did not complete."
When targeting cannot complete because of lateral range-of-motion limitations in the system	"Targeting could not complete. Consider un-docking and driving the laser lines to the endoscope port."
The system could not reach the optimal height for docking and sterile clearance	"Targeting could not complete. da Vinci could not reach its optimal height for sterile clearance."
Targeting completes successfully	"Targeting Complete. Dock the remaining arms."
Targeting can only be performed with one arm docked. If the user docks multiple arms right away, the targeting prompt will be skipped.	"Workspace may be limited if targeting is skipped."

End of Section

Appendix E System Specifications

Contents

E.1 Design Life E-1
E.2 Power Requirements – Main Components E-1
E.3 Power Specifications – Main Components E-4
E.4 Power Specifications – Vision Cart Components E-5
E.5 Power Specifications – Integrated Equipment E-5
E.6 Laser Specifications – Patient Cart E-6
E.7 Physical Dimensions E-6
E.8 Environmental Specifications E-7
E.9 Crate Dimensions E-7
E.10 Electromagnetic Compatibility E-7
E.11 Wireless Communication E-16

E.1 Design Life

The da Vinci system has a design life of five years; however, even after five years, the standard maintenance contract provides for preventive maintenance, inspection and re-qualification by qualified Intuitive personnel that extends the service life of the system until the next scheduled service, which occurs at least every two years.

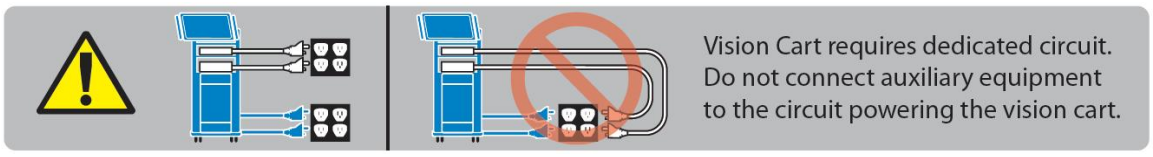
E.2 Power Requirements – Main Components

The system has three main components requiring electrical power: the Surgeon Console, the Patient Cart, and the Vision Cart. The integrated VIO dV electrosurgical unit also requires electrical power. To ensure optimum performance, make sure each component of the system (including the VIO dV) is connected to a dedicated, noise-free and well-grounded AC power outlet.

⚠ **CAUTION:** To avoid overloading circuits, all three components – Vision Cart, Patient Cart, and Surgeon Console – must operate on separate, dedicated power circuits. Do not connect ancillary devices such as insufflators or energy devices on the same circuit as the system components, particularly the Vision Cart because it has large power requirements. Ancillary devices must be connected to wall outlets on separate circuits from all system components.

A label on the rear of the Vision Cart reinforces this caution. Its text appears below the label image.

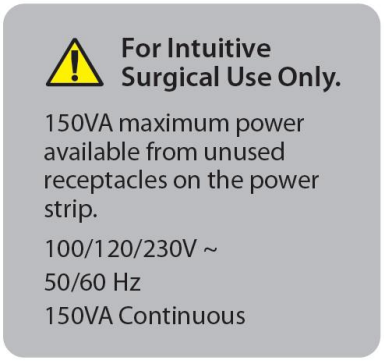
Figure E.1 Vision Cart Power Caution Label



"Vision Cart requires dedicated circuit. Do not connect auxiliary equipment to the circuit powering the Vision Cart."

The integrated power strip in the Vision Cart also has the label below:

Figure E.2 Vision Cart Integrated Power Strip Caution Label



For Intuitive Surgical Use Only.

150VA maximum power available from unused receptacles on the power strip.

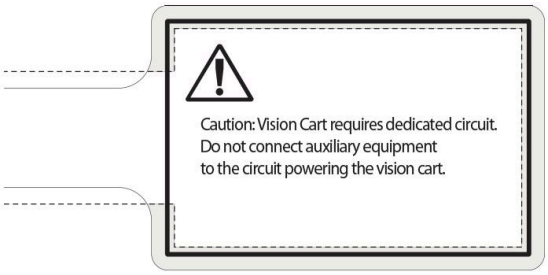
100/120/230V~

50/60 Hz

150VA Continuous

A label wrapped around the Vision Cart power cord also reinforces this point:

Figure E.3 Vision Cart Power Cord Caution Label



Caution: Vision Cart requires dedicated circuit. Do not connect auxiliary equipment to the circuit powering the Vision Cart.

The tables below provides dedicated circuit requirements for each component.

Table E.1 Dedicated Circuits Required for 115 VAC, 60 cycle at 15 Ampere

System Component	Circuit	Voltage VAC	Ampere Service
Surgeon Console 1	1	115	15
Surgeon Console 2 (optional)	2	115	15
Patient Cart	3	115	15
Vision Cart	4	115	15[a]
VIO dV (integrated electrosurgical unit (ESU)) (optional) This circuit can be shared with other auxiliary devices such as an insufflator, third-party electrosurgical unit, video recorder, etc.	5	115	As needed

Notes

a. Circuit breaker for the Vision Cart needs to be suitable for motor-transformer loads. (For example, tripping characteristic “K”.)

Table E.2 Dedicated Circuits Required for 230 VAC, 50 cycle at 10 Ampere

System Component	Circuit	Voltage VAC	Ampere Service
Surgeon Console 1	1	230	10
Surgeon Console 2 (optional)	2	230	10
Patient Cart	3	230	10
Vision Cart	4	230	10[a]
VIO dV (integrated electrosurgical unit (ESU)) (optional) This circuit can be shared with other auxiliary devices such as an insufflator, third-party electrosurgical unit, video recorder, etc.	5	230	As needed
Notes a. Circuit breaker for the Vision Cart needs to be suitable for motor-transformer loads. (For example, tripping characteristic "K".)			

The Surgeon Console, Patient Cart, and Vision Cart automatically adapt to 100–230 VAC. This technique is called "Auto Sense". (See table below.) Refer to the electrical rating label located on the bottom rear panel of the da Vinci system components.

Table E.3 Auto Sense

System Component	Voltage	Rating
Surgeon Console	100-230 V~ 50/60 Hz Auto Sense	1000 VA Continuous
Patient Cart	100-230 V~ 50/60 Hz Auto Sense	1200 VA Continuous
Vision Cart– includes Core, Endoscope Controller and Video Processor	100-230 V~ 50/60 Hz Auto Sense	1500 VA Continuous
Core[a,b]	100-230 V~ 50/60 Hz Auto Sense	650 VA Continuous
Endoscope Controller[a]	100-230 V~ 50/60 Hz Auto Sense	450 VA Continuous

(continues on next page)

Table E.3 Auto Sense (continued)

System Component	Voltage	Rating
Video Processor[a]	100-230 V~ 50/60 Hz Auto Sense	175 VA Continuous

Notes

a. Core, Endoscope Controller power requirements are included in the Vision Cart. These are provided separately for reference only.

b. If any of the carts in the system are to be run on voltage higher than 120 VAC in the U.S., it must be powered from a center-tapped, single phase circuit.

E.3 Power Specifications – Main Components

Table E.4 Power Specifications for Main Components

	Surgeon Console	Patient Cart	Vision Cart (Includes Core, Video Processor, and Endoscope Controller)
Voltage	100-230 VAC 50/60 Hz Auto Sense	100-230 VAC 50/60 Hz Auto Sense	100-230 VAC 50/60 Hz Auto Sense
Rating and Typical Current	1000 VA Continuous 8.4 A at 115 V~ 4.2 A at 230 V~	1200 VA Continuous 7.5 A at 115 V~ 3.8 A at 230 V~	1500 VA Continuous 12 A at 115 V~ 6 A at 230 V~
Typical current in sleep mode	0.7 A at 115 V~ 0.35 A at 230 V~	1.0 A at 115 V~ 1.0 A at 230 V~	2.0 A at 115 V~ 1.2 A at 230 V~
Typical current in sleep mode (battery charging)	NA	8.5 A at 115 V~ 4.6 A at 230 V~	NA
Max inrush current at 230 VAC	24.1 A	56.0 A	63.6 A
Backup Power	NA	5 min	NA
Surge Protected	Yes	Yes	No

E.4 Power Specifications – Vision Cart Components

	Core[a,b]	Endoscope Controller	Video Processor
Voltage	100–230 VAC 50/60 Hz Auto Sense	100–230 VAC 50/60 Hz Auto Sense	100–230 VAC 50/60 Hz Auto Sense
Power	650 VA Continuous	450 VA continuous	175 VA continuous
Backup Power	NA	NA	NA
Surge Protected	No	No	No

Notes

a. Core power requirements are included in the Vision Cart. These are provided separately for reference only.

b. If the Core is powered separately from the Vision Cart, it must be powered from a center-tapped, 240 V, single phase circuit. This requirement applies to the U.S. only.

E.5 Power Specifications – Integrated Equipment

Table E.5 Power Specifications for Integrated Equipment (VIO dV)

	VIO dV (electrosurgical unit)
Voltage	100–120 or 220–240 VAC 50/60 Hz T8 A/T4 A
Power	920 VA max
Backup Power	NA

E.6 Laser Specifications – Patient Cart

Table E.6 Patient Cart Laser Classification

 **CLASS 1 LASER PRODUCT** **Complies with 21 CFR 1040.10 and 1040.11** **Except for deviations pursuant to laser notice No. 50** **Dated June 24, 2007**		
Feature/Light Source	**Laser Class**	**Specification**
Horizontal Laser	Class 1	EN 60825-1
Positioning Laser	Class 1	EN 60825-1

Table E.7 Patient Cart Laser Radiation and Source Characteristics

Feature/Light Source	Wavelength	Specification
Horizontal Laser	520 nm ± 10 nm	IEC 60825-1
Positioning Laser	520 nm ± 10 nm	IEC 60825-1

E.7 Physical Dimensions

The values listed below represent the weight and dimensions of each cart once it has been fully installed.

	Surgeon Console	Patient Cart	Vision Cart
Height (min)	57 in. (145 cm)	71.5 in. (182 cm)	76 in. (193 cm) with touchscreen stowed
Height (max)	71 in. (180 cm)	98.5 in. (250.2 cm)	87.5 in. (223 cm) with touchscreen extended
Width	38 in. (96.5 cm)	41 in. (104 cm)	27 in. (68.6 cm)
Depth	34 in. (86 cm)	60 in. (150 cm)	36.5 in. (92.7 cm)
Weight	620 lbs. (281 kg)	1900 lbs. (861 kg)	887 lbs. (402 kg) including auxiliary equipment
Ground Clearance	1.9 in. (48 mm)	1.9 in. (48 mm)	4 in. (10.2 cm)

E.8 Environmental Specifications

Table E.8 Environmental Conditions: Operating

Environmental Conditions: operating	
Temperature:	10 to 30 °C (50 to 86 °F)
Humidity:	10 to 85% non-condensing
Atmospheric Pressure:	The da Vinci system shall function properly in atmospheric pressures ranging from 523 mm HG (10,000 ft) to 774 mm HG (-500 ft). For every 1000 feet above sea level, the 30 °C operational temperature limit specified above will be reduced by 1 °C. (For example, the maximum operating temperature at 5000 feet will be 25 °C, and the maximum operating temperature at 10,000 feet will be 20 °C.)

Table E.9 Environmental Conditions: Storage and Transport

Environmental Conditions: Storage and Transport	
Temperature:	-20 to 60 °C (-4 to 140 °F)
Humidity:	5 to 90% non-condensing

Note: Storage and transport of the system are not affected by atmospheric pressure.

E.9 Crate Dimensions

The values below represent the shipping weight and dimensions for each cart. Note that some components on the Vision Cart ship separately.

	L x W x H	Weight
Surgeon Console	46" x 48" x 65.5" (1.17 m x 1.22 m x 1.66 m)	793 lbs (360 kg)
Patient Cart	70" x 50" x 78" (1.78 m x 1.27 m x 1.98 m)	2400 lbs(1089 kg)
Vision Cart	44" x 48" x 82" (1.12 m x 1.22 m x 2.08 m)	788 lbs (357.4 kg)

E.10 Electromagnetic Compatibility

The system has been tested and found to be in compliance with IEC 60601-1-2:2007 or IEC 60601-1-2:2014, depending on the date of manufacture. For more information on IEC compliance, contact Intuitive Customer Service.

It is intended to be used in an operating room environment and operation of the system is unaffected when used in the electromagnetic environment as specified in Tables 2 – 4 in the EMC Tables section. Special precautions and installation information for the system for electromagnetic compatibility (EMC) are provided in this section.

The performance of the system is unaffected when exposed to full range of electromagnetic environment as described in the IEC 60601-1-2 standard. There is no degradation of performance and therefore no risks to the patient or other devices due to Electromagnetic Interference (EMI) when used in the electromagnetic environment as specified in Tables 2 – 4 below in the EMC Tables section.

Use only Intuitive branded interconnection cables and accessories. Performance of cables or accessories other than those specified by Intuitive as replacement parts for internal components cannot be guaranteed. Any resulting damage to the system will not be covered under warranty.

WARNING: Use of cables or accessories other than those specified by Intuitive may result in increased electromagnetic emissions or decreased immunity of the system. If current leaks, patient or user harm can result.

Equipment in the operating room, including the system and other portable or mobile communications equipment, can produce Electromagnetic Interference (EMI), which may affect the function of these devices. Such effects are prevented by use of equipment with EMI characteristics proven below recognized limits, as identified in the EMC tables.

WARNING: The system should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it is used. If current leaks, patient or user harm can result.

WARNING: Be aware of hazards related to wireless interference to prevent erroneous system behavior or potential patient harm. For information to restart the system, see B.7 Restart the System on page B-7.

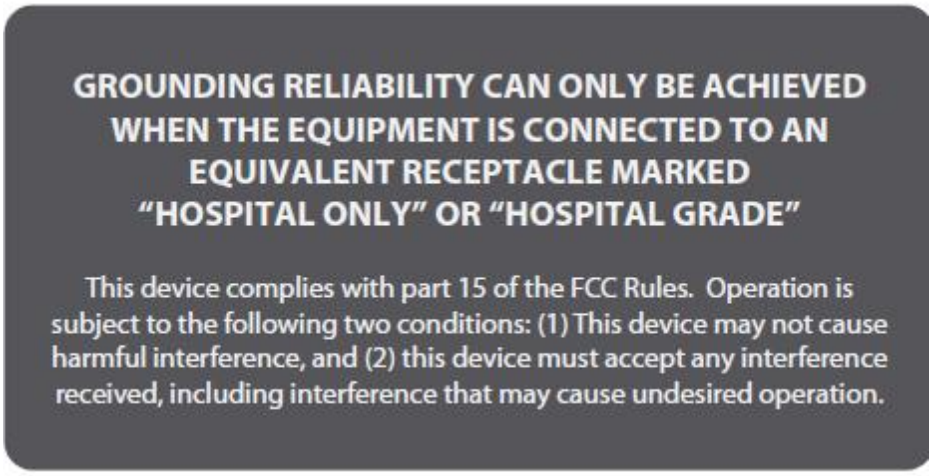
WARNING: Symptoms of interference could include repeated faults, unintentional movement of arms, instruments or endoscope, loss or frozen video, loss of wireless connectivity. In the event of suspected interference from other equipment, which prevents the proper functioning of the system, contact Intuitive and discontinue use of the system until the problem can be remedied.

Note: This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

FCC Compliance

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their own expense.

In regard to grounding reliability and electromagnetic interference, see the label below, which appears on the Surgeon Console and Patient Cart. Its text is repeated below the label image:



GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN THE EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED "HOSPITAL ONLY" OR "HOSPITAL GRADE"

This device complies with part 15 of the FCC Rules. operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Essential Performance

The essential performance for the system during EMC testing was defined as follows during the required tests.

- The system shall display a real-time image of the surgical site with acceptable clinical performance. If the displayed image is not live, such as when displaying a recorded image or in the event of system malfunction, it shall be obvious to the user that the displayed image is not a live image. There shall be no uncontrolled or unexpected motions of the endoscope or instrument tips.
- To meet the basic safety and essential performance criteria during immunity testing, the following conditions are not allowed:
  - Faults that cause system restart while in READY MODE — HEAD IN state unless allowed by the Medical standard
  - Unintentional movement of the arms
  - Loss or frozen image where transient flicker is acceptable

- Persistent loss of wireless connectivity. The loss of connectivity is acceptable if the connection can be re-established after the test.

EMC Tables

IEC 60601-1-2:2007

The system has been tested and found to be in compliance with IEC 60601-1-2:2007 International standard for Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

The following tables contain the Manufacturer's declaration and additional information required by IEC 60601-1-2:2007.

Table 1: IEC 60601-1-2:2007, Manufacturer's Declaration - Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic environment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2: IEC 60601-1-2:2007, Manufacturer's Declaration - Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	NA
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a U.S. commercial or hospital environment with highly reliable service.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a U.S. commercial or hospital environment with highly reliable service.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec.	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a U.S. commercial or hospital environment with highly reliable service. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage before application of the test level.			

Table 3: IEC 60601-1-2:2007, Manufacturer's Declaration - Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 **Radiated RF IEC 61000-4-3**	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Notes

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the system.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: IEC 60601-1-2:2007, Recommended separation distances between portable and mobile RF communications equipment and the system

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter watts (W)	Separation distance according to frequency of transmitter meters (m)		
	150 kHz – 80 MHz $d = 1.2\sqrt{P}$	80 MHz – 800 MHz $d = 1.2\sqrt{P}$	800 MHz – 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

IEC 60601-1-2:2014

During immunity testing, in order to meet the basic safety and essential performance criteria, the following conditions are not allowed:

- Non-recoverable faults that require system power cycling to recover (unless specifically allowed by the Medical standard IEC 60601-1-2)
- Unintentional movement of the arms or instruments
- Loss or frozen image (temporary image degradation is acceptable)
- Persistent loss of connectivity for the Wireless Connectivity Option
- Loss of instrument recognition by the system or integrated electrosurgical Unit (ESU)
- Unintentional ESU energy delivery

The following tables contain the Manufacturer's declaration and additional information required by IEC 60601-1-2:2014.

Table 1: IEC 60601-1-2:2014, Manufacturer's Declaration - Electromagnetic Emissions		
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic environment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 2: IEC 60601-1-2:2014, Manufacturer's Declaration - Electromagnetic Immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV ±4 kV ±8 kV ±15 kV air	±8 kV contact ±2 kV ±4 kV ±8 kV ±15 kV air	NA
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a U.S. commercial or hospital environment with highly reliable service.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a U.S. commercial or hospital environment with highly reliable service.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 250 cycles	<5% UT (>95% dip in UT) for 0.5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 250 cycles	Mains power quality should be that of a U.S. commercial or hospital environment with highly reliable service. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC mains voltage before application of the test level.			

Table 3: IEC 60601-1-2:2014, Manufacturer's Declaration - Electromagnetic Immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM/ Amateur band	3 Vrms 6 Vrms	Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 9 V/m to 28 V/m Proximity fields	3 V/m 9 V/m to 28 V/m	
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. In all cases, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the system.			

E.11 Wireless Communication

Overview

There are three types of wireless communication used by the da Vinci system: Radio Frequency Identification (RFID), Table Motion IEEE 802.15.4 (ZigBee), and infrared (IR).

RFID communication is used by the da Vinci system to detect and identify instruments and endoscopes that are installed on the system.

In the event of suspected interference from other equipment, which prevents the proper functioning of the da Vinci system, contact Intuitive and/or discontinue use of the system until the problem can be remedied. The RFID transceiver within the da Vinci system has been tested and found to be in compliance with IEC 14443 requirements for Type B Proximity Contactless Identification Cards. The effective radiated power is less than -90 dBm.

ZigBee and IR wireless communication is used by the da Vinci system, when the table motion feature is enabled, to allow pairing and system communication between the operating table and the da Vinci system.

Note: Due to the intentional use of wireless communication, the da Vinci system may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

Specification

RFID communication is at 13.56 MHz, and complies with the following standards:

- ISO/IEC 14443 Type B

ZigBee communication is at 2.405-2.480 GHz, and complies with the following standards:

- IEEE 802.15.4
- Modulation type is O-QPSK (Offset Quadrature Phase Shift Keying) with an RF bandwidth of 2 MHz, and an output power (Watts, EIRP) of 0.000603, Emission Designation 1M67G1D

Security

RFID

- Mutual authentication (using a pre-shared key) is conducted between the da Vinci and the RFID tag.
- Data transmitted between the da Vinci and the RFID tag is encrypted using a Secure Hash Algorithm.

ZigBee

- Custom Communications protocol is used between the operating table and the da Vinci system.

RFID Module and ZigBee Information

The da Vinci system supports two models of RFID and ZigBee modules. Information about the model used in each system is indicated in the label on the Patient Cart vent panel.

Figure E.4 Location of RFID and ZigBee model information

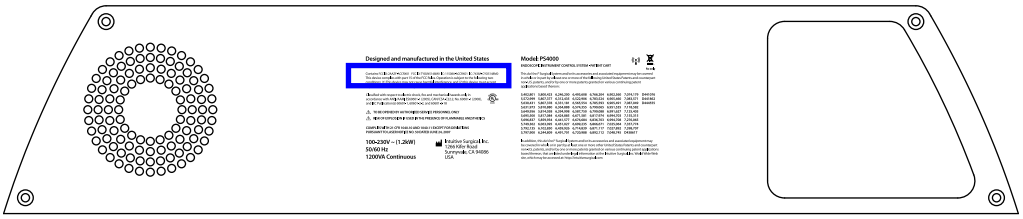


Table E.10 RFID module and ZigBee information

Model	FCC ID	IC
ACCRX01 JN5148-T01-M00	2AAZF-ACCRX01 TYOJN5148M0	11508A-ACCRX01 7438A-CYO5148M0
ACCRX02 ISM-Module TruSystem ANY	2AAZF-ACCRX02 2AGCQANY2400SC1REV0	11508A-ACCRX02 20829-0ANY2400SC1

RFID ACCRX01 and ACCRX02

The Intuitive Surgical Inc. RFID models ACCRX01 and ACCRX02 are RFID 13.56 MHz transceiver modules that are intended to assist in the accurate control of endoscopic instruments.

Per MIIT Announcement [2019] No. 52 and its attachment "Micro Power short-range radio transmission equipment category and technical requirements". RFID models ACCRX01 and ACCRX02 should be categorized as Class C.

The RFID only works in ASK mode, the modulation mode is not adjustable / changeable by the user. The RFID has no separate power switch. It would be installed in and powered from the Patient Side Cart (PSC). Technical specifications are listed in the following tables.

Table E.11 Technical Specifications

Specification Name	Specification
Equipment name	da Vinci system with RFID model ACCRX01 or ACCRX02
Antenna type	Integrated antenna on PCB
Main function	Data transfer
Modulation mode	ASK
Frequency range	13.56 MHz
Frequency tolerance	≤100 ppm
Transmitting power	≤42 dBμA/m (at 10 m, quasi-peak value)
Spurious emission limits	≤27 dBμA/m (at 10 m, quasi-peak value)

(continues on next page)

Table E.11 Technical Specifications (continued)

Specification Name	Specification
Working temperature	+10°C to +30°C
Working voltage	3.3 VDC

Table E.12 Frequency Range of measuring Radiated Spurious Emission

Working frequency range	Measured frequency range of spurious radiation	
	Lower limit	Upper limit
9 kHz – 100 MHz	9 kHz	1 GHz

Table E.13 Radiated Transmission Spurious Emission Limit

Trans-mission State	Frequency range	Test bandwidth	ACCRX01 test data	ACCRX02 test data	Limit	Detection mode
Transmitter with maximum power	9 – 150 kHz	200 Hz (6 dB)	-29.3 dBµA/m at 9.6 kHz	0.8 dBµA/m at 10 kHz	27 dBµA/m at 10 m (Drop by 3 dB per octave)	Quasi-peak value
	150 kHz – 10 MHz	9 kHz (6 dB)	-32.7 dBµA/m at 644 kHz	-12.3 dBµA/m at 635 kHz		
	10 – 30 MHz	9 kHz(6 dB)	-39.4 dBµA/m at 27.144 MHz	-13.9 dBµA/m At 13.56 MHz	-3.5 dBµA/m at 10 m	
	30 MHz – 1 GHz	100 kHz (3 dB)	-60.2 dBm at 176.28 MHz	-64.7 dBm at 189.846 MHz	-36 dBm	RMS
Transmitter standby or idle	9 – 150 kHz	200 Hz (6 dB)	-28.5 dBµA/m at 9.5 kHz	-48.0 dBµA/m at 12 kHz	6 dBµA/m at 10 m (Drop by 3 dB per octave)	Quasi-peak value
	150 kHz – 10 MHz	9 kHz (6 dB)	-34.2 dBµA/m at 581 kHz	-60.5 dBµA/m at 150 kHz		
	10 – 30 MHz	9 kHz (6 dB)	-50 dBµA/m at 20 MHz	-39.3 dBµA/m at 29.649 MHz	-24.5 dBµA/m at 10 m	
	30 MHz – 1 GHz	100 kHz (3 dB)	-63.5 dBm at 527.33 MHz	-68.73 dBm at 192.003 MHz	-47 dBm	RMS

Wireless Connectivity Option Overview

A wireless bridge is installed on the da Vinci Xi system to enable the Wireless Connectivity Option. A hospital-supplied Wireless Access Point with Internet access is required to establish wireless connectivity.

Note: The Ethernet networks (both wired and wireless) are subject to losses of connectivity that could disrupt use of OnSite or make data unreliable when it is received at a remote location. Such disruptions, if they occur, have no effect on the performance or functionality of the da Vinci system.

Specification

- The Wireless Connectivity Option utilizes the IEEE 802.11 wireless standard using either 802.11b or 802.11g at 2.4 GHz Industrial, Scientific, and Medical (ISM) band.
- The Wireless Bridge operates as a client to the hospital supplied Wireless Access Point, transmitting data back and forth between the hospital network and da Vinci applications.
- The Wireless Access Point must be located within 75 feet (22.86 m) of the system.

Security

Wireless Network Infrastructure

- Intuitive has tested the Wireless Connectivity Option in WPA2 pre-shared key mode with AES encryption, and recommends that the Wireless Connectivity Option is integrated into the hospital network using this security configuration.

OnSite Software Application

- The OnSite Software Application uses a Secure Socket Layer (SSL) session based on unique certificates on the system and the OnSite server.
- Data being transmitted from the system to the server is 128–bit encrypted.

Quality of Service

Wireless Bridge

- Uses a maximum latency of 50 ms between the Wireless Bridge and the hospital supplied Wireless Access Point.
- Uses a wireless channel that has 20% or less utilization.

Overall Network

- Maximum end to end packet loss of less than 10%
- Network latency should not exceed 300 ms

Wireless Coexistence

Wireless coexistence with other devices that transmit in the 13.56 MHz range is a concern since it can impact the reliability of the system RFID communication. This section summarizes the testing conducted by Intuitive in an environment with other wireless devices representative of a typical operating room to demonstrate that the RFID communication functioned as expected. The test setup represented the worst case system setup, and the position of the common wireless devices was defined to ensure that they were located near the RFID transmitter and receiver.

For the RFID communication in the 13.56 MHz range, the common wireless device we expect to encounter is an RFID tag reader typically used for inventory control. In the testing conducted, we used a Socket Antimocrobial hand-held SoMo 655Rx RFID Reader as a representative device.

Wireless coexistence with other devices that transmit in the 2.4 GHz range is a concern since it can impact the reliability of system communication with the operating table. This section summarizes the testing conducted by Intuitive in an environment with other wireless devices representative of a typical operating room to demonstrate that the operating table communication functioned as expected. The test setup represented the worst-case system setup, and the position of common wireless devices was defined to ensure they were located near the operating table transmitters and receivers.

For operating table wireless communication in the 2.4 GHz range, the common wireless devices we expect to encounter are other 802.15.4 wireless modules. In the testing conducted, we used a ZigBee 2.4 GHz 802.15.4 as a representative device.

For IR communication, the common devices we expect to encounter are IR remote controls and IR barcode scanners. In the testing conducted, we used a ViewSonic IR remote control as a representative device.

Note: If different types of wireless or IR devices will be used in the operating room, or if the wireless or IR devices are used in different locations than what is described, then Intuitive recommends that performance is tested with the devices active before use. If issues using wireless or IR in the presence of other wireless devices in the operating room, contact Intuitive Customer Service.

Note: The wireless coexistence testing conducted by Intuitive does not cover use in the presence of MRI or diathermy machines.

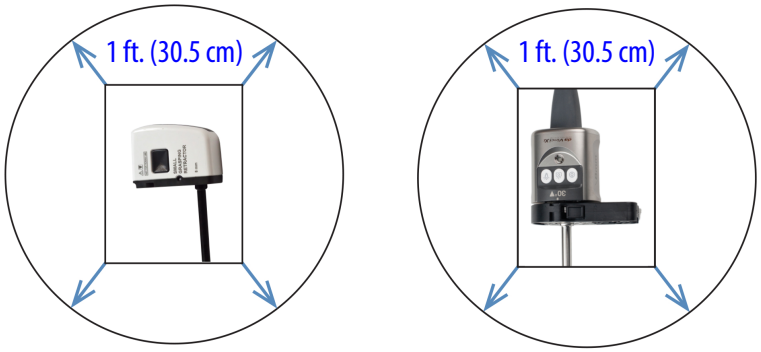
Devices Known to Interfere

RFID Readers

Testing conducted by Intuitive determine that RFID readers can disrupt RFID communication in certain configurations.

- Intuitive recommends keeping RFID readers (-67.5 dBm) at least 1 foot (30.5 cm) from the instrument or endoscope.

Figure E.5 Placement boundaries for RFID Readers



RFID Communication Problems

If instrument or endoscope detection problems occur when installing them on the system, Intuitive recommends doing the following:

- Determine if a device transmitting in the 13.56 MHz range is in the room, and if so, disable the device to see if it resolves the problem.

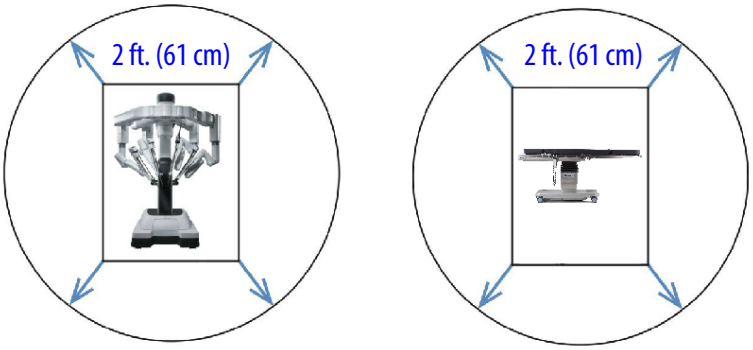
  If you are unable to resolve the problem, contact Intuitive Customer Service.

IR Transmitters

Testing conducted by Intuitive determined that IR Transmitters can disrupt operating table communication in certain configurations.

- Intuitive recommends keeping IR Transmitters at least 2 feet (61 cm) from the Patient Cart column and/or the operating table column.

Figure E.6 Placement boundaries for IR Transmitters



Operating Table Communication Problems

If wireless signal disturbance occurs between the operating table and the da Vinci system, Intuitive recommends the following:

- Determine if a device transmitting in IR spectrum is in the room, and if so, disable the device to see if it resolves the problem.
- Connect the optional connection cable (Trumpf PN 1816914) and pair the da Vinci system to the operating table with the wired connection.

If you are unable to resolve the issue, contact Intuitive Customer Service.

End of Section

Appendix F Video and Audio Connections

Contents

F.1 Video and Audio Connections F-1
F.2 Select Video Output. F-4

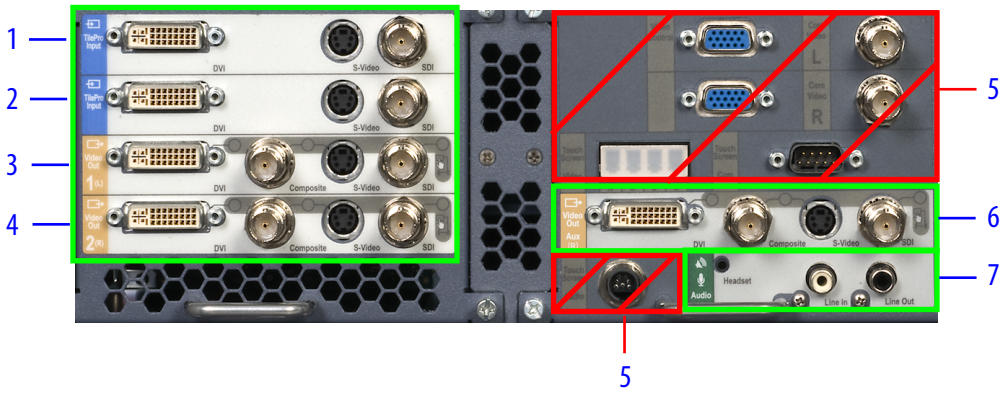
F.1 Video and Audio Connections

The back of the Vision Cart has six auxiliary connection bays: two for video input, three for video output and one for audio input/output. Each bay has 3-4 connectors, but supports use of only one connection at a time. A connection panel on the back of the Surgeon Console supplies the default TilePro inputs. Additionally, the back of the Video Processor has two video outputs. For additional information, see the Core Connections Diagram on page F-4.

Note: Each input and output bay supports only one video format at a time.

Vision Cart Connections

Figure F.1 Video and audio connections on back of Vision Cart



1. TilePro Input (L)
2. TilePro Input (R)
3. Video Out bay 1
4. Video Out bay 2
5. Not for connection by users
6. Video Out bay Aux
7. Audio In/Out

Note: Connectors on the Vision Cart labeled with gray text on a dull background, as those indicated by red boxes in Figure F.1 above, are connected as necessary by authorized Intuitive personnel when they install or service the system. Therefore no instructions are provided for connecting them in this user manual, although the labels themselves are described in Appendix D Symbols, Icons, Audio Messages on page D-1. **Do not unplug any of these connections.**

Surgeon Console Connections

- The Video Out L and Video Out R bays on the Surgeon Console support transmission of the left and right eye video seen in the Surgeon Console via DVI connection. These bays operate independently from the optional Video Out 1 and Video Out 2 bays on the Core.
- The Audio bay supports transmission of Surgeon Console audio with connectors for RCA output (Line Out), RCA input (Line In) and a 2.5 mm input/output headset jack (Headset).

Figure F.2 Connections on back of Surgeon Console



1. TilePro in (L)
2. TilePro in (R)
3. Video out (L)
4. Video out (R)
5. Audio

WARNING: Be careful to use the system electrical components safely and effectively to prevent electrical shock.

WARNING: To avoid an electrical hazard, do not touch the patient while touching any connectors at the same time.

Vision Cart Video Outputs

The Vision Cart has three video output bays (Figure F.1).

- **Video Out 1 (L)**
- **Video Out 2 (R)**
- **Video Out Aux (R)**

Video output from all three can include the icons and text messages displayed in the Surgeon Console. The (L) or (R) indicates the video source is from the left or right eye. Each video output bay supports a single DVI, HD-SDI, S-Video, or Composite signal.

Video Processor Video Outputs

Two auxiliary video outputs are available on the back of the Video Processor. The left-eye (L) and right-eye (R) DVI video outputs provide the surgical image without icons or text messages.

Surgeon Console Video Outputs

The Surgeon Console has two video output bays (Figure F.2).

- **Video Out L**
- **Video Out R**

Each bay has a single DVI connector, and transmits the indicated L (left) or R (right) eye video from the Surgeon Console, one of which can include the overlaid icons and text messages. These bays operate independently from the Video Out 1 and Video Out 2 bays on the Vision Cart; They are not configurable via the touchscreen, like those on the Vision Cart (see F.2 Select Video Output on page F-4).

Audio Inputs and Outputs

The Vision Cart (Figure F.1) and Surgeon Console (Figure F.2) each have three audio connectors.

- **Headset:** 2.5 mm input/output headset jack
- **Line In:** RCA input
- **Line Out:** RCA output

Video Inputs (TilePro)

All video inputs enable TilePro multi-image display mode in the Surgeon Console view. The Vision Cart has two TilePro video input bays (Figure F.1).

- **TilePro Input** (L)
- **TilePro Input** (R)

The Surgeon Console also has two TilePro video input bays (Figure F.2).

- **TilePro In** (L)
- **TilePro In** (R)

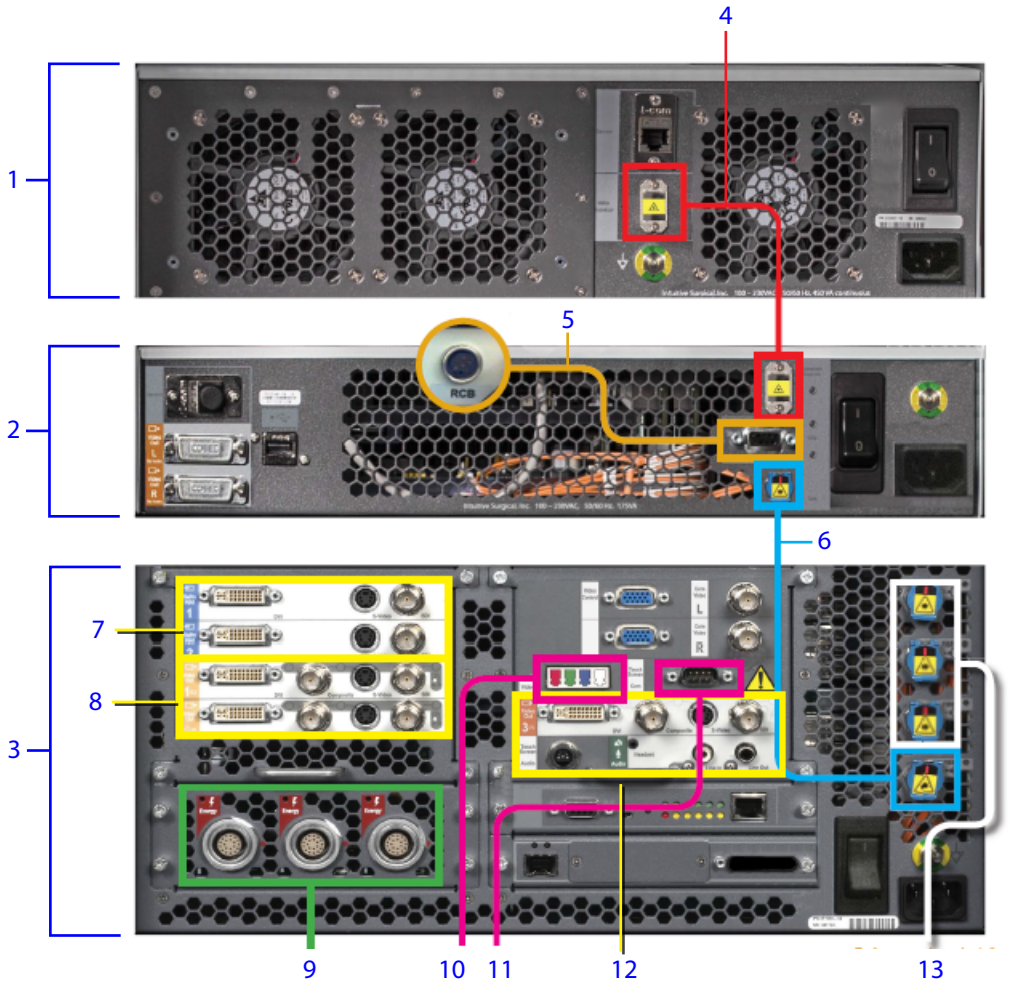
The (L) left and (R) right indicate in which eye's display the input video appears. Each video input bay accepts a single DVI, HD-SDI, or S-Video connection.

2D and 3D TilePro

TilePro multi-image mode enables the surgeon to see up to two additional video inputs in the three-dimensional (3D) viewer of the Surgeon Console, along with the live endoscopic video image. Most video sources connect using only one input connector, which yields a two-dimensional (2D) image. If dual consoles are present, activating TilePro on one console affects the other console.

- **3D TilePro**: To display a 3D TilePro video source in the 3D viewer, connect a compatible (stereo) video source to both the **TilePro** (L) and (R) connectors at once and tap **3D** on the touchpad.
- Considering the **TilePro Input** bays on the Core (see Figure F.1) along with those on the Surgeon Console, use either set of TilePro inputs, but not more than two.
- The system automatically checks for TilePro connections in order: first on the Core (if present), then on the Surgeon Console. The Core TilePro inputs take precedence if they are in use.

Core Connections Diagram



1. Endoscope Controller
2. Video Processor
3. Core
4. Endoscope Controller to Video Processor –fiber connector
5. Video Processor to VIO dV – DB-9 connector
6. Video Processor to Core – fiber connector
7. Core to TilePro video 1 – customer equipment
8. Core to Video in/out 2 – customer equipment
9. Core to ESUs – energy activation cables
10. Core to Vision Cart touchscreen – Video cable
11. Core to Vision Cart touchscreen – DB-9 serial port
12. Core to Video/audio in/ out 3 – Customer equipment
13. Core to Surgeon Console(s), Patient Cart – System cable

F.2 Select Video Output

Tap the **Settings** tab on the touchscreen and then tap **Video Input/Output** to adjust the video settings.

Figure F.3 Example of video output option selections



The software buttons on this screen correspond to the applicable Video Out connector bay as explained below in Table F.1.

Vision Cart Video Connections

Table F.1 Video Output Connections – Vision Cart

Connector Label	Connector Type	Output Format	Resolution
DVI	DVI-I	DVI (analog and digital)	Automatically configured[a]
		DVI (digital)	720p (1280 x 720 x 59.94Hz)
Composite	BNC	Composite (analog)	NTSC (720 x 486 x 29.97Hz) or PAL (720 x 576 x 25Hz)[b]
S-Video	4-pin mini-DIN	S-Video (analog)	NTSC (720 x 486 x 29.97Hz) or PAL (720 x 576 x 25Hz)[b]

(continues on next page)

Table F.1 Video Output Connections – Vision Cart (continued)

Connector Label	Connector Type	Output Format	Resolution
SDI	BNC	SD-SDI (digital)	NTSC (720 x 486 x 29.97Hz) or PAL (720 x 576 x 25Hz)[b]
		HD-SDI (digital)	720p (1280 x 720 x 59.94Hz)
		HD-SDI (digital)	1080i (1920 x 1080 x 29.97Hz)

Notes

a. Automatically configured video format supports XGA, SXGA, WXGA-Plus analog and digital; 720p digital only. Not all DVI receiving devices support automatic configuration. To ensure format 720p video output, select the **DVI-D (720p)** button instead.

b. NTSC or PAL is determined by country.

Table F.2 Video Input Connections – Vision Cart

Connector Label	Connector Type	Input Format	Resolution
DVI	DVI-I	DVI (analog and digital)	Automatically configured[a]
S-Video	4-pin mini-DIN	S-Video (analog)	NTSC (720 x 486 x 29.97Hz) and PAL (720 x 576 x 25Hz)
SDI	BNC	SDI (digital)	NTSC (720 x 486 x 29.97Hz) and PAL (720 x 576 x 25Hz)
		HD-SDI (digital)	1080i (1920 x 1080 x 29.97Hz) and 720p (1280 x 720 x 59.94Hz)

Notes

a. Automatically configured video format supports XGA, SXGA, WXGA-Plus analog and digital; 720p digital only.

Note: Each input and output bay supports only one video format at a time.

End of Section

Appendix G Natural Rubber Latex

For the following elastomeric/pliable Intuitive products referenced in this manual, materials that are intended to contact users or patients during normal use and handling are not made with natural rubber latex:

- Column Drape (20 pack), PN 470341
- Instrument Arm Drape (20 pack), PN 470015
- Energy Activation Cable, PN 371716

End of Section

Appendix H Representative Uses

This appendix provides supporting information for the representative uses in 1.4 Important Regulatory Information on page 1-3.

Contents

H.1 IS4000 Performance Data H-1
H.2 Additional Performance Data H-12

H.1 IS4000 Performance Data

Performance test data to support substantial equivalence to the predicate device and that the design output meets the design input requirements consist of bench testing, animal/cadaver validation, simulated clinical procedures in live animal, and Human Factor assessment.

Bench Verification

The bench testing conducted consisted of dimensional measurements, mechanical and functional verification, electrical safety, and reliability. For the IS4000, the Surgeon Console was not subjected to any bench testing since there was no change made to the hardware. Changes were made to the software, graphical user interface, and cosmetic changes that were tested as part of the overall system. The suites of bench tests are:

Table H.1 PSC Bench Tests

Test	Description
Design Verification–PSC	The purpose of these tests was to verify that the physical, mechanical, electrical, and system level requirements and design specifications were met for each sub-components of the Patient Cart (PSC). Sample size varied from 1 to 6 units depending on the test case. Test methods were based on predefined test procedures. Objective pass/fail criteria are defined and used. The following PSC sub-components were tested: • Cart Drive • Setup Structure (SUS) • Setup Joint (SUJ) • Universal Surgical Manipulator (USM) • PSC Overload Testing • Audio Intercom Hardware

Table H.2 VSC Bench Tests

Test	Description
Design Verification–VSC	The purposes of these tests was to verify the sub-components of the Vision Cart (VSC) met the functional requirements as defined in the applicable Functional Specification Documents. Sample size was 1 unit except for the Endoscope and Endoscope adapter where 4 to 5 units were tested. Test methods were based on predefined test procedures. Objective pass/fail criteria were defined and used. The following VSC sub-components were tested: • Video Processor hardware • Endoscope Controller hardware • 8.5 mm Endoscope • Endoscope adapter
Instrument Design Verification	The purposes of these tests was to verify the IS4000 instruments met the physical, mechanical, and electrical requirement and specifications. Instrument compatibility to software parameters and user interface specifications were also verified. Samples sizes up to 5 units for all 24 instruments were used. For load handling and grip forces verification, worst case representative instruments were tested. The following design verification tests were performed: • All Instrument types (24) • Instrument Electrical Testing • Load Handling • Grip Force Comparison for grasping instruments

(continues on next page)

Table H.2 VSC Bench Tests (continued)

Test	Description
Instrument Reliability/ Life Testing	The purpose of this test was to confirm the instruments met the projected life of each re-usable instrument. A sample of 9 instruments types was subjected to life testing representing worst case for all 24 instruments. A sample size of 4 units of each type was tested. Test instruments were tested up to 10 life cycles to establish a projected life of 10 clinical uses. Each life cycle consisted of cleaning, sterilizing, performance measurements, and simulated surgical use. Objective pass/fail criteria were defined and used. The following instruments were evaluated: • Monopolar Curved Scissors • Maryland Bipolar Forceps • Large Needle Driver • Black Diamond Micro Forceps • Mega SutureCut Needle Driver • ProGrasp Forceps • Tenaculum Forceps • Permanent Cautery Hook • Small Clip Applier
Accessories Testing	• The purpose of this test was to confirm that Column and Instrument Arm Drapes with sterile adapters met the specifications and requirements for maintenance of sterility. A sample of 5 units of each type was evaluated per the verification protocol. Objective pass/fail criteria were defined and used. • Reusable trocars were tested for physical, mechanical, and interface requirements. A sample of 4 units of each type of reusable trocar was tested per the verification protocol. Objective pass/fail criteria were defined and used.

Preclinical Verification via Cadaver and Animal Models

The IS4000 system was evaluated for surgical access for seven representative procedures using multiple patient positions and port locations involving 10 cadavers (2 male and 8 female) and one 20 kg porcine model. Test cases validated requirements across all system components associated with system setup, positioning, docking, transporting and procedure specific requirements for achieving external access and internal surgical targets. Specifically, the protocol focused on the IS4000 system's ability to safely and effectively:

- Maneuver the PSC and USMs into proper surgical position for the target procedure
- Reach and attach the USMs to the ports
- Maintain adequate external clearance between the system and its surroundings at all times (for example, during transport, roll-up, and intraoperative use)
- Reach the internal surgical targets with the instruments and endoscope
- Maximize patient access

The following table shows the types of procedures used to set up and deploy the system:

Table H.3 Procedures to set up and deploy the system

Procedure/ # of cases	Port Location	Port Spacing	Work Volume	Body Wall Type	Patient Position	Working Distance
Low Anterior Resection/2 (cadaver)	Anterior Transverse / Anterior Oblique	8–11 cm	>3k cm^3	Abdomen	Trendelenburg Right roll Lithotomy	3–15 cm
Gastric Bypass/3 (cadaver)	Anterior Transverse	8–11 cm	Between 1–3k cm^3	Thick Abdomen	Reverse Trendelenburg Lithotomy	4–12 cm
Mitral Valve Repair /1 (cadaver)	Lateral, Anterior, Coronal	2–8 cm	<1k cm^3	Ribs	Supine, Left roll right arm down	2–8 cm
Hysterectomy/3 (cadaver)	Anterior Transverse	8–11 cm	>3k cm^3	Abdomen	Trendelenburg Lithotomy	3–15 cm
Cardiac Revascula-rization/ 1 (cadaver)	Lateral, Anterior, Coronal	5–8 cm	Between 1–3k cm^3	Ribs	Supine, drop Left shoulder	2–8 cm
Nephrectomy w/ partial Ureter-ectomy/3 (cadaver)	Anterior, Lateral, Sagittal	5–11 cm	Between 1–3k cm^3	Abdomen	Lateral decubitus, flex	2–9 cm
Pediatric / 1 (small porcine <20 kg)	Variable	2–5 cm	Between 1–3k cm^3	Abdomen	Variable	2–10 cm

Representative Surgical Procedures in Live Animal Models

A series of six evaluations in which surgeons performed complete procedures on live animal models were conducted covering the range of specialties listed in the indication statement. Each study included clinical endpoints to assess safety and effectiveness of the IS4000 system that were appropriate for the procedure being performed. The evaluations for five of the six specialties involved surviving the animal models for a minimum of 21 days.

Table H.4 General Laparoscopic Surgical Procedures

Right Colectomy Prospective Study	**Canine Model (N=4) with weights 25–35 kg**
No. of Investigators	One (trained on system 4–6 weeks prior to use)
Success Criteria Safety	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during postoperative period.
Success Criteria Effectiveness	Ileocolic anastomosis intact and looking healthy at day of euthanasia. Normal eating and bowel movements over postoperative period.
Instrumentation Used	Fenestrated Bipolar Forceps, Tip-Up Grasper, 30° down endoscope, Monopolar Curved Scissors, EndoGIA® Ultra-Universal stapler, Endopouch® specimen retrieval bag, and LigaClips.
Findings	• Surgical time ranged from 30–65 minutes shorter times noted with each subsequent case. • There was no conversion to open surgery. • Estimated blood loss was 10 mL in all cases.
Adverse Events	• Unanticipated splenic injury with placement of port. Splenic injury was repaired and procedure continued without further incident. • There were no device-related adverse events.

(continues on next page)

Table H.4 General Laparoscopic Surgical Procedures (continued)

Right Colectomy Prospective Study	Canine Model (N=4) with weights 25–35 kg
Postmortem Assessment Protocol	• Animals were euthanized and the operative site examined grossly for intactness of the ileoclic anastomosis and tissue health. • Blood samples collected for hematology and chemistry analysis. • Histopathology if needed on abnormal tissue as determined by Veterinary Pathologist.
Postmortem Findings	• All four animals survived for 26 days with normal vital signs and absence of device-related adverse events intraoperatively and during the postoperative period. • One animal presented with intermittent inappetance, moderate weight loss and clinical pathology results indicative of ongoing inflammation. • The ileocolic anastomoses were intact and functional at the end of the survival period. In the animal with irregular clinical observations, solid feces were found distal to the anastomosis with surrounding tissue inflammation (not device-related) at the end of the survival period. • All animals had a loop of small bowel covering the staple line, as observed during the post survival evaluation surgery. This did not cause obstruction of the anastomosis in any of the animals. All other animals were free of clinically significant variances in observations or clinical pathology.

Table H.5 General Laparoscopic Surgical Procedures (Pediatric)

Nissen Fundoplication Prospective Study	Canine Model (N=4) with weights 9–15 kg (representative of pediatric population)
No. of Investigators	One
Success Criteria Safety	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during postoperative period.
Success Criteria Effectiveness	Fundoplication wrap intact and looking healthy at day of euthanasia. Normal eating over postoperative period.
Instrumentation Used	Monopolar Curved Scissors, Fenestrated Bipolar Grasper, Tip-Up Grasper, 30° down endoscope, Large Needle Drivers

(continues on next page)

Table H.5 General Laparoscopic Surgical Procedures (Pediatric) (continued)

Nissen Fundoplication Prospective Study	Canine Model (N=4) with weights 9–15 kg (representative of pediatric population)
Findings	• Surgery time ranged from 48–68 min • No animal required conversion to open surgery • Estimated blood loss average was 13.8 mL • Moderate weight loss occurred in all four animals during the course of the study, and ranged from a 1.1–1.7 kg decrease. • All animals retained good appetites and were clinically healthy throughout the duration of the survival period with no observations of vomiting, regurgitation, or other GI upset, and no reported loss of body condition. The weight loss was likely due to decreased caloric intake as a result of the postoperative dietary change to canned food/gruel to accommodate GI tract changes from the Nissen fundoplication.
Adverse Events	One animal sustained a splenic injury during takedown of the gastro-colic ligament using the Monopolar Curved Scissors. Bleeding was controlled by applying standard surgical techniques of pressure to the puncture site with a 4x4 gauze and monopolar electrocautery. Hemostasis was achieved and this event had no impact on the clinical outcome for the animal. This was felt to be related to surgical error rather than instrumentation as the scissor was under the command of the surgeon and not a result of motions from the system.
Postmortem Assessment Protocol	• Animals were euthanized and the operative site examined grossly for intactness of the fundal wrap and tissue health. • Blood samples collected for hematology and chemistry analysis. • Histopathology if needed on abnormal tissue as determined by Veterinary Pathologist.
Postmortem Findings	• In the post survival evaluation surgeries on Day 24, all wraps were found to be intact with no abnormalities noted in the surrounding tissue. • One slight adhesion was noted at a port site in one animal.

Table H.6 General Urologic Surgical Procedures (Pediatric)

Pyeloplasty Prospective Study	Porcine Model (N=4) with weights 25–30 kg
No. of Investigators	One
Success Criteria Safety	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during intraoperative and postoperative periods.

(continues on next page)

Table H.6 General Urologic Surgical Procedures (Pediatric) (continued)

Pyeloplasty Prospective Study	**Porcine Model (N=4) with weights 25–30 kg**
Success Criteria Effectiveness	Normal passage of urine throughout the survival period Normal peristalsis of ureter at day of euthanasia No stricture of ureter at day of euthanasia Normal eating and bowel movements over postoperative period
Instrumentation Used	Tip Up Grasper, Monopolar Curved Scissors, Maryland Bipolar Forceps, Large Needle Driver
Findings	• Surgical time range from 50–62 minutes. • There were no conversions to an open procedure. • Estimated blood loss average was 15 ml.
Adverse Events	• One animal was noted to have thickened port sites with some purulent material expressed. Peritoneal wounds on this animal had healed normally. • There were no device-related adverse events.
Postmortem Assessment Protocol	• Animals were euthanized and the operative site examined grossly for intactness of the pyeloplasty, presence or absence of intraperitoneal fluid, peristaltic activity. • Blood samples collected for hematology and chemistry analysis. • The anastomotic segment was explanted and histopathology performed by Veterinary Pathologist.
Postmortem Findings	• All four animals survived for 26 days with normal vital signs and absence of device-related adverse events intraoperatively and during the postoperative period. All animals were free of clinically significant variances in observations or clinical pathology. • The ureteral anastomoses were intact and functional at the end of the survival period. There was no evidence of stricture as evidenced by the successful passage of a 6F dilator. • All animals were found to have 20 cc clear abdominal fluid at euthanasia. This was the same finding prior to beginning the surgery.

Table H.7 Urologic Surgical Procedures

Radical Nephrectomy Prospective Study	**Female Porcine Model (N=4) with weights 50–60 kg**
No. of Investigators	One (trained on system 6 weeks prior to study)
Success Criteria Safety	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during intraoperative and postoperative periods.

(continues on next page)

Table H.7 Urologic Surgical Procedures (continued)

Radical Nephrectomy Prospective Study	Female Porcine Model (N=4) with weights 50–60 kg
Success Criteria Effectiveness	Successful organ removal Normal eating and bowel movements over postoperative period
Instrumentation Used	Tip Up Grasper, Monopolar Curved Scissors, Fenestrated Bipolar Forceps, Laparoscopic EndoGIA Ultra-Universal stapler
Findings	• Surgical time range from 35–42 minutes. • There were no conversions to an open procedure. • Successful removal of kidney in all animals • Estimated blood loss average 12.5 mL
Adverse Events	• One splenic injury during port placement controlled with local measures. • There were no device-related adverse events.
Postmortem Assessment Protocol	• Animals were sedated and the operative site palpated for pain and swelling and then euthanized. All port sites healed. • Blood samples collected for hematology and chemistry analysis. • Histopathology performed by Veterinary Pathologist on abnormal tissue if needed.
Postmortem Findings	• All four animals survived for the 25–28 days with normal vital signs and absence of device-related adverse events intraoperatively and during the postoperative period. • No inappetance or other GI disturbances were reported, and all animals remained in good condition throughout the duration of the survival period. • None of the animals showed any signs of pain reaction.

Table H.8 Gynecologic Laparoscopic Surgical Procedures

Hysterectomy Prospective Study	Female Porcine Model (N=4) with weights 35–40 kg
No. of Investigators	One (trained on system 2 weeks prior to study)
Success Criteria Safety	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during intraoperative and postoperative periods.
Success Criteria Effectiveness	Successful organ removal Normal eating and bowel movements over postoperative period
Instrumentation Used	Tip Up Grasper, Monopolar Curved Scissors, Fenestrated Bipolar Forceps, Mega SutureCut Needle Driver

(continues on next page)

Table H.8 Gynecologic Laparoscopic Surgical Procedures (continued)

Hysterectomy Prospective Study	**Female Porcine Model (N=4) with weights 35–40 kg**
Findings	• Surgical time range from 29–55 minutes shorter time noted with each subsequent case. • There was no conversion to an open procedure. • Estimated blood loss average 10 ml. • Successful removal of uterus in all animals.
Adverse Events	There were no device-related adverse events.
Postmortem Assessment Protocol	• Animals were euthanized and the vaginal cuff closure assessed. A transvaginal leak test was performed. • Blood samples collected for hematology and chemistry analysis. • Histopathology performed by Veterinary Pathologist on abnormal tissue if needed.
Postmortem Findings	• All four animals survived for 21 days with normal vital signs and absence of device-related adverse events intraoperatively and during the postoperative period. • All vaginal cuffs were found to be intact with no abnormalities noted in the surrounding tissue. • There were no leaks observed in the transvaginal air leak testing.

Table H.9 General Thoracoscopic Surgical and Thoracoscopically-Assisted Cardiotomy Procedures

Mitral Valve Repair Prospective Study	**Canine Model (N=9) with weights 28–35 kg** **Comparative performance study of da Vinci IS3000 to the IS4000**
No. of Investigators	Two board certified cardiothoracic surgeons each performed 4 procedures, 2 using the IS3000 and 2 using the IS4000.
Success Criteria Safety	Ability to perform procedure without intraoperative adverse events.
Success Criteria Effectiveness	• Placing a cardioplegia catheter • Simulating pacemaker lead placement • Closing a leaflet defect • Perform an annuloplasty with a flexible band • Intraoperative valve leak test as surrogate for assessment of mitral regurgitation
Instrumentation Used	Large Needle Driver, Resano Forceps, Graspers, Atrial Retractor Short Right, Monopolar Curved Scissors
Procedural Steps	• Placing a cardioplegia catheter • Simulating pacemaker lead placement • Closing a leaflet defect • Perform an annuloplasty with a flexible band

(continues on next page)

Table H.9 General Thoracoscopic Surgical and Thoracoscopically-Assisted Cardiotomy Procedures (continued)

Mitral Valve Repair Prospective Study	Canine Model (N=9) with weights 28–35 kg Comparative performance study of da Vinci IS3000 to the IS4000
Findings	• Total surgical time for all steps was 67–93 minutes for the IS3000 and 76–101 minutes for the IS4000. • Time to cardioplegia catheter averaged 8.71 minutes for the IS3000 and 8.12 minutes for the IS4000. • Time for lead placement averaged 13.25 minutes for the IS3000 and 13.5 minutes for the IS4000. • Time to completion of annuloplasty averaged 14.74 minutes for the IS3000 and 14.57 minutes for the IS4000. • All animals had measures for mitral valve regurgitation that were equal to preoperative measures. All changes were acceptable to surgeons.
Adverse Events	One animal (D955) in the IS4000 group died intraoperatively due to a non device-related adverse event, an acute onset pulmonary complication leading to bronchial obstruction with reduced O2 exchange. This animal was excluded from the study, and another animal (D999) added to the study.
Postmortem Assessment Protocol	None as animals were euthanized during the procedures to simulate bypass machine.

The results of the animal testing demonstrate that the IS4000 Surgical System can be used to safely and effectively perform procedures from all of the specialties listed in the indications for use statement.

Human Factors

A Human Factor (HF) engineering process was followed in accordance with FDA guidelines for medical devices:

- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, 2000
- Draft Guidance for Industry and Food and Drug Administration Staff-Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 2011

The HF process focused primarily on identifying and mitigating use-related risks to safe levels while also providing a user friendly product. For the IS4000 system, an extensive HF process was followed documenting many user research, design iteration, and formative evaluations prior to usability validation testing. A summative usability validation study was conducted with 15 teams of users (surgeons and OR team). This study was conducted in a simulated OR and involved representative typical workflow scenarios as well as troubleshooting scenarios that involved safety-critical tasks. Training materials and user manuals were developed in concert with the product hardware and software, and were incorporated in the validation study.

The study assessed the following:

- ensure intended users could perform essential and high risk tasks in the expected use environments in a safe and effective manner,

- validate that use-related risks have been mitigated to acceptable levels of residual risk,
- assess the overall ease of use and usability of the IS4000 Surgical System,
- this study evaluated whether the design introduced any previously unknown use-related risks.

Fifteen surgeons from different surgical specialties (urology, gynecology, general surgery and thoracic) from novice (<20 cases) to very experienced (>200 cases) participated in the study. In addition, fifteen OR staff (5 circulating nurses, 9 scrub nurse/tech, and 1 physician's assistant) provided OR support during the sixteen study sessions. Each participant received one-half day of hands-on training prior to conducting testing. A simulated OR environment was provided to perform preoperative setup tasks (for example, docking, draping, power on), intraoperative tasks (for example, installing and activating instruments, instrument exchange, manipulating instruments), and postoperative tasks (for example, undocking, cleaning, sorting for reprocessing). Data collected included both objective performance data and subjective feedback from participants. Objective performance data included observations of user's ability to complete tasks, use-errors, close calls, and any difficulties encountered. Subjective feedback included open-ended questions about risks and safety, multiple choice ratings, and follow-up interviews.

The Model IS4000 da Vinci Surgical System has been assessed and found to be safe and effective for its intended uses, by the intended users, in its intended use environment. The Human Factor engineering process, culminating in a usability validation study, was to identify and assess the use-related risks associated with the IS4000 Surgical System. The safety and usability of the IS4000 Surgical System was assessed to ensure residual risk is at acceptable levels, and that the use-safety of the system has not diminished in comparison to the IS3000 Surgical System.

H.2 Additional Performance Data

Performance test data to support substantial equivalence to the predicate device and that the design output meets the design input requirements consist of bench testing, animal/cadaver validation, simulated clinical procedures in live animal, and Human Factor assessment. Additionally, published clinical data were provided in support of the representative specific procedures under the general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures, and urologic surgical procedures indications.

IS3000 and IS4000 Performance Data

The following data was collected from the da Vinci Si system and the da Vinci Xi system and is applicable to the da Vinci X system.

Table H.10 Gynecologic Laparoscopic Surgical Procedures

Hysterectomy Prospective Study	Female Porcine Model (N=4)[a] with weights 35–40 kg
No. of Investigators	One (trained on system two weeks prior to study)
Success Criteria Safety	• Ability to perform procedure without intraoperative adverse events • Normal vital signs and absence of device-related adverse events during intraoperative and postoperative periods
Success Criteria Effectiveness	• Successful organ removal • Normal eating and bowel movements over postoperative period
Instrumentation Used	Tip Up Grasper, Monopolar Curved Scissors, Fenestrated Bipolar Forceps, Mega SutureCut Needle Driver
Findings	• Surgical time range from 29–55 minutes, shorter time noted with each subsequent case • There was no conversion to an open procedure • Estimated blood loss average 10 mL • Successful removal of uterus in all animals
Adverse Events	There were no device-related adverse events.
Postmortem Assessment Protocol	• Animals were euthanized and the vaginal cuff closure assessed. A transvaginal leak test was performed. • Blood samples were collected for hematology and chemistry analysis. • Histopathology performed by Veterinary Pathologist on abnormal tissue, if needed.
Postmortem findings	• All four animals survived for 21 days with normal vital signs and absence of device-related adverse events intraoperatively and during the postoperative period. • All vaginal cuffs were found to be intact with no abnormalities noted in the surrounding tissue. • There were no leaks observed in the transvaginal air leak testing.
Notes a. Additional animals (N=3) were evaluated in a comparable study with similar results in support of the da Vinci Xi Vessel Sealer clearance (Reference K141089).	

Clinical Study Data

Published clinical data support use of the da Vinci X Surgical System for the representative, specific procedures that fall under the cleared "gynecologic laparoscopic surgical procedures" general Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the more complex/higher risk representative, specific procedures (referred to as "umbrella" procedures). The published data on these "umbrella" procedures were deemed sufficient to cover the less complex/lower risk procedures (referred to as "covered" procedures), so published clinical data on the covered procedures were not provided.

Umbrella Procedures

Published clinical data were provided for the following umbrella procedures: Hysterectomy (Radical) Salpingectomy, Oophorectomy, Lymphadenectomy, Myomectomy and Sacrocolpopexy. Twenty one (21) publications were identified for these umbrella procedures based on specific search criteria and filters. These publications included randomized controlled trials, meta-analyses, systematic reviews or Health Technology Assessments and comparative studies. A detailed summary of the published clinical data on these procedures is provided in Table H.11 through Table H.13.

The findings from the Hysterectomy, Salpingectomy, Oophorectomy and Lymphadenectomy publications show that da Vinci-assisted procedures are associated with comparable or fewer complications and blood transfusions and a shorter length of hospital stay as compared to both open and laparoscopic surgical procedures. These publications also noted increased operative times in the da Vinci procedures as compared to open procedures. However, this increase did not correlate with an increase in the reported complication rates. Additionally, these publications report comparable operative times and comparable or lower conversion rates for da Vinci-assisted procedures as compared to laparoscopic procedures.

Outcomes reported in the Myomectomy publications demonstrate that da Vinci-assisted procedures are associated with comparable complication rates, comparable or lower blood transfusion rates (Two publications reported a higher transfusion rate in the da Vinci-assisted cohorts as compared to the laparoscopic groups. However, Barakat noted that the cases completed with the laparoscopic approach were less challenging than those completed with da Vinci assistance and Gargiulo noted that the majority of transfusions in the da Vinci-assisted procedures were planned preoperatively.), and comparable or shorter length of hospital stays as compared to both open and laparoscopic surgical procedures. These publications also noted increased operative times in the da Vinci procedures as compared to open procedures. However, this increase did not correlate with an increase in the reported complication rates. Additionally, these publications report comparable conversion rates for da Vinci-assisted procedures as compared to laparoscopic procedures.

The data provided in the Sacrocolpopexy publications show that da Vinci-assisted procedures are associated with comparable or lower complication rates, comparable blood transfusion rates and comparable or shorter length of hospital stays as compared to both open and laparoscopic surgical procedures. These publications also noted increased operative times in the da Vinci procedures as compared to open and laparoscopic procedures. However, this increase did not correlate with an increase in the reported complication rates. Additionally, these publications reported comparable conversion rates for da Vinci-assisted procedures as compared to laparoscopic procedures.

Table H.11 Da Vinci vs. Open and da Vinci vs. Laparoscopic Hysterectomy (Radical), Salpingectomy, Oophorectomy, Lymphadenectomy

Publications		Operative Time (minutes)	Transfusions (%)	Length of Stay (days)	Complications (%)
1. Gaia (2010) (Simple Total)	Da Vinci	207–219	1.7–2.6	1.2–1.4	2.0–3.8
	Open	130	7.2	3.9	14.5
	Lap	209	5.0	1.9	3.8
2. a. Reza (2010) (Simple Total)	Da Vinci	177–283	0–5	1.0–2.3	7.1–8.3
	Open	79–146.5	1.5–15	3.2–5.3	27.0
	Lap	171.1–255	2.5–10	1.2–2.0	13.0
2. b. Reza (2010) (Radical)	Da Vinci	144–290	0–7.5	1.0–3.7	13.9–30.4
	Open	114–247.8	8.2–35.7	3.2–5.6	19.4
	Lap	132–220.4	0	2.3–2.4	30.2
3. O'Sullivan (2011) (Simple Total, Radical)	Da Vinci	173–231	6	1.5–1.9	18
	Open	181	27	4.4	36
	Lap	161	10	1.9	26
4. a. O'Neill (2012) (Simple Total)	Da Vinci	242	5	3.7	21
	Open	79–187.9	0–42.9	3.0–10.8	13.2–33.0
	Lap	82.9–287.0	0–16	1.2–7.7	2.5–21.9

(continues on next page)

Table H.11 Da Vinci vs. Open and da Vinci vs. Laparoscopic Hysterectomy (Radical), Salpingectomy, Oophorectomy, Lymphadenectomy (continued)

Publications		Operative Time (minutes)	Transfusions (%)	Length of Stay (days)	Complications (%)
4. b. O'Neill (2012) (Radical)	Da Vinci	202	4	1.7	11
	Open	114–283	8.2–42.5	2.8–9.5	4.7–70.8
	Lap	132–300	0	2.2–8.0	23.5–85.7
5. Ran (2015) (Simple Total)	Da Vinci	96.7–331.8	1.0–3.8	1.0–7.9	8.4–13.2
	Open	79–187.9	10.0	4.0–10.8	35.6
	Lap	80–287	1.7	1.2–8.1	13.2
6. Geetha (2012) (Radical)	Da Vinci	253.6	2.1	3.1	3.9[a]
	Open	219.7	25.2	8.4	18.2[a]
	Lap	259.7	5.3	5.6	6.6[a]
7. Shazly (2015) (Radical)	Da Vinci	144–383	3.4–4.0	1.7–13.5	17.1–22.4
	Open	114–302.9	17.3	4.0–16.9	16.8
	Lap	132–364.2	6.6	2.0–10.0	20.2

Notes

a. Rates reported are for "Infectious" complications, non-infectious complication rates were 7.8%, 19.4% and 18.3% for the da Vinci-assisted, open and lap cohorts, respectively.

Table H.12 Da Vinci vs. Open and da Vinci vs. Laparoscopic Myomectomy

Publications		Operative Time (minutes)	Transfusions (%)	EBL (mL)	Length of Stay (days)	Complications (%)
8. Pundir (2013)	Da Vinci	181–231.4	0–5	100–370	0.5–1.5	0–11.1
	Open	92.5–161.7	6.4–14.3	NA[a]	3.0–3.6	0.3–13.0
	Lap	115–203	0–0.9	85.3–420	1.0–3.0	0.9–2.5
9. Barakat (2011)[b]	Da Vinci		2.2	100		
	Lap		0	150		
10. Bedient (2009)[b]	Da Vinci		4.8	100		
	Lap		5.0	250		
11. Gargiulo (2012)[b]	Da Vinci		5.7	112.2		
	Lap		0.9	85.3		
12. Nezhat (2008)[b]	Da Vinci		0	370		
	Lap		0	420		
13. Hsaio (2013)[b]	Da Vinci		20	175		
	Lap		14	200		
14. Pluchino (2013)[b]	Da Vinci		0	125.8		
	Lap		4.6	222.1		
15. Gobern (2013)[b]	Da Vinci		6	100		
	Lap		12	100		

(continues on next page)

Table H.12 Da Vinci vs. Open and da Vinci vs. Laparoscopic Myomectomy (continued)

Publications		Operative Time (minutes)	Transfusions (%)	EBL (mL)	Length of Stay (days)	Complications (%)
16. Gocmen (2013)[b]	Da Vinci		Not Reported[c]	101.33		
	Lap			119.78		
17. Behera (2011)[b]	Da Vinci		0	Not Reported		
	Lap		0			

Notes

a. EBL volumes not provided. Author states "Pooled results showed that the mean EBL was significantly lower in the RLM group compared with the AM group".

b. Transfusion and/or EBL (estimated blood loss) data only were provided for this publication.

c. Transfusion rates not reported

Table H.13 Da Vinci vs. Open and da Vinci vs. Laparoscopic Sacrocolpopexy

Publications		Operative Time (minutes)	Transfusions (%)	Length of Stay (days)	Complica-tions (%)
18. Serati (2014)	Da Vinci	265	0.9	1.5	17.1
	Open	212	<1	3.0	27.6
	Lap	206	1.4	1.2	12.6
19. Paraiso (2011)	Da Vinci	265	Not Reported	43 hours	Not Reported[a].
	Lap	199		34 hours	
20. Anger (2014)	Da Vinci	202.8	Not Reported	Not Reported	15
	Lap	178.4			26
21. Flack (2015)	Da Vinci	Not Reported	Not Reported	1.0	8.0
	Lap			2.0	7.0

Notes

a. Not Reported, but publication states that there were no differences in intraoperative or post-operative complications.

Table H.14 Gynecologic Laparoscopic Surgical Procedures

Hysterectomy Prospective Study	Female Porcine Model (N=4[a]) with weights 35–40 kg
No. of Investigators:	One (trained on system 2 weeks prior to study)
Success Criteria Safety:	Ability to perform procedure without intraoperative adverse events. Normal vital signs and absence of device-related adverse events during intraoperative and postoperative periods.
Success Criteria Effectiveness:	Successful organ removal Normal eating and bowel movements over postoperative period
Instrumentation Used:	Tip Up Grasper, Monopolar Curved Scissors, Fenestrated Bipolar Forceps, Mega SutureCut Needle Driver
Findings:	• Surgical time range from 29–55 minutes shorter time noted with each subsequent case. • There was no conversion to an open procedure. • Estimated blood loss average 10 mL. • Successful removal of uterus in all animals.
Adverse Events:	There were no device-related adverse events.

(continues on next page)

Table H.14 Gynecologic Laparoscopic Surgical Procedures (continued)

Hysterectomy Prospective Study	Female Porcine Model (N=4[a]) with weights 35–40 kg
Postmortem Assessment Protocol:	• Animals were euthanized and the vaginal cuff closure assessed. A transvaginal leak test was performed. • Blood samples collected for hematology and chemistry analysis. • Histopathology performed by Veterinary Pathologist on abnormal tissue if needed.
Postmortem findings:	• All four animals survived for 21 days with normal vital signs and absence of device-related adverse events intraoperatively and during the postoperative period. • All vaginal cuffs were found to be intact with no abnormalities noted in the surrounding tissue. • There were no leaks observed in the transvaginal air leak testing.
Notes a. Additional animals (N=3) were evaluated in a comparable study with similar results in support of the da Vinci Xi Vessel Sealer clearance (Reference K141089).	

Table H.15 General Thoracoscopic Surgical and Thoracoscopically-Assisted Cardiotomy Procedures

Mitral Valve Repair Prospective Study	Canine Model (N=9[a].) with weights 28–35 kg Comparative performance study of da Vinci IS3000 to the IS4000
No. of Investigators	Two board certified cardiothoracic surgeons each performed 4 procedures, 2 using the IS3000 and 2 using the IS4000.
Success Criteria Safety	Ability to perform procedure without intraoperative adverse events.
Success Criteria Effectiveness	• Placing a cardioplegia catheter • Simulating pacemaker lead placement • Closing a leaflet defect • Perform an annuloplasty with a flexible band • Intraoperative valve leak test as surrogate for assessment of mitral regurgitation
Instrumentation Used	Large Needle Driver, Resano Forceps, Graspers, Atrial Retractor Short Right, Monopolar Curved Scissors
Procedural Steps	• Placing a cardioplegia catheter • Simulating pacemaker lead placement • Closing a leaflet defect • Perform an annuloplasty with a flexible band

(continues on next page)

Table H.15 General Thoracoscopic Surgical and Thoracoscopically-Assisted Cardiotomy Procedures (continued)

Mitral Valve Repair Prospective Study	Canine Model (N=9[a.]) with weights 28–35 kg Comparative performance study of da Vinci IS3000 to the IS4000
Findings	• Total surgical time for all steps was 67–93 minutes for the IS3000 and 76–101 minutes for the IS4000. • Time to cardioplegia catheter averaged 8.71 minutes for the IS3000 and 8.12 minutes for the IS4000. • Time for lead placement averaged 13.25 minutes for the IS3000 and 13.5 minutes for the IS4000. • Time to completion of annuloplasty averaged 14.74 minutes for the IS3000 and 14.57 minutes for the IS4000. • All animals had measures for mitral valve regurgitation that were equal to preoperative measures. All changes were acceptable to surgeons.
Adverse Events	One animal (D955) in the IS4000 group died intraoperatively due to a non device-related adverse event, an acute onset pulmonary complication leading to bronchial obstruction with reduced O2 exchange. This animal was excluded from the study, and another animal (D999) added to the study.
Postmortem Assessment Protocol	None as animals were euthanized during the procedures to simulate bypass machine.

Notes

a. Additional animal studies were conducted in support of the da Vinci Xi Stapler 45 clearance and Stapler 30 pending clearance. Such studies included the following procedures: Lung Resection (i.e., Wedge Resection) and Lobectomy.

Clinical Study Data

Published clinical data support use of the da Vinci Xi Surgical System for the representative, specific procedures that fall under the cleared “thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the more complex/higher risk representative, specific procedures (referred to as “umbrella” procedures). The published data on these “umbrella” procedures were deemed sufficient to cover the less complex/lower risk procedures (referred to as “covered” procedures), so published clinical data on the covered procedures were not provided.

Umbrella Procedures

Published clinical data were provided for the following umbrella procedures: Lobectomy, Mediastinal Mass Resection and Thymectomy. Forty (40) publications were identified for these umbrella procedures based on specific search criteria and filters. These publications included retrospective, comparative and single arm studies. A detailed summary of the published clinical data on these procedures is provided in Table H.16, Table H.17, and Table H.18.

The findings from the Lobectomy publications show that da Vinci-assisted procedures are associated with comparable or lower mortality rates; comparable complications; comparable or lower blood transfusion rates; and comparable or shorter lengths of hospital stay as compared to both open and VATS surgical procedures. Five (5) studies reported comparable or shorter operative times for da Vinci-assisted procedures as compared to VATS procedures. Thirteen (13) publications noted increased operative times in the da Vinci-assisted procedures as compared to open and VATS procedures; however, this increase did not correlate with an increase in the reported mortality rates. Lastly, these publications report comparable or lower conversion rates for da Vinci-assisted procedures as compared to VATS procedures.

Outcomes reported in the Mediastinal Mass Resection comparative publications demonstrate that da Vinci-assisted procedures are associated with comparable mortality rates and operative times, comparable or lower complication rates and comparable or shorter lengths of hospital stay as compared to open surgical procedures. Data from five (5) publications reporting on single-arm studies using the da Vinci system for mediastinal mass resection procedures demonstrate that use of the da Vinci system can be accomplished with no reports of mortality and low complication rates. Intraoperative complications were <1% in two (2) of the single-arm publications and postoperative complication rates were ≤14% in all five (5) publications. Two (2) of the single-arm publications reported on conversion rates (0.65% and 4.3%) and three (3) publications reported low transfusion rates (0–1.4%). Operative times in the single- arm publications ranged from 85.9 minutes to 210.0 minutes and length of stay ranged from 1.0 to 12.8 days.

The data provided in the Thymectomy comparative publications show that da Vinci-assisted procedures are associated with comparable mortality rates; comparable or lower complication rates; comparable or shorter lengths of hospital stay; and comparable or lower transfusion rates/ estimated blood loss as compared to both open and VATS surgical procedures. Operative times were comparable or longer in the da Vinci-assisted procedures as compared to open and VATS procedures, however, this increase did not correlate with higher mortality rates. Data from ten (10) publications reporting on single-arm studies using the da Vinci system for thymectomy procedures demonstrate that use of the da Vinci system in such procedures can be accomplished with no reports of mortality and low complication rates. No intraoperative complication rates were reported in eight (8) of the single-arm publications; two (2) of the publications reported intraoperative complication rates of 1.3% and 15.4%. Postoperative complication rates in the single-arm publications ranged from 3.6–15.4% and conversion rates ranged from 0–15.4%. Operative times in the single-arm publications ranged from 85.2 minutes to 155 minutes and length of stay ranged from 2.0–5.0 days.

Table H.16 Comparison of da Vinci vs. Open and VATS Lobectomy

Publications		Sample Size (N)	Operative Time (minutes)[a]	Transfusions (%) and/or EBL (mL)	Length of Stay (days)[a]	Complications (%)
22. Cerfolio (2011)	Da Vinci	106	132.0	30 mL	2.0	26.4
	Open	318	90.0	90 mL	4.0	37.8
23. Veronesi (2010)	Da Vinci	54	236.0	0	5.0	20.4
	Open	54	154.0	6.0	6.0	20.4
24. Kent (2013)	Da Vinci	430	NR	NR	4.0	44.4
	Open	20,238	NR	NR	6.0	55.1
	VATS	12,427	NR	NR	5.0	43.6
25. Oh (2013)	Da Vinci	43	217.0	100 mL	4.0	28.0[b] /2.0[c]
	Open	88	168.0	200 mL	10.0	24[b] /3.0
26. Adams (2014)	Da Vinci	120	241.5	0.9/0.9[d]	4.7	5.2[e] /0.9[f]
	Open	5,913	175.5	5.0/7.8[d]	7.3	10.8[e]/1.1[f]
	VATS	4,612	179.8	1.4/3.8[d]	5.3	8.9[e]/1.0[f]
27. Deen (2014)	Da Vinci	57	223.0	NR	4.6	32.0
	Open	69	180.0	NR	5.5	30.0
	VATS	58	202.0	NR	4.8	31.0

(continues on next page)

Table H.16 Comparison of da Vinci vs. Open and VATS Lobectomy (continued)

Publications		Sample Size (N)	Operative Time (minutes)[a]	Transfusions (%) and/or EBL (mL)	Length of Stay (days)[a]	Complications (%)
28. Farivar (2014)	Da Vinci	181	199.2	0/0[d]	3.2	6.1[e]
	Open	5,913	243.7	4.8/7.8[d]	7.3	10.7[e]
	VATS	4,612	239.0	1.3/3.7[d]	5.3	8.9[e]
29. Augustin (2013)	Da Vinci	26	215.0	NR	11.0	42.3
	VATS	26	183.0	NR	9.0	38.4
30. Bodner (2011)	Da Vinci	26	228.0	NR	11.0	11.5
	VATS	114	183.0	NR	9.5	7.0
31. Jang (2011)	Da Vinci	40	240.0	219.0 mL	6.0	10.0
	VATS	40	257.0	374.0 mL	9.0	32.5
32. B. Lee (2012)	Da Vinci	100	209.0	NR	6.3	9.0
	VATS	100	157.0	NR	8.9	21.0
33. Louie (2012)	Da Vinci	45	213.0	154.0 mL	4.0	43.5
	VATS	35	207.0	134.0 mL	4.5	35.3
34. B. Lee (2014)	Da Vinci	35	161.0	0	3.0	11.0
	VATS	34	128.0	0	3.0	18.0
35. Swanson (2013)	Da Vinci	295	269.4	NR	6.1	16.95[g]/36.95[h]
	VATS	295	253.8	NR	5.8	18.98[g]/38.31[h]

(continues on next page)

Table H.16 Comparison of da Vinci vs. Open and VATS Lobectomy (continued)

Publications		Sample Size (N)	Operative Time (minutes)[a]	Transfusions (%) and/or EBL (mL)	Length of Stay (days)[a]	Complications (%)
36. Paul (2014)	Da Vinci	2,498	NR	NR	5.0	50.1[i]
	VATS	37,595	NR	NR	5.0	45.2[i]
37. Spillane (2014)	Da Vinci	22	261.0	143 mL	4.4	9.0
	VATS	22	159.0	223 mL	5.5	22.0
38. B. Lee (2015)	Da Vinci	53	161.0	NR	3.0	11.0
	VATS	158	123.0	NR	3.0	24.0
39. Mahieu (2015)	Da Vinci	28	190.0	100 mL	6.0	50.0
	VATS	28	185.0	200 mL	7.0	42.8

Notes

a. Mean or median reported
b. Air leak >24 hours.
c. Return to OR.
d. Intraoperative/Postoperative values.
e. Air leak >5 days.
f. Bleeding requiring reoperation.
g. Major complications.
h. Minor complications.
i. Authors reported all complications which included Iatrogenic Complications (that is, Intraoperative Complications).

Table H.17 Comparison of da Vinci vs. Open and Single Arm Mediastinal Mass Resection Procedures

Publications		Sample Size (N)	Operative Time (minutes)[a]	Transfusions (%) and/or EBL (mL)	Length of Stay (days)[a]	Complications (%)
40. Balduyck (2011)	Da Vinci	14	224.2	NR	9.6	21.4
	Open	22	243.8	NR	11.8	22.5
41. Seong (2014)	Da Vinci	34	157.2	NR	2.7	0
	Open	34	139.3	NR	5.5	14.7
42. Cerfolio (2012)	Da Vinci	75	95.0	NR	1.0	12.0
43. Huang (2014)	Da Vinci	48	85.9	NR	3.9	2.0
44. Melfi (2012)	Da Vinci	69	124.3	1.4	4.3	7.2
45. Nakamura (2014)	Da Vinci	52	142.6–184.3	0	7.7–12.8	5.8
46. Seder (2013)	Da Vinci	19	210.0	0	2.0	14.0

Notes

a. Mean or median reported.

Table H.18 Comparison of da Vinci vs. Open and VATS and Single Arm Thymectomy Procedures

Publications		Sample Size (N)	Operative Time (minutes)[a]	Transfusions (%) and/or EBL (mL)	Length of Stay (days)[a]	Complications (%)
47. Weksler (2011)	Da Vinci	15	130.0	41.67 mL	1.0	6.7
	Open	35	NR	151.43 mL	4.0	57.1
48. Ye (2014)	Da Vinci	23	97.0	0%/61.3 mL	3.7	4.3
	Open	51	214.5	0%/466.1 mL	11.6	3.9
49. Renaud (2013)	Da Vinci	6	189.2	<10 mL	5.0	0
	Open	15	55.0	24.6 mL	8.7	15.0
50. Ye (2013)	Da Vinci	21	96.2	0%/58.6 mL	3.7	4.8
	VATS	25	103.6	4.0%/86.8 mL	6.7	4.0
51. Ruckert (2010)	Da Vinci	75	187.0	NR	NR	2.7
	VATS	79	198.0	NR	NR	2.5
52. Jun (2014)	Da Vinci	56	139.8	NR	7.18	10.7
	VATS	60	121.07	NR	7.23	6.66
53. Freeman (2011)	Da Vinci	75	113.0	NR	2.2	5.3
54. Goldstein (2010)	Da Vinci	26	127.0	NR	2.0	15.4
55. Huang (2013)	Da Vinci	23	85.2	NR	3.6	4.3
56. Keijzers (2014)	Da Vinci	125	123.0	NR	3.0	7.2
57. Marulli (2012)	Da Vinci	79	155.0	1.2%	3.0	12.7

(continues on next page)

Table H.18 Comparison of da Vinci vs. Open and VATS and Single Arm Thymectomy Procedures (continued)

Publications		Sample Size (N)	Operative Time (minutes)[a]	Transfusions (%) and/or EBL (mL)	Length of Stay (days)[a]	Complications (%)
58. Marulli (2013)	Da Vinci	100	120.0	3.0%	3.0	6.0
59. Mussi (2011)	Da Vinci	14	139.0	NR	4.0	14.2
60. Rea (2011)	Da Vinci	108	120.0	1.8%	3.0	3.6
61. Schneiter (2013)	Da Vinci	20	NR	NR	5.0	10.0

Notes
a. Mean or median reported.

Clinical Study Data

Published clinical data support use of the da Vinci Xi Surgical System for the representative, specific procedures that fall under the cleared "urologic laparoscopic surgical procedures" general Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the more complex/higher risk representative, specific procedures (referred to as "umbrella" procedures). The published data on these "umbrella" procedures were deemed sufficient to cover the less complex/lower risk procedures (referred to as "covered" procedures), so published clinical data on the covered procedures were not provided.

Umbrella Procedures

Published clinical data were provided for the following umbrella procedures: Prostatectomy (Radical), Nephrectomy (Partial, Radical), and Cystectomy (Radical). Sixty one (61) publications were identified for these umbrella procedures based on specific search criteria and filters. These publications included prospective randomized controlled trials, meta-analyses, systematic reviews, Health Technology Assessments (HTAs), large database studies and comparative studies. A detailed summary of the published clinical data on these procedures is provided in Table H.19, Table H.20, Table H.21, and Table H.22.

The findings from the Prostatectomy (Radical) publications show that da Vinci-assisted procedures are associated with comparable or lower mortality rates; comparable or lower blood transfusion rates and EBL volumes; comparable or shorter lengths of hospital stay; comparable or lower intraoperative and postoperative complication rates; comparable rates of positive surgical margins; comparable or higher potency and continence rates; and, comparable or shorter operative times as compared to both open and laparoscopic surgical procedures. Several publications also noted increased operative times in the da Vinci procedures as compared to open procedures. However, this increase did not correlate with an increase in the reported mortality or complication rates. Additionally, these publications report comparable or lower conversion rates for da Vinci-assisted procedures as compared to laparoscopic procedures. One publication reported a higher intraoperative complication rate for da Vinci-assisted procedures as compared to open procedures; one publication reported a higher postoperative complication rate for da Vinci-assisted procedures as compared to laparoscopic procedures; and one publication reported a higher surgical margin rate for da Vinci-assisted procedures as compared to laparoscopic procedures.

Outcomes reported in the Nephrectomy (Partial) publications demonstrate that da Vinci-assisted procedures are associated with comparable or lower mortality rates; comparable or lower blood transfusion rates and EBL volumes; comparable or shorter lengths of hospital stay; comparable or lower intraoperative and postoperative complication rates; comparable rates of positive surgical margins; comparable or shorter warm ischemia times; and, comparable or shorter operative times as compared to both open and laparoscopic surgical procedures. Several publications also noted increased operative times in the da Vinci procedures as compared to open procedures. However, this increase did not correlate with an increase in the reported mortality or complication rates. Additionally, these publications report comparable or lower conversion rates for da Vinci-assisted procedures as compared to laparoscopic procedures. Two publications reported higher warm ischemia times for da Vinci-assisted procedures as compared to open procedures.

The data provided in the Nephrectomy (Radical) publications show that da Vinci-assisted procedures are associated with comparable or lower mortality rates; comparable or lower blood transfusion rates; comparable EBL volumes; comparable or shorter lengths of hospital stay; and, comparable or lower intraoperative and postoperative complication rates; and, comparable or shorter operative times as compared to both open and/or laparoscopic surgical procedures. Additionally, these publications report comparable operative times and conversion rates for da Vinci-assisted procedures as compared to laparoscopic procedures. One publication reported a higher blood transfusion rate for da Vinci-assisted procedures as compared to open and laparoscopic procedures; one publication reported a longer length of stay and a higher "any" complication rate for da Vinci-assisted procedures as compared to laparoscopic procedures.

The findings from the Cystectomy (Radical) publications show that da Vinci-assisted procedures are associated with comparable or lower mortality rates; comparable or lower blood transfusion rates and EBL volumes; comparable or shorter lengths of hospital stay; comparable or lower intraoperative and postoperative complication rates; comparable rates of positive surgical margins; and, comparable operative times as compared to both open and laparoscopic surgical procedures. Several publications also noted increased operative times in the da Vinci procedures as compared to open and laparoscopic procedures. However, this increase did not correlate with an increase in the reported mortality or complication rates. One publication reported comparable conversion rates for da Vinci-assisted procedures as compared to laparoscopic procedures. One publication reported a higher postoperative 90-day complication rate for da Vinci-assisted procedures as compared to open procedures.

Table H.19 Da Vinci vs. Open and da Vinci vs. Laparoscopic Prostatectomy (Radical)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (mL)	Length of Stay (days)	Postoperative Complications (%)
62. Pan (2014)	Da Vinci	798	220.0–330.0	0.94–16.88%	Not Reported	1.4/5.8[a]
	Open	1571	151.0–289.0	1.99–65.0%		2.6/12.2[a]
63. Trinh (2013)	Da Vinci	11,889	Not Reported	1.95%	12.86%[b]	0.36/8.20
	Open	7389		7.74%	39.56%	0.99/11.14
64. Davis (2013)	Da Vinci	27,348	264.0	2.3%	2.2	10.6
	Open	30,124	204.0	11.5%	3.4	15.8
65. Pilecki (2013)	Da Vinci	4,374	212.3	1.87%	Not Reported	5.62
	Open	1,097	174.0	17.68%		23.2
66. Ellimoottil (2014)	Da Vinci	5,503	Not Reported	2.2%	19.4%[c]	2.1/16.6
	Open	3,605		11.2%	46.3%[c]	3.5/21.6
67. Asimakopoulos (2011)	Da Vinci	64	Not Reported	0%	Not Reported	8
	Lap	64		5%		15
68. Porpiglia (2012)	Da Vinci	60	147.6	202.0 mL	4.6	16.6
	Lap	60	138.1	234.1 mL	4.8	11.6
69. Robertson (2013)	Da Vinci	6,768	225	3.5%	Not Reported	0.5–3.9[b]
	Lap	4,952	239	5.0%		0.8–7.2[b]

(continues on next page)

Table H.19 Da Vinci vs. Open and da Vinci vs. Laparoscopic Prostatectomy (Radical) (continued)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (mL)	Length of Stay (days)	Postoperative Complications (%)
70. Novara (2012)	Da Vinci	2,446/977	153.0–330.0	0–13.33%	1.9	1.89–41.67
	Open	2,843	127.0–289.0	1.67–80.65%	5.5–17.0	0.97–83.87
	Lap	903	159.5–267.0	0–48.57%	2.6–16.4	7.06–74.29
71. Tewari (2012)	Da Vinci	62,389	Not Reported	1.8%	1.4	7.8
	Open	167,184		16.5%	3.1	17.9
	Lap	57,303		4.7%	2.1	11.1
72. De Carlo (2014)	Da Vinci	4,044	187.91	4.66%	5.87	18.52
	Open	7,047	179.03	19.93%	7.87	23.2
	Lap	2,841	236.54	6.3%	9.02	13.42
73. Moran (2013)	Da Vinci	1,581	160–341	0–20.0%	1.0–8.0	2.13–22.86
	Open	1,365	127.2–330	0–90.0%	1.3–17.0	4.79–40.0
	Lap	2,166	160.0–264.0	0–9.8%	1.76–6.1	6.34–9.02
74. Yu (2012)	Da Vinci	11,506	Not Reported	1.6%	1.7	8.4
	Open	9,694		5.2%	2.4	10.1
	Lap	611		≤1.8%	2.0	14.5

(continues on next page)

Table H.19 Da Vinci vs. Open and da Vinci vs. Laparoscopic Prostatectomy (Radical) (continued)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (mL)	Length of Stay (days)	Postoperative Complications (%)
75. Laird (2015)	Da Vinci	424	Not Reported	0%	2.5	10.3
	Open	558		2.7%	4.7	8.8
	Lap	1181		0.4%	2.9	14.6
76. Gandaglia (2014)	Da Vinci	3476	Not Reported	1.9%	1	22.2
	Open	2439		8.9%	2	23.8
77. Hyams (2013)	Da Vinci	1499	Not Reported		1.7	Not Reported
	Open	2565			1.9	
78. Kim (2013)	Da Vinci	20,424	Not Reported		1	8.2
	Open	9413			2	11.3
79. Lundstrom (2016)[d]	Da Vinci	7256	Not Reported			0.07, 0.08, 0.06
	Open	9787				0.01, 0.02, 0
80. Monn (2016)	Da Vinci	9248	210	Not Reported	1	Not Reported
	Open	3206	162		2	
81. Pearce (2016)	Da Vinci	73,131	Not Reported		11.6%[e]	Not Reported
	Open	23,804			39.0%[e]	
82. Seo (2016)	Da Vinci	15,766	32–341	0–20.0	1–9	Not Reported
	Open	16,628	74–289	1.7–90	1–17	

(continues on next page)

Table H.19 Da Vinci vs. Open and da Vinci vs. Laparoscopic Prostatectomy (Radical) (continued)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (mL)	Length of Stay (days)	Postoperative Complications (%)
83. Yaxley (2016)	Da Vinci	157	202.03	0.6	1.55	3.8
	Open	151	234.34	4.0	3.27	9.3
84. Huang (2016)	Da Vinci	4114	145.5–280.8	0–7.6	2.2–6.4	3.6–21.0
	Lap	5064	118.1–283.2	0–25.1	2.2–6.6	6.0–42.6
85. Weiner (2015)	Da Vinci	82,338	Not Reported			
	Lap	5077				
86. Anderson (2012)	Da Vinci	12,588	Not Reported		1.7 (vs. O), 1.9 (vs. L)	Not Reported
	Open	8968			2.5	
	Lap	547			1.8	
87. Basto (2016)	Da Vinci	233	Not Reported	0%	1.4	Not Reported
	Open	882		6%	3.6	
	Lap	233		15%	4.8	
88. Stolzenburg (2016)	Da Vinci	2495	Not Reported	2.6%	Not Reported	4.6
	Open	14,741		12.4%		5.4
	Lap	2831		3.8%		3.9

(continues on next page)

Table H.19 Da Vinci vs. Open and da Vinci vs. Laparoscopic Prostatectomy (Radical) (continued)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (mL)	Length of Stay (days)	Postoperative Complications (%)
89. Sugihara (2014)[f]	Da Vinci	2126	322	Auto: 12.2% Homo: 0.7%	11	0.8
	Open	7202	268	Auto: 82.6% Homo: 7.3%	14	5.3
	Lap	2483	329	Auto: 41.8% Homo: 2.3%	11	3.9
90. Wen (2014)	Da Vinci	61,656	Not Reported		Odds Ratio 0.4[g]	Not Reported
	Open	111,361				

Notes

a. Complication rates reported for: Bladder Neck Dissection/Inguinal Hernia.
b. Range includes complications reported for Clavien I–IV.
c. Percentage of cases with prolonged length of stay >2 days reported.
d. Rates reported for abdominal wall defects, wound dehiscence surgery and peritoneal drainage.
e. Percentage of patients with LOS of 2 or more days.
f. Sugihara reports anesthesia time and intraoperative and postoperative complications.
g. Wen, et al. reports odds ratio only.

Table H.20 Da Vinci vs. Open and da Vinci vs. Laparoscopic Nephrectomy (Partial)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (mL)	Length of Stay (days)	Postoperative Complications (%)
91. Aboumarzouk (2012)	Da Vinci	313	152.17–233	122.4–368 mL	2.51–6.2	0–33.3
	Lap	404	117.5–226.05	136.7–580 mL	2.2–5.3	0–33.3
92. Choi (2015)	Da Vinci	1,152	140–376	93.3–368 mL	2–6.2	10.91–37.03[a] 2.67–11.11[b]
	Lap	1,088	156–293	100–400 mL	2–6.9	6.67–30.56[a] 0–15.56[b]
93. Froghi (2013)	Da Vinci	101	153.2–242	139.2–355.7 mL	2.8–6.2	8.53–18.52
	Lap	155	117.5–256	146.3–456.3 mL	2.95–5.3	0–20.34
94. Mir (2011)	Da Vinci	477	188	Not Reported	2.6	Not Reported
	Lap	2,220	200		3.2	
	Open	2,745	193		5.9	
95. Zhang (2013)	Da Vinci	425	151.17–233	122.40–323.00 mL	2.51–6.20	0–22.22
	Lap	341	117.50–226.50	146.30–387.50 mL	2.71–6.80	0–31.11
96. Zhang (2014)	Da Vinci	705	152–376	100–368 mL	2–6.2	0.78–26.63[a] 2.67–7.75[b]
	Lap	835	117.5–361	150–400 mL	2–14	2.54–30.56[a] 1.33–11.76[b]

(continues on next page)

Table H.20 Da Vinci vs. Open and da Vinci vs. Laparoscopic Nephrectomy (Partial) (continued)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (mL)	Length of Stay (days)	Postoperative Complications (%)
97. Wu (2014)	Da Vinci	757	168–231.8	3.81–7.91%	2.5–6.2	9.52–40.66
	Open	2661	123–238.8	4.7–10.61%	4.5–18	13.79–54.21
98. Ghani (2014)[c]	Da Vinci	9095	Not Reported	5.8%	12.4%	22.1
	Lap	3508		7.1%	17.6%	24.9
	Open	25,461		10.6%	34.8%	30.5
99. Kates (2015)	Da Vinci	1078	Not Reported		2.51	Not Reported
	Lap	282			3.0	
100. Hadjipavlou (2016)	Da Vinci	83	179	272 mL	Not Reported	16.0
	Lap	192	159	322 mL		16.3
	Open	412	126	335 mL		18.5
101. Leow (2016)	Da Vinci	2671	108–376	88–490 mL	2.51–10.9	0–3 0.8
	Lap	2238	111–361	61–626 mL	2.0–14.0	4.8–27.8
102. Xia (2016)	Da Vinci	1216	122.3–263.0	0–14.5%/57.5–322mL	1.51–9.67	0–25.5
	Open	2335	123.0–288.7	0–37.8%/ 183.33–653.6mL	2.47–18.0	0–30.1

Notes

a. Minor complications.

b. Major complications.

c. Ghani reports prolonged length of stay.

Table H.21 Da Vinci vs. Open and da Vinci vs. Laparoscopic Nephrectomy (Radical)

Publications		Sample Size (N)	Operative Time (minutes)	Transfusions (%)	Length of Stay (days)	Postoperative Complications (%)
103. Yu (2012)	Da Vinci	327	Not Reported	23.5	5.2	29.9
	Lap	2,601		7.4	4.2	33.8
	Open	11,287		14.1	5.9	37.4
104. Yang (2014)	Da Vinci	7,787	Not Reported		3.0, IQR[a] 2–4	11.0
	Lap	16,525			3.0, IQR[a] 2–5	12.0
105. Kates (2015)	Da Vinci	376	Not Reported		3.52	4.0[b]
	Lap	1,098			4.0	4.0[b]
106. Boger (2010)	Da Vinci	13	168.0	Not Reported	2.0	15.4
	Lap	46	171.0		2.0	2.2
107. Weinberg (2016)	Da Vinci	5,849	Not Reported	4.5	2.12	27.8
	Lap	18,329		4.7	2.04	26.4
	Open	100,284		7.1	3.89	35.3
108. Park (2012)	Da Vinci	20	Not Reported		6	Not Reported
	Lap	20			7.4	
	Open	20			8	

Notes

a. IQR = Interquartile Range.

b. Readmission rates provided in study publication.

Table H.22 Da Vinci vs. Open and da Vinci vs. Laparoscopic Cystectomy (Radical)

Publications		Study Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (mL)	Length of Stay (days)	Postoperative Complications (%)
109. Ishii (2014)	Da Vinci	461	252–455	2–40	Not Reported	25.0–66.34
	Open	287	211–393	19–50		25.0–61.54
110. Li (2013)	Da Vinci	364	252–606	2–52.63	4.4–40.2	33.33–66
	Open	598	210–420	24–71.43	5.3–37.0	50–73.33
111. Novara (2015)	Da Vinci	565/ 62	308–638	4.17–57.14	8.0–40.2	15.38–83.33
	Open	943	259–507	24.0–86.96	8.0–37.0	16.67–78.57
	Lap	78	316–419	25.9–70.0	9.4–16	55.0–81.0
112. Tang (2014)	Da Vinci	382	252–638	0–53.85	5.0–40.2	15.38–66.0
	Open	510	211.2–507	30.30–86.96	6.0–27.0	16.67–85.00
113. Xia (2015)	Da Vinci	787	285.5–606	4.0–52.53	5.5–28.9	40.96–66
	Open	992	222–500.6	24.0–80.95	8–27.1	58.65–73.33
114. Bochner (2014)	Da Vinci	60	456	516 mL	8.0	62.0
	Open	58	329	676 mL	8.0	66.0
115. Messer (2014)	Da Vinci	20	300	40%/400 mL	6.0	25.0
	Open	20	285.5	50%/800 mL	6.0	25.0

(continues on next page)

Table H.22 Da Vinci vs. Open and da Vinci vs. Laparoscopic Cystectomy (Radical) (continued)

Publications		Study Size (N)	Operative Time (minutes)	Transfusions (%) or EBL (mL)	Length of Stay (days)	Postoperative Complications (%)
116. Fonseka (2015)	Da Vinci	728	252–638	212–422 mL	5.1–40.2	28.0
	Lap	276	300–419	331–653 mL	9.13–16.1	72.1
	Open	1100	211–507	398–1790 mL	6–37.0	47.2
117. Khan (2015)	Da Vinci	20	389	585 mL	11.96	55
	Lap	19	301	460 mL	9.7	26
	Open	20	293	808 mL	14.4	70
118. Bagi (2016)	Da Vinci	348	Not Reported		8–15.5	Not Reported
	Open	1509			9–32	
119. Hu (2016)	Da Vinci	439	Not Reported	RR 0.97 (0.96–0.98)	10.1	Not Reported
	Open	7308			11.9	
120. Leow (2014)	Da Vinci	2667	386	Not Reported	10.2	Any 90d: 59.7
	Open	40,980	338		11.8	Any 90d: 56.8
121. Matulewicz (2016)	Da Vinci	2397	Not Reported			
	Open	9639				
122. Monn (2014)	Da Vinci	3733	Not Reported		7	Any in-hospital: 33.2
	Open	25,986			8	Any in-hospital: 37.0

Covered Procedures

The published data on the above cited umbrella procedures were used to support clearance of the following covered procedures: Cystectomy (Partial), Donor Nephrectomy, Cyst Removal, Ureteral Implantation, Lysis of Adhesions and Lymphadenectomy.

Clinical Study Data - Inguinal Hernia Repair

A retrospective, multi-center, non-randomized controlled clinical study evaluating the use of the da Vinci system in Inguinal Hernia Repair procedures compared with open surgical procedures was conducted. This study included 652 and 602 subjects in the robotic-assisted and open cohorts, respectively, and was conducted at six (6) investigational sites in the United States. Post operative data was collected throughout the thirty (30) day follow up period.

Longer term endpoints such as inguinal hernia repair recurrence and chronic pain were not assessed in this study, and thus no claims regarding these clinical outcomes data should be inferred. The results demonstrated the safety and effectiveness of robotic-assisted inguinal hernia repair procedures. Additionally, such data provides information comparing the use of the da Vinci system in inguinal hernia repair procedures with open surgery in the following key measures. (Propensity matched results are the same as the reported outcomes unless stated otherwise):

- Length of Stay: comparable outpatient and inpatient lengths of hospital stay were reported for both the robotic-assisted and open cohorts. A statistically lower inpatient length of stay was found when propensity matched analysis was conducted.
- Intraoperative Complications: comparable intraoperative complication rates were reported for both the robotic-assisted and open cohorts.
- Transfusions: comparable blood transfusion rates were reported in both cohorts.
- Postoperative Complications through Discharge: comparable postoperative through discharge complication rates were reported for both the robotic-assisted and open cohorts.
- Postoperative Complications (Discharge through 30 days[1]): a lower rate of postoperative complications from discharge through 30 day follow up was reported for the robotic-assisted cohort as compared to the open cohort.
- Readmission Rates: comparable readmission rates were reported for both the robotic-assisted and open cohorts.
- Reoperation Rates (Postoperative to Discharge): comparable reoperation rates were reported for the robotic-assisted cohort as compared to the open cohort.
- Reoperation Rates (Discharge through 30 days): lower reoperation rates were reported for the robotic-assisted cohort as compared to the open cohort. This statistically lower rate of reoperations was not observed in the propensity matched analysis. The results of the propensity matched analysis showed comparable reoperation rates.
- Mortality: comparable mortality rates were reported in both cohorts.
- Operative Time: longer operative times were reported for the robotic-assisted cohort as compared to open surgery. The longer operative time for the robotic-assisted cohort was not associated with increases in the complication, readmission, reoperation, or mortality rates.

1. Based on the results of the multivariate analysis, age greater than 65 years, presence of comorbidities and open inguinal hernia repair are associated with a higher likelihood of a postoperative complication within 30 days of surgery. Furthermore, propensity matched analyses showed that age greater than 65 years and open inguinal hernia are associated with a higher likelihood of a postoperative complication within 30 days of surgery.

The data from both cohorts of the retrospective study are compared to data on laparoscopic procedures from eleven (11) publications referenced in Bittner, et al., "Update of guidelines on laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia (International Endohernia Society", Chapter 4: "TEP versus TAPP: which is better?" Surg Endosc 29:289-321 (2015).

Table H.23 Da Vinci, Open, and Laparoscopic Inguinal Hernia Repair

Outcome	Robotic-Assisted Cohort N=652[a]	Open Cohort N=602[a]	Laparoscopic Cohort N = 20–N = 3,457[b]
Patient Demographics Mean age, y (±SD or range) Female Gender, n (%) Male Gender, n (%) Mean BMI, kg/m^2 (± SD or range)	55.8 ±15.6 64 (9.8) 588 (90.2) 27.3 ±5.1	57.2 ±16.6 60 (10.0) 542 (90.0) 26.7 ±5.0	34.91–62.3 0–6.1% 88–100% 22.4–26.8
Length of Stay Inpatient (days) Outpatient (hours)	3.01 ±4.65 (n=52) 7.16 ±3.01	4.86[c] ±5.35 (n=51) 6.89 ±2.77	0.8–5 days
Intraoperative Complications, n (%)	2 (0.3)	0	0–8%
Transfusions, n (%) Perioperative Intraoperative	0 2 (0.3)	0 2 (0.3)	Not Reported
Postoperative Complications, n (%) Postop to discharge Post discharge to 30 days	15 (2.3) 28 (4.3)	10 (1.7) 44 (7.3)[e]	0–36%[d]
Readmission Rates, n (%)[f]	23 (3.5)	26 (4.3)[g]	Not Reported
Reoperation Rates Postop to discharge Post discharge to 30 days	3 (0.5)[f] 0[f]	2 (0.3)[f] 8 (1.3)[f,h]	0–2.5%[d]
Mortality, n	0	1	0
Operative Time, min (± SD or range)	79.7 ±31.7	45.0 ±21.7	32.6–110

(continues on next page)

Table H.23 Da Vinci, Open, and Laparoscopic Inguinal Hernia Repair (continued)

Outcome	Robotic-Assisted Cohort N=652[a]	Open Cohort N=602[a]	Laparoscopic Cohort N = 20–N = 3,457[b]
Adverse Events, n[i]	44	49[j]	Not Applicable
All Complications, n (%)[k]	45 (6.9)	51 (8.5)[l]	7.9–8.7%
Conversion Rate, n (%)	6 (0.9)	Not Applicable	0–4%

Notes

a. Data from a retrospective, multi-center, non-randomized controlled clinical study evaluating the use of the da Vinci Surgical System in Inguinal Hernia Repair procedures compared with open surgical procedures. This table includes all subjects with complete data (missing data is omitted), despite propensity scores showing that one third of investigational subjects did not have an appropriate match among control subjects and large site to site differences.

b. Data from eleven (11) publications referenced in Bittner, et al., "Update of guidelines on laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia (International Endohernia Society", Chapter 4: "TEP versus TAPP: which is better?" Surg Endosc 29:289-321 (2015).

c. The results are heavily influenced by one site. See also other footnotes below. Without this site, the mean number of inpatient days for open procedures is 3.00.

d. Post operative complications and reoperation rates were not segregated by specific time-frames. [Note: One publication (Bracale, et al (2012) reported only relative risk and mean differences for post operative complications and operative time/length of stay.]

e. The results are heavily influenced by one site. See also other footnotes below. Without this site, the mean number of inpatient days for open procedures is 3.00.

f. Related to Inguinal Hernia Repair Procedure.

g. 14/26 readmissions were at one site.

h. Of the 10 reoperations, 80% (8/10) were done at one site.

i. Adverse Events defined as death or serious injury (that is, Clavien Grade IIIa or higher). Publications cited in Bittner, et al. did not categorize complications/events by severity (that is, serious).

j. 30/49 AEs occurred at one site.

k. 30/51 were reported at one site.

l. 30/51 were reported at one site.

Clinical Study Data - Low Anterior Resection/Total Mesorectal Excision (LAR/TME) and Intersphincteric Resection (ISR)

Clinical Study Data

Published clinical data support use of the da Vinci Xi and da Vinci X Surgical Systems in the subject representative, specific procedures that fall under the cleared "general laparoscopic surgical procedures" Indication for Use. Clinical data were not provided for all of the representative, specific procedures.

Instead, clinical data were provided only for the most complex/highest risk representative, specific procedures of Low Anterior Resection/Total Mesorectal Excision "LAR/TME" and Intersphincteric Resection "ISR" (referred to as the "umbrella" procedures). The published data on these "umbrella" procedures were deemed sufficient to cover the less complex/lower risk procedures (referred to as "covered" procedures), so published clinical data on the covered procedures were not provided.

Umbrella Procedure 1- Low Anterior Resection/Total Mesorectal Excision

Published clinical data were provided for the "Low Anterior Resection/Total Mesorectal Excision" umbrella procedure. Eleven (11) publications were identified for this umbrella procedure based on specific search criteria and filters. These publications included a prospective randomized controlled trial, meta-analyses, systematic reviews and large database comparative studies. A detailed summary of the published clinical data on this procedure is provided in Table H.24 Part One and Table H.24 Part Two below.

The findings from the LAR/TME publications show that da Vinci-assisted procedures are associated with:

- Mortality: comparable mortality rates,
- Transfusions: comparable or lower blood transfusion rates and EBL volumes,
- Length of Stay: comparable or shorter lengths of hospital stay,
- Complications: comparable or lower complication rates,
- Surgical Margins: comparable rates of positive surgical margins,
- Anastomotic Leak: comparable anastomotic leak rates, and
- ED: comparable or lower erectile dysfunction ED rates as compared to both open and laparoscopic surgical procedures.
- Operative Time: Increased operative times were associated with da Vinci procedures as compared to open and laparoscopic procedures. However, this increase was not associated with an increase in the mortality or complication rates.
- Urologic Function: Additionally, these publications reported comparable urologic function and comparable or lower conversion rates for da Vinci-assisted procedures as compared to laparoscopic procedures.

Umbrella Procedure 2: Intersphincteric Resection

Published clinical data were provided for the "Intersphincteric Resection" umbrella procedure. Two (2) publications provided ISR data. One (1) publication reported the results from a retrospective comparative cohort study and one (1) publication reported the results from a prospective comparative cohort study. A summary of the published clinical data on this procedure is provided in Table H.25 Part One and Table H.25 Part Two below.

The findings from the ISR publications show that da Vinci-assisted procedures are associated with:

- Mortality: comparable mortality rates,
- Transfusions: comparable blood transfusion rates and EBL volumes,
- Length of Stay: comparable lengths of hospital stay,
- Complications: comparable complication rates,
- Surgical Margins: comparable rates of positive surgical margins,
- Anastomotic Leak: comparable anastomotic leak rates,
- ED: lower erectile dysfunction ED rates, and
- Continence: comparable or higher fecal continence rates as compared to both open and laparoscopic surgical procedures.
- Operative Time: Increased operative times were associated with da Vinci procedures as compared to open and laparoscopic procedures. However, this increase was not associated with an increase in the mortality or complication rates.
- Urologic Function: Additionally, these publications reported comparable urologic function and comparable conversion rates for da Vinci-assisted procedures as compared to laparoscopic procedures.

Covered Procedures

- The published data on the above cited LAR/TME and ISR umbrella procedures were extrapolated to support clearance of the following covered procedures:
- Colectomy (Right, Left, Transverse, Total, Hemi & Sigmoidectomy),
- Small Bowel Resection,
- Rectopexy, and Abdominoperineal Resection (APR)

Table H.24 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Low Anterior Resection/Total Mesorectal Excision

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss "EBL" (mL)	Length of Stay (days)	PostOp Complica-tions (%)	IntraOp Complica-tions (%)	Mortality Rate (%)	Transfusion Rate (%)
123. Midura (2015)	da Vinci	331	Not Reported	Not Reported	5	Not Reported	Not Reported	1.20	Not Reported
	Open	4403			6			1.70	
	Lap	5935			5			1.20	
124. Liao (2016)	da Vinci	498	191–337.9	0–187.5[a]	6–10.8	25.7	Not Reported	1.1	4.6
	Open	576	124 –273.8	120–275.48[a]	7–16	26.6		1.5	7.9
125. Soma-shekhar (2015)	da Vinci	25	310.3	165.14	7.52	0/0[b]	4	0	Not Reported
	Open	25	246.3	406.04	13.24	16/4[b]	0	0	
126. Lee (2015)	da Vinci	1043	202–396.5	45.7–188.8	2.9–11.9	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	1181	158.1–298.8	59.2–229.2	3.9–13.5				
127. Lin (2011)	da Vinci	268	202–232.6	100–137.40	6.9–11.9	22.01	Not Reported	Not Reported	Not Reported
	Lap	393	158.10–208	127–150	8.7–9.8	19.34			
128. Memon (2012)	da Vinci	353	190.1–385.3	Not Reported	5.7–11.9	10.7–32.2	Not Reported	Not Reported	Not Reported
	Lap	401	168.6–315.0		6–14.4	18.9–27.1			
129. Sun Y (2016)	da Vinci	1217	Not Reported	Not Reported	5	16	Not Reported	0.40	Not Reported
	Lap	4700			5	19.1		0.76	

(continues on next page)

Table H.24 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Low Anterior Resection/Total Mesorectal Excision (continued)

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss "EBL" (mL)	Length of Stay (days)	PostOp Complica-tions (%)	IntraOp Complica-tions (%)	Mortality Rate (%)	Transfusion Rate (%)
130. Sun Z (2015)	da Vinci	324	190.1–325.5	Not Reported	4–8	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	268	190–280		3.6–10				
131. Trastulli (2012)	da Vinci	125	190.1–385.3	Not Reported	5.7–11.9	29.30	Not Reported	0	Not Reported
	Lap	156	158.1–297.3		6.6–14.4	23.10		0	
132. Xiong (2014)	da Vinci	554	202–309.7	100–200	6.5–11.9	10–32.4	Not Reported	0	Not Reported
	Lap	675	158.1–315	126.2–300	6–13.5	12.2–27.9		0	
133. Yang (2012)	da Vinci	300	190.1–296	100– 200	5.7–11.9	10.7–32.2	Not Reported	Not Reported	Not Reported
	Lap	426	158.1–315	127–300	6–9.8	12.2–27.1	Not Reported		Not Reported

Notes

a. Intraoperative Transfusions were also reported (robotic cohort: 1.9–5.4%, open cohort: 0–12.4%)

b. Minor and Major Complications Reported

Table H.24 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Low Anterior Resection/Total Mesorectal Excision

Publications	Sample Size (N)		PSM Rate (%)	Urologic-Function	Conversion Rate (%)	No. of Lymph Nodes Harvested	CRM/ Positive CRM Rate (%)	DRM/ Positive DRM Rate (%)	Anastomotic Leak Rate (%)	Erectile Dysfunction
123. Midura (2015)	da Vinci	331	4.30	Not Reported	Not Reported	71.6% ≥2	Not Reported	Not Reported	Not Reported	Not Reported
	Open	4403	6.10			66.3% ≥2				
	Lap	5935	4.70			68.7% ≥2				
124. Liao (2016)	da Vinci	498	Not Reported	Not Reported	Not Reported	17.4	8.41	2.08	6.63	Not Reported
	Open	576				16.5	8.62	2.02	4.51	
125. Somashekhar (2015)	da Vinci	25	0	Not Reported	0	16.88	0	3.6 cm /0% 0%	0	18%[a]
	Open	25	0		N/A	15.2	0	2.4 cm /0% 0%	4	26%[a]

(continues on next page)

Table H.24 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Low Anterior Resection/Total Mesorectal Excision (continued)

Publications	Sample Size (N)		PSM Rate (%)	Urologic-Function	Conversion Rate (%)	No. of Lymph Nodes Harvested	CRM/ Positive CRM Rate (%)	DRM/ Positive DRM Rate (%)	Anastomotic Leak Rate (%)	Erectile Dysfunction
126. Lee (2015)	da Vinci	1043	Not Reported	3 mo: 3.6–8.36[b] 6mo: 3.5–8[b] 12mo: 3.53–6[b]	1.19	10.3–20	Not Reported	Not Reported	0–20	3mo:3.8–8.0[c] 6mo:2.4–4.5[b]
	Lap	1181		3mo: 5.5–11.7[b] 6mo: 3.2–8.2[b] 12mo: 4.2–8[b]	6.50	11.07–17.4			2.7–14	3mo: 5.9–13[b] 6mo: 4.5–6.8[b]
127. Lin (2011)	da Vinci	268	Not Reported	Not Reported	1.87	15.3	1.69%	2.8	Not Reported	Not Reported
	Lap	393			7.63	13.8	3.17%	3.6		
128. Memon (2012)	da Vinci	353	Not Reported	Not Reported	1.42	MD[d]: -0.9 [-1.94, 1.80]	3.1	2.0–4.0	Not Reported	Not Reported
	Lap	401			7.73		3.2	2.0–4.5		
129. Sun Y (2016)	da Vinci	1217	7	Not Reported	8.22	16.8	4.76	3.5%	Not Reported	Not Reported
	Lap	4700	7		15.76	16.4	9.3	4%		

(continues on next page)

Table H.24 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Low Anterior Resection/Total Mesorectal Excision (continued)

Publications	Sample Size (N)		PSM Rate (%)	Urologic-Function	Conversion Rate (%)	No. of Lymph Nodes Harvested	CRM/ Positive CRM Rate (%)	DRM/ Positive DRM Rate (%)	Anastomotic Leak Rate (%)	Erectile Dysfunction
130. Sun Z (2015)	da Vinci	324	Not Reported	Not Reported	0	15	5	Not Reported	Not Reported	Not Reported
	Lap	268			7.94	14	5			
131. Trastulli (2012)	da Vinci	125	Not Reported	Not Reported	2.8	13.1–19.4	2.8	2–3.6	8	Not Reported
	Lap	156			6.7	15.9–17	4.0	2–3.8	6.3	
132. Xiong (2014)	da Vinci	554	Not Reported	Not Reported	1.08	10.3–19.4	2.74	1.9–2.8	4–11	3.3–5.5[e]
	Lap	675			5.19	11.1–17	5.78	2–4.5	2.7–14	16.6–43.3[e]
133. Yang (2012)	da Vinci	300	Not Reported	Not Reported	1.67	10.3–20	0 –7.1	2–4	1.8–13.6	Not Reported
	Lap	426			7.98	11.1–21	0–8.8	2–4.5	2.7–10.2	

Notes

a. Erectile dysfunction and retrograde ejaculation were assessed in all male patients during follow-up using the European Organization for Research and Treatment of Cancer (EORTC) questionnaire QLQ-C38. A total of 18% of male patients in the RA group and 26% in the OA group had sexual dysfunction features.

b. Publication reported the IPSS score for Urologic function.

c. Publications utilized IIEF Questionnaires.

d. Mean difference reported with 95% confidence interval.

e. One publication used a non-standardized questionnaire to assess ED and the other used the IIEF Questionnaire.

Table H.25 Part One Da Vinci vs. Open vs. Laparoscopic Intersphincteric Resection (ISR)

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss "EBL" mL	Length of Stay (days)	PostOp Complica-tions (%)	IntraOp Complica-tions (%)	Mortality Rate	Transfusion Rate (%)
134. Park (2012)	da Vinci	40	235.5	45.7	10.6	15	Not Reported	0	0
	Lap	40	185.4	59.2	11.3	12.5		0	0
135. Kim (2014)	da Vinci	108	191	Not Reported	7	22.2	1.9	0	4.6
	Open	114	124		7.6	17.5	4.4	0	7.0

Table H.25 Part Two Da Vinci vs. Open vs. Laparoscopic Intersphincteric Resection (ISR)

Publications	Sample Size (N)		PSM Rate (%)	Urologic Function	Conversion Rate (%)	No. of Lymph Nodes Retrieved	CRM (cm)	DRM (cm)	Anastomotic Leak Rate (%)	Erectile Dysfunction	Fecal Incontinence
134. Park (2012)	da Vinci	40	Not Reported	3.6/3.5[a]	0	12.9	6.2 mm	1.4	7.5	11.6/13.0[b]	8.2/7.8[c]
	Lap	40		5.5/3.2[a]	0	13.3	6.9 mm	1.3	5	7.6/9.0[b]	11.2/8.4[b]
135. Kim (2014)	da Vinci	108	Not Reported		0	18.6	0.9%[d]	1.4	4.6	12.5[e]	12.5/7.7[f]
	Open	114			N/A	16.7	0%[c]	1.2	4.4	34.1[d]	14.2/10.3[e]

Notes

a. IPSS at 3 and 6 months.

b. IIEF-5 at 3 and 6 months

c. Wexner Scores at 3 and 6 months

d. CRM involvement, ≤1 mm

e. Sexual dysfunction represented >1/3 functional impairments of erectile or ejaculatory potency in male patients aged ≤65 years. These parameters were assessed in 40 patients (RA group) and 44 patients (open group), respectively, at 6 months after surgery or chemoradiotherapy.

f. Assessed at 6 and 12 months

Clinical Study Data

Published clinical data support use of the da Vinci Xi® Surgical System and the da Vinci X® Surgical System for the representative, specific procedures that fall under the cleared "general laparoscopic surgical procedures" Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the more complex/higher risk representative, specific procedures of Pancreatectomy and Pancreaticoduodenectomy (Whipple Procedure) (referred to as the "umbrella" procedures). The published data on these "umbrella" procedures were deemed sufficient to cover the less complex/lower risk procedures (referred to as "covered" procedures), so published clinical data on the covered procedures were not provided.

Umbrella Procedures

Umbrella Procedure 1: Pancreatectomy

Published clinical data were provided for the umbrella procedure "Pancreatectomy". Eleven (11) publications were identified for this umbrella procedure based on specific search criteria and filters. These publications included a prospective randomized controlled trial, meta-analyses, systematic reviews and large database comparative studies. A detailed summary of the published clinical data on this procedure is provided in Table H.26 Part One,Table H.26 Part Two, Table H.27 Part One and Table H.27 Part Two below.

The findings from the Pancreatectomy publications show that da Vinci-assisted procedures as compared to open and laparoscopic procedures are associated with:

- Mortality: comparable mortality rates,
- Estimated Blood Loss and/or Transfusion Rates: comparable or lower blood transfusion rates and/or EBL volumes,
- Lengths of Hospital Stay: comparable or shorter length of hospital stay as compared to laparoscopy and open surgery,
- Complication Rates: comparable or lower complication rates,
- Spleen Preservation Rates: higher or comparable spleen preservation rates,
- Gastric Emptying Rates: lower or comparable delayed gastric emptying rates,
- Reoperation Rates: comparable reoperation rates,
- Readmission Rates: comparable or higher readmission rates, and
- Pancreatic Fistula Rates: comparable pancreatic fistula rates as compared to both open and laparoscopic surgical procedures.
- Operative Time: Increased operative times were associated with da Vinci procedures as compared to open and laparoscopic procedures. However, this increase was not associated with an increase in the mortality or complication rates.
- Conversion Rates: comparable or lower conversion rates were reported for da Vinci-assisted procedures as compared to laparoscopic procedures.

Umbrella Procedure #2: Pancreaticoduodenectomy

Published clinical data were provided for the umbrella procedure "Pancreaticoduodenectomy". Eight (8) publications were identified for this umbrella procedure based on specific search criteria and filters. These publications included meta-analyses, systematic reviews and a large database comparative study. A detailed summary of the published clinical data on this procedure is provided in Table H.28 Part One, Table H.28 Part Two, Table H.29 Part One, and Table H.29 Part Two below.

The findings from the Pancreaticoduodenectomy publications show that da Vinci-assisted procedures as compared to open and laparoscopic procedures are associated with:

- Mortality: comparable mortality rates,
- Estimated Blood Loss Volume[2]: comparable EBL volumes,
- Lengths of Hospital Stay: comparable length of hospital stay as compared to laparoscopy and comparable or shorter length of hospital stay as compared to open surgery,
- Complication Rates: comparable or lower complication rates,
- Gastric Emptying Rates: lower or comparable delayed gastric emptying rates,
- Reoperation Rates: comparable reoperation rates, and
- Pancreatic Fistula Rates: comparable pancreatic fistula rates as compared to both open and laparoscopic surgical procedures
- Operative Time: Increased operative times were associated with da Vinci procedures as compared to open and laparoscopic procedures. However, this increase was not associated with an increase in the mortality or complication rates.
- Conversion Rates: comparable or lower conversion rates for da Vinci-assisted procedures were reported as compared to laparoscopic procedures

The published data on the above cited Pancreatectomy and Pancreaticoduodenectomy (Whipple Procedure) umbrella procedures were used to support clearance of the following covered procedures: Splenectomy and Cholecystectomy.

2. One publication (Orti-Rodriguez, et al) reported a higher EBL volume, a longer length of stay and a higher pancreatic fistula rate for the da Vinci cohort as compared to the laparoscopic cohort. These outcomes were not associated with increased complication or mortality rates.

Table H.26 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreatectomy

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss (EBL) (ml)	Length of Stay (days)	PostOp Complica-tions (%)
136. Adam (2015)	da Vinci	61	Not Reported	Not Reported	8	Not Reported
	Lap	474			6	
	Open	1198			9	
137. Chen S (2017)	da Vinci	50	160	50	15.6	46
	Open	50	193	200	21.7	60
138. Chen Y (2013)	da Vinci	67/45	range (293–719)	range (150–372)	range (3.8–16.4)	Not Reported
	Lap	137	range (224–372)	range (150–667)	range (6.4–7.3)	
	Open	45	range (234–420)	range (210–858)	range (7.7–24.3)	
139. Gavrilidis (2016)	da Vinci	246	range (213–349)	Not Reported	range (5–11.6)	16
	Lap	391	range (174–372)		range (6.0–14.7)	17

(continues on next page)

Table H.26 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreatectomy (continued)

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss (EBL) (ml)	Length of Stay (days)	PostOp Complications (%)
140. Huang (2016)	da Vinci	238	range (293–349)	Not Reported	range (6.1–8.9)	Not Reported
	Lap	929	range (250–372)		range (6.0–19.2)	
141. Konstantinidis (2017)	da Vinci	115	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	365				
	Open	558				
142. Wright (2016)	da Vinci	195	230	172	8	18
	Lap	349	249	281	7	17
143. Xourafas (2017)	da Vinci	200	243	Not Reported	5	37
	Lap	694	205		5	36
	Open	921	222		7	45
144. Zhang (2013)	da Vinci	22	range (298–432)	range (275–279)	range (4–14.6)	17.6–20[a]
	Open	32	range (234–286.5)	range (681–858.3)	range (8–22.1)	18.2–50[a]

(continues on next page)

Table H.26 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreatectomy (continued)

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss (EBL) (ml)	Length of Stay (days)	PostOp Complica-tions (%)
145. Zhou (2016)	da Vinci	211	range (150–372)	range (100–375)	range (3.8–11.6)	43.6
	Lap	357	range (193–295)	range (262–667)	range (5–14.7)	52.4
146. Zureikat (2017)	da Vinci	258	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	684				
	Open	3743				

Notes

a. Authors reported on “Overall Complication Rate”

Table H.26 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreatectomy

Publications	Procedure Type	Mortality Rate (%)	Transfusion Rate (%)	Reoperation Rate (%)	Readmission Rate (%)
136. Adam (2015)	da Vinci	0	Not Reported	Not Reported	suppressed 12.9
	Lap	suppressed			11
	Open	2			9
137. Chen S (2017)	da Vinci	0	0	4	2
	Open	0	10	8	2
138. Chen Y (2013)	da Vinci	Not Reported	Not Reported	Not Reported	Not Reported
	Lap				
	Open				
139. Gavrilidis (2016)	da Vinci	0.4	Not Reported	Not Reported	5.6–36.7
	Lap	0.3			0–23.4
140. Huang (2016)	da Vinci	0	13.9	Not Reported	Not Reported
	Lap	0	11.4		
141. Konstantinidis (2017)	da Vinci	Not Reported	Not Reported	Not Reported	Not Reported
	Lap				
	Open				
142. Wright (2016)	da Vinci	0	Not Reported	Not Reported	Not Reported
	Lap	<1			

(continues on next page)

Table H.26 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreatectomy (continued)

Publications	Procedure Type	Mortality Rate (%)	Transfusion Rate (%)	Reoperation Rate (%)	Readmission Rate (%)
143. Xourafas (2017)	da Vinci	0.5	6	3	17
	Lap	1	5	3	14
	Open	1.5	21	5	18
144. Zhang (2013)	da Vinci	0	Not Reported	0	Not Reported
	Open	0		2	
145. Zhou (2016)	da Vinci	1.4	8.3	Not Reported	Not Reported
	Lap	2.0	11.1		
146. Zureikat (2017)	da Vinci	Not Reported	Not Reported	Not Reported	Not Reported
	Lap				
	Open				

Table H.27 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreatectomy

Publications	Sample Size (N)		Spleen Preservation Rate (%)	R0 Resection Rate (%)	R1 Resection Rate (%)
136. Adam (2015)	da Vinci	61	Not Reported	Not Reported	suppressed 12.9
	Lap	474			11
	Open	1198			9
137. Chen S (2017)	da Vinci	50	Not Reported	Not Reported	2
	Open	50			2
138. Chen Y (2013)	da Vinci	67/45	81.1	98	Not Reported
	Lap	137	48.8	83	
	Open	45	13.6	82	
139. Gavrilidis (2016)	da Vinci	246	Not Reported	100	5.6–36.7
	Lap	391		98	0–23.4
140. Huang (2016)	da Vinci	238	35.4	Not Reported	Not Reported
	Lap	929	27.7		
141. Konstantinidis (2017)	da Vinci	115	Not Reported	Not Reported	Not Reported
	Lap	365			
	Open	558			

(continues on next page)

Table H.27 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreatectomy (continued)

Publications	Sample Size (N)		Spleen Preservation Rate (%)	R0 Resection Rate (%)	R1 Resection Rate (%)
142. Wright (2016)	da Vinci	195	Not Reported	Not Reported	Not Reported
	Lap	349			
143. Xourafas (2017)	da Vinci	200	8	Not Reported	17
	Lap	694	9		14
	Open	921	10		18
144. Zhang (2013)	da Vinci	22	Not Reported	Not Reported	Not Reported
	Open	32			
145. Zhou (2016)[a]	da Vinci	211	53.6	100	Not Reported
	Lap	357	27.8	92.6	
146. Zureikat (2017)[a]	da Vinci	258	Not Reported	Not Reported	Not Reported
	Lap	684			
	Open	3743			

Notes

a. Authors provided combined data for pancreatectomy and pancreaticoduodenectomy procedures.

Table H.27 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreatectomy

Publications	Procedure Type	Lymph Node Yield (n)	Delayed Gastric Emptying Rate (%)	Pancreatic Fistula Rate (%)	Conversion Rate (%)
136. Adam (2015)	da Vinci	12	Not Reported	Not Reported	Suppressed 14.8
	Lap	127			23
	Open	13			NA
137. Chen S (2017)	da Vinci	Not Reported	A (12), B (6), C (6)	44	Not Reported
	Open		A (22), B (8), C (4)	54	
138. Chen Y (2013)	da Vinci	Not Reported	Not Reported	30.2	Not Reported
	Lap			36.6	
	Open			31.1	
139. Gavrilidis (2016)	da Vinci	Not Reported	Not Reported	24.3	9
	Lap			24.0	20
140. Huang (2016)	da Vinci	Not Reported	Not Reported	29.9	8.9
	Lap			31.3	23.0
141. Konstantinidis (2017)	da Vinci	Not Reported	Not Reported	Not Reported	11.3
	Lap				21.9
	Open				NA

(continues on next page)

Table H.27 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreatectomy (continued)

Publications	Procedure Type	Lymph Node Yield (n)	Delayed Gastric Emptying Rate (%)	Pancreatic Fistula Rate (%)	Conversion Rate (%)
142. Wright (2016)	da Vinci	Not Reported	Not Reported	Not Reported	10
	Lap				19
143. Xourafas (2017)	da Vinci	Not Reported	1	21	8
	Lap		3	18	16
	Open		5	17	NA
144. Zhang (2013)	da Vinci	Not Reported	Not Reported	4.5	0–12
	Open			25.0	NA
145. Zhou (2016) [a]	da Vinci	range (5–19)	Not Reported	25.8	16.1
	Lap	range (5–15.2)		24.7	23.0
146. Zureikat (2017)[a]	da Vinci	Not Reported	Not Reported	Not Reported	10
	Lap				18.2
	Open				NA

Notes

a. Authors provided combined data for pancreatectomy and pancreaticoduodenectomy procedures.

Table H.28 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreaticoduodenectomy

Publication	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss "EBL" (ml)	Length of Stay (days)	PostOp Complications (%)
147. de Rooij (2016)	da Vinci	160	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	641				
	Open	1123				
148. Lei P (2014)	da Vinci	102	range (444–719)	range (154–485)	range (13–16.4)	43.14[b]
	Lap	107	range (338–657)	range (195–448)	range (8–48)	57.01[b]
	Open	144/285	range (265–559)	range (210–1510)	range (12.4–43)	54.9/65.3[b]
149. Orti Rodriguez (2012)	da Vinci	109	394.77	319.06	15.31	16.5
	Lap	192	388.8	178.7	9.9	35.9
150. Pedziwiatr (2017)	da Vinci	476	range (400–718)	range (100–775)	range (7.4–20.0)	37.7
	Lap	229	range (361–513)	range (260–492.4)	range (6.0–10.0)	59.5
	Open	1162/319	range (300–559)	range (210–867)	range (8.0–25.8)	31.9/80.0

(continues on next page)

Table H.28 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreaticoduodenectomy (continued)

Publication	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss "EBL" (ml)	Length of Stay (days)	PostOp Complications (%)
151. Peng (2016)	da Vinci	245	range (410–718.8)	range (100–650)	range (13–20)	35
	Open	435	range (264.9–559)	range (210–840)	range (14.6–25.8)	45
152. Shin (2016)	da Vinci	160	range (340–492)	range (100–500)	range (7–20)	37.1
	Lap	450	range (342–551)	range (195–609)	range (6–25)	40.8
	Open	294/718	range (264–410)	range (293–1032)	range (8–26)	47.7/50.9
144. Zhang (2013)	da Vinci	115	range (444–718.8)	range (153.75–537)	range (7–16.38)	25–36.4[a]
	Open	171	range (364–559)	range (210–840)	range (13.26–24.25)	23.2–75[a]
146. Zureikat (2017)	da Vinci	258	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	684				
	Open	3743				

Notes

a. Authors reported on "Overall Complication Rate"

b. Authors reported both intraoperative and post-operative complication rates.

Table H.28 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreaticoduodenectomy

Publication	Sample Size (N)	Mortality Rate (%)	Transfusion Rate (%)	Reoperation Rate (%)	Readmission Rate (%)
147. de Rooij (2016)	da Vinci	2.5	Not Reported	Not Reported	Not Reported
	Lap	3.0			
	Open	3.7			
148. Lei P (2014)	da Vinci	Not Reported	Not Reported	Not Reported	Not Reported
	Lap				
	Open				
149. Orti Rodriguez (2012)	da Vinci	3	Not Reported	Not Reported	Not Reported
	Lap	2.7			
150. Pedziwiatr (2017)	da Vinci	Not Reported	Not Reported	Not Reported	Not Reported
	Lap				
	Open				
151. Peng (2016)	da Vinci	2.9	Not Reported	7.3	Not Reported
	Open	2.8		13.0	
152. Shin (2016)	da Vinci	Not Reported	Not Reported	Not Reported	Not Reported
	Lap				
	Open				
144. Zhang (2013)	da Vinci	0–4.5	Not Reported	6.5	Not Reported
	Open	0–12.5		18.6	

(continues on next page)

Table H.28 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreaticoduodenectomy (continued)

Publication	Sample Size (N)	Mortality Rate (%)	Transfusion Rate (%)	Reoperation Rate (%)	Readmission Rate (%)
146. Zureikat (2017)	da Vinci	Not Reported	Not Reported	Not Reported	Not Reported
	Lap				
	Open				

Table H.29 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreaticoduodenectomy

Publication	Sample Size (N)		Spleen Preservation Rate (%)	R0 Resection Rate (%)	R1 Resection Rate (%)
147. de Rooij (2016)	da Vinci	160	Not Reported	Not Reported	Not Reported
	Lap	641			
	Open	1123			
148. Lei P (2014)	da Vinci	102	Not Reported	Not Reported	Not Reported
	Lap	107			
	Open	144/285			
149. Orti Rodriguez (2012)	da Vinci	109	Not Reported	Not Reported	Not Reported
	Lap	192			
150. Pedziwiatr (2017)	da Vinci	476	Not Reported	Not Reported	35.5
	Lap	229			20.7
	Open	1162/319			29.5/23.0
151. Peng (2016)	da Vinci	245	Not Reported	93.1	Not Reported
	Open	435		81.5	
152. Shin (2016)	da Vinci	160	Not Reported	Not Reported	13.4
	Lap	450			21.6
	Open	294/718			22.8/22.1

(continues on next page)

Table H.29 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreaticoduodenectomy (continued)

Publication	Sample Size (N)		Spleen Preservation Rate (%)	R0 Resection Rate (%)	R1 Resection Rate (%)
144. Zhang (2013)	da Vinci	115	Not Reported	Not Reported	3.1
	Open	171			14.8
146. Zureikat (2017)	da Vinci	258	Not Reported	Not Reported	Not Reported
	Lap	684			
	Open	3743			

Table H.29 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreaticoduodenectomy

Publication	Procedure Type	Lymph Node Yield (n)	Delayed Gastric Emptying Rate (%)	Pancreatic Fistula Rate (%)	Conversion Rate (%)
147. de Rooij (2016)	da Vinci	Not Reported	Not Reported	7.6	8
	Lap			12.7	7
	Open			18.4	NA
148. Lei P (2014)	da Vinci	Not Reported	4.3	20.6	Not Reported
	Lap		13.1	23.4	
	Open			19.4/17.5	
149. Orti Rodriguez (2012)	da Vinci	Not Reported	Not Reported	30	12
	Lap			14.5	8.3
150. Pedziwiatr (2017)	da Vinci	range (15–37)	23.7	20.2	Not Reported
	Lap	range (8.7–23)	8.7	15.7	
	Open	range (9.6–36)	20.1/17.2	12.7/17.6	
151. Peng (2016)	da Vinci	range (10.0–16.8)	6.8	17.9	7.3
	Open	range (10.0–12.5)	14.1	21.4	NA
152. Shin (2016)	da Vinci	range (10–15)	8.8	18.5	7.5
	Lap	range (8.7–23.4)	9.6	29.8	7.8
	Open	range (9.6–25.0)	15.6/14.2	21.6/23.0	NA

(continues on next page)

Table H.29 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Pancreaticoduodenectomy (continued)

Publication	Procedure Type	Lymph Node Yield (n)	Delayed Gastric Emptying Rate (%)	Pancreatic Fistula Rate (%)	Conversion Rate (%)
144. Zhang (2013)	da Vinci	Not Reported	Not Reported	14.4	Not Reported
	Open			22.0	
146. Zureikat (2017)	da Vinci	Not Reported	Not Reported	Not Reported	14.8
	Lap				31.9
	Open				NA

Clinical Study Data

Published clinical data support use of the da Vinci Xi Surgical System (Model IS4000) and the da Vinci X Surgical System (Model IS4200) in the subject representative, specific procedures that fall under the cleared “general laparoscopic surgical procedures” Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the most complex/highest risk representative, specific procedure of Gastric Bypass (Roux-en-Y) (referred to as the “umbrella” procedure). The published data on this “umbrella” procedure were deemed sufficient to cover the less complex/lower risk procedure (referred to as a “covered” procedure), so published clinical data on the covered procedure were not provided.

Umbrella Procedure

Published clinical data were provided for the umbrella procedure "Gastric Bypass (Roux-en-Y)". Ten (10) publications were identified for this umbrella procedure based on specific search criteria and filters.

These publications included two (2) non-randomized, controlled, prospective studies (LOE 2b) and 8 retrospective cohort studies (LOE 3b) comparing da Vinci-assisted procedures with laparoscopic and/or open cohorts. A detailed summary of the published clinical data on this procedure is provided in Table H.30 Part One and Table H.30 Part Two below.

The findings from the Gastric Bypass publications show that da Vinci-assisted procedures as compared to open procedures are associated with:

- Mortality: comparable mortality rates,
- Lengths of Hospital Stay: shorter lengths of hospital stay,
- Intraoperative Complication Rates: comparable intraoperative complication rates,
- Postoperative Complication Rates: comparable or lower postoperative complication rates,
- Anastomotic Leak Rate: comparable anastomotic leak rates,
- Anastomotic Stricture Rate: comparable anastomotic stricture rates,
- Reoperation Rate: comparable or lower reoperation rates[3] , and
- Operative Time: Increased operative times were associated with da Vinci procedures. However, this increase was not associated with an increase in the mortality or complication rates.

The findings from the Gastric Bypass publications show that da Vinci-assisted procedures as compared to laparoscopic procedures are associated with:

- Mortality: comparable mortality rates,
- Estimated Blood Loss: comparable EBL volumes,
- Lengths of Hospital Stay: comparable or shorter lengths of hospital stay[4],
- Intraoperative Complication Rates: comparable intraoperative complication rates,
- Postoperative Complication Rates: comparable or lower postoperative complication rates,
- Anastomotic Leak Rate:
  - Comparable anastomotic leak rates when comparing hand-sewn gastrojejunal anastomoses in both cohorts,
  - Comparable or lower anastomotic leak rates when comparing stapled laparoscopic gastrojejunal anastomoses with hand-sewn robotic-assisted gastrojejunal anastomoses.
- Anastomotic Stricture Rate[4] :
  - Comparable anastomotic stricture rates when comparing hand-sewn gastrojejunal anastomoses in both cohorts,

3. No publications comparing da Vinci-assisted and open procedures reported readmission rates.
4. One (1) publication (Benizri, et al) reported a longer length of stay, a higher reoperation rate and a higher 30-90 day anastomotic stricture rate for the robotic cohort. These outcomes were not associated with increased intraoperative, overall postoperative complication or mortality rates.

  - Comparable or lower anastomotic stricture rates when comparing stapled laparoscopic gastrojejunal anastomoses with hand-sewn robotic-assisted gastrojejunal anastomoses.

- Reoperation Rate: comparable or lower reoperation rates[5]
- Readmission Rate: comparable readmission rates, and
- Operative Time: comparable or shorter operative times (N = 3 publications). Increased operative times were associated with da Vinci procedures as compared laparoscopic procedures (N = 7 publications). However, this increase was not associated with an increase in the mortality or complication rates.
- Conversion Rates: comparable or lower conversion rates were reported for da Vinci-assisted procedures as compared to laparoscopic procedures.

Covered Procedure

The published data on the Gastric Bypass (Roux-en-Y) umbrella procedure were used to support clearance of Gastric Sleeve procedures.

5. One (1) publication (Benizri, et al) reported a longer length of stay, a higher reoperation rate and a higher 30-90 day anastomotic stricture rate for the robotic cohort. These outcomes were not associated with increased intraoperative, overall postoperative complication or mortality rates.

Table H.30 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastric Bypass (Roux-en-Y)

Author	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Conversion Rate (%)	Intraop Comp Rate
153. Ahmad (2015)	da Vinci	172	155.0	11.6	2.4	0.0%	0.0%
	Lap	173	135.3	13.4	2.5	0.0%	0.0%
154. Ayloo (2016)	da Vinci	61	213.1	24	2.8	3.3%	3.3
	Lap	46	234.0	20.2	2.5	0.0%	0.0%
155. Benizri (2013)	da Vinci	100	130	Not Reported	9.3	3.0%	21.0%[a]
	Lap	100	147		6.7	1.0%	16.0%[a]
156. Myers (2013)	da Vinci	100	144	Not Reported	1.55	0.0%	Not Reported
	Lap	100	87		2.17	0.0%	
157. Smeenk (2016)	da Vinci	100	67	Not Reported	2	0.0%	Not Reported
	Lap	100	31		2	0.0%	
158. Stefanidis (2017)	da Vinci	125	213	49	1.7	0.0%	0.0%
	Lap	121	155	56	2.1	0.8%	0.0%
159. Wood (2014)	da Vinci	100	182.29	Not Reported	3.15	Not Reported	Not Reported
	Lap	100	158.91		2.77		
160. Buchs (2016)	da Vinci	65	244	Not Reported	6	3.1%	1.5%
	Lap	54	238		16	13.0%	3.7%
	Open	95	217		14	NA	1.1%

(continues on next page)

Table H.30 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastric Bypass (Roux-en-Y) (continued)

Author	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Conversion Rate (%)	Intraop Comp Rate
161. Buchs (2014)	da Vinci	388	245.0	Not Reported	6.2	0.8%	0.8%
	Lap	389	215.8		10.4	4.9%	1.5%
162. Hagen (2012)	da Vinci	143	293	Not Reported	7.4	1.4%	Not Reported
	Lap	323	206		11.0	5.0%	
	Open	524	NR		10.9	NA	

Notes

a. Authors reported “intraoperative difficulties”.

Table H.30 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastric Bypass (Roux-en-Y)

Author	Procedure Type	PostOp Comp Rate	Mortality (in-hospital or 30 days)	Anastomotic Leak Rate (%)	Anastomotic Stricture Rate (%)	Reoperation Rate (%)	Readmission Rate (%)
153. Ahmad (2015)	Robotic	0.0%	0.0%	0.0%	0.0%	0	Not Reported
	Lap	0.0%	0.0%	0.0%	0.0%	0	
154. Ayloo (2016)	Robotic	9.8%, 1.6%[a]	0.0%	0%[b]	Not Reported	1.6	Not Reported
	Lap	15.2%, 0%[a]	0.0%	2.2%[b]		2.2	
155. Benizri (2013)	Robotic	24.0%[c]	1%	3	7%[d]	9	Not Reported
	Lap	21.0%[c]	0%	0	0[d]	1	
156. Myers (2013)	Robotic	11.0%	0.0%	1.0%	6.0%	2.0	3.0
	Lap	15.0%	0.0%	1.0%	2.0%	1.0	8.0
157. Smeenk (2016)	Robotic	5%, 17%[e]	0.0%	0.0%	0.0%	3.0	Not Reported
	Lap	5%, 13%[e]	0.0%	0.0%	1.0%	1.0	
158. Stefanidis (2017)	Robotic	12.0%	0.0%	0	0.8%[f]	0.8	5.6
	Lap	20.0%	0.0%	0	2.4%[f]	6.6	8.2
159. Wood (2014)	Robotic	22%, 37%[g]	0.0%	0.0%	9%	0.0	8.0
	Lap	19%, 30%[g]	0.0%	0.0%	7%	0.0	7.0

(continues on next page)

Table H.30 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastric Bypass (Roux-en-Y) (continued)

Author	Procedure Type	PostOp Comp Rate	Mortality (in-hospital or 30 days)	Anastomotic Leak Rate (%)	Anastomotic Stricture Rate (%)	Reoperation Rate (%)	Readmission Rate (%)
160. Buchs (2016)	Robotic	13.8%	0.0%	0.0%	0.0%	3.1	Not Reported
	Lap	27.8%	1.9%	3.7%	0.0%	13.0	
	Open	27.4%	1.1%	4.2%	1.1%	36.8	
161. Buchs (2014)	Robotic	11.6%	0.3%	0.3%	Not Reported	1.0	Not Reported
	Lap	16.7%	0.3%	3.6%		3.3	
162. Hagen (2012)	Robotic	16.1%	0.0%	0.0%	0.0%	0.7	Not Reported
	Lap	18.0%	0.0%	4.0%	6.8%	4.0	
	Open	12.4%	0.6%	1.9%	1.1%	1.9	

Notes

a. Authors reported perioperative and long-term rates, respectively.
b. Authors reported GI leak
c. 30-day rates reported
d. Authors reported 30 to 90-day stricture rate
e. Table 5.2 Authors reported 30 day and overall rates, respectively.
f. 1 year time point reported
g. Authors reported surgical and all complications, respectively.

Ventral Hernia Repair

Real-World Evidence from the AHSQC Registry Database

Real-world evidence (RWE) from the AHSQC registry database support use of the da Vinci Xi Surgical System (Model IS4000) and da Vinci X Surgical System (Model IS4200) in "Ventral Hernia Repair" (VHR) procedures that fall under the cleared "general laparoscopic surgical procedures" Indication for Use. The RWE provided included propensity matched comparative data from robotic-assisted, open and laparoscopic cohorts in non-complex VHR procedures. Non-complex VHR procedures were defined as ventral (for example, incisional, epigastric, umbilical) hernia repairs without myofascial release. Additionally, propensity matched comparative data from robotic-assisted and open cohorts and unmatched comparative data from robotic-assisted and laparoscopic cohorts in complex VHR procedures were also included. Complex VHR procedures were defined as incisional hernia repair plus myofascial release. Longer term endpoints beyond 30 days, such as ventral hernia repair recurrence and chronic pain were not assessed in this analysis, and thus no claims regarding these clinical outcomes data should be inferred. The results demonstrated the safety and effectiveness of robotic-assisted ventral hernia repair procedures.

Non-Complex VHR Procedures: Robotic-Assisted v. Open Surgery

Table H.31 summarizes the results of the RWE that compared the results of non-complex robotic-assisted and open VHR procedures. The RWE included information comparing the use of the da Vinci System in non-complex Ventral Hernia Repair procedures with open surgery in the following key measures:

- Length of Stay: comparable lengths of hospital stay were reported for both the robotic-assisted and open cohorts.
- Intraoperative Complications: comparable intraoperative complication rates were reported for both the robotic-assisted and open cohorts.
- Transfusions: comparable intraoperative and postoperative blood transfusion rates were reported in both the robotic-assisted and open cohorts.
- Postoperative Complications through 30 days: comparable postoperative complications through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- Readmission Rates through 30 days: comparable readmission rates through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- Re-encounter Rates through 30 days: a lower clinic re-encounter rate through 30 days follow up was reported for the robotic-assisted cohort (29%) as compared to the open cohort (41%). Comparable emergency room re-encounter rates through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- Reoperation Rates through 30 days: comparable reoperation rates were reported for both the robotic-assisted and open cohorts.
- Recurrence Rates through 30 days: comparable surgeon reported recurrence rates were reported for both the robotic-assisted and open cohorts through the 30-day postoperative period.
- Mortality through 30 days: comparable mortality rates were reported in both the robotic-assisted and open cohorts through the 30-day postoperative period.
- Operative Time: longer operative times were reported for the robotic-assisted cohort as compared to the open cohort[6].

6. The longer operative time for the robotic-assisted cohort was not associated with increases in the complication, readmission, reoperation or mortality rates.

Table H.31 Propensity Score Matched da Vinci and Open Non-Complex Ventral Hernia Repair (without myofascial release)[b]

Outcome	Robotic-Assisted Cohort (N=871)	Open Cohort (N=871)
Patient Demographics		
Mean age, y (± SD)	56 ± 14	55 ± 14
Female Gender, n (%)	399 (46)	361 (41)
Male Gender, n (%)	472 (54)	510 (59)
Mean BMI, kg/ m2 (± SD)	33 ± 7	32 ± 7
Length of Stay (days), mean ± SD	2 ± 7	2 ± 14
Intraoperative Complications, n (%)	11 (1)	5 (1)
Transfusions, n (%)		
Intraoperative	1 (< 1)	0 (0)
Postoperative	0 (0)	2 (< 1)
Postoperative Complications, n (%)[a]	64 (9)	75 (11)
Readmission Rates, n (%)[a]	14 (2)	21 (3)
Reoperation Rates, n (%)[a]	3 (< 1)	8 (1)
Re-encounter Rates, n (%)[a]		
Clinic	207 (29)	291 (41)
Emergency Room	31 (4)	20 (3)
Mortality, n (%)[a]	0 (0)	0 (0)

(continues on next page)

Table H.31 Propensity Score Matched da Vinci and Open Non-Complex Ventral Hernia Repair (without myofascial release) (continued)

Outcome	Robotic-Assisted Cohort (N=871)	Open Cohort (N=871)
Operative Time, minutes, n (%)		
0–59	111 (13)	432 (50)
60–119	396 (45)	304 (35)
120–179	247 (28)	86 (10)
180–239	81 (9)	28 (3)
240+	36 (4)	21 (2)
Conversion Rate, n (%)	5 (1)	Not Applicable
Recurrence Rate, n (%)[a]	5 (1)	0 (0)

Notes

a. Through 30 days post-operatively

b. Includes data from the AHSQC registry for procedures that occurred between July 7, 2013 and January 1, 2017. The total number of non-complex VHR procedures in the registry during this time period was 873 and 3,979 for the robotic-assisted and open cohorts, respectively. The total number in the propensity matched cohorts is 871 as noted in the column header of the above table.

Non-Complex VHR Procedures: Robotic-Assisted v. Laparoscopic Surgery

Table H.32 summarizes the results of the RWE that compared the results of non-complex robotic-assisted and open VHR procedures. The RWE included information comparing the use of the da Vinci System in non-complex Ventral Hernia Repair procedures with laparoscopic surgery in the following key measures:

- Length of Stay: a shorter length of hospital stay was reported for the robotic-assisted cohort (2 days ± 7) as compared to the laparoscopic cohort (4 days ± 13).
- Intraoperative Complications: comparable intraoperative complication rates were reported for both the robotic-assisted and laparoscopic cohorts.
- Transfusions: comparable intraoperative and postoperative blood transfusion rates were reported in both the robotic-assisted and laparoscopic cohorts.
- Conversion Rate: a comparable conversion rate was reported for the robotic-assisted cohort as compared to the laparoscopic cohort.
- Postoperative Complications through 30 days: comparable postoperative complications through 30 days follow up were reported for both the robotic-assisted and laparoscopic cohorts.
- Readmission Rates through 30 days: comparable readmission rates through 30 days follow up were reported for both the robotic-assisted and laparoscopic cohorts.
- Re-encounter Rates through 30 days: comparable clinic and emergency room re-encounter rates through 30 days follow up were reported for the robotic-assisted cohort as compared to the laparoscopic cohort.
- Reoperation Rates through 30 days: comparable reoperation rates were reported for both the robotic-assisted and laparoscopic cohorts.
- Recurrence Rates through 30 days: comparable surgeon reported recurrence rates were reported for both the robotic-assisted and laparoscopic cohorts through the 30-day postoperative period.
- Mortality through 30 days: comparable mortality rates were reported in both the robotic-assisted and laparoscopic cohorts through the 30-day postoperative period.
- Operative Time: longer operative times were reported for the robotic-assisted cohort as compared to the laparoscopic cohort[7].

7. The longer operative time for the robotic-assisted cohort was not associated increases in the complication, readmission, reoperation or mortality rates.

Table H.32 Propensity Score Matched da Vinci and Laparoscopic Non-Complex Ventral Hernia Repair (without myofascial release)[b]

Outcome	Robotic-Assisted Cohort (N=615)	Laparoscopic Cohort (N=615)
Patient Demographics		
Mean age, y (± SD)	55 ± 14	56 ± 14
Female Gender, n (%)	305 (50)	284 (46)
Male Gender, n (%)	310 (50)	331 (54)
Mean BMI, kg/ m2 (± SD)	33 ± 7	33 ± 8
Length of Stay (days), mean ± SD	2 ± 7	4 ± 13
Intraoperative Complications, n (%)	6 (1)	8 (1)
Transfusions, n (%)		
Intraoperative	1 (< 1)	0 (0)
Postoperative	0 (0)	1 (< 1)
Postoperative Complications, n (%)[a]	55 (10)	59 (11)
Readmission Rates, n (%)[a]	8 (2)	17 (3)
Reoperation Rates, n (%)[a]	1 (< 1)	5 (1)
Re-encounter Rates, n (%)[a]		
Clinic	153 (29)	181 (35)
Emergency Room	21 (4)	18 (4)
Mortality, n (%)[a]	1 (< 1)	0 (0)

(continues on next page)

Table H.32 Propensity Score Matched da Vinci and Laparoscopic Non-Complex Ventral Hernia Repair (without myofascial release) (continued)

Outcome	Robotic-Assisted Cohort (N=615)	Laparoscopic Cohort (N=615)
Operative Time, minutes, n (%)		
0–59	86 (14)	175 (28)
60–119	265 (43)	308 (50)
120–179	175 (28)	103 (17)
180–239	60 (10)	21 (3)
240+	29 (5)	8 (1)
Conversion Rate, n (%)	3 (< 1)	14 (2)
Recurrence Rate, n (%)[a]	4 (1)	4 (1)

Notes

a. Through 30 days post-operatively

b. Includes data from the AHSQC registry for procedures that occurred between July 7, 2013 and January 1, 2017. The total number of non-complex VHR procedures in the registry during this time period was 873 and 1,961 for the robotic-assisted and laparoscopic cohorts, respectively. The total number in the propensity matched cohorts is 615 as noted in the column header of the above table.

Complex VHR Procedures: Robotic-Assisted v. Open Surgery

Table H.33 summarizes the results of the RWE that compared the results of complex robotic-assisted and open VHR procedures. The RWE included information comparing the use of the da Vinci System in complex Ventral Hernia Repair procedures with open surgery in the following key measures:

- Length of Stay: a shorter length of hospital stay was reported in the robotic-assisted cohort (2 days ± 3) as compared to the open cohort (5 days ± 7).
- Intraoperative Complications: comparable intraoperative complication rates were reported for both the robotic-assisted and open cohorts.
- Transfusions: comparable intraoperative and postoperative blood transfusion rates were reported in both the robotic-assisted and open cohorts.
- Postoperative Complications through 30 days: comparable postoperative complication rates through 30 days follow up were reported for both the robotic-assisted cohort and open cohort.
- Readmission Rates through 30 days: comparable readmission rates through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- Re-encounter Rates through 30 days: a lower clinic re-encounter rate through 30 days follow up was reported for the robotic-assisted cohort (16%) as compared to the open cohort (27%). Comparable emergency room re-encounter rates through 30 days follow up were reported for both the robotic-assisted and open cohorts.
- Reoperation Rates through 30 days: comparable reoperation rates were reported for both the robotic-assisted cohort and open cohorts.
- Recurrence Rates through 30 days: comparable surgeon reported recurrence rates were reported for both the robotic-assisted and open cohorts through the 30-day postoperative period.
- Mortality through 30 days: comparable mortality rates were reported in both the robotic-assisted and open cohorts through the 30-day postoperative period.
- Operative Time: longer operative times were reported for the robotic-assisted cohort as compared to the open cohort[8].

8. The longer operative time for the robotic-assisted cohort was not associated with increases in the intraoperative complication, readmission, recurrence or mortality rates.

Table H.33 Propensity Score Matched da Vinci and Open Complex Ventral Hernia Repair (with myofascial release)[b]

Outcome	Robotic-Assisted Cohort (N=297)	Open Cohort (N=297)
Patient Demographics		
Mean age, y (± SD)	57 ± 13	57 ± 13
Female Gender, n (%)	169 (57)	159 (54)
Male Gender, n (%)	128 (43)	138 (46)
Mean BMI, kg/ m2 (± SD)	33 ± 7	33 ± 7
Length of Stay (days), mean ± SD	2 ± 3	5 ± 7
Intraoperative Complications, n(%)	7 (2)	9 (3)
Transfusions, n (%)		
Intraoperative	0 (0)	0 (0)
Postoperative	0 (0)	1 (< 1)
Postoperative Complications, n (%)[a]	66 (24)	54 (20)
Readmission Rates, n (%)[a]	19 (7)	12 (4)
Reoperation Rates, n (%)[a]	8 (3)	4 (1)
Re-encounter Rates, n (%)[a]		
Clinic	44 (16)	74 (27)
Emergency Room	14 (5)	12 (4)
Mortality, n (%)[a]	1 (< 1)	0 (0)

(continues on next page)

Table H.33 Propensity Score Matched da Vinci and Open Complex Ventral Hernia Repair (with myofascial release) (continued)

Outcome	Robotic-Assisted Cohort (N=297)	Open Cohort (N=297)
Operative Time, minutes, n(%)		
0–59	0 (0)	8 (3)
60–119	12 (4)	84 (28)
120–179	53 (18)	106 (36)
180–239	98 (33)	48 (16)
240+	134 (45)	51 (17)
Conversion Rate, n (%)	12 (4)	Not Applicable
Recurrence Rate, n (%)[a]	4 (1)	2 (1)

Notes

a. Through 30 days post-operatively

b. Includes data from the AHSQC registry for procedures that occurred between July 7, 2013 and January 1, 2017. The total number of complex VHR procedures in the registry during this time period was 305 and 3,106 for the robotic-assisted and open cohorts, respectively. The total number in the propensity matched cohorts is 297 as noted in the column header of the above table.

Complex VHR Procedures: Robotic-Assisted v. Laparoscopic Surgery

Table H.34 provides a summary of the results of the RWE that compared the results of complex robotic-assisted and laparoscopic VHR procedures and a summary of the published literature on complex laparoscopic VHR procedures. The limited sample size of the complex laparoscopic cohort in the AHSQC Registry Database precluded matching and a comparative analysis between these cohorts in the AHSQC Registry Database. Table H.34 includes the detailed data from nine (9) publications reporting on complex laparoscopic VHR procedures. These publications were selected based on specific search criteria and filters and included 6 comparative studies (LOE 2 & 3b) and 3 single-arm studies (LOE 5). The results from the literature were not matched with the available robotic-assisted data from the AHSQC Registry Database and no comparative analysis was conducted. Clinical analysis of the da Vinci Surgical Systems in robotic-assisted complex ventral hernia repair procedures raises no new issues of safety or effectiveness for the proposed labeling modification and therefore is substantially equivalent.

Table H.34 Unmatched[b] da Vinci and Laparoscopic Complex Ventral Hernia Repair from the AHSQC Registry Database (with myofascial release)

Outcome	Robotic-Assisted Cohort (N=305)	AHSQC Laparoscopic Cohort (N= 27)	Published Literature Laparoscopic Cohort (N = 3–53)
Patient Demographics			
Mean age, y (± SD)	57 ± 13	58 ± 12	48.6–70 years
Female Gender, n (%)	175 (57)	14 (52)	20–68%
Male Gender, n (%)	130 (43)	13 (48)	32–80%
Mean BMI, kg/ m2 (± SD)	33 ± 7	34 ± 7	29.71–36 kg/ m^2
Length of Stay (days), mean ± SD	2 ± 3	4 ± 3	1–9.2 days
Intraoperative Complications, n (%)	7 (2)	3 (11)	0–1.5%
Transfusions, n (%)			
Intraoperative	0 (0)	0 (0)	Transfusions: 0 Estimated Blood Loss: 51–91.7 ml
Postoperative	0 (0)	0 (0)	
Postoperative Complications, n (%)[a]	66 (24)	3 (11)	0–60%
Readmission Rates, n (%)[a]	19 (7)	2 (7)	0–13%
Reoperation Rates, n (%)[a]	8 (3)	0 (0)	0–20%
Re-encounter Rates, n (%)[a]			
Clinic	48 (17)	6 (22)	0
Emergency Room	14 (5)	4 (15)	
Mortality, n (%)[a]	1 (< 1)	0 (0)	0–1.9%

(continues on next page)

Table H.34 Unmatched da Vinci and Laparoscopic Complex Ventral Hernia Repair from the AHSQC Registry Database (with myofascial release) (continued)

Outcome	Robotic-Assisted Cohort (N=305)	AHSQC Laparoscopic Cohort (N= 27)	Published Literature Laparoscopic Cohort (N = 3–53)
Operative Time, minutes, n (%)			
0–59	0 (0)	0 (0)	
60–119	12 (4)	3 (11)	
120–179	54 (18)	8 (30)	125–372 minutes
180–239	100 (33)	11 (41)	
240+	139 (46)	5 (19)	
Conversion Rate, n (%)	12 (4)	19 (70)	0
Recurrence Rate, n (%)[a]	4 (1)	0 (0)	Not Reported

Notes

a. Through 30 days post-operatively

b. The data presented in this table are not propensity score matched and include the results for all complex VHR cases in the AHSQC registry during the access dates between July 7, 2013 and January 1, 2017 for both the robotic-assisted and laparoscopic cohorts.

Table H.35 Part One Published Literature Results - Laparoscopic Complex Ventral Hernia Repair (with myofascial release)

Author/Year	Lap/Endoscopic Study Size (N)	Mean Age, y (±SD)	Gender (M/F)	Mean BMI, kg/m2 (SD)	Mean Operation Time (minutes) (SD)
163. Azoury (2014)	25	59 (11)	32%/68%	35.4 (8)	278 (73)
164. Belyanksy (2016)	3	70	66.7%/33.3%	30.1	329 (OR time)
165. Belyanksy (2017)	38	NR Not stratified by cohort			NR
166. Daes (2014)	5	NR Not stratified by cohort			NR
167. Giurgius (2012)	21	51 (13)	48%/52%	36 (7)	229 (57)
168. Moazzez (2013)	5	48.6 (7.9)	80%/20%	29.71 (3.4)	372 (104)
169. Muse (2018)	53	54.4	40%/60%	35.3	224
170. Parker (2011)	8	64.4	1.7:1 (reported as ratio)	30.5	226.8
171. Schroeder (2013)	43 (27 incisional)	57	62.8%/37.2%	NR	125

Table H.35 Part Two Published Literature Results - Laparoscopic Complex Ventral Hernia Repair (with myofascial release)

Author/Year	EBL (ml) or Transfusions	Length of Stay, days (SD)	Conversion Rate (%)	Intraoperative Complication Rate (%)	Postoperative Complication Rate (%)
163. Azoury (2014)	63 (29)	4 (2)	NR	NR	20% (Wound complications)
164. Belyanksy (2016)	91.7	4.7	0.0%	0.0%	33% (1/3 subjects, prolonged ileus prior to discharge)
165. Belyanksy (2017)	NR	NR	NR	NR	2.6% (1/38)
166. Daes (2014)	NR	1	NR	0	0.0%
167. Giurgius (2012)	NR	6.3 (3.6)	NR	NR	19.0%
168. Moazzez (2013)	0 transfusions (No significant bleeding reported)	9.2 (5.4)	0.0%	0.0%	60% (3/5) subjects with acute (<30d)/in-hospital complications
169. Muse (2018)	NR	5	NR	NR	13% (Wound complications)
170. Parker (2011)	51 mL 0 units transfused	5.4	NR	NR	0% (Wound complications, timeframe NR)
171. Schroeder (2013)	NR	3.4	NR	1.5%	7.0%

Table H.35 Part Three Published Literature Results - Laparoscopic Complex Ventral Hernia Repair (with myofascial release)

Author/Year	Mortality (in-hospital or 30 days)	Reoperation Rate (30d)	Re-encounter Rate (30d)	Readmission Rate (30 d)	Recurrence Rate (30d)
163. Azoury (2014)	0.0%	NR	NR	NR	NR
164. Belyanksy (2016)	0.0%	0.0%	0.0%	0.0%	NR
165. Belyanksy (2017)	0%	0 (90d)	NR (likely 0 from inference)	0 (90d)	NR
166. Daes (2014)	0.0%	0.0%	0.0%	0.0%	NR
167. Giurgius (2012)	NR	NR	NR	NR	NR
168. Moazzez (2013)	0.0%	20% (1/5)	NR	NR	NR for 30 day (60% with median of 12.6m)
169. Muse (2018)	1.9% (Timeframe NR)	NR	NR	13%	NR for 30 day (15% overall)
170. Parker (2011)	1.9%	NR	NR	0%	NR
171. Schroeder (2013)	NR	NR	NR	NR	NR for 30 d (0 overall through f/u)

Clinical Study Data

Published clinical data were provided to support use of the da Vinci Xi Surgical System (Model IS4000) and the da Vinci X Surgical System (Model IS4200) in "Gastrectomy" procedures to demonstrate that the intended use of the devices is the same as the predicate devices. Sixteen (16) publications were identified for this procedure based on specific search criteria and filters. These publications included two (2) randomized controlled trials (1b), ten (10) systematic reviews/meta-analysis (2a), and four (4) database studies (2c) comparing da Vinci-assisted procedures with laparoscopic and/or open cohorts. A detailed summary of the published clinical data on this procedure is provided in Table H.36 Part One, Table H.36 Part Two, Table H.37 Part One, and Table H.37 Part Two below.

The findings from the Gastrectomy publications show that da Vinci-assisted procedures as compared to laparoscopic procedures are associated with:

- Mortality: comparable mortality rates,
- Estimated Blood Loss (EBL): comparable or lower[9] EBL volumes,
- Blood Transfusion: comparable blood transfusion rates,
- Lengths of Hospital Stay (LOS): comparable or shorter[10] lengths of hospital stay,
- Intraoperative Complication Rates: comparable intraoperative complication rates,
- Postoperative Complication Rates: comparable postoperative complication rates,
- Conversion Rates: comparable conversion rates,
- Reoperation Rates: comparable reoperation rates,
- Readmission Rates: comparable readmission rates,[11]
- Anastomotic Leak Rates: comparable anastomotic leak rates,
- Anastomotic Stenosis Rates: comparable anastomotic stenosis rates, and
- Operative Time: comparable or longer operative times. However, this increase was not associated with an increase in the mortality or complication rates.

The findings from the Gastrectomy publications show that da Vinci-assisted procedures as compared to open procedures are associated with:

9. Nine (9) publications reported EBL data. One (1) publication (Reference #45) reported comparable values between the da Vinci and laparoscopic cohorts, seven (7) publications reported lower EBL values for the da Vinci cohort as compared to the laparoscopic cohort (References #37, 39, 44, 46, 47, 49, 51), and one (1) publication reported higher EBL values for the da Vinci cohort as compared to the laparoscopic cohort (Reference #42). The higher EBL value in the da Vinci cohort was not associated with increased blood transfusion, complication or mortality rates. EBL values are provided in .
10. Eleven (11) publications reported LOS data. Three (3) publications (References #37, 45, 47) reported shorter LOS values for the da Vinci cohort, and seven (7) publications reported comparable LOS values (References #41, 42, 44, 46, 48, 49, 51) for the da Vinci and laparoscopic cohorts. One publication (Reference #40) reported comparable LOS values for the da Vinci, laparoscopic and open cohorts. LOS values are provided in .
11. One (1) publication (Reference #40) reported comparable readmission rates for the da Vinci, laparoscopic and open cohorts.

- Mortality: comparable mortality rates,
- Estimated Blood Loss (EBL): lower EBL volumes,[12]
- Blood Transfusion: comparable blood transfusion rates,
- Lengths of Hospital Stay (LOS): comparable or shorter lengths of hospital stay,[13]
- Intraoperative Complication Rates: comparable intraoperative complication rates,
- Postoperative Complication Rates: comparable postoperative complication rates,
- Reoperation Rates: comparable reoperation rates,
- Readmission Rates: comparable readmission rates,[14]
- Anastomotic Leak Rates: comparable anastomotic leak rates,
- Anastomotic Stenosis Rates: comparable anastomotic stenosis rates, and
- Operative Time: longer operative times. However, this increase was not associated with an increase in the mortality or complication rates.

12. Six (6) publications reported EBL data. All six (6) publications reported lower EBL values (References #38, 39, 42, 43, 50, 51) for the da Vinci cohorts as compared to the open cohorts. EBL values are provided in .
13. Eight (8) publications reported LOS data. Five (5) publications (References #38, 42, 43, 50, 51) reported shorter LOS values for the da Vinci cohort as compared to the open cohort, and two (2) publications reported comparable LOS values (References #41, 48) for the da Vinci and open cohorts. One publication (Reference #40) reported comparable LOS values across the da Vinci, laparoscopic and open cohorts. LOS values are provided in .
14. One (1) publication (Reference #40) reported comparable readmission rates for the da Vinci, laparoscopic and open cohorts.

Table H.36 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures

Author	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Transfusion Rate (%)
172. Pan (2017)	Robotic	102	153.11	41.27	3.75	Not Reported
	Lap	61	151.97	83.69	5.36	
173. Wang (2016)	Robotic	151	242.7	94.2	5.7	0.66
	Open	145	192.4	152.8	6.4	0.69
174. Eom (2016[a])	Robotic	53	268.4	74.2	Not Reported	
	Lap	541	227.3	137.7		
	Open	2654	200.4	272.4		
175. Glenn (2015)[b]	Robotic	223	Not Reported		12.2	Not Reported
	Lap	789			12.1	
	Open	8585			13.0	
176. Greenleaf (2017)[b]	Robotic	223	Not Reported		8	Not Reported
	Lap	1487			8	
	Open	4717			9	
177. Parisi (2017)	Robotic	151	365.44	117.91	8.85	2.6/8.6[c]
	Lap	151	220.37	95.93	9.07	4.6/8.6[c]
	Open	302	198.67	127.26	12.68	3.0-6.3[c]

(continues on next page)

Table H.36 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures (continued)

Author	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Transfusion Rate (%)
178. Caruso (2017)	Robotic	689	226–415.9	30.3–208.2	5.1–11.3	Not Reported
	Open	5434	126.7–331.8	78.8–564.6	6.4–16.5	
179. Chen (2017)	Robotic	1830	202.1–439	30.3–176.6	5.1–14	Not Reported
	Lap	4123	166.7–361	34–212.5	5.9–15	
180. Chuan (2015)	Robotic	551	226–361	30.3–130.48	5.1–12.1	Not Reported
	Lap	1245	176–345	44.7–131.3	6.5–17.3	
181. Duan (2017)	Robotic	993	202–439	30.3–131.3	5.1–12.1	Not Reported
	Lap	2510	170.7–345	44.7–173.45	6.5–17.3	
182. Hu (2016)	Robotic	1096	178–439	47–171.3	4.5–11	Not Reported
	Lap	2484	137.6–319.8	87.1–152.8	5.7–13.2	
183. Kostakis (2017)	Robotic	85	Not Reported		9.6	Not Reported
	Lap	1281			8–16.9	
	Open	11194			11.5–24	
184. Wang (2017)	Robotic	1134	202.1–415.9	30.3–214.2	4.5–12.1	Not Reported
	Lap	2610	173.5–362.2	44.7–212.5	4.3–17.3	
185. Yang (2017)	Robotic	606	Not Available[d,e]	Not Available[d,f]	Not Available[d,g]	Not Reported
	Open	5364	Not Available[d,e]	Not Available[d,f]	Not Available[d,g]	

(continues on next page)

Table H.36 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures (continued)

Author	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Transfusion Rate (%)
186. Zong (2014)	Robotic	520/997	202–344	30.3–197.6	5.1–10.5	Not Reported
	Lap	2207	134–235	39.5–173.45	6.2–11.9	
	Open	5260	126.7–222	78.8–386.1	6.7–13.4	
187. Guerra (2018)	Robotic	570	206.4–439.0	Not Reported	6.75–10.5	Not Reported
	Lap	1456	167.1–361.0		6.7–13.0	

Notes

a. Data reported for “total” gastrectomy procedures herein. Authors reported similar results for “distal” gastrectomy procedures.

b. The years 2010, 2011 and 2012 overlap between the two (2) databases used in the Glenn and Greenleaf publications. As such, there is a possibility of data overlap in the reported results.

c. Intra-op and post-op reported.

d. Absolute rates/means not available.

e. WMD 63.72 [33.83, 93.61].

f. WMD 129.74 [-178.31, -81.16].

g. WMD -2.39 [-2.92, -1.87].

Table H.36 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures

Author	Procedure Type	Intraop Comp Rate (%)	Postop Comp Rate (%)	Mortality (in-hospital - 30 days %)	Reoperation Rate (%)	Conversion Rate (%)
172. Pan (2017)	Robotic	Not Reported	4.9	0	Not Reported	0
	Lap		19.7	0		0
173. Wang (2016)	Robotic	Not Reported	9.3	0	Not Reported	
	Open		10.3	0		
174. Eom (2016)[a]	Robotic	Not Reported				
	Lap					
	Open					
175. Glenn (2015)[b]	Robotic	Not Reported	33.6[c]	4.9	Not Reported	
	Lap		27.8[c]	1.9		
	Open		31.7[c]	2.6		
176. Greenleaf (2017)[b]	Robotic	Not Reported	Not Reported	Not Available[d,e]	Not Reported	7.6
	Lap		Not Reported	Not Reported		19
	Open		Not Reported	Not Available[d,e]		N/A
177. Parisi (2017)	Robotic	1.3	17.9	0	1.3	4.6
	Lap	2.0	11.9	0	3.3	5.3
	Open	1.7	19.5	0	3.6	N/A

(continues on next page)

Table H.36 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures (continued)

Author	Procedure Type	Intraop Comp Rate (%)	Postop Comp Rate (%)	Mortality (in-hospital - 30 days %)	Reoperation Rate (%)	Conversion Rate (%)
178. Caruso (2017)	Robotic	Not Reported	12.77	0.44	Not Reported	1.4
	Open		11.94	0.64		N/A
179. Chen (2017)	Robotic	Not Reported	10.60	0.84	1.9	0.57
	Lap		10.11	0.52	1.11	0.73
180. Chuan (2015)	Robotic	Not Reported	12.70	Not Reported		
	Lap		13.01			
181. Duan (2017)	Robotic	Not Reported	12.22	Not Reported		
	Lap		12.68			
182. Hu (2016)	Robotic	Not Reported	UK	0.26	Not Reported	1.91
	Lap		UK	0.60		1.30
183. Kostakis (2017)	Robotic	Not Reported	10.71	3.45	3.45	0–18.2
	Lap		7.99	3.06	5.98	0–27.7
	Open		5.83	5.35	4.04	N/A
184. Wang (2017)	Robotic	Not Reported	11.7	Not Reported		
	Lap		10.7			

(continues on next page)

Table H.36 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures (continued)

Author	Procedure Type	Intraop Comp Rate (%)	Postop Comp Rate (%)	Mortality (in-hospital - 30 days %)	Reoperation Rate (%)	Conversion Rate (%)
185. Yang (2017)	Robotic	Not Reported	12.71	Not Reported		
	Open		12.08			
186. Zong (2014)	Robotic	Not Reported	11.54	0.50–0.58	Not Reported	
	Lap		12.01	0.32		
	Open		11.50	0.67		
187. Guerra (2018)	Robotic	Not Reported				
	Lap					

Notes

a. Data reported for “total” gastrectomy procedures herein. Authors reported similar results for “distal” gastrectomy procedures.

b. The years 2010, 2011 and 2012 overlap between the two (2) databases used in the Glenn and Greenleaf publications. As such, there is a possibility of data overlap in the reported results.

c. In-hospital overall complication rate.

d. Absolute rates/means not available

e. OR 1.07 [0.42, 2.75].

Table H.37 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures

Author	Study Size (N)		Positive Surgical Margin Rate (%)	Proximal Resection Margin (cm)	Distal Resection Margin (cm)
172. Pan (2017)	Robotic	102	Not Reported		
	Lap	61			
173. Wang (2016)	Robotic	151	Not Reported	5.3 ± 1.5	5.5 ± 1.7
	Open	145		5.1 ± 1.9	5.3 ± 1.5
174. Eom (2016)[a]	Robotic	53	Not Reported		
	Lap	541			
	Open	2654			
175. Glenn (2015)[b]	Robotic	223	Not Reported		
	Lap	789			
	Open	8585			
176. Greenleaf (2017)[b]	Robotic	223	5.8	Not Reported	
	Lap	1487	10.9		
	Open	4717	14.6		
177. Parisi (2017)	Robotic	151	2.0	Not Reported	
	Lap	151	4.0		
	Open	302	5.0		

(continues on next page)

Table H.37 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures (continued)

Author	Study Size (N)		Positive Surgical Margin Rate (%)	Proximal Resection Margin (cm)	Distal Resection Margin (cm)
178. Caruso (2017)	Robotic	689	Not Reported		
	Open	5434			
179. Chen (2017)	Robotic	1830	Not Reported	2.6–5.9	4–7.4
	Lap	4123		2.9–5.7	3.8–7.7
180. Chuan (2015)	Robotic	551	Not Reported	3.8–5.6	7.3–12.4
	Lap	1245		3.68–5.7	6.12–11.6
181. Duan (2017)	Robotic	993	Not Reported		
	Lap	2510			
182. Hu (2016)	Robotic	1096	Not Reported	UK	UK
	Lap	2484		UK	UK
183. Kostakis (2017)	Robotic	85	0	Not Reported	
	Lap	1281	4.63		
	Open	11194	8.07		
184. Wang (2017)	Robotic	1134	Not Reported	range (3.8–5.8)	range (5.1–12.4)
	Lap	2610		range (3.68–5.7)	range (5.6–11.6)
185. Yang (2017)	Robotic	606	Not Reported	Not Available[c,d]	Not Available[c,e]
	Open	5364		Not Available[c,d]	Not Available[c,e]

(continues on next page)

Table H.37 Part One Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures (continued)

Author	Study Size (N)		Positive Surgical Margin Rate (%)	Proximal Resection Margin (cm)	Distal Resection Margin (cm)
186. Zong (2014)	Robotic	520/997	Not Reported		
	Lap	2207			
	Open	5260			
187. Guerra (2018)	Robotic	570	Not Reported		
	Lap	1456			

Notes

a. Data reported for "total" gastrectomy procedures herein. Authors reported similar results for "distal" gastrectomy procedures.

b. The years 2010, 2011 and 2012 overlap between the two (2) databases used in the Glenn and Greenleaf publications. As such, there is a possibility of data overlap in the reported results.

c. Absolute rates/means not available.

d. WMD 0.10 [-0.43, 0.64].

e. WMD 0.52 [-0.76, 1.79].

Table H.37 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures

Author	Procedure Type	Lymph Node Yield (n)	Anastomotic Leak Rate (%)	Anastomotic Stenosis Rate (%)
172. Pan (2017)	Robotic	36.06	0	Not Reported
	Lap	30.03	3.3	
173. Wang (2016)	Robotic	30.1	2.6	Not Reported
	Open	29.1	2.1	
174. Eom (2016)[a]	Robotic	Not Reported		
	Lap			
	Open			
175. Glenn (2015)[b]	Robotic	Not Reported		
	Lap			
	Open			
176. Greenleaf (2017)[b]	Robotic	129/223 (57.8%)[c]	Not Reported	
	Lap	791/1487 (53.2%)[c]		
	Open	2352/4717 (49.9%)[c]		
177. Parisi (2017)	Robotic	27.78	2.6	0.7
	Lap	24.58	2.6	0.7
	Open	25.82	3.6	0.3

(continues on next page)

Table H.37 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures (continued)

Author	Procedure Type	Lymph Node Yield (n)	Anastomotic Leak Rate (%)	Anastomotic Stenosis Rate (%)
179. Chen (2017)	Robotic	22–41.1	Not Reported	
	Lap	20–46.5		
178. Caruso (2017)	Robotic	23.1–47.2	3.0	Not Reported
	Open	25.2–43.3	1.6	
180. Chuan (2015)	Robotic	32.8–44.3	2.55	Not Reported
	Lap	32.6–43.2	2.68	
181. Duan (2017)	Robotic	25–44.3	Not Reported	
	Lap	26–43.2		
182. Hu (2016)	Robotic	25.3–44	Not Reported	
	Lap	20.7–40		
183. Kostakis (2017)	Robotic	Not Reported	0–3.4	0
	Lap		0–5.6	2.4–5.6
	Open		0–5.8	0–1.4
184. Wang (2017)	Robotic	25–44.3	2.4	0.50
	Lap	26–43.2	2.3	1.20
185. Yang (2017)	Robotic	Not Available[d,e]	3.0	Not Reported
	Open	Not Available[d,e]	1.6	

(continues on next page)

Table H.37 Part Two Da Vinci vs. Open and da Vinci vs. Laparoscopic Gastrectomy Procedures (continued)

Author	Procedure Type	Lymph Node Yield (n)	Anastomotic Leak Rate (%)	Anastomotic Stenosis Rate (%)
186. Zong (2014)	Robotic	25–42.8	2.7	Not Reported
	Lap	26–42.7	1.6	
	Open	31.7–43.3	2.3	
187. Guerra (2018)	Robotic	Not Available[d,f]	Not Reported	
	Lap	Not Available[d,f]		

Notes

a. Data reported for "total" gastrectomy procedures herein. Authors reported similar results for "distal" gastrectomy procedures.

b. The years 2010, 2011 and 2012 overlap between the two (2) databases used in the Glenn and Greenleaf publications. As such, there is a possibility of data overlap in the reported results.

c. N reported for cases with > 15 LN.

d. Absolute rates/means not available.

e. WMD -1.36 [-3.69, 0.97].

f. MD 2.92 [0.32, 5.53].

Esophagectomy

Clinical Study Data

Published clinical data were provided to support use of the da Vinci Xi Surgical System (Model IS4000) and da Vinci X Surgical System (Model IS4200) in "Esophagectomy" procedures to demonstrate that the intended use of the devices is the same as the predicate devices. Seventeen (17) publications were identified for this procedure based on specific search criteria and filters used in three (3) search engines: PubMed, Scopus and Embase and two (2) separate searches. The search terms, inclusion/exclusion criteria and the flowcharts depicting the results from these searches are provided in Figure H.1 and Figure H.2. These publications included: one (1) prospective study (LOE 2b), five (5) database studies (LOE 2b/2c) and eleven (11) retrospective studies (LOE 3b) comparing da Vinci-assisted procedures with minimally invasive, laparoscopic and/or video-assisted cohorts. A detailed summary of the published clinical data on this procedure is provided in Table H.38 Part One and Table H.38 Part Two.

The findings from the Esophagectomy publications demonstrate that da Vinci-assisted procedures as compared to minimally invasive, laparoscopic and/or video-assisted procedures are found to be substantially equivalent based on the following endpoints:

- Mortality Rates
- Estimated Blood Loss (EBL) Volumes
- Blood Transfusion Rates
- Lengths of Hospital Stay (LOS)
- Intraoperative Complication Rates
- Postoperative Complication Rates
- Conversion Rates
- Reoperation Rates
- Readmission Rates
- Anastomotic Leak Rates
- Operative Times

Anastomotic Leak Rate (ALRs) Subgroup Analysis

In the da Vinci-assisted group, the handsewn sutured cohort had an ALR of 14.73% and the stapled cohort had an ALR of 9.24% (difference of 5.49%). In the MIE group, the handsewn sutured cohort had an ALR of 8.72% and the stapled cohort had an ALR of 9.86% (difference 1.14%). Importantly, the vast majority of the sutured anastomoses for both cohorts were performed in an open manner in the neck. Although the handsewn sutures cohort of the da Vinci group (14.73%) had the highest leak rates amongst the 4 groups compared, this number still appears to be within the reported range (roughly 5- 15%) for ALR for esophagectomy procedures. While taking into consideration these published data showing potentially less risk of anastomotic leak with a stapled anastomosis during robotic-assisted esophagectomy, ultimately the appropriate location and technique for the anastomosis should be based on clinical assessment of patient factors as well as the experience and training of the surgeon.

Learning Curve Publications

A total of 17 publications that evaluated the learning curve associated with da Vinci-assisted esophagectomy procedures across different surgeons with varying levels of clinical and surgical expertise were also evaluated. These published reports identified a learning curve of 3–80 cases associated with da Vinci-assisted esophagectomy procedures. This information is reflected in the following statement included in the device labeling:

The da Vinci Xi or X Surgical System should only be used in esophagectomy procedures performed by experienced foregut and/or thoracic surgeons who have credentials and privileges to perform such procedures at their institution. Additionally, Intuitive recommends experience with the da Vinci Xi or X Surgical Systems in less complex procedures (for example, thymectomy, Nissen Fundoplication) prior to use of the system in esophagectomy procedures. Published literature indicates that the learning curve associated with stabilization of operative time of da Vinci assisted esophagectomy procedures can range from 3-80 cases. Intuitive encourages the use of a proctor or preceptor during use of the device in early esophagectomy procedures.

Table H.38 Part One da Vinci vs. Minimally Invasive/Laparoscopic/Video-Assisted Esophagectomy ("MIE") Procedures

Author/ Year	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Transfusion Rate (%)	Intraop Comp Rate (%)	Postop Comp Rate (%)	Mortality (in-hospital - 30 days, %)	Reoperation Rate (%)	Readmission Rate (%)	Conversion Rate (%)
188. Weksler (2017)[a.]	Robotic	569	Not Reported						5.6	Not Reported	7.0	Not Reported
	MIE	569							2.8		6.5	
189. Yerokun (2016)[a.]	Robotic	170	Not Reported		10[b.]	Not Reported			3.7	Not Reported	5.9	Not Reported
	MIE	170			10[b.]				2.7		8.8	
190. Diez del Val (2015)	Robotic	34	Not Reported		17.4	Not Reported		41.18	0	12.8	Not Reported	8.8
	MIE	17			25.9			64.71	4.5	14.9		11.8
191. Suda (2012)	Robotic	16	692.5[b.]	144.5	22	Not Reported			0	Not Reported		
	MIE	20	649.5[b.]	139	35.5				0			
192. Chao (2019)	Robotic	39	149.33	83.33	16.36	15.4	Not Reported	20.5	0[c.]	12.8	10.3	0
	MIE	67	156.05	120.75	17.82	9.0		34.3	4.5[c.]	14.9	16.9	0
193. Park (2016)	Robotic	62	490.3 ± 84.0	462.9 ± 493.9	Not Reported	Not Reported			1.6	Not Reported		1.6
	MIE	43	458.4 ± 111.9	466.8 ± 333.0					0			2.3

(continues on next page)

Table H.38 Part One da Vinci vs. Minimally Invasive/Laparoscopic/Video-Assisted Esophagectomy ("MIE") Procedures (continued)

Author/ Year	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Transfusion Rate (%)	Intraop Comp Rate (%)	Postop Comp Rate (%)	Mortality (in-hospital - 30 days, %)	Reoperation Rate (%)	Readmission Rate (%)	Conversion Rate (%)
194. Weksler (2012)	Robotic	11	439 ± 70	200 ± 150	8.7 ± 3.4	Not Reported	0	36.4	0.0	Not Reported		0
	MIE	26	483.8 ± 76.5	226 ± 372	10.0 ± 7.7		0	38.5	7.7			3.85
195. Deng (2018)	Robotic	79	353	96.3	14.3	0	Not Reported	28.8[d.]	3.8[c.]	Not Reported		0
	MIE	72	274	127.5	12.7	0		23.1[d.]	3.8[c.]			0
196. He (2018)	Robotic	27	349 ± 45	119 ± 72	13.8 ± 2.0	Not Reported		37e	0	Not Reported		
	MIE	27	285 ± 66	158 ± 82	12.8 ± 2.7			33.3e	3.7			
197. Motoyama (2019)	Robotic	21	634.0	492	Not Reported	Not Reported						
	MIE	38	598.5	385								
198. Zhang (2019)	Robotic	76	303.5	200	9.0	Not Reported		31.6[e.]	0	Not Reported		2.6
	MIE	108	277.2	200	9.0			33.3[e.]	0			0
199. Tagkalos (2019)	Robotic	50	388	339	12.0	Not Reported			5.0[c.]	Not Reported		
	MIE	50	321	343	12.5				2.5[c.]			

(continues on next page)

Table H.38 Part One da Vinci vs. Minimally Invasive/Laparoscopic/Video-Assisted Esophagectomy ("MIE") Procedures (continued)

Author/ Year	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Transfusion Rate (%)	Intraop Comp Rate (%)	Postop Comp Rate (%)	Mortality (in-hospital - 30 days, %)	Reoperation Rate (%)	Readmission Rate (%)	Conversion Rate (%)
200. Harbison (2019)	Robotic	100	445	Not Reported	10	10.0	Not Reported	31.0[e.]	3.0	17.0	18.0	11.0
	MIE	625	418		12	9.76		39.2[e.]	2.2	16.3	11.7	8.48
201. Meredith (2019)	Robotic	144	409	155	9	Not Reported		23.6	1.4	Not Reported		0
	MIE	158	231-299	189-242	9-10			29.5-49.2	2.1-3.2			7.4-12.7
202. Washington (2019)	Robotic	18	168	Not Reported	9.9	Not Reported		5.6[d.]	0	Not Reported		
	MIE	18	164		9.8			11.2[d.]	5.6			
203. Chen (2019)	Robotic	68	187.2	118.9	17.1	Not Reported			0	0	Not Reported	
	MIE	74	193.4	116.5	15.2				0	0		
204. Yang (2019)	Robotic	271	244.5	210.7	11.0	Not Reported		45.0	0[c.]	1.5	Not Reported	.07
	MIE	271	276.0	209.6	11.0			37.3	0.7[c.]	3.3		5.9

Notes

a. The years 2010, 2011 and 2012 overlap between the two (2) databases used in the Weksler and Yerokun publications. As such, there is a possibility of data overlap in the reported results

b. Medians reported.

c. 90-day mortality rate.

d. Major complications.

e. Overall complications.

Table H.38 Part Two Da Vinci vs. Minimally Invasive/Laparoscopic/Video-Assisted Esophagectomy ("MIE") Procedures

Author/Year	Study Size (N)		Positive Surgical Margin Rate (%)	R0 Resection Rate (%)	Lymph Node Yield (n)	Anastomotic Leak Rate (%)
188. Weksler (2017)	Robotic	569	Not Reported	95.1	16.0	Not Reported
	MIE	569		94.6	16.0	
189. Yerokun (2016)	Robotic	170	6.5	93.5	median 16	Not Reported
	MIE	170	4.1	95.9	median 16	
190. Diez del Val (2015)	Robotic	34	Not Reported		20.9	20.6
	MIE	17			24.4	29.4
191. Suda (2012)	Robotic	16	12.5	87.5	37.5	37.5
	MIE	20	10.0	90	39	10.0
192. Chao (2019)	Robotic	39	0	94.9	29	12.8
	MIE	67	2.9	88.1	28	9.0
193. Park (2016)	Robotic	62	Not Reported	98	37.3	8.1
	MIE	43		98	28.7	2.3
194. Weksler (2012)	Robotic	11	0	100	23 ± 10	9.1
	MIE	26	0	100	23 ± 10	15.4
195. Deng (2018)	Robotic	79	0	100	21.5	7.6
	MIE	72	0	100	17.3	5.6
196. He (2018)	Robotic	27	Not Reported		20 ± 7	11.11
	MIE	27			19 ± 5	3.70

(continues on next page)

Table H.38 Part Two Da Vinci vs. Minimally Invasive/Laparoscopic/Video-Assisted Esophagectomy ("MIE") Procedures (continued)

Author/Year	Study Size (N)		Positive Surgical Margin Rate (%)	R0 Resection Rate (%)	Lymph Node Yield (n)	Anastomotic Leak Rate (%)
197. Motoyama (2019)	Robotic	21	Not Reported		52	4.8
	MIE	38			59	7.9
198. Zhang (2019)	Robotic	76	Not Reported	100	19.7	9.2
	MIE	108		99.1	20.3	5.6
199. Tagkalos (2019)	Robotic	50	Not Reported	95	27	12.0
	MIE	50		97.5	23	18.0
200. Harbison (2019)	Robotic	100	6.0	Not Reported		14.0
	MIE	625	6.7			15.4
201. Meredith (2019)	Robotic	144	Not Reported	100	20	2.8
	MIE[15]	158		60-93.5%	9	5.2
202. Washington (2019)	Robotic	18	Not Reported	94.4	14.28	5.6
	MIE	18		94.4	13.9	5.6
203. Chen (2019)	Robotic	68	Not Reported	100	25.4	8.8
	MIE	74		100	24.7	2.7
204. Yang (2019)	Robotic	271	Not Reported	94.1	20.3	11.8
	MIE	271		93.7	19.2	14.4

Notes

a. The years 2010, 2011 and 2012 overlap between the two (2) databases used in the Weksler and Yerokun publications. As such, there is a possibility of data overlap in the reported results.

15. Publication reported on two (2) MIE cohorts: "TL–thoracoscopic/laparoscopic" and "TH–transhiatal".

Figure H.1 Search Criteria and Flowchart for Literature Search Conducted in January 2019

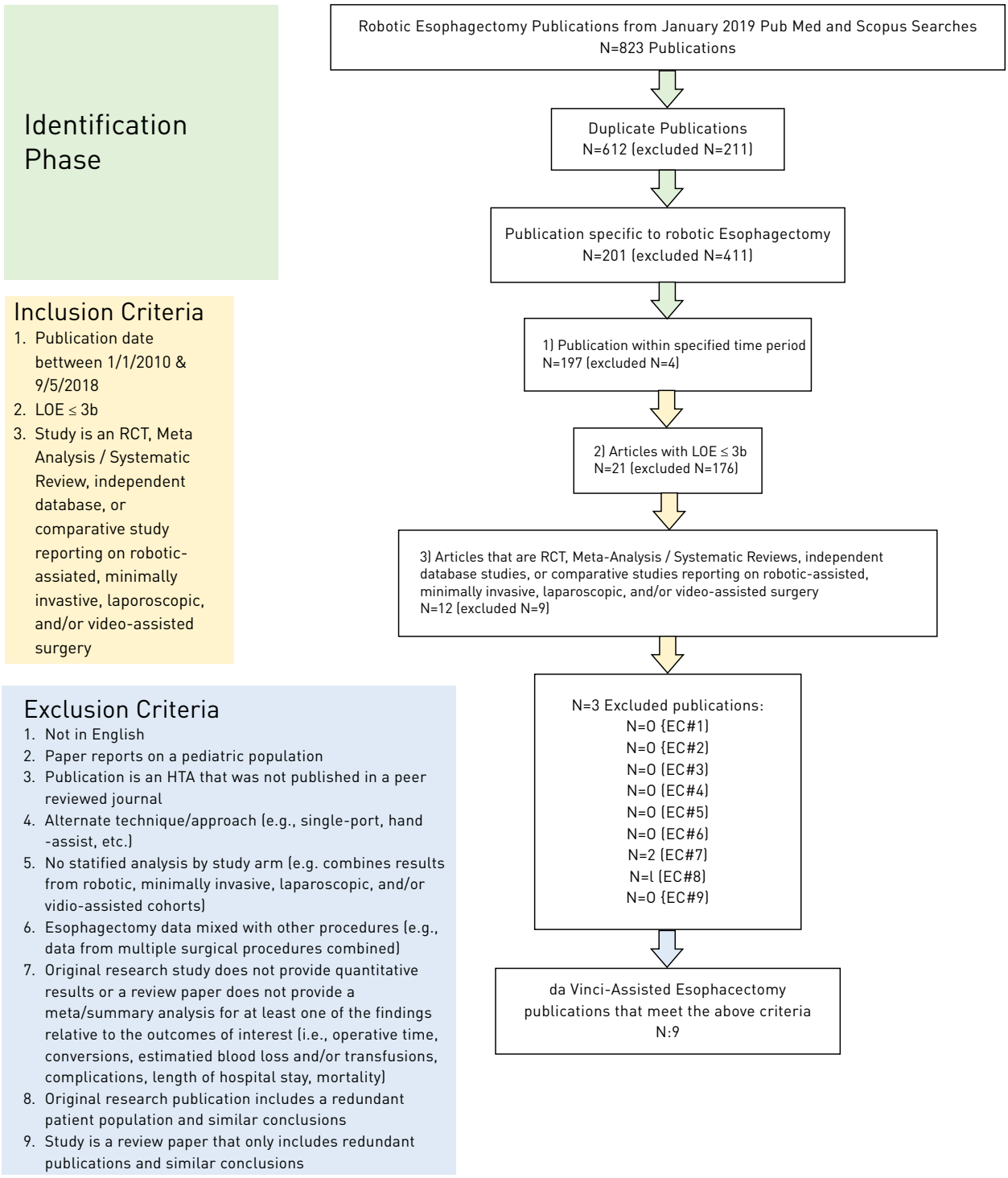


Figure H.1 and the below search terms are associated with the identification of references 188 through 196 listed in Table H.38 Part One and Table H.38 Part Two.

PubMed Search Terms: robotic, robot, robot assist, robotically assisted, robot assist, da Vinci, da Vinci, Intuitive Surgical, robot surgery, esophagectomy, esophageal

Scopus Search Terms: da Vinci, robotic surgery, Intuitive Surgical, robotic assist, robot surgery, esophagectomy, esophageal

Figure H.2 Search Criteria and Flowchart for Literature Search Conducted in December 2019

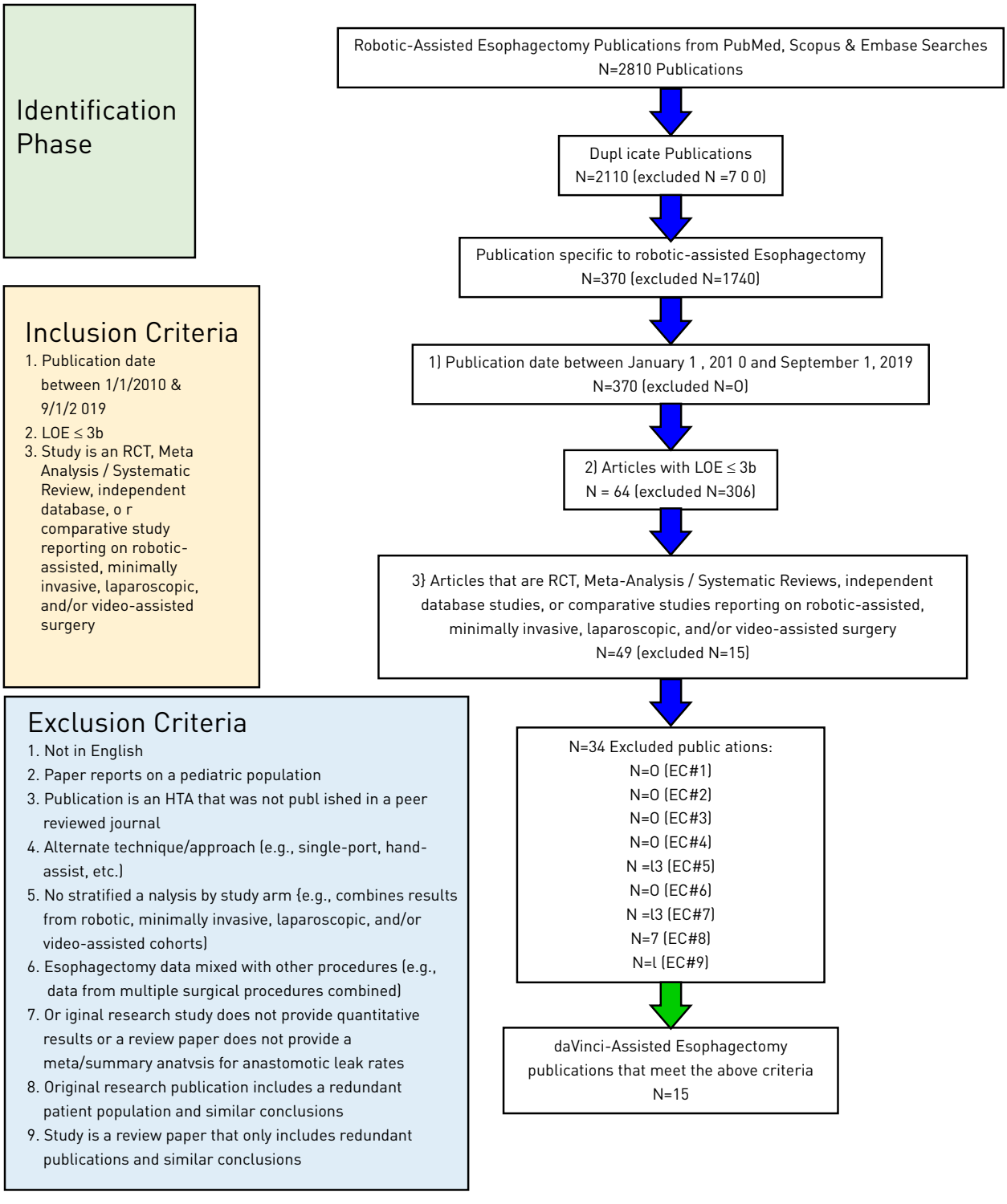


Figure H.2 and the below search terms are associated with the identification of references 190 through 204 listed in Table H.38 Part One and Table H.38 Part Two.

PubMed Search Terms: robotic, robot, robot assist, robotically assisted, robot assist, da Vinci, da Vinci, Intuitive Surgical, robot surgery, esophagectomy, esophageal, esophagus

Scopus Search Terms: da Vinci, robotic surgery, Intuitive Surgical, robotic assist, robot surgery, robotic assist, esophagectomy, esophageal, esophagus

Embase Search Terms: da Vinci, da Vinci, Intuitive Surgical, endowrist, esophagectomy, esophageal, esophagus

Heller Myotomy and Hiatal, Paraesophageal, and Sliding Hernia Repair

Clinical Study Data

Published clinical data were provided to support use of the da Vinci Xi and X Surgical Systems (Models IS4000 and IS4200) in the subject representative, specific foregut procedures that fall under the cleared "general laparoscopic surgical procedures" Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the most complex/highest risk representative, specific procedures: Heller Myotomy and Hiatal, Paraesophageal, and Sliding Hernia Repair (referred to as "umbrella" procedures). The published data for these "umbrella" procedures were deemed sufficient to cover the less complex/lower risk procedures (referred to as "covered" procedures), so published clinical data on the covered procedures of "Dor Fundoplication" and "Toupet Fundoplication" were not provided. Fifteen (15) publications were identified for the two (2) umbrella procedures based on specific search criteria and filters used in three (3) databases: PubMed, Scopus and Embase. The search terms, inclusion/exclusion criteria and a flowchart depicting the results from these searches is provided in Figure H.3. These publications included: two (2) systematic reviews/meta-analyses (LOE 2a), one (1) prospective study (LOE 2b), two (2) database studies (LOE 2c) and ten (10) retrospective studies (LOE 3b) comparing da Vinci-assisted procedures with minimally invasive/laparoscopic cohorts. Detailed summaries of the published clinical data on these procedures are provided in Table H.39 Part One, Table H.39 Part Two, Table H.40 Part One, and Table H.40 Part Two.

Umbrella Procedure 1: Heller Myotomy

The findings from the Heller Myotomy publications demonstrate that da Vinci-assisted procedures as compared to minimally invasive/laparoscopic procedures are found to be substantially equivalent based on the following endpoints:

- Mortality Rates
- Estimated Blood Loss (EBL) Volumes
- Lengths of Hospital Stay (LOS)
- Intraoperative Complication Rates
- Post/Peri-Operative Complication Rates
- Conversion Rates
- Readmission Rates
- Perforation Rates

- Operative Times

Umbrella Procedure 2: Hiatal, Paraesophageal, and Sliding Hernia Repair

The findings from the Hiatal, Paraesophageal, and Sliding Hernia Repair publications demonstrate that da Vinci-assisted procedures as compared to minimally invasive/laparoscopic procedures are found to be substantially equivalent based on the following endpoints:

- Mortality Rates
- Estimated Blood Loss (EBL) Volumes
- Blood Transfusion Rates
- Lengths of Hospital Stay (LOS)
- Intraoperative Complication Rates
- Postoperative Complication Rates
- Conversion Rates
- Reoperation Rates
- Readmission Rates
- Operative Times

Learning Curve Publications

Four (4) publications evaluated the learning curve associated with da Vinci-assisted Heller Myotomy and Paraesophageal, Hiatal, and Sliding hernia repair procedures across different surgeons with varying levels of clinical and surgical expertise. These published reports identified a learning curve of 16-30 cases associated with da Vinci-assisted Heller Myotomy and Paraesophagealm, Hiatal, and Sliding hernia repair procedures. This information is reflected in the following statement included in the device labeling:

The da Vinci Xi or X Surgical System should only be used in Heller Myotomy and Paraesophagecal, Hiatal, and Sliding Hernia Repair procedures performed by experienced foregut surgeons who have credentials and privileges to perform such procedures at their institution. Additionally, Intuitive recommends experience with the da Vinci Xi or da Vinci X Surgical Systems in less complex procedures (such as Nissen Fundoplication) prior to use of the system in Heller Myotomy and Paraesophageal, Hiatal, and Sliding Hernia Repair procedures. Published literature indicates that the learning curve associated with stabilization of operative time of da Vinci-assisted Heller Myotomy and Paraesophageal, Hiatal, and Sliding Hernia Repair procedures can range from 16-30 cases. Intuitive encourages the use of a proctor or preceptor during use of the device in early Heller Myotomy and Paraesophageal, Hiatal, and Sliding Hernia Repair procedures.

Table H.39 Part One Da Vinci vs. Minimally Invasive/Laparoscopic Heller Myotomy Procedures

Author/Year	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Intraop Comp Rate (%)
222. Ali (2019)	Robotic	44	Median: 183.5	Not Reported	Median: 1	0
	Lap	40	Median: 157		Median: 1	15
227. Kim (2018)	Robotic	37	158	41	2.02	Not Reported
	Lap	35	157	56	2.17	
228. Maseo (2010)	Robotic	102	202.9 ± 97.0	Not Reported		
	Lap	150	183.7 ± 79.8			
229. Milone (2019)	Robotic	338	164.9 ± 747	36.4 ± 13.6	2.3 ± 0.5	Not Reported
	Lap	2287	159.9 ± 70.2	45.8 ± 11.6	2.4 ± 0.2	
231. Perry (2014)	Robotic	56	133 ± 29	25	Median: 1	Not Reported
	Lap	19	121 ± 22	50	Median: 1	
232. Sanchez (2012)	Robotic	13	79 ± 20	Not Reported		0
	Lap	18	76 ± 13			5.5
233. Shaligram (2011)	Robotic	149	Not Reported		2.42	Not Reported
	Lap	2116			2.70	
236. Villamere (2014)	Robotic	314	Not Reported		2.26	Not Reported
	Lap	3135			2.78	

Table H.39 Part Two Da Vinci vs. Minimally Invasive/Laparoscopic Heller Myotomy Procedures

Author/Year	Procedure Type	Post/Peri-Op Comp Rate (%)	Mortality (in-hospital-30 days, %)	Reoperation Rate (%)	Readmission Rate (%)	Conversion Rate (%)	Perforation (%)
222. Ali (2019)	Robotic	Not Reported	0	Not Reported	2.3	0	0
	Lap		0	2.5	7.5	5	2.5
227. Kim (2018)	Robotic	0	0			0	2.7
	Lap	0	0			8.6	11.4
228. Maseo (2010)	Robotic	Not Reported					0
	Lap						11
229. Milone (2019)	Robotic	Not Reported				0	3.0
	Lap					3.0	12.2
231. Perry (2014)	Robotic	Not Reported	0	Not Reported		0	0
	Lap		0			0	15.8
232. Sanchez (2012)	Robotic	Not Reported				0	0
	Lap					0	505
233. Shaligram (2011)	Robotic	4.02	0	Not Reported	2.84	Not Reported	
	Lap	5.19	0.14		1.41		
236. Villamere (2014)	Robotic	1.27	0	Not Reported	0.66	Not Reported	
	Lap	1.02	0		1.5		

Table H.40 Part One Da Vinci vs. Minimally Invasive, Laparoscopic Hiatal, Paraesophageal, and Sliding Hernia Repair Procedures

Author/Year	Study Size (N)		Operation Time (minutes)	EBL (ml)	Length of Stay (days)	Intraop Comp Rate (%)
223. Gehrig (2013)	Robotic	12	172 ± 31	33 ± 85	7.8 ± 3.9	8.3
	Lap	17	168 ± 42	24 ± 42	6.5 ± 1.6	5.9
224. Gerull (2020)	Robotic	830	174.1 ± 63	27.3 ± 5.9	1.8 ± 0.6	Not Reported
	Lap	1024	187.3 ± 65	89.3 ± 27.8	2.9 ± 1.4	
225. Hosein (2020)	Robotic	835	Not Reported		3.44 ± 5.01	Not Reported
	Lap	6774			3.9 ± 5.22	
226. Howell (2020)	Robotic	44	Not Reported		Median: 2.0	Not Reported
	Lap	84			Median: 1.0	
230. O'Connor (2020)	Robotic	114	179	Not Reported	2.3	Not Reported
	Lap	279	175	1.4[a]	3.3	
234. Soliman (2019)	Robotic	142	186.5	2.0	1.3 ± 1.8	Not Reported
	Lap	151	158.0	Not Reported	1.8 ± 1.5	
235. Tolboom (2016)	Robotic	45	120	Not Reported	Median: 1.0	15.56
	Lap	30	95		Median: 4.0	13.3

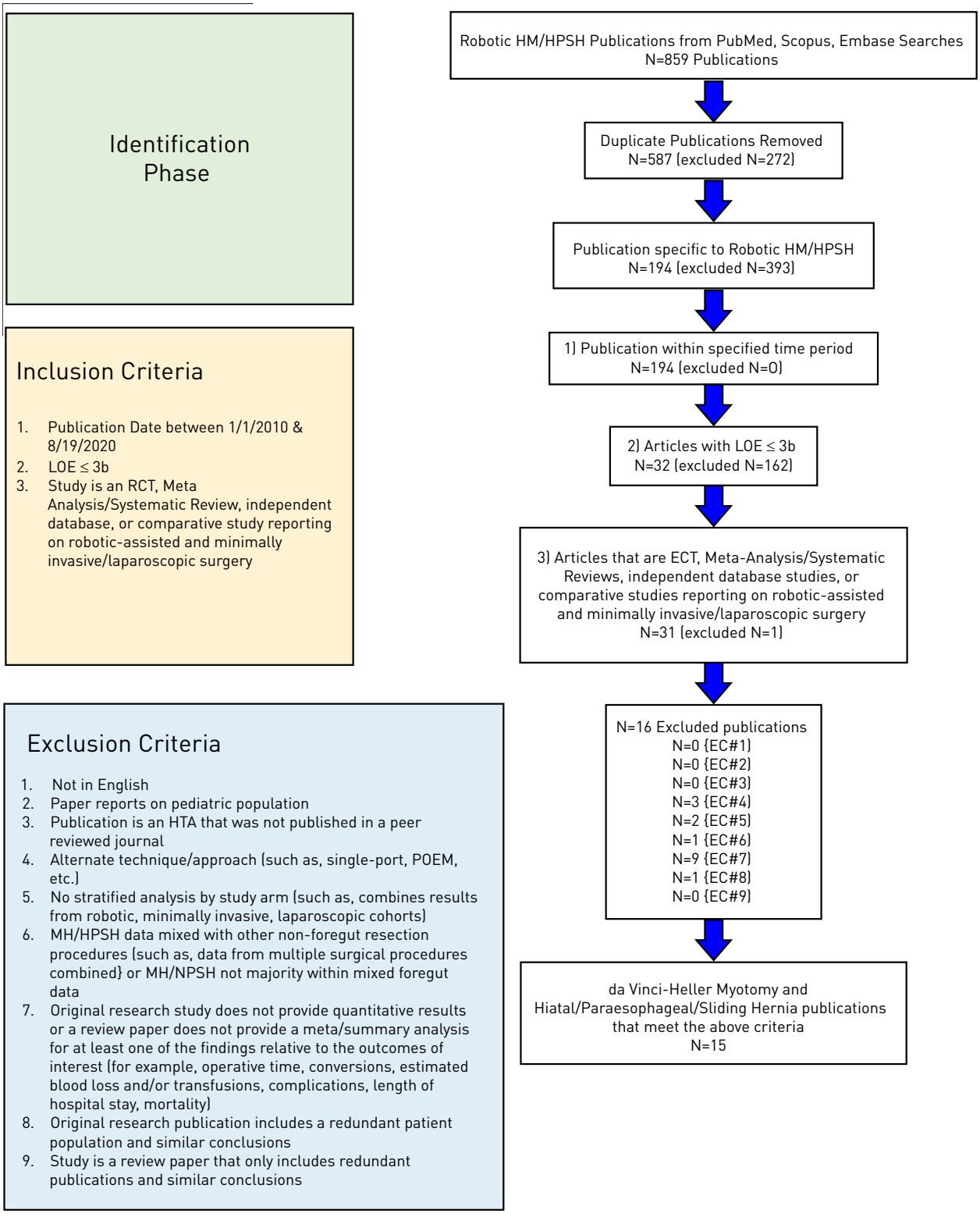
Notes

a. Post-operative blood transfusion rates reported

Table H.40 Part Two Da Vinci vs. Minimally Invasive, Laparoscopic Hiatal, Paraesophageal, and Sliding Hernia Repair Procedures

Author/Year	Study Size (N)	Postop Comp Rate (%)	Mortality (in-hospital — 30 days, %)	Reoperation Rate (%)	Readmission Rate (%)	Conversion Rate (%)
223. Gehrig (2013)	Robotic	8.3	0	8.3	Not Reported	0
	Lap	11.8	0	0		5.9
224. Gerull (2020)	Robotic	Not Reported	0	0.2	Not Reported	0
	Lap		0.5	0.8		7.0
225. Hosein (2020)	Robotic	2	0.1	Not Reported	Not Reported	Not Reported
	Lap	3.7	0.4			
226. Howell (2020)	Robotic	13.6	0	0	4.6	0
	Lap	11.9	0	2.4	8.3	0
230. O'Connor (2020)	Robotic	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported
	Lap					
234. Soliman (2019)	Robotic	6.3	0	1.4	3.50	0.7
	Lap	19.2	0	2.0	4.00	0
235. Tolboom (2016)	Robotic	Not Reported	0	8.89	ICU: 0	2.2
	Lap		0	13.33	ICU: 6.67	16.7

Figure H.3 Search Criteria & Flowchart for Identification of Heller Myotomy, Hiatal, Paraesophageal, and Sliding Hernia Repair Publications



PubMed Search Terms: robotic, robot, robot assist, robotically assisted, robot assist, da vinci, davinci, intuitive surgical, robot surgery, achalasia, achalasias, heller myotomy, cardiospasm, cardiomyotomy, foregut, hiatal hernia, paraesophageal hernia, hernia, paraesophageal, sliding hernia

Scopus Search Terms: davinci, robotic surgery, intuitive surgical, robotic assist, robot surgery, robotic assist, achalasia, achalasias, esophageal achalasia, heller myotomy, foregut, hiatal hernia, paraesophageal hernia, hernia, paraesophageal, sliding hernia

Embase Search Terms: da vinci, davinci, intuitive surgical, endowrist, achalasia, achalasias, esophagus achalasia, heller myotomy, foregut, hiatal hernia, paraesophageal hernia, hernia, paraoesophageal, sliding hernia

Clinical Study Data - Hepatectomy

Published clinical data were provided to support use of the da Vinci Xi and X Surgical Systems (Models IS4000 and IS4200) in the subject representative, specific procedure of "Hepatectomy/ Liver Resection" that falls under the cleared "general laparoscopic surgical procedures" Indication for Use. Thirty-eight (38) publications were identified for the subject procedure based on specific search criteria and filters used in three (3) databases: PubMed, Scopus and Embase. The search terms, inclusion/exclusion criteria and a flowchart depicting the results from these searches is provided in Figure H.4. These publications included: one (1) prospective study (LOE 2b), five (5) database studies (LOE 2c) and thirty-two (32) retrospective studies (LOE 3b) comparing da Vinci-assisted procedures with minimally invasive/ laparoscopic cohorts. Detailed summaries of the published clinical data on these procedures are provided in Table H.41 Part One, Table H.41 Part Two, and Table H.42.

The findings from the Hepatectomy/Liver Resection publications demonstrate that da Vinci-assisted procedures as compared to minimally invasive/laparoscopic procedures are found to be substantially equivalent based on the following endpoints:

- Mortality Rates
- Estimated Blood Loss (EBL) Volumes
- Transfusion Rates
- Lengths of Hospital Stay (LOS)
- Post/Peri - Operative Complication Rates
- Conversion Rates
- Readmission Rates
- Perforation Rates
- Operative Times
- Biliary/Bile Leak Rates
- Liver Failure Rates

Learning Curve Assessment

Eight (8) publications evaluated the learning curve associated with da Vinci-assisted Hepatectomy/Liver Resection procedures across different surgeons with varying levels of clinical and surgical expertise. A bibliography of these publications is provided herein.

The da Vinci Xi or X Surgical System should only be used in Hepatectomy/Liver Resection procedures performed by experienced hepatobiliary surgeons who have credentials and privileges to perform such procedures at their institution. Additionally, Intuitive recommends experience with the da Vinci Xi or X Surgical Systems in less complex procedures (for example, Cholecystectomy) prior to use of the system in Hepatectomy/Liver Resection procedures. Published literature indicates that the learning curve associated with stabilization of operative time and perioperative outcomes of da Vinci-assisted Hepatectomy/Liver Resection procedures can range from 13-45 cases. Intuitive encourages the use of a proctor or preceptor during use of the device in early Hepatectomy/Liver Resection procedures.

Table H.41 Part One Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures

Author	Study Size (N)		Operation Time (minutes)	Conversion to Open Rate (%)	Peri/Postoperative Complication Rate (%)	EBL (ml)
237. Efanov (2017)	Robotic	40	407 (85–980)	5%	20%	465 (0–2000)
	Lap	91	296 (70–605)	4%	17%	302 (0–2200)
238. Lim (2019)	Robotic	61	277 ± 156	3.2%	25%	Not Reported
unmatched	Lap	111	263 ± 109	11.2%	15%	
matched	Robotic	55	254 ± 143	Not Reported	22%	
	Lap	55	257 ± 102		13%	
239. Spampinato (2014)	Robotic	25	430 (240–725)	4.0%	16%	250 (100–1900)
	Lap	25	360 (180–600)	4.0%	36%	400 (50–1200)
240. Berber (2010)	Robotic	9	258.5 ± 27.9	11.1%	11.1%	136 ± 61
	Lap	23	233.6 ± 16.4	0.0%	17.4%	155 ± 54
241. Chong (2019)	Robotic	91	259.3 ± 127.0	7.7%	9.9%	274.6 ± 568.1
	Lap	92	216.8 ± 79.2	12.0%	5.4%	212.4 ± 313.3
242. Croner (2016)	Robotic	10	321 (138–458)	Not Reported	10%	306
	Lap	19	242 (80–478)		16%	356
243. Fruscione (2019)	Robotic	57	194 (152–255)	Not Reported	28.1%	250 (125–600)
	Lap	116	204 (149–280)		35.3%	400 (150–750)

(continues on next page)

Table H.41 Part One Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)		Operation Time (minutes)	Conversion to Open Rate (%)	Peri/Postoperative Complication Rate (%)	EBL (ml)
244. Hu (2019)	Robotic	58	107.0 ± 45.2	0%	2%	80.1 ± 144.4
	Lap	54	95.7 ± 47.5	1.9%	4%	108.9 ± 180.8
245. Lai (2016)	Robotic	100	207.4 ± 77.1	4.0%	14%	334.6 (5–3500)
	Lap	35	134.2 ± 41.7	5.7%	20%	336.0 (5–2000)
246. Lee KF (2016)	Robotic	70	251.5 (97–620)	5.7%	11.4%	100 (2–2500)
	Lap	66	215 (90–420)	12.1%	4.5%	100 (5–1610)
247. Lee JS (2019)	Robotic	13	LH: 248.6 ± 37.5 LLS: 160.8 ± 33.6	0%	7.7%	320.3 ± 331.9
	Lap	10	LH: 226.7 ± 26.6 LLS: 116.3 ± 8.7	10%	10%	392.8 ± 374.5
248. Marino (2018)	Robotic	14	425 ± 139	14.3%	21.4%	335.15 ± 139.8
	Lap	20	565.18 ± 183.73	25.0%	15.0%	423.95 ± 205.15
249. Mejia (2019)	Robotic	35	121 [107–178]	0%	0%	150 [100–200]
Minor	Lap	85	148 [113–180]	1.2%	4.7%	135 [50–275]
Major	Robotic	8	222 [168.5–240.5]	0%	0%	500 [225–780]
	Lap	13	195 [180–210]	7.7%	23.1%	250 [100–300]

(continues on next page)

Table H.41 Part One Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)		Operation Time (minutes)	Conversion to Open Rate (%)	Peri/Postoperative Complication Rate (%)	EBL (ml)
250. Montali (2015)	Robotic	36	306 ± 182	13.9%	19.4%	415 ± 414
	Lap	72	295 ± 107	9.7%	19.4%	437 ± 523
251. Packiam (2012)	Robotic	11	175 (156–253)	0%	27%	30 (30–50)
	Lap	18	188 (156–222)	0%	0%	30 (30–30)
252. Tranchart (2014)	Robotic	28	210 (45–480)	14.3%	17.9%	200 (0–1800)
	Lap	28	176 (30–420)	7.1%	17.9%	150 (0–1000)
253. Troisi (2013)	Robotic	40	271 ± 100	20%	12.5%	330 ± 303
	Lap	223	262 ± 111	7.6%	12.6%	174 ± 133
254. Tsung (2013)	Robotic	57	253 (180–355)	7%	19.3%	200 (50–337.5)
	Lap	114	198.5 (138–262)	8.8%	26%	100 (50–350)
255. Wang (2019)	Robotic	92	195.53 ± 67.00	1.1%	13%	243.04 ± 171.87
	Lap	48	198.98 ± 72.94	10.4%	10.4%	346.04 ± 234.17
256. Wu (2014)	Robotic	38	380 ± 166	5.3%	8%	325 ± 480
	Lap	41	227 ± 80	12.2%	9.8%	173 ± 165
257. Yu (2014)	Robotic	13	291.5 ± 85.1	0%	0%	388.5 ± 65.0
	Lap	17	240.9 ± 68.6	0%	11.8%	342.6 ± 84.7

(continues on next page)

Table H.41 Part One Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)		Operation Time (minutes)	Conversion to Open Rate (%)	Peri/Postoperative Complication Rate (%)	EBL (ml)
258. Beard (2019) unmatched	Robotic	115	272 ± 115	5.2%	Not Reported	
	Lap	514	253 ± 118	63 (12.1%)		
matched	Robotic	115	Not Reported		31.3%	Not Reported
	Lap	115			27.8%	
259. Cortolillo (2018)	Robotic	204	Not Reported			
	Lap	520				
260. Di Sandro (2014)	Robotic	10	236 (140–360)	0%	Not Reported	220 (50–450)
	Lap	10	185 (85–310)	NR		350 (50–1200)
261. Hu (2020)	Robotic	19	256.3 ± 57.7	Not Reported	5.3%	319.5 ± 206.0
	Lap	13	268.4 ± 93.6		7.7%	476.9 ± 210.8
262. Kim (2016)	Robotic	12	403.8 ± 139.0	0%	25%	225 (125–275)
	Lap	31	245.9 ± 100.7	3.2%	22.6%	150 (50–425)
263. O'Connor (2017)	Robotic	39	216 (80–300)	7.7%	18.0%	298 (5–1650)
	Lap	50	216 (120–330)	28.0%	34.0%	306 (5–3000)

(continues on next page)

Table H.41 Part One Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)		Operation Time (minutes)	Conversion to Open Rate (%)	Peri/Postoperative Complication Rate (%)	EBL (ml)
264. Aziz (2021) unmatched	Robotic	109	Not Reported		3.7%–7.3%	Not Reported
	Lap	343			9.8%–13.1%	
matched	Robotic	101			7.3%	
	Lap	202			9.1%	
265. Chen (2017)	Robotic	81	343 (140–715)	0%	4.9%	282 (50–2200)
	Lap	41	228 (83–391)	12.2%	9.8%	191 (50–600)
266. Han (2016)	Robotic	16	Not Reported	0%	Not Reported	
	Lap	83		9.6%		
267. Lin (2015)	Robotic	25	318.8 ± 44.1	0%	24%	270.8 ± 161.6
	Lap	11	314.6 ± 56.3	0%	27.3%	294.6 ± 205.1
268. Lorenz (2021)	Robotic	41	330.5 ± 132.2	Not Reported	19.5%[a]	439.8 ± 346.3
	Lap	72	181.3 ± 100.4		5.6%[a]	425.4 ± 590.1
269. Magistri (2016)	Robotic	22	318 ± 113.5	0%	100%	400 (50–1500)
	Lap	24	211 ± 78.13	16.7%	68.2%	328 (100–1100)
270. Miller (2021)	Robotic	227	217 ± 101	Not Reported		
	Lap	227	175 ± 92			

(continues on next page)

Table H.41 Part One Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)		Operation Time (minutes)	Conversion to Open Rate (%)	Peri/Postoperative Complication Rate (%)	EBL (ml)
271. Salloum (2017)	Robotic	16	190 ± 87	12.5%	12.5%	247 ± 239
unmatched	Lap	80	162 ± 51	2.5%	11.3%	206 ± 205
matched	Robotic	14	203 ± 87	14.3%	7.1%	265 ± 253
	Lap	14	140 ± 33	0%	7.1%	121 ± 99
272. Stewart (2019)	Robotic	354	Not Reported		21%	Not Reported
	Lap	6186			19%	
273. Stiles (2017)	Robotic	73	Not Reported	6.8%	Not Reported	
	Lap	989		20.0%		
274. Ji (2011)	Robotic	13	338 (150–720)	0%	7.7%	280
	Lap	20	130 (40–210)	5%	10%	350

Notes

a. Major complications
b. 90 day rate
c. 6 month rate
d. 45 day rate

Table H.41 Part Two Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures

Author	Study Size (N)	Transfusion Rate (%)	Mortality Rate (%) (in - hospital, 30, 90 days)	Length of Stay (days)	ReoperationRate (%)	M
237. Efanov (2017)	Robotic	8%	0%[d]	11 (6–30)	2.5%	Not Reported
	Lap	4%	0%/1.1%[d]	9 (4–90)	1.1%	
238. Lim (2019)	Robotic	14.8%	0%	9 ± 12	1.6%	0%
unmatched	Lap	1.8%	0%	7 ± 6	0%	0.9%
matched	Robotic	10.9%	0%	9 ± 13	1.8%	0%
	Lap	3.6%	0%	7 ± 5	0%	0%
239. Spampinato (2014)	Robotic	44%	0%[d]	8 (4–22)	4.0%	0%[d]
	Lap	16%	4%[d]	7 (5–22)	4.0%	4%[d]
240. Berber (2010)	Robotic	Not Reported				
	Lap					
241. Chong (2019)	Robotic	Not Reported		4.8 ± 1.8	Not Reported	
	Lap			4.9 ± 2.0		
242. Croner (2016)	Robotic	Not Reported	0%	7 (5–13)	0%	Not Reported
	Lap		5.0%	8 (4–33)	0%	
243. Fruscione (2019)	Robotic	Not Reported	0%	4 (3–5)	1.8%	7.0%[d]
	Lap		0%	5 (3–6)	0.9%	28.4%[d]

(continues on next page)

Table H.41 Part Two Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)	Transfusion Rate (%)	Mortality Rate (%) (in - hospital, 30, 90 days)	Length of Stay (days)	ReoperationRate (%)	M
244. Hu (2019)	Robotic	5.2%	0%	4.3 ± 1.8	Not Reported	
	Lap	1.9%	0%	4.4 ± 1.8		
245. Lai (2016)	Robotic	9.0%	0%	7.3 ± 5.3	Not Reported	
	Lap	11.4%	0%	7.1 ± 2.6		
246. Lee KF (2016)	Robotic	4.3%	0%	5 (2–22)	0%	Not Reported
	Lap	1.5%	0%	5 (2–15)	0%	
247. Lee JS (2019)	Robotic	0%	0%	7.0 ± 2.4	0%	Not Reported
	Lap	0%	0%	7.3 ± 2.9	0%	
248. Marino (2018)	Robotic	0%	0%	9 ± 1.4	0%	Not Reported
	Lap	0%	0%	8.6 ± 1.5	5.0%	
249. Mejia (2019) Minor	Robotic	8.6%	0%	2 [2–4]	Not Reported	
	Lap	4.7%	0%	3 [2–3]		
Major	Robotic	25.0%	0%	3 [2.5–5.5]	Not Reported	
	Lap	7.7%	0%	3 [3–5]		
250. Montali (2015)	Robotic	Not Reported	2.8%	6 ± 2.9	Not Reported	
	Lap		0%	4.9 ± 2.95		

(continues on next page)

Table H.41 Part Two Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)	Transfusion Rate (%)	Mortality Rate (%) (in - hospital, 30, 90 days)	Length of Stay (days)	ReoperationRate (%)	M
251. Packiam (2012)	Robotic	0%	0%	4 (3–5)	0%	9.1%
	Lap	0%	0%	3 (2–3)	0%	0%
252. Tranchart (2014)	Robotic	14.3%	0%	6 (1–15)	Not Reported	
	Lap	3.6%	3.6%	5.5 (1–50)		
253. Troisi (2013)	Robotic	Not Reported	0%	6.1 ± 2.6	Not Reported	
	Lap		0%	5.9 ± 3.8		
254. Tsung (2013)	Robotic	3.8%	0%[d]	4.0 (3.0–5.5)	Not Reported	
	Lap	7.4%	0.9%/1.8%[d]	4.0 (3.0–5.0)		
255. Wang (2019)	Robotic		0%	7.41 ± 2.64	0%	Not Reported
	Lap		0%	7.06 ± 3.35	0%	
256. Wu (2014)	Robotic	Not Reported	0%	7.9 ± 4.7	Not Reported	
	Lap		0%	7.2 ± 4.4		
257. Yu (2014)	Robotic	0%	0%	7.8 ± 2.3	Not Reported	
	Lap	0%	0%	9.5 ± 3.0		
258. Beard (2019) unmatched	Robotic	9.6%	Not Reported			
	Lap	32.5%				

(continues on next page)

Table H.41 Part Two Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)	Transfusion Rate (%)	Mortality Rate (%) (in - hospital, 30, 90 days)	Length of Stay (days)	ReoperationRate (%)	M
matched	Robotic	Not Reported	0.9%	5 (IQR: 3–6)	0.9%	7.0%
	Lap		0.9%	4 (IQR: 2–6)	3.5%	7.0%
259. Cortolillo (2018)	Robotic	Not Reported	0.5%	4.5 ± 3.8	Not Reported	7.9%
	Lap		2.1%	6.8 ± 6.0		13.0%
260. Di Sandro (2014)	Robotic	Not Reported	0%	6.8 (5–9)	0%	Not Reported
	Lap		0%	6.5 (4–10)	0%	
261. Hu (2020)	Robotic	26.3%	0%	5.5 ± 2.1	Not Reported	
	Lap	30.8%	0%	4.7 ± 1.7		
262. Kim (2016)	Robotic	8.3%	0%	7 (7–8)	8.3%	Not Reported
	Lap	3.2%	0%	7 (5–8)	6.5%	
263. O'Connor (2017)	Robotic	5%	Not Reported	3.0 (1–9)	Not Reported	
	Lap	6%		3.3 (1–12)		
264. Aziz (2021)	Robotic		0%[c]	4.5 ± 3.8	Not Reported	6.6%/18.3%
unmatched	Lap		2.2%[c]	6.1 ± 2.7		12.7%/26.7%
matched	Robotic		0%[c]	Not Reported	1.5%	14.3%
	Lap		1.7%[c]		1.9%	16.5%

(continues on next page)

Table H.41 Part Two Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)	Transfusion Rate (%)	Mortality Rate (%) (in - hospital, 30, 90 days)	Length of Stay (days)	ReoperationRate (%)	M
265. Chen (2017)	Robotic	Not Reported	0%[c]	7.5 (3–26)	0%	Not Reported
	Lap		0%	6.3 (2–16)	0%	
266. Han (2016)	Robotic	Not Reported				
	Lap					
267. Lin (2015)	Robotic	Not Reported	0%	7.5 ± 1.7	Not Reported	
	Lap		0%	7.0 ± 1.3		
268. Lorenz (2021)	Robotic	17%	0%	13.4 ± 12.5	4.9%	Not Reported
	Lap	9.7%	2.80%	8.7 ± 5.8	1.4%	
269. Magistri (2016)	Robotic	4.5%	0%	5.1 ± 2.4	0%	Not Reported
	Lap	4.2%	0%	6.2 ± 2.57	4.2%	
270. Miller (2021)	Robotic	10.6%	0.90%	4 ± 4	0.9%	8.80%
	Lap	4.8%	0%	3 ± NR	1.3%	5.30%
271. Salloum (2017) unmatched	Robotic	6.3%	0%	6 ± 4	Not Reported	
	Lap	2.5%	1.30%	7 ± 8		
matched	Robotic	7.1%	0%	6 ± 3		
	Lap	0%	0%	6 ± 2		

(continues on next page)

Table H.41 Part Two Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)	Transfusion Rate (%)	Mortality Rate (%) (in - hospital, 30, 90 days)	Length of Stay (days)	ReoperationRate (%)	M
272. Stewart (2019)	Robotic	Not Reported				
	Lap					
273. Stiles (2017)	Robotic	Not Reported				
	Lap					
274. Ji (2011)	Robotic	0%	Not Reported	6.7	Not Reported	
	Lap	15%		5.2		

Notes

a. Major complications

b. 90 day rate

c. 6 month rate

d. 45 day rate

Table H.42 Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures

Author	Study Size (N)		R0 Resection Rate (%)	PSM/R1 Resection Rate (%)	Bile leak Rate (%)	Liver failure Rate (%)
237. Efanov (2017)	Robotic	40	Not Reported		10.0%	0%
	Lap	91			4.4% (bile comps)	1.1%
238. Lim (2019) unmatched	Robotic	61	Not Reported	11.5%	Not Reported	
	Lap	111		15.3%		
matched	Robotic	55		10.9%		
	Lap	55		16.4%		
239. Spampinato (2014)	Robotic	25	100%	0%	0%	0% (transient)
	Lap	25	91.3%	8.7%	8.0%	8% (transient)
240. Berber (2010)	Robotic	9	Not Reported			
	Lap	23				
241. Chong (2019)	Robotic	91	98.9%	Not Reported		
	Lap	92	98.9%			
242. Croner (2016)	Robotic	10	100%	Not Reported		
	Lap	19	100%			
243. Fruscione (2019)	Robotic	57	91.9%	8.1%	Not Reported	
	Lap	116	92.6%	7.4%		

(continues on next page)

Table H.42 Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)		R0 Resection Rate (%)	PSM/R1 Resection Rate (%)	Bile leak Rate (%)	Liver failure Rate (%)
244. Hu (2019)	Robotic	58	100%	0%	Not Reported	
	Lap	54	100%	0%		
245. Lai (2016)	Robotic	100	96.0%	Not Reported	2%	1%
	Lap	35	91.4%		0%	0%
246. Lee KF (2016)	Robotic	70	Not Reported	1.8%	1.40%	Not Reported
	Lap	66		1.6%	0%	
247. Lee JS (2019)	Robotic	13	100%	0%	Not Reported	
	Lap	10	NR	NR		
248. Marino (2018)	Robotic	14	91.7%	8.3%	7.1%	7.1% (transient)
	Lap	20	85.0%	10.0%	10.0%	5% (transient)
249. Mejia (2019) minor	Robotic	35	Not Reported	9.1%	0%	Not Reported
	Lap	85		9.4%	1.2%	
major	Robotic	8	Not Reported	0%	Not Reported	
	Lap	13		25.0%		
250. Montali (2015)	Robotic	36	Not Reported	11.1%	2.8%	5.6%
	Lap	72		12.5%	1.4%	0%

(continues on next page)

Table H.42 Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)		R0 Resection Rate (%)	PSM/R1 Resection Rate (%)	Bile leak Rate (%)	Liver failure Rate (%)
251. Packiam (2012)	Robotic	11	Not Reported			
	Lap	18				
252. Tranchart (2014)	Robotic	28	Not Reported			
	Lap	28				
253. Troisi (2013)	Robotic	40	Not Reported	7.5%	5%	Not Reported
	Lap	223		5.4%	1.3%	
254. Tsung (2013)	Robotic	57	95%	Not Reported	1.8%^	Not Reported
	Lap	114	92%		0%	
255. Wang (2019)	Robotic	92	Not Reported			
	Lap	48				
256. Wu (2014)	Robotic	38	Not Reported		2.6%	Not Reported
	Lap	41			NR	
257. Yu (2014)	Robotic	13	Not Reported			
	Lap	17				
258. Beard (2019) matched	Robotic	115	73.7%	20.2%	Not Reported	
	Lap	115	77.4%	20.9%		

(continues on next page)

Table H.42 Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

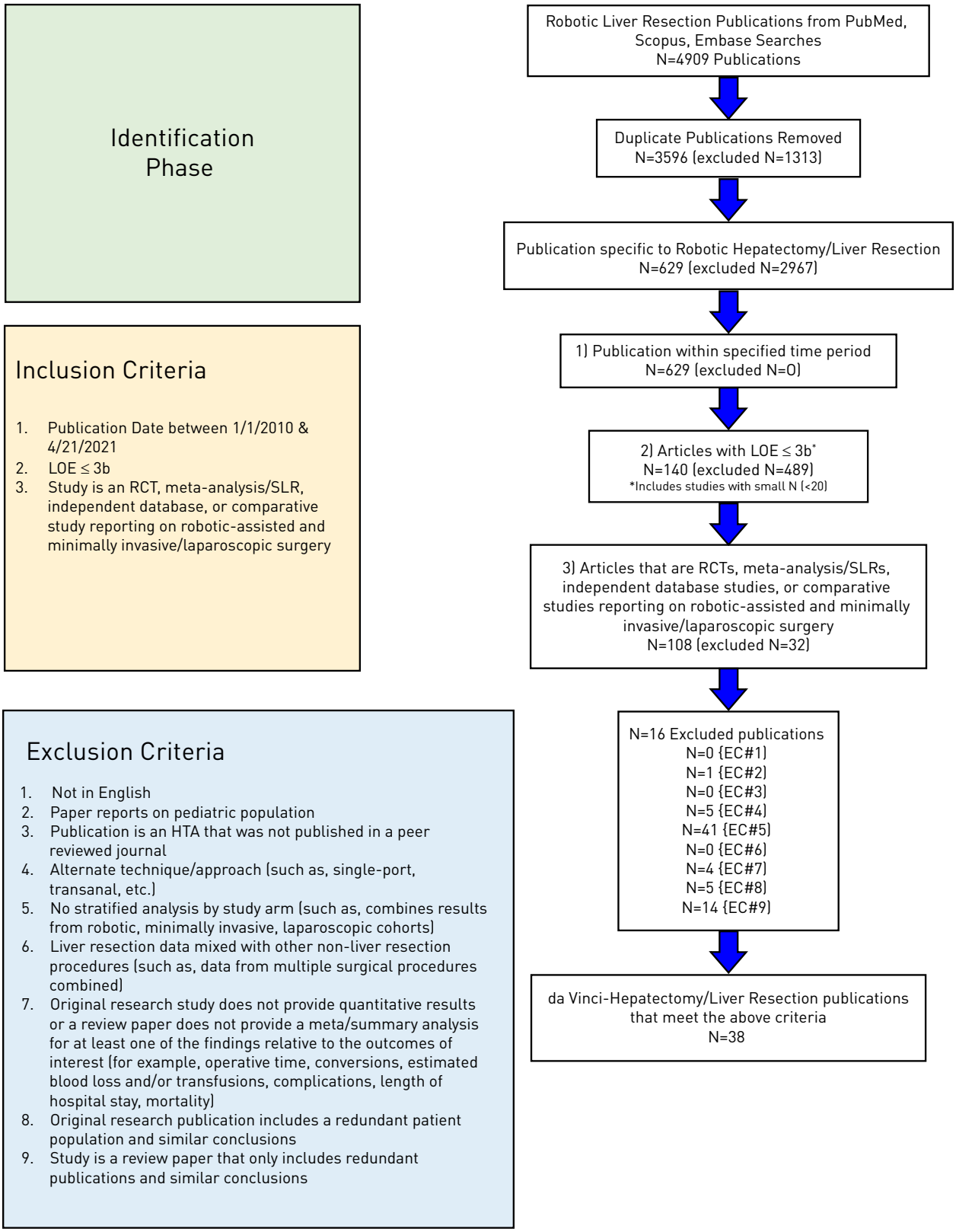
Author	Study Size (N)		R0 Resection Rate (%)	PSM/R1 Resection Rate (%)	Bile leak Rate (%)	Liver failure Rate (%)
259. Cortolillo (2018)	Robotic	204	Not Reported			
	Lap	520				
260. Di Sandro (2014)	Robotic	10	Not Reported	0%	0%	0%
	Lap	10		10.0%	0%	
261. Hu (2020)	Robotic	19	Not Reported			
	Lap	13				
262. Kim (2016)	Robotic	12	Not Reported		8.3%	Not Reported
	Lap	31			6.5%	
263. O'Connor (2017)	Robotic	39	90%	Not Reported		
	Lap	50	88%			
264. Aziz (2021) matched	Robotic	101	Not Reported			0.8%
	Lap	202				1.1%
265. Chen (2017)	Robotic	81	Not Reported			
	Lap	41				
266. Han (2016)	Robotic	16	Not Reported			
	Lap	83				

(continues on next page)

Table H.42 Da Vinci vs. Minimally Invasive/Laparoscopic Hepatectomy/Liver Resection Procedures (continued)

Author	Study Size (N)		R0 Resection Rate (%)	PSM/R1 Resection Rate (%)	Bile leak Rate (%)	Liver failure Rate (%)
267. Lin (2015)	Robotic	25	100%	0%	4%	Not Reported
	Lap	11	100%	0%	0%	
268. Lorenz (2021)	Robotic	41	93.8%	Not Reported	2.4%	Not Reported
	Lap	72	87.9%		0%	
269. Magistri (2016)	Robotic	22	95.5%	4.5%	0%	Not Reported
	Lap	24	95.8%	4.2%	4.2%	
270. Miller (2021)	Robotic	227	Not Reported			
	Lap	227				
271. Salloum (2017) unmatched	Robotic	16	Not Reported	0%	0%	0%
	Lap	80		2.1%	0%	1.3%
matched	Robotic	14		0%	0%	Not Reported
	Lap	14		0%	0%	
272. Stewart (2019)	Robotic	354	Not Reported			
	Lap	6186				
273. Stiles (2017)	Robotic	73	Not Reported			
	Lap	989				
274. Ji (2011)	Robotic	13	100%	0%	7.7% (transient)	Not Reported
	Lap	20	Not Reported	Not Reported	5% (transient)	

Figure H.4 Search Criteria & Flowchart for Identification of Hepatectomy/Liver Resection Publications



Key Search Terms: liver cancer, hepatocellular cancer, hepatocellular carcinoma, liver cirrhosis, hepatic/liver hemangioma, liver adenocarcinoma, liver/hepatic cyst, focal nodular hyperplasia, giant hepatic tumor, liver tumor, liver surgery, hepatic surgery, hepatic surgery, partial hepatectomy, hepatectomies, hepatectomy, segmentectomy, segmentectomies, hepatic resection, liver resection, pericystectomy, hepatic segmentectomy, hepatic sectionectomy, wedge resection, hepatic lobectomy, hepatic nodular hyperplasia, hepatic adenoma

Clinical Publications

Hysterectomy (Radical)

1. Gaia, G., et al. (2010). Robotic-assisted hysterectomy for endometrial cancer compared with traditional laparoscopic and laparotomy approaches: a systematic review. Obstetrics and Gynecology. 116: 1422-1431.
2. Reza, M., et al. (2010). Meta-analysis of observational studies on the safety and effectiveness of robotic gynaecological surgery. British Journal of Surgery.
3. O'Sullivan, S. (2011). HIQA Ireland Health technology assessment of robot-assisted surgery in selected surgical procedures.
4. O'Neill, M., et al. (2013). Robot-assisted hysterectomy compared to open and laparoscopic approaches: systematic review and metaanalysis. Archives of Gynecology and Obstetrics. 287: 907-918.
5. Ran, L., et al. (2014) Comparison of robotic surgery with laparoscopy and laparotomy for treatment of endometrial cancer: a metaanalysis. PLoS ONE. 9: e108361.
6. Geetha, P. and M. Nair (2012). Laparoscopic, robotic and open method of radical hysterectomy for cervical cancer: A systematic review. Journal of Minimal Access Surgery. 8: 67–73.
7. Shazly, S. A., et al. (2015). Robotic radical hysterectomy in early stage cervical cancer: A systematic review and meta-analysis. Gynecologic Oncology.

Myomectomy

8. Pundir, et al. (2014). Robotic-Assisted Laparoscopic vs Abdominal and Laparoscopic Myomectomy: Systematic Review and Meta- Analysis. *Journal of Minimally Invasive Gynecology*. 20, 335–345.
9. Barakat, et al. Robotic-Assisted, Laparoscopic, a Abdominal Myomectomy: A Comparison of Surgical Outcomes. *Obstet Gynecol*. 2011;117:256–265.
10. Bedient, et al. Comparison of Robotic and Laparoscopic Myomectomy. Am J *Obstet Gynecol.* 2009:201:1.e1 – 1.e5.
11. Gargiulo, et al. Robot-Assisted Laparoscopic Myomectomy Compared with Standard Laparoscopic Myomectomy. *Obstet Gynecol.* 2012;120:284–291.; (2013) 287:91–96.
12. Nezhat, et al. Robotic-Assisted Laparoscopic Myomectomy Compared with Standard Laparoscopic Myomectomy - A Retrospective Matched Control Study. *Fertility & Sterility*. 2009 Feb;91(2):556-9. doi: 10.1016/.fertnstert.2007.11.092. Epub 2008 Apr 18.
13. Hsiao, et al. Comparison of Robot-Assisted Laparoscopic Myomectomy and Traditional Laparoscopic Myomectomy. *J. Obstet. Gynaecol*. Res. Vol. 39, No. 5: 1024-1029, May 2013.

14. Pluchino, et al. Comparison of the Initial Surgical Experience with Robotic and Laparoscopic Myomectomy. *Int J Med Robotics Comput Assist Surg* 2013 DOI: 10.1002/rcs.1542.

15. Gobern, et al. Comparison of Robotic, Laparoscopic, and Abdominal Myomectomy in a Community Hospital. *JSLS* (2013)17:116-120.

16. Gocmen, et al. Comparison of Robotic-Assisted Laparoscopic Myomectomy Outcomes with Laparoscopic Myomectomy. *Arch Gynecol Obstet*.

17. Behera, et al. Cost Analysis of Abdominal, Laparoscopic, and Robotic-Assisted Myomectomies. *J Minim Invasiv Gyn*. 19(1)Jan-Feb 2012, 52-57.

Sacrocolpopexy

18. Serati, et al. (2014). Robot-assisted Sacrocolpopexy for Pelvic Organ Prolapse: A Systematic Review and Meta- Analysis of Comparative Studies. *European Urology*. 66:202-318.

19. Paraiso, et al. (2011). Laparoscopic Compared with Robotic Sacrocolpopexy for Vaginal Prolapse. A Randomized Controlled Trial. *Obstetrics & Gynecology*. 118(5)1005-1013.

20. Anger, et al. (2014). Robotic Compared with Laparoscopic Sacrocolpopexy. A Randomized Controlled Trial. *Obstetrics & Gynecology*. 123(1)5-12.

21. Flack, et al. (2015). National Trends in the Performance of Robot-Assisted Sacrocolpopexy. *J Endourology*. Jul;29(7):777-83. doi: 10.1089/end.2014.0710. Epub 2015 Mar 10.1.

Lobectomy

22. Cerfolio, R. J., et al. (2011). Initial consecutive experience of completely portal robotic pulmonary resection with 4 arms. *Journal of Thoracic and Cardiovascular Surgery*.

23. Veronesi, G. G., D.; Maisonneuve, P.; Melfi, F.; Schmid, R. A.; Borri, A.; Vannucci, F.; Spaggiari, L. (2010). Four-arm robotic lobectomy for the treatment of early-stage lung cancer. *Journal of Thoracic and Cardiovascular Surgery*. 140: 19-25.

24. Kent, M., et al. (2013). Open, Video-Assisted Thoracic Surgery, and Robotic Lobectomy: Review of a National Database. *Annals of Thoracic Surgery*.

25. Oh, D.S., et al. (2013). Early Adoption of Robotic Pulmonary Lobectomy: Feasibility and Initial Outcomes. *The American Surgeon*. 79:1075-1080.

26. Adams, R. D., et al. (2014). Initial Multicenter Community Robotic Lobectomy Experience: Comparisons to a National Database. *Annals of Thoracic Surgery*.

27. Deen, S. A., et al. (2014). Defining the Cost of Care for Lobectomy and Segmentectomy: A Comparison of Open, Video-Assisted Thoracoscopic, and Robotic Approaches. *Annals of Thoracic Surgery*.

28. Farivar, A. S., et al. (2014). Comparing Robotic Lung Resection With Thoracotomy and Video-Assisted Thoracoscopic Surgery Cases Entered Into The Society of Thoracic Surgeons Database. *Innovations (Phila)*. 9: 10-15.

29. Augustin, F., et al. (2013). Robotic-assisted minimally invasive vs. thoracoscopic lung lobectomy: comparison of perioperative results in a learning curve setting. *Langenbeck's Archives of Surgery*.

30. Bodner, J., et al. (2011). Minimally invasive approaches for lung lobectomy - From VATS to robotic and back! *European Surgery - Acta Chirurgica Austriaca*. 43(4): 224-228.

31. Jang, H. J. L., H. S.; Park, S. Y.; Zo, J. I. (2011). Comparison of the early robot-assisted lobectomy experience to video-assisted thoracic surgery lobectomy for lung cancer: A single-institution case series matching study. Innovations: *Technology and Techniques in Cardiothoracic and Vascular Surgery*. 6: 305-310.

32. Lee, H. S. J., H. J. (2012). Thoracoscopic mediastinal lymph node dissection for lung cancer. *Seminars in Thoracic and Cardiovascular Surgery*. 24(2): 131-141.

33. Louie, B. E. F., A. S.; Aye, R. W.; Vallieres, E. (2012). Early Experience With Robotic Lung Resection Results in Similar Operative Outcomes and Morbidity When Compared With Matched Video-Assisted Thoracoscopic Surgery Cases. *Annals of Thoracic Surgery*.

34. Lee, B. E., et al. (2013). Transitioning from video-assisted thoracic surgical lobectomy to robotics for lung cancer: Are there outcomes advantages? *Journal of Thoracic and Cardiovascular Surgery*.

35. Swanson, S. J., et al. (2013). Comparing robot-assisted thoracic surgical lobectomy with conventional video-assisted thoracic surgical lobectomy and wedge resection: Results from a multihospital database (Premier). *Journal of Thoracic and Cardiovascular Surgery*.

36. Paul, S., et al. (2014). Comparative Effectiveness of Robotic-Assisted vs. Thoracoscopic Lobectomy. Chest.

37. Spillane, J., et al. (2014). Developing a Robotic Program in Thoracic Surgery at Cape Code Hospital. *J Robotic Surg.* 8:213-220.

38. Lee, B. E., et al. (2015). Nodal Upstaging in Robotic and Video Assisted Thoracic Surgery Lobectomy for Clinical N0 Lung Cancer. *Annals of Thoracic Surgery*.

39. Mahieu, J., et al. (2015). Robot-Assisted Thoracoscopic Surgery versus Video-Assisted Thoracoscopic Surgery for Lung Lobectomy: Can a Robotic Approach Improve Short-Term Outcomes and Operative Safety? *Thoracic and Cardiovascular Surgeon*.

Mediastinal Mass Resection

40. Balduyck, B. H., J. M.; Lauwers, P.; Mercelis, R.; Ten Broecke, P.; Van Schil, P. (2011). Quality of life after anterior mediastinal mass resection: A prospective study comparing open with robotic-assisted thoracoscopic resection. *European Journal of Cardiothoracic Surgery*. 39: 543-548.

41. Seong, Y. W., et al. (2014). Early clinical outcomes of robot-assisted surgery for anterior mediastinal mass: its superiority over a conventional sternotomy approach evaluated by propensity score matching. *European Journal of Cardiothoracic Surgery*. 45: e68-73; discussion e73.

42. Cerfolio, R. J., et al. (2012). Operative techniques in robotic thoracic surgery for inferior or posterior mediastinal pathology. *Journal of Thoracic and Cardiovascular Surgery*.

43. Huang, J., et al. (2014). Initial experience of robot-assisted thoracoscopic surgery in China. *International of Medical Robots and Computer Assisted Surgery*.

44. Melfi, F., et al. (2012). Ten-year experience of mediastinal robotic surgery in a single referral centre. *European journal of cardiothoracic surgery*: official journal of the European Association for Cardiothoracic Surgery. 41(4): 847-851.

45. Nakamura, H., et al. Initial results of robot-assisted thoracoscopic surgery in Japan. *General Thoracic and Cardiovascular Surgery.* (2014).

46. Seder, C. W., et al. Navigating the pathway to robotic competency in general thoracic surgery. *Innovations (Phila)*. 8(3): 184-189 (2013).

Thymectomy

47. Weksler, B. T., J.; Newhook, T. E.; Greenleaf, C. E.; Diehl, J. T. (2011). Robot-assisted thymectomy is superior to transsternal thymectomy. *Surgical Endoscopy*: 1-6.

48. Ye, B., et al. (2014). Surgical treatment of early-stage thymomas: robot-assisted thoracoscopic surgery versus transsternal thymectomy. *Surgical Endoscopy*. 28: 122-126.

49. Renaud, S., et al. Robotic-assisted thymectomy with da Vinci II versus sternotomy in the surgical treatment of non-thymomatous myasthenia gravis: early results. *Revue Neurologique*. 169(1): 30-36 (2013).

50. Ye, B., et al. (2013). Video-assisted thoracoscopic surgery versus robotic-assisted thoracoscopic surgery in the surgical treatment of Masaoka stage I thymoma. *World Journal of Surgical Oncology*. 11: 157.

51. Ruckert, J. C. S., M.; Ismail, M. (2011). Comparison of robotic and nonrobotic thoracoscopic thymectomy: A cohort study. *Journal of Thoracic and Cardiovascular Surgery*. 141: 673-677.

52. Jun, Y., et al. da Vinci robot-assisted system for thymectomy: experience of 55 patients in China. *International of Medical Robots and Computer Assisted Surgery*. (2014).

53. Freeman, R. K., et al. Long-term follow-up after robotic thymectomy for nonthymomatous myasthenia gravis. *Annals of Thoracic Surgery*. 92(3): 1018-1023.

54. Goldstein, S. D. and S. C. Yang. Assessment of robotic thymectomy using the Myasthenia Gravis Foundation of America Guidelines. *Annals of Thoracic Surgery*. 89(4): 1080-1085; discussion 1085-1086 (2010).

55. Huang, P., et al. Experience with the da Vinci robotic system for early-stage thymomas: Report of 23 cases. *Thoracic Cancer*. 5(4): 325-329 (2014).

56. Keijzers, M., et al. Robotic thymectomy in patients with myasthenia gravis: neurological and surgical outcomes. *European Journal of Cardiothoracic Surgery*. (2014).

57. Marulli, G., et al. Robot-aided thoracoscopic thymectomy for early-stage thymoma: A multicenter European study. *Journal of Thoracic and Cardiovascular Surgery*. (2012).

58. Marulli, G., et al. Surgical and neurologic outcomes after robotic thymectomy in 100 consecutive patients with myasthenia gravis. *Journal of Thoracic and Cardiovascular Surgery*. (2013).

59. Mussi, A., et al. Robotic extended thymectomy for early-stage thymomas. *European Journal of Cardiothoracic Surgery*. 41(4): e43-47 (2012).

60. Rea, F., et al. Single-institution experience on robot-assisted thoracoscopic operations for mediastinal diseases. Innovations: *Technology and Techniques in Cardiothoracic and Vascular Surgery*. 6(5): 316-322 (2011).

61. Schneiter, D., et al. Minimally invasive resection of thymomas with the da Vinci® surgical system. *European Journal of Cardiothoracic Surgery*. 43(2): 288-292 (2013).

Prostatectomy (Radical)

62. Pan, X. W., X. M. Cui, J. F. Teng, D. X. Zhang, Z. J. Wang, F. J. Qu, Y. Gao, X. G. Cui and D. F. Xu (2015). Robot-Assisted Radical Prostatectomy vs. Open Retropubic Radical Prostatectomy for Prostate Cancer: A Systematic Review and Meta-analysis. *Indian Journal of Surgery.* 77 (Suppl 3): 1326-1333.

63. Trinh, Q. D., J. Sammon, M. Sun, P. Ravi, K. R. Ghani, M. Bianchi, W. Jeong, S. F. Shariat, J. Hansen, J. Schmitges, C. Jeldres, C. G. Rogers, J. O. Peabody, F. Montorsi, M. Menon and P. I. Karakiewicz (2012). Perioperative outcomes of robot-assisted radical prostatectomy compared with open radical prostatectomy: results from the nationwide inpatient sample. *Eur Urol.* 61(4): 679-685.

64. Davis, J. W., U. S. Kreaden, J. Gabbert and R. Thomas (2014). Learning curve assessment of robot-assisted radical prostatectomy compared with open-surgery controls from the premier perspective database. *J Endourol.* 28(5): 560-566.

65. Pilecki, M. A., B. B. McGuire, U. Jain, J. Y. Kim and R. B. Nadler (2014). National multi-institutional comparison of 30-day postoperative complication and readmission rates between open retropubic radical prostatectomy and robot-assisted laparoscopic prostatectomy using NSQIP. *J Endourol.* 28(4): 430-436.

66. Ellimoottil, C., F. Roghmann, R. Blackwell, A. Kadlec, K. Greco, M. L. Quek, M. Sun, Q. D. Trinh and G. Gupta (2015). Open versus robotic radical prostatectomy in obese men. *Current Urology.* 8: 156-161.

67. Asimakopoulos, A. D. P. F., C. T.; Annino, F.; Pasqualetti, P.; Calado, A. A.; Mugnier, C. (2011). Randomized Comparison between Laparoscopic and Robot-Assisted Nerve-Sparing Radical Prostatectomy. *Journal of Sexual Medicine.* 8(5): 1503-1512.

68. Porpiglia, F., I. Morra, M. Lucci Chiarissi, M. Manfredi, F. Mele, S. Grande, F. Ragni, M. Poggio and C. Fiori (2013). Randomised controlled trial comparing laparoscopic and robot-assisted radical prostatectomy. *Eur Urol.* 63(4): 606-614.

69. Robertson, C., A. Close, C. Fraser, T. Gurung, X. Jia, P. Sharma, L. Vale, C. Ramsay and R. Pickard (2013). Relative effectiveness of robot-assisted and standard laparoscopic prostatectomy as alternatives to open radical prostatectomy for treatment of localised prostate cancer: a systematic review and mixed treatment comparison meta-analysis. *BJU International.* 112(6): 798-812.

70. Novara, G., J. W. F. Catto, T. Wilson, M. Annerstedt, K. Chan, D. G. Murphy, A. Motttrie, J. O. Peabody, E. C. Skinner, P. N. Wiklund, K. A. Guru and B. Yuh (2015). Systematic Review and Cumulative Analysis of Perioperative Outcomes and Complications After Robot-assisted Radical Cystectomy. *European Urology.* 67(3): 376-401.

71. Tewari, A., P. Sooriakumaran, D. A. Bloch, U. Seshadri-Kreaden, A. E. Hebert and P. Wiklund (2012). Positive Surgical Margin and Perioperative Complication Rates of Primary Surgical Treatments for Prostate Cancer: A Systematic Review and Meta-Analysis Comparing Retropubic, Laparoscopic, and Robotic Prostatectomy. *Eur Urol.* 62(1): 1-15.

72. De Carlo, F., F. Celestino, C. Verri, F. Masedu, E. Liberati and S. M. Di Stasi (2014). Retropubic, laparoscopic, and robot-assisted radical prostatectomy: surgical, oncological, and functional outcomes: a systematic review. *Urol Int.* 93(4): 373-383.

73. Moran, P. S., M. O'Neill, C. Teljeur, M. Flattery, L. A. Murphy, G. Smith and M. Ryan (2013). Robot-assisted radical prostatectomy compared with open and laparoscopic approaches: A systematic review and meta-analysis. *Int J Urol.* 20(3): 312-321.

74. Yu, H. Y., N. D. Hevelone, S. R. Lipsitz, K. J. Kowalczyk and J. C. Hu (2012). Use, Costs and Comparative Effectiveness of Robotic Assisted, Laparoscopic and Open Urological Surgery. *J Urol.* 187(4): 1392-1398.

75. Laird, A., S. Fowler, D. W. Good, G. D. Stewart, V. Srinivasan, D. Cahill, S. F. Brewster, S. A. McNeill and S. British Association of Urological (2015). Contemporary practice and technique-related outcomes for radical prostatectomy in the UK: a report of national outcomes. *BJU Int*. 115(5): 753-763.

76. Gandaglia, G., J. D. Sammon, S. L. Chang, T. K. Choueiri, J. C. Hu, P. I. Karakiewicz, A. S. Kibel, S. P. Kim, R. Konijeti, F. Montorsi, P. L. Nguyen, S. Sukumar, M. Menon, M. Sun and Q. D. Trinh (2014). Comparative effectiveness of robot-assisted and open radical prostatectomy in the postdissemination era. *J Clin Oncol*. 32(14): 1419-1426.

77. Hyams, E. S., J. K. Mullins, P. M. Pierorazio, A. W. Partin, M. E. Allaf and B. R. Matlaga (2013). Impact of robotic technique and surgical volume on the cost of radical prostatectomy. *Journal of Endourology*. 27(3): 298-303.

78. Kim, S. P., N. D. Shah, R. J. Karnes, C. J. Weight, N. D. Shippee, L. C. Han, S. A. Boorjian, M. C. Smaldone, I. Frank, M. T. Gettman, M. K. Tollefson and R. H. Thompson (2013). Hospitalization costs for radical prostatectomy attributable to robotic surgery. *Eur Urol.* 64 (1): 11-16.

79. Lundstrom, K. J., Y. Folkvaljon, S. Loeb, A. B. Axelson, P. Stattin and P. Nordin (2016). Small bowel obstruction and abdominal pain after robotic versus open radical prostatectomy. *Scandinavian Journal of Urology*. 50(3): 155-159.

80. Monn, M. F., K. R. Jaqua, A. C. Calaway, M. J. Mellon, M. O. Koch and R. S. Boris (2016). Impact of Obesity on Wound Complications Following Radical Prostatectomy Is Mitigated by Robotic Technique. *J Endourol.* 30(8): 890-895.

81. Pearce, S. M., J. J. Pariser, T. Karrison, S. G. Patel and S. E. Eggener (2016). Comparison of Perioperative and Early Oncologic Outcomes between Open and Robotic Assisted Laparoscopic Prostatectomy in a Contemporary Population Based Cohort. *J Urol.* 196(1): 76-81.

82. Seo, H. J., N. R. Lee, S. K. Son, D. K. Kim, K. H. Rha and S. H. Lee (2016). Comparison of Robot-Assisted Radical Prostatectomy and Open Radical Prostatectomy Outcomes: A Systematic Review and Meta-Analysis. *Yonsei Med J.* 57(5): 1165-1177.

83. Yaxley, J. W., G. D. Coughlin, S. K. Chambers, S. Occhipinti, H. Samaratunga, L. Zajdlewicz, N. Dunglison, R. Carter, S. Williams, D. J. Payton, J. Perry-Keene, M. F. Lavin and R. A. Gardiner (2016). Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study. *Lancet*.

84. Huang, X., L. Wang, X. Zheng and X. Wang (2016). Comparison of perioperative, functional, and oncologic outcomes between standard laparoscopic and robotic-assisted radical prostatectomy: a systemic review and meta-analysis. *Surg Endosc.*

85. Weiner, A. B., P. Murthy, K. A. Richards, S. G. Patel and S. E. Eggener (2015). Population based analysis of incidence and predictors of open conversion during minimally invasive radical prostatectomy. *J Urol.* 193(3): 826-831.

86. Anderson, J. E., D. C. Chang, J. K. Parsons and M. A. Talamini (2012). The first national examination of outcomes and trends in robotic surgery in the United States. *J Am Coll Surg.* 215(1): 107-114; discussion 114-106.

87. Basto, M., N. Sathianathen, L. Te Marvelde, S. Ryan, J. Goad, N. Lawrentschuk, A. J. Costello, D. A. Moon, A. G. Heriot, J. Butler and D. G. Murphy (2016). Patterns-of-care and health economic analysis of robot-assisted radical prostatectomy in the Australian public health system. *BJU Int.* 117(6): 930-939.

88. Stolzenburg, J. U., I. Kyriazis, C. Fahlenbrach, C. Gilfrich, C. Gunster, E. Jeschke, G. Popken, L. Weissbach, C. von Zastrow and H. Leicht (2016). National trends and differences in morbidity among surgical approaches for radical prostatectomy in Germany. *World J Urol*.

89. Sugihara, T., H. Yasunaga, H. Horiguchi, H. Matsui, T. Fujimura, H. Nishimatsu, H. Fukuhara, H. Kume, Y. Changhong, M. W. Kattan, K. Fushimi and Y. Homma (2014). Robot-assisted versus other types of radical prostatectomy: population-based safety and cost comparison in Japan, 2012-2013. *Cancer Sci.* 105(11): 1421-1426.

90. Wen, T., C. M. Deibert, F. S. Siringo and B. A. Spencer (2014). Positioning-related complications of minimally invasive radical prostatectomies. *Journal of Endourology.* 28(6): 660-667.

Nephrectomy (Partial)

91. Aboumarzouk, O. M., R. J. Stein, R. Eyraud, G. P. Haber, P. L. Chlosta, B. K. Somani and J. H. Kaouk (2012). Robotic versus laparoscopic partial nephrectomy: a systematic review and meta-analysis. *Eur Urol.* 62(6): 1023-1033.

92. Choi, J. E., J. H. You, D. K. Kim, K. H. Rha and S. H. Lee (2015). Comparison of perioperative outcomes between robotic and laparoscopic partial nephrectomy: a systematic review and meta-analysis. *Eur Urol.* 67(5): 891-901.

93. Froghi, S., K. Ahmed, M. S. Khan, P. Dasgupta and B. Challacombe (2013). Evaluation of robotic and laparoscopic partial nephrectomy for small renal tumours (T1a). *BJU International*. 112(4): E322-333.

94. Mir, S. A., J. A. Cadeddu, J. P. Sleeper and Y. Lotan (2011). Cost comparison of robotic, laparoscopic, and open partial nephrectomy. *J Endourol.* 25(3): 447-453.

95. Zhang, X., Z. Shen, S. Zhong, Z. Zhu, X. Wang and T. Xu (2013). Comparison of peri-operative outcomes of robot-assisted vs laparoscopic partial nephrectomy: a meta-analysis. *BJU Int.* 112 (8): 1133-1142.

96. Zhang, X., J. Yan, Y. Ren, C. Shen, X. Ying and S. Pan (2014). Robot-assisted versus laparoscopic partial nephrectomy for localized renal tumors: a meta-analysis. *Int J Clin Exp Med.* 7(12): 4770-4779.

97. Wu, Z., M. Li, B. Liu, C. Cai, H. Ye, C. Lv, Q. Yang, J. Sheng, S. Song, L. Qu, L. Xiao, Y. Sun and L. Wang (2014). Robotic versus Open Partial Nephrectomy: A Systematic Review and Meta-Analysis. *PLoS One*. 9(4): e94878.

98. Ghani, K. R., S. Sukumar, J. D. Sammon, C. G. Rogers, Q. D. Trinh and M. Menon (2014). Practice patterns and outcomes of open and minimally invasive partial nephrectomy since the introduction of robotic partial nephrectomy: results from the nationwide inpatient sample. *J Urol.* 191(4): 907-912.

99. Kates, M., M. W. Ball, H. D. Patel, M. A. Gorin, P. M. Pierorazio and M. E. Allaf (2015). The financial impact of robotic technology for partial and radical nephrectomy. *J Endourol.* 29(3): 317-322.

100. Hadjipavlou, M., F. Khan, S. Fowler, A. Joyce, F. X. Keeley and S. Sriprasad (2016). Partial vs radical nephrectomy for T1 renal tumours: an analysis from the British Association of Urological Surgeons Nephrectomy Audit. *BJU Int.* 117(1): 62-71.

101. Leow, J. J., N. H. Heah, S. L. Chang, Y. L. Chong and K. S. Png (2016). Outcomes of Robotic versus Laparoscopic Partial Nephrectomy: an Updated Meta-Analysis of 4,919 Patients. *J Urol.*

102. Xia, L., X. Wang, T. Xu and T. J. Guzzo (2016). Systematic Review and Meta-Analysis of Comparative Studies Reporting Perioperative Outcomes of Robot-Assisted Partial Nephrectomy versus Open Partial Nephrectomy. *J Endourol.*

Nephrectomy (Radical)

103. Yu, H. Y., N. D. Hevelone, S. R. Lipsitz, K. J. Kowalczyk and J. C. Hu (2012). Use, Costs and Comparative Effectiveness of Robotic Assisted, Laparoscopic and Open Urological Surgery. **J Urol.** 187(4): 1392-1398.

104. Yang, D. Y., M. F. Monn, C. D. Bahler and C. P. Sundaram (2014). Does robotic assistance confer an economic benefit during laparoscopic radical nephrectomy? *J Urol.* 192(3): 671-676.

105. Kates, M., M. W. Ball, H. D. Patel, M. A. Gorin, P. M. Pierorazio and M. E. Allaf (2015). The financial impact of robotic technology for partial and radical nephrectomy. *J Endourol.* 29(3): 317-322.

106. Boger, M., et al. (2010). Comparison of robot-assisted nephrectomy with laparoscopic and hand-assisted laparoscopic nephrectomy. *Journal of the Society of Laparoendoscopic Surgeons*. 14(3): 374-380.

107. Weinberg, A. C., M. J. Whalen, D. J. Paulucci, S. Woldu, C. M. Deibert, R. Korets and K. K. Badani (2016). Utilization of the Robotic Surgical Platform for Radical Nephrectomy: A National Comparison of Trends for Open, Laparoscopic and Robotic Approaches. *Urology Practice.* 3(3): 187-194.

108. Park, J. W., K. H. Choi, S. C. Yang and W. K. Han (2012). Cost aspects of radical nephrectomy for the treatment of renal cell carcinoma in Korea: Open, laparoscopic, robot-assisted laparoscopic, and video-assisted minilaparotomy surgeries. *Korean Journal of Urology.* 53(8): 519-523.

Cystectomy (Radical)

109. Ishii, H., B. P. Rai, J. U. Stolzenburg, P. Bose, P. L. Chlosta, B. K. Somani, G. Nabi, H. A. Qazi, K. Rajbabu, H. Kynaston and O. M. Aboumarzouk (2014). Robotic or Open radical cystectomy, which is safer? A systematic review and Meta-analysis of comparative studies. *J Endourol.* 28 (10): 1215-1223.

110. Li, K., T. Lin, X. Fan, K. Xu, L. Bi, Y. Duan, Y. Zhou, M. Yu, J. Li and J. Huang (2013). Systematic review and meta-analysis of comparative studies reporting early outcomes after robot-assisted radical cystectomy versus open radical cystectomy. *Cancer Treat.* Rev 39(6): 551-560.

111. Novara, G., V. Ficarra, R. C. Rosen, W. Artibani, A. Costello, J. A. Eastham, M. Graefen, G. Guazzoni, S. F. Shariat, J. U. Stolzenburg, H. Van Poppel, F. Zattoni, F. Montorsi, A. Mottrie and T. G. Wilson (2012). Systematic review and meta-analysis of perioperative outcomes and complications after robot-assisted radical prostatectomy. *Eur Urol.* 62(3): 431-452.

112. Tang, K., et al. (2014). Robotic vs. open radical cystectomy in bladder cancer: A systematic review and meta-analysis. *Eur J Surg Oncol.* 40(11): 1399-1411.

113. Xia, L., X. Wang, T. Xu, X. Zhang, Z. Zhu, L. Qin, X. Zhang, C. Fang, M. Zhang, S. Zhong and Z. Shen (2015). Robotic versus Open Radical Cystectomy: An Updated Systematic Review and Meta-Analysis. *PLoS One*. 10(3): e0121032.

114. Bochner, B. H., et al. (2015). Comparing Open Radical Cystectomy and Robot-assisted Laparoscopic Radical Cystectomy: A Randomized Clinical Trial. *Eur Urol.* 67(6): 1042-1050.

115. Messer, J. C., S. Punnen, J. Fitzgerald, R. Svatek and D. J. Parekh (2014). Health Related Quality of Life From A Prospective Randomized Clinical Trial of Robotic Assisted Laparoscopic Versus Open Radical Cystectomy. *BJU Int*. 114(6): 896-902.

116. Fonseka, T., K. Ahmed, S. Froghi, S. A. Khan, P. Dasgupta and M. Shamim Khan (2015). Comparing robotic, laparoscopic and open cystectomy: a systematic review and meta-analysis. *Arch Ital Urol Androl*. 87(1): 41-48.

117. Khan, M. S., et al. (2016). A Single-centre Early Phase Randomised Controlled Three-arm Trial of Open, Robotic, and Laparoscopic Radical Cystectomy (CORAL). *Eur Urol.* 69(4): 613-621.

118. Bagi, P., C. B. Nordsten and H. Kehlet (2016). Cystectomy for bladder cancer in Denmark during the 2006-2013 period. *Dan Med J.* 63(4).

119. Hu, J. C., et al. (2016). Perioperative Outcomes, Health Care Costs, and Survival After Robotic-assisted Versus Open Radical Cystectomy: A National Comparative Effectiveness Study. *Eur Urol.* 70(1): 195-202.

120. Leow, J. J., et al. (2014). Propensity-matched comparison of morbidity and costs of open and robot-assisted radical cystectomies: a contemporary population-based analysis in the United States. *Eur Urol.* 66(3): 569-576.

121. Matulewicz, R. S., J. O. L. Delancey, A. Manjunath, J. Tse, S. D. Kundu and J. J. Meeks (2016). National comparison of oncologic quality indicators between open and robotic-assisted radical cystectomy. Urologic Oncology: *Seminars and Original Investigations*.

122. Monn, M. F., K. C. Cary, H. Z. Kaimakliotis, C. K. Flack and M. O. Koch (2014). National trends in the utilization of robotic-assisted radical cystectomy: An analysis using the Nationwide Inpatient Sample. *Urol Oncol.*

Low Anterior Resection/Total Mesorectal Excision (LAR/TME) and Intersphincteric Resection (ISR)

123. Midura, E. F., et al. (2015). "The effect of surgical approach on short-term oncologic outcomes in rectal cancer surgery." *Surgery* **158**(2): 453-459.

124. Liao, G., et al. (2016). "Robotic-assisted surgery versus open surgery in the treatment of rectal cancer: the current evidence." *Sci Rep* **6**: 26981.

125. Somashekhar, S. P., et al. (2015). "Prospective Randomized Study Comparing Robotic-Assisted Surgery with Traditional Laparotomy for Rectal Cancer-Indian Study." *Indian J Surg* **77**(Suppl 3): 788-794.

126. Lee, S. H., et al. (2015). "Robotic versus conventional laparoscopic surgery for rectal cancer: systematic review and meta-analysis." *Ann Surg Treat Res* **89**(4): 190-201.

127. Lin, S., et al. (2011). "Meta-analysis of robotic and laparoscopic surgery for treatment of rectal cancer." *World Journal of Gastroenterology* **17**(47): 5214-5220.

128. Memon, S., et al. (2012). "Robotic versus laparoscopic proctectomy for rectal cancer: a meta-analysis." *Ann Surg Oncol* **19**(7): 2095-2101.

129. Sun, Y., et al. (2016). "Robotic versus laparoscopic low anterior resection for rectal cancer: a meta-analysis." *World J Surg Oncol* 14(1): 61.

130. Sun, Z., et al. (2016). "Minimally Invasive Versus Open Low Anterior Resection: Equivalent Survival in a National Analysis of 14,033 Patients With Rectal Cancer." Ann Surg. 263(6):1152-8.

131. Trastulli, S., et al. (2012). "Robotic resection compared with laparoscopic rectal resection for cancer: Systematic review and meta-analysis of short-term outcome." *Colorectal Disease* **14** (4): e134-e156.

132. Xiong, B., et al. (2014). "Robotic versus laparoscopic total mesorectal excision for rectal cancer: a meta-analysis." *J Surg Res* **188**(2): 404-414.

133. Yang, Y., et al. (2012). "Robot-assisted versus conventional laparoscopic surgery for colorectal disease, focusing on rectal cancer: a meta-analysis." *Ann Surg Oncol* **19**(12): 3727-3736.

134. Park, SY, et al., "Short-term clinical outcome of robot-assisted intersphincteric resection for low rectal cancer: a retrospective comparison with conventional laparoscopy" Surg Endosc DOI 10.1007/s00464-012-2405-2. Presented and honored with a Gerald Marks Rectal Cancer Award at the SAGES 2012 Annual Meeting, San Diego, CA, March 7–10, 2012.

135. Kim, J. C. *et al.* Completely abdominal intersphincteric resection for lower rectal cancer: feasibility and comparison of robot-assisted and open surgery. *Surg Endosc* 28, 2734–2744 (2014).

Pancreatectomy

136. Adam, M. A., et al. (2015). "Minimally Invasive Distal Pancreatectomy for Cancer: Short-Term Oncologic Outcomes in 1,733 Patients." World J Surg 39(10): 2564-2572.

137. Chen, S., et al. (2017). "Robot-assisted laparoscopic versus open middle pancreatectomy: short-term results of a randomized controlled trial." Surg Endosc 31(2): 962-971.

138. Chen, Y., et al. (2013). "A meta-analysis of robotic-assisted pancreatectomy versus laparoscopic and open pancreatectomy." Saudi Med J 34(12): 1229-1236.

139. Gavrilidis, P., et al. (2016). "Robotic versus laparoscopic distal pancreatectomy - The first meta-analysis." HPB 18(7): 567-574.

140. Huang, B., et al. (2016). "Systematic review and meta-analysis of robotic versus laparoscopic distal pancreatectomy for benign and malignant pancreatic lesions." Surg Endosc 30(9): 4078-4085.

141. Konstantinidis, I. T., et al. (2017). "Minimally invasive distal pancreatectomy: greatest benefit for the frail." Surg Endosc.

142. Wright, G. P. and A. H. Zureikat (2016). "Development of Minimally Invasive Pancreatic Surgery: an Evidence-Based Systematic Review of Laparoscopic Versus Robotic Approaches." J Gastrointest Surg 20(9): 1658-1665.

143. Xourafas, D., et al. (2017). "Comparison of Perioperative Outcomes between Open, Laparoscopic, and Robotic Distal Pancreatectomy: an Analysis of 1815 Patients from the ACS-NSQIP Procedure-Targeted Pancreatectomy Database." J Gastrointest Surg.

144. Zhang, J., et al. (2013). "Robotic versus open pancreatectomy: a systematic review and meta-analysis." Ann Surg Oncol 20(6): 1774-1780.

145. Zhou, J. Y., et al. (2016). "Robotic versus Laparoscopic Distal Pancreatectomy: A Meta-Analysis of Short-Term Outcomes." PLoS One 11(3): e0151189.

146. Zureikat, A. H., et al. (2017). "Minimally invasive hepatopancreatobiliary surgery in North America: an ACS-NSQIP analysis of predictors of conversion for laparoscopic and robotic pancreatectomy and hepatectomy." HPB (Oxford).

147. De Rooij, T., et al. (2016). "Minimally Invasive Versus Open Pancreatoduodenectomy: Systematic Review and Meta-analysis of Comparative Cohort and Registry Studies." Annals of Surgery 264(2): 257-267.

148. Lei, P., et al. (2014). "Minimally invasive surgical approach compared with open pancreaticoduodenectomy: a systematic review and meta-analysis on the feasibility and safety." Surg Laparosc Endosc Percutan Tech 24(4): 296-305.

149. Orti-Rodríguez, R. J. (2012). "Is Robotic pancreatic surgery expected access by the minimal access pancreatic surgeons?" World Journal of Laparoscopic Surgery 5(1): 49-53.

150. Pedziwiatr, M., et al. (2017). "Minimally invasive versus open pancreatoduodenectomy-systematic review and meta-analysis." Langenbecks Arch Surg.

151. Peng, L., et al. (2016). "Systematic review and meta-analysis of robotic versus open pancreaticoduodenectomy." Surg Endosc.

152. Shin, S. H., et al. (2016). "Totally laparoscopic or robot-assisted pancreaticoduodenectomy versus open surgery for periampullary neoplasms: separate systematic reviews and meta-analyses." Surg Endosc.

Bariatric

153. Ahmad, A., et al. (2016). "Laparoscopic versus robotic-assisted Roux-en-Y gastric bypass: a retrospective, single-center study of early perioperative outcomes at a community hospital." Surg Endosc 30(9): 3792-3796.

154. Ayloo, S., et al. (2016). "Laparoscopic, hybrid, and totally robotic Roux-en-Y gastric bypass." J Robot Surg 10(1): 41-47.

155. Benizri, E. I., et al. (2013). "Perioperative outcomes after totally robotic gastric bypass: a prospective nonrandomized controlled study." Am J Surg 206(2): 145-151.

156. Myers, S. R., et al. (2013). "Robot-assisted versus laparoscopic gastric bypass: comparison of short-term outcomes." Obes Surg 23(4): 467-473.

157. Smeenk, R. M., et al. (2016). "The Results of 100 Robotic Versus 100 Laparoscopic Gastric Bypass Procedures: a Single High Volume Centre Experience." Obes Surg 26(6): 1266-1273.

158. Stefanidis, D., et al. (2017). "Robotic gastric bypass may lead to fewer complications compared with laparoscopy." Surg Endosc.

159. Wood, M. H., et al. (2013). "A comparison of outcomes between the traditional laparoscopic and totally robotic Roux-en-Y gastric bypass procedures." Journal of Robotic Surgery 8(1): 29-34.

160. Buchs, N. C., et al. (2016). "Roux-en-Y gastric bypass for super obese patients: what approach?" Int J Med Robot 12(2): 276-282.

161. Buchs, N. C., et al. (2014). "Laparoscopic versus robotic Roux-en-Y gastric bypass: lessons and long-term follow-up learned from a large prospective monocentric study." Obes Surg 24(12): 2031-2039.

162. Hagen, M. E., et al. (2012). "Reducing cost of surgery by avoiding complications: the model of robotic Roux-en-Y gastric bypass." Obes Surg 22(1): 52-61.

Ventral Hernia

163. Azoury, S.C., et al., "Endoscopic component separation for laparoscopic and open ventral hernia repair: a single institutional comparison of outcomes and review of the technique." Hernia, 2014. 18(5): p. 637-45.

164. Belyansky, I., H.R. Zahiri, and A. Park, "Laparoscopic Transversus Abdominis Release, a Novel Minimally Invasive Approach to Complex Abdominal Wall Reconstruction." Surgical Innovation, 2016. 23(2): p. 134-141.

165. Belyansk, I., et al., "The trend toward minimally invasive complex abdominal wall reconstruction: is it worth it?" Surgical Endoscopy and Other Interventional Techniques, 2018. 32(4): p. 1701-1707.

166. Daes, J., "Endoscopic subcutaneous approach to component separation." J Am Coll Surg, 2014. 218(1): p. e1-4.

167. Giurgius, M., et al., "The endoscopic component separation technique for hernia repair results in reduced morbidity compared to the open component separation technique." Hernia, 2012. 16(1): p. 47-51.

168. Moazzez, A., et al., "Totally laparoscopic abdominal wall reconstruction: Lessons learned and results of a short-term follow-up." Hernia, 2013. 17(5): p. 633-638.

169. Muse, T.O., et al., "Outcomes after Ventral Hernia Repair Using the Rives-Stoppa, Endoscopic, and Open Component Separation Techniques." Am Surg, 2018. 84(3): p. 433-437.

170. Parker, M., et al., "Preliminary experience and development of an algorithm for the optimal use of the laparoscopic component separation technique for myofascial advancement during ventral incisional hernia repair." Journal of Laparoendoscopic and Advanced Surgical Techniques, 2011. 21(5): p. 405-410.

171. Schroeder, A.D., et al., "Laparoscopic transperitoneal sublay mesh repair: A new technique for the cure of ventral and incisional hernias." Surgical Endoscopy and Other Interventional Techniques, 2013. 27(2): p. 648-654.

Gastrectomy

172. Pan, H. F., et al. (2017). "Robotic Versus Laparoscopic Gastrectomy for Locally Advanced Gastric Cancer." Surg Laparosc Endosc Percutan Tech 27(6): 428-433.

173. Wang, G., et al. (2016). "Assessing the safety and efficacy of full robotic gastrectomy with intracorporeal robot-sewn anastomosis for gastric cancer: A randomized clinical trial." J Surg Oncol 113(4): 397-404.

174. Eom, B. W., et al. (2016). "Korean gastric cancer association nationwide survey on gastric cancer in 2014." Journal of Gastric Cancer 16(3): 131-140.

175. Glenn, J. A., et al. (2015). "Minimally invasive gastrectomy for cancer: current utilization in US academic medical centers."Surg Endosc 29(12): 3768-3775.

176. Greenleaf, E. K., et al. (2017). "Minimally invasive surgery for gastric cancer: the American experience." Gastric Cancer 20(2):368-378.

177. Parisi, A., et al. (2017). "Minimally invasive surgery for gastric cancer: A comparison between robotic, laparoscopic and open surgery." World J Gastroenterol 23(13): 2376-2384.

178. Caruso, S., et al. (2017). "Robot-assisted laparoscopic vs open gastrectomy for gastric cancer: Systematic review and meta-analysis." World J Clin Oncol 8(3): 273-284.

179. Chen, K., et al. (2017). “Robotic versus laparoscopic Gastrectomy for gastric cancer: a systematic review and updated meta-analysis.“ BMC Surg 17(1): 93.

180. Chuan, L., et al. (2015). “Meta-analysis of the short-term outcomes of robotic-assisted compared to laparoscopic gastrectomy.“ Minim Invasive Ther Allied Technol 24(3): 127-134.

181. Duan, B. S., et al. (2017). “Robotic Verse Laparoscopic Gastrectomy for Gastric Cancer: A Pooled Analysis of 11 Individual Studies.“ Surg Laparosc Endosc Percutan Tech 27(3): 147-153.

182. Hu, L. D., et al. (2016). “Robotic versus Laparoscopic Gastrectomy for Gastric Carcinoma: a Meta-Analysis of Efficacy and Safety.“ Asian Pac J Cancer Prev 17(9): 4327-4333.

183. Kostakis, I. D., et al. (2017). “Comparison Between Minimally Invasive and Open Gastrectomy for Gastric Cancer in Europe: A Systematic Review and Meta-analysis.“ Scand J Surg 106(1): 3-20.

184. Wang, Y., et al. (2017). “A systematic review and meta-analysis of robot-assisted versus laparoscopically assisted gastrectomy for gastric cancer.“ Medicine (Baltimore) 96(48): e8797.

185. Yang, Y., et al. (2017). “Robotic gastrectomy versus open gastrectomy in the treatment of gastric cancer.“ J Cancer Res Clin Oncol 143(1): 105-114.

186. Zong, L., et al. (2014). “Efficacy evaluation of subtotal and total gastrectomies in robotic surgery for gastric cancer compared with that in open and laparoscopic resections: a meta-analysis.“ PLoS One 9(7): e103312.

187. Guerra, F., et al. (2018). “Pancreatic Complications After Conventional Laparoscopic Radical Gastrectomy Versus Robotic Radical Gastrectomy: Systematic Review and Meta-Analysis.“ J Laparoendosc Adv Surg Tech A.

Esophagectomy

188. Weksler, B. and J. L. Sullivan (2017). "Survival After Esophagectomy: A Propensity-Matched Study of Different Surgical Approaches." Ann Thorac Surg.

189. Yerokun, B. A., et al. (2016). "Minimally Invasive Versus Open Esophagectomy for Esophageal Cancer: A Population-Based Analysis." Ann Thorac Surg 102(2): 416-423.

190. Diez del Val, I., et al. (2015). "The IDEAL prospective development study format for reporting surgical innovations. An illustrative case study of robotic oesophagectomy." Int J Surg 19: 111014.

191. Suda, K., et al. (2012). "Robot-assisted thoracoscopic lymphadenectomy along the left recurrent laryngeal nerve for esophageal squamous cell carcinoma in the prone position: technical report and short-term outcomes." World Journal of Surgery 36(7): 1608-1616.

192. Chao, Y. K., et al. (2019). "Transition from video-assisted thoracoscopic to robotic esophagectomy: a single surgeon's experience." Diseases of the esophagus : official journal of the International Society for Diseases of the Esophagus.

193. Park, S., et al. (2016). "Comparison of robot-assisted esophagectomy and thoracoscopic esophagectomy in esophageal squamous cell carcinoma." Journal of Thoracic Disease 8(10): 2853-2861.

194. Weksler, B., et al. (2012). "Robot-assisted minimally invasive esophagectomy is equivalent to thoracoscopic minimally invasive esophagectomy." Dis Esophagus 25(5): 403-409.

195. Deng, H. Y., et al. (2018). "Does robot-assisted minimally invasive esophagectomy really have the advantage of lymphadenectomy over video-assisted minimally invasive esophagectomy in treating esophageal squamous cell carcinoma? A propensity score-matched analysis based on short-term outcomes." Dis Esophagus.

196. He, H., et al. (2018). "Short-term outcomes of robot-assisted minimally invasive esophagectomy for esophageal cancer: A propensity score matched analysis." Journal of Cardiothoracic Surgery 13(1): 52.

197. Motoyama, S., et al. (2019). "Extensive lymph node dissection around the left laryngeal nerve achieved with robot-assisted thoracoscopic esophagectomy." Anticancer Research 39(3): 1337-1342.

198. Zhang, Y., et al. (2019). "Early Outcomes of Robot-Assisted Versus Thoracoscopic-Assisted Ivor Lewis Esophagectomy for Esophageal Cancer: A Propensity Score-Matched Study." Annals of Surgical Oncology.

199. Tagkalos, E., et al. (2019). "Robot-assisted minimally invasive esophagectomy (RAMIE) compared to conventional minimally invasive esophagectomy (MIE) for esophageal cancer: a propensity-matched analysis." Diseases of the esophagus : official journal of the International Society for Diseases of the Esophagus.

200. Harbison, G. J., et al. (2019). "Outcomes of robotic versus non-robotic minimally-invasive esophagectomy for esophageal cancer: An American College of Surgeons NSQIP database analysis." Am J Surg.

201. Meredith, K., et al. (2019). "Comparative outcomes of minimally invasive and robotic-assisted esophagectomy." Surgical Endoscopy.

202. Washington, K., et al. (2019). "Oncologic Resection in Laparoscopic Versus Robotic Transhiatal Esophagectomy." Jsls 23(2).

203. Chen, J. et al (2019). “Comparisons of short-term outcomes between robot-assisted and thoraco-laparoscopic esophagectomy with extended two-field lymph node dissection for resectable thoracic esophageal squamous cell carcinoma”. Journal of Thoracic Disease, Vol 11, No 9.

204. Yang, Y, et al (2019). “Short- and mid-term outcomes of robotic versus thoraco-laparoscopic McKeown esophagectomy for squamous cell esophageal cancer: a propensity score-matched study.” Diseases of the esophagus : official journal of the International Society for Diseases of the Esophagus.

Esophagectomy “Learning Curve Publications”

205. Grimminger, P. P., E. Tagkalos, E. Hadzijusufovic, F. Corvinus, B. Babic and H. Lang (2019). "Change from Hybrid to Fully Minimally Invasive and Robotic Esophagectomy is Possible without Compromises." Thorac Cardiovasc Surg 67(7): 589-596.

206. Chao, Y. K., Y. W. Wen, W. Y. Chuang and R. J. Cerfolio (2019). "Transition from video-assisted thoracoscopic to robotic esophagectomy: a single surgeon's experience." Dis Esophagus.*

207. Osaka, Y., S. Tachibana, Y. Ota, T. Suda, Y. Makuuti, T. Watanabe, K. Iwasaki, K. Katsumata and A. Tsuchida (2018). "Usefulness of robot-assisted thoracoscopic esophagectomy." Gen Thorac Cardiovasc Surg 66(4): 225-231.

208. Dunn, D. H., E. M. Johnson, J. A. Morphew, H. P. Dilworth, J. L. Krueger and N. Banerji (2013). "Robot-assisted transhiatal esophagectomy: a 3-year single-center experience." Diseases of the Esophagus 26(2): 159-166.

209. Fuchs, H. F., D. T. Müller, J. M. Leers, W. Schröder and C. J. Bruns (2019). "Modular step-up approach to robot-assisted transthoracic esophagectomy-experience of a German high volume center." Translational Gastroenterology and Hepatology 4(August).

210. Goel, A., S. H. Shah, V. P. P. Selvakumar, S. Garg and K. Kumar (2018). "Robot-Assisted Mckeown Esophagectomy is Feasible After Neoadjuvant Chemoradiation. Our Initial Experience." Indian J Surg 80(1): 1-6.

211. Guerra, F., A. Vegni, E. Gia, S. Amore Bonapasta, M. Di Marino, M. Annecchiarico and A. Coratti (2018). "Early experience with totally robotic esophagectomy for malignancy. Surgical and oncological outcomes." Int J Med Robot 14(3): e1902.

212. Harrison, L. E., A. Yiengpruksawan, J. Patel, A. Itskovich, B. Lee and R. Korst (2015). "Robotic gastrectomy and esophagogastrectomy: A single center experience of 105 cases." J Surg Oncol 112(8): 888-893.

213. Kim, D. J., W. J. Hyung, C. Y. Lee, J. G. Lee, S. J. Haam, I. K. Park and K. Y. Chung (2010). "Thoracoscopic esophagectomy for esophageal cancer: Feasibility and safety of robotic assistance in the prone position." Journal of Thoracic and Cardiovascular Surgery 139(1): 53-59.e.51.

214. Meredith, K., J. Huston, O. Andacoglu and R. Shridhar (2018). "Safety and feasibility of robotic-assisted Ivor-Lewis esophagectomy." Dis Esophagus 31(7).

215. Park, S., K. Hyun, H. J. Lee, I. K. Park, Y. T. Kim and C. H. Kang (2018). "A study of the learning curve for robotic oesophagectomy for oesophageal cancer." Eur J Cardiothorac Surg 53(4): 862-870.

216. Park, S. Y., D. J. Kim, D. R. Kang and S. J. Haam (2017). "Learning curve for robotic esophagectomy and dissection of bilateral recurrent laryngeal nerve nodes for esophageal cancer." Dis Esophagus 30(12): 1-9.

217. Sarkaria, I. S., N. P. Rizk, R. Grosser, D. Goldman, D. J. Finley, A. Ghanie, C. S. Sima, M. S. Bains, P. S. Adusumilli, V. W. Rusch and D. R. Jones (2016). "Attaining Proficiency in Robotic-Assisted Minimally Invasive Esophagectomy While Maximizing Safety During Procedure Development." Innovations (Phila) 11(4): 268-273.

218. Somashekhar, S. P. and R. C. Jaka (2017). "Total (Transthoracic and Transabdominal) Robotic Radical Three-Stage Esophagectomy-Initial Indian Experience." Indian J Surg 79(5): 412-417.

219. van der Sluis, P. C., J. P. Ruurda, S. van der Horst, L. Goense and R. van Hillegersberg (2018). "The Learning Curve for Robot-Assisted Minimally Invasive Thoracoscopic Esophagectomy: Results from 312 Cases." Ann Thorac Surg 106(1): 264-271.

220. Zhang, H., L. Chen, Z. Wang, Y. Zheng, Y. Geng, F. Wang, D. Liu, A. He, L. Ma, Y. Yuan and Y. Wang (2018). "The Learning Curve for Robotic McKeown Esophagectomy in Patients With Esophageal Cancer." Ann Thorac Surg 105(4): 1024-1030.

221. Zhang, X., Y. Su, Y. Yang, Y. Sun, B. Ye, X. Guo, T. Mao, R. Hua and Z. Li (2018). "Robot assisted esophagectomy for esophageal squamous cell carcinoma." Journal of Thoracic Disease 10(6): 3767-3775.

Heller Myotomy

222. Ali, A. B., N. A. Khan, D. T. Nguyen, R. Chihara, E. Y. Chan, E. A. Graviss, B. J. Dunkin and M. P. Kim (2020). "Robotic and per-oral endoscopic myotomy have fewer technical complications compared to laparoscopic Heller myotomy." Surg Endosc 34(7): 3191-3196.

223. Gehrig, T., A. Mehrabi, L. Fischer, H. Kenngott, U. Hinz, C. N. Gutt and B. P. Muller-Stich (2013). "Robotic-assisted paraesophageal hernia repair–a case-control study." Langenbecks Arch Surg 398(5): 691-696.

224. Gerull, W. D., D. Cho, S. Arefanian, B. S. Kushner and M. M. Awad (2020). "Favorable peri-operative outcomes observed in paraesophageal hernia repair with robotic approach." Surg Endosc.

225. Hosein, S., T. Carlson, L. Flores, P. R. Armijo and D. Oleynikov (2020). "Minimally invasive approach to hiatal hernia repair is superior to open, even in the emergent setting: a large national database analysis." Surg Endosc.

226. Howell, R. S., H. H. Liu, P. Petrone, M. F. Anduaga, M. J. Servide, K. Hall, A. Barkan, S. Islam and C. E. M. Brathwaite (2020). "Short-Term Outcomes in Patients Undergoing Paraesophageal Hiatal Hernia Repair." Sci Rep 10(1): 7366.

227. Kim, S. S., J. Guillen-Rodriguez and A. G. Little (2019). "Optimal surgical intervention for achalasia: laparoscopic or robotic approach." J Robot Surg 13(3): 397-400.

228. Maeso, S., M. Reza, J. A. Mayol, J. A. Blasco, M. Guerra, E. Andradas and M. N. Plana (2010). "Efficacy of the Da Vinci surgical system in abdominal surgery compared with that of laparoscopy: a systematic review and meta-analysis." Ann Surg 252(2): 254-262.

229. Milone, M., M. Manigrasso, S. Vertaldi, N. Velotti, G. Aprea, F. Maione, N. Gennarelli, G. De Simone, B. De Conno, M. Pesce, G. Sarnelli and G. D. De Palma (2019). "Robotic versus laparoscopic approach to treat symptomatic achalasia: systematic review with meta-analysis." Dis Esophagus 32(10): 1-8.

230. O'Connor, S. C., M. Mallard, S. S. Desai, F. Couto, M. Gottlieb, A. Ewing, W. S. Cobb, A. M. Carbonell and J. A. Warren (2020). "Robotic Versus Laparoscopic Approach to Hiatal Hernia Repair: Results After 7 Years of Robotic Experience." Am Surg: 3134820943547.

231. Perry, K. A., A. Kanji, J. M. Drosdeck, J. G. Linn, A. Chan, P. Muscarella and W. S. Melvin (2014). "Efficacy and durability of robotic Heller myotomy for achalasia: patient symptoms and satisfaction at long-term follow-up." Surg Endosc 28(11): 3162-3167.

232. Sanchez, A., O. Rodriguez, E. Nakhal, H. Davila, R. Valero, R. Sanchez, R. Pena and M. F. Visconti (2012). "Robotic-assisted Heller myotomy versus laparoscopic Heller myotomy for the treatment of esophageal achalasia: a case-control study." J Robot Surg 6(3): 213-216.

233. Shaligram, A., J. Unnirevi, A. Simorov, V. M. Kothari and D. Oleynikov (2012). "How does the robot affect outcomes? A retrospective review of open, laparoscopic, and robotic Heller myotomy for achalasia." Surg Endosc 26(4): 1047-1050.

234. Soliman, B. G., D. T. Nguyen, E. Y. Chan, R. K. Chihara, L. M. Meisenbach, E. A. Graviss and M. P. Kim (2020). "Robot-assisted hiatal hernia repair demonstrates favorable short-term outcomes compared to laparoscopic hiatal hernia repair." Surg Endosc 34(6): 2495-2502.

235. Tolboom, R. C., W. A. Draaisma and I. A. Broeders (2016). "Evaluation of conventional laparoscopic versus robot-assisted laparoscopic redo hiatal hernia and antireflux surgery: a cohort study." J Robot Surg 10(1): 33-39.

236. Villamere, J., A. Gebhart, S. Vu and N. T. Nguyen (2015). "Utilization and outcome of laparoscopic versus robotic general and bariatric surgical procedures at Academic Medical Centers." Surg Endosc 29(7): 1729-1736.

Hepatectomy

Publications Providing Clinical Outcomes Data (N=38)

237. Efanov, M., et al. (2017). "Comparative analysis of learning curve in complex robot-assisted and laparoscopic liver resection." HPB.

238. Lim, C., et al. (2019). "Short- and Long-term Outcomes after Robotic and Laparoscopic Liver Resection for Malignancies: A Propensity Score-Matched Study." World Journal of Surgery.

239. Spampinato, M. G., et al. (2014). "Perioperative outcomes of laparoscopic and robot-assisted major hepatectomies: an Italian multi-institutional comparative study." Surgical Endoscopy.

240. Berber, E. A., H. Y.; Aucejo, F.; Gunasekaran, G.; Chalikonda, S.; Fung, J. (2010). "Robotic versus laparoscopic resection of liver tumours." HPB (Oxford) **12**(8): 583-586.

241. Chong, C. C. N., et al. (2019). "Robotic versus laparoscopic hepatectomy: application of the difficulty scoring system." Surgical Endoscopy.

242. Croner, R. S., et al. (2016). "Robotic liver surgery for minor hepatic resections: a comparison with laparoscopic and open standard procedures." Langenbeck's Archives of Surgery.

243. Fruscione, M., et al. (2019). "Robotic-assisted versus laparoscopic major liver resection: analysis of outcomes from a single center." HPB.

244. Hu, M., et al. (2019). "Robotic versus laparoscopic liver resection in complex cases of left lateral sectionectomy." International Journal of Surgery **67**: 54-60.

245. Lai, E. C. and C. N. Tang (2016). "Long-term Survival Analysis of Robotic Versus Conventional Laparoscopic Hepatectomy for Hepatocellular Carcinoma: A Comparative Study." Surgical Laparoscopy, Endoscopy and Percutaneous Techniques **26**(2): 162-166.

246. Lee, K. F., et al. (2015). "Laparoscopic and robotic hepatectomy: experience from a single centre." ANZ Journal of Surgery.

247. Lee, S. J., et al. (2019). "The feasibility of robotic left-side hepatectomy with comparison of laparoscopic and open approach: Consecutive series of single surgeon." International of Medical Robots and Computer Assisted Surgery: e1982.

248. Marino, M. V., et al. (2018). "Comparative Study of the Initial Experience in Performing Robotic and Laparoscopic Right Hepatectomy with Technical Description of the Robotic Technique." Digestive Surgery.

249. Mejia, A., et al. (2019). "Minimally invasive liver resection in the era of robotics: analysis of 214 cases." Surgical Endoscopy.

250. Montalti, R., et al. (2015). "Robotic versus laparoscopic resections of posterosuperior segments of the liver: a propensity score-matched comparison." Surgical Endoscopy and Other Interventional Techniques.

251. Packiam, V. B., D. L.; Tohme, S.; Reddy, S.; Marsh, J. W.; Geller, D. A.; Tsung, A. (2012). "Minimally Invasive Liver Resection: Robotic Versus Laparoscopic Left Lateral Sectionectomy." Journal of Gastrointestinal Surgery **16**(12): 2233-2238.

252. Tranchart, H., et al. (2014). "Traditional versus Robot-Assisted Full Laparoscopic Liver Resection: A Matched-Pair Comparative Study." World Journal of Surgery.

253. Troisi, R. I. P., A.; Montalti, R.; Casciola, L. (2013). "Robot assistance in liver surgery: a real advantage over a fully laparoscopic approach? Results of a comparative bi-institutional analysis." International of Medical Robots and Computer Assisted Surgery.

254. Tsung, A., et al. (2013). "Robotic versus laparoscopic hepatectomy: A matched comparison." Annals of Surgery.

255. Wang, Z. Z., et al. (2019). "Robotic vs laparoscopic hemihepatectomy: A comparative study from a single center." Journal of Surgical Oncology.

256. Wu, Y. M., et al. (2014). "Robotic-assisted minimally invasive liver resection." Asian J Surg.

257. Yu, Y. D., et al. (2014). "Robotic versus laparoscopic liver resection: a comparative study from a single center." Langenbeck's Archives of Surgery **399**(8): 1039-1045.

258. Beard, R. E., S. Khan, R. I. Troisi, R. Montalti, A. Vanlander, Y. Fong, T. P. Kingham, T. Boerner, E. Berber, B. Kahramangil, J. F. Buell, J. B. Martinie, D. Vrochides, C. Shen, M. Molinari, D. A. Geller and A. Tsung (2019). "Long-Term and Oncologic Outcomes of Robotic Versus Laparoscopic Liver Resection for Metastatic Colorectal Cancer: A Multicenter, Propensity Score Matching Analysis." World Journal of Surgery 44(3): 887-895.

259. Cortolillo, N., C. Patel, J. Parreco, S. Kaza and A. Castillo (2019). "Nationwide outcomes and costs of laparoscopic and robotic vs. open hepatectomy." J Robot Surg 13(4): 557-565.

260. Di Sandro, S., A. Lauterio, A. Giacomoni, G. Concone, I. Mangoni, P. Mihaylov and L. De Carlis (2014). "Totally robotic liver resection for hepatocellular carcinoma in cirrhotic patients: safety and feasibility." Journal of Robotic Surgery 8(4): 357-364.

261. Hu, M., K. Chen, X. Zhang, C. Li, D. Song and R. Liu (2020). "Robotic, laparoscopic or open hemihepatectomy for giant liver haemangiomas over 10 cm in diameter." BMC Surg 20(1): 93.

262. Kim, J. K., J. S. Park, D. H. Han, G. H. Choi, K. S. Kim, J. S. Choi and D. S. Yoon (2016). "Robotic versus laparoscopic left lateral sectionectomy of liver." Surg Endosc 30(11): 4756-4764.

263. O'Connor, V., B. Vuong, S. T. Yang and A. Difronzo (2017). "Robotic minor hepatectomy offers a favorable learning curve and may result in superior perioperative outcomes compared with laparoscopic approach." American Surgeon 83(10): 1085-1088.

264. Aziz, H., K. Hanna, N. Lashkari, N. U. Ahmad, Y. Genyk and M. R. Sheikh (2021). "Hospitalization Costs and Outcomes of Open, Laparoscopic, and Robotic Liver Resections." Am Surg: 31348211011063.

265. Chen, P. D., C. Y. Wu, R. H. Hu, W. H. Chou, H. S. Lai, J. T. Liang, P. H. Lee and Y. M. Wu (2017). "Robotic Versus Open Hepatectomy for Hepatocellular Carcinoma: A Matched Comparison." Ann Surg Oncol 24(4): 1021-1028.

266. Han, D. H., S. H. Choi, E. J. Park, D. R. Kang, G. H. Choi and J. S. Choi (2016). "Surgical outcomes after laparoscopic or robotic liver resection in hepatocellular carcinoma: a propensity-score matched analysis with conventional open liver resection." Int J Med Robot 12 (4): 735-742.

267. Lin, Q., Q. Ye, D. Zhu, Y. Wei, L. Ren, P. Zheng, P. Xu, L. Ye, M. Lv, J. Fan and J. Xu (2015). "Comparison of minimally invasive and open colorectal resections for patients undergoing simultaneous R0 resection for liver metastases: a propensity score analysis." Int J Colorectal Dis 30(3): 385-395.

268. Lorenz, E., J. Arend, M. Franz, M. Rahimli, A. Perrakis, V. Negrini, A. A. Gumbs and R. S. Croner (2021). "Robotic and laparoscopic liver resection—comparative experiences at a high-volume German academic center." Langenbeck's Archives of Surgery 406(3): 753-761.

269. Magistri, P., G. Tarantino, C. Guidetti, G. Assirati, T. Olivieri, R. Ballarin, A. Coratti and F. Di Benedetto (2016). "Laparoscopic versus robotic surgery for hepatocellular carcinoma: The first 46 consecutive cases." Journal of Surgical Research 217: 92-99.

270. Miller, H. P., A. Hakim, A. Kellish, M. Wozniak, J. Gaughan, R. Sensenig, U. M. Atabek, F. R. Spitz and Y. K. Hong (2021). "Cost-Benefit Analysis of Robotic vs. Laparoscopic Hepatectomy: A Propensity-Matched Retrospective Cohort Study of American College of Surgeons National Surgical Quality Improvement Program Database." Am Surg: 31348211011124.

271. Salloum, C., C. Lim, E. Lahat, C. G. Gavara, E. Levesque, P. Compagnon and D. Azoulay (2017). "Robotic-Assisted Versus Laparoscopic Left Lateral Sectionectomy: Analysis of Surgical Outcomes and Costs by a Propensity Score Matched Cohort Study." World J Surg 41(2): 516-524.

272. Stewart, C. L., P. H. G. Ituarte, K. A. Melstrom, S. G. Warner, L. G. Melstrom, L. L. Lai, Y. Fong and Y. Woo (2019). "Robotic surgery trends in general surgical oncology from the National Inpatient Sample." Surg Endosc 33(8): 2591-2601.

273. Stiles, Z. E., S. W. Behrman, E. S. Glazer, J. L. Deneve, L. Dong, J. Y. Wan and P. V. Dickson (2017). "Predictors and implications of unplanned conversion during minimally invasive hepatectomy: an analysis of the ACS-NSQIP database." HPB (Oxford) 19(11): 957-965.

274. Ji, W. B., H. G. Wang, Z. M. Zhao, W. D. Duan, F. Lu and J. H. Dong (2011). "Robotic-assisted laparoscopic anatomic hepatectomy in China: initial experience." Ann Surg 253(2): 342-348.

Publications Providing Learning Curve Assessments

275. Ceccarelli, G., E. Andolfi, A. Fontani, F. Calise, A. Rocca and A. Giuliani (2018). "Robot-assisted liver surgery in a general surgery unit with a "referral centre Hub&Spoke learning program". Early outcomes after our first 70 consecutive patients." Minerva Chir **73**(5): 460-468.

276. Chen, P. D., C. Y. Wu, R. H. Hu, C. N. Chen, R. H. Yuan, J. T. Liang, H. S. Lai and Y. M. Wu (2016). "Robotic major hepatectomy: Is there a learning curve?" Surgery **161**(3): 642-649.

277. Efanov, M., R. Alikhanov, V. Tsvirkun, I. Kazakov, O. Melekhina, P. Kim, A. Vankovich, K. Grendal, S. Berelavichus and I. Khatkov (2017). "Comparative analysis of learning curve in complex robot-assisted and laparoscopic liver resection." HPB **19**(9): 818-824.

278. Gravetz, A., I. Sucandy, C. Wilfong, N. Patel, J. Spence, S. Ross and A. Rosemurgy (2019). "Single-institution early experience and learning curve with robotic liver resections." American Surgeon **85**(1): 115-119.

279. Liu, Q., T. Zhang, M. Hu, Z. Zhao, G. Zhao, C. Li, X. Zhang, W. Y. Lau and R. Liu (2020). "Comparison of the learning curves for robotic left and right hemihepatectomy: A prospective cohort study." International Journal of Surgery **81**: 19-25.

280. O'Connor, V., B. Vuong, S. T. Yang and A. Difronzo (2017). "Robotic minor hepatectomy offers a favorable learning curve and may result in superior perioperative outcomes compared with laparoscopic approach." American Surgeon **83**(10): 1085-1088.

281. Tsung, A., D. A. Geller, D. C. Sukato, S. Sabbaghian, S. Tohme, J. Steel, W. Marsh, S. K. Reddy and D. L. Bartlett (2014). "Robotic versus laparoscopic hepatectomy: a matched comparison." Annals of Surgery **259**(3): 549-555.

282. Zhu, P., W. Liao, Z. Y. Ding, L. Chen, W. G. Zhang, B. X. Zhang and X. P. Chen (2018). "Learning Curve in Robot-Assisted Laparoscopic Liver Resection." Journal of Gastrointestinal Surgery **23**(9): 1778-1787.

End of Section

Appendix I Sterilization Methods

The following tables list the sterilization methods used for single-use drapes.

Drapes

Product	Base PN	Method of Sterilization
Four primary arm drapes The arm drapes include: instrument sterile adapter, cannula sterile adapter, and arm clip.	470015	EO Sterilization
Column Drape	470341	EO Sterilization

End of Section

Appendix J Glossary

Table J.1 Glossary

Term	Meaning
3D	Three-dimensional
3D display	The three dimensional image created by two optical channels on the endoscope, seen in the 3D viewer on the Surgeon Console.
3D viewer	The viewing system that comprises the upper portion of the Surgeon Console, where the surgeon looks to see the 3D image.
AC	Alternating current, also represented by the AC symbol: ~. “AC” or “AC power” refers to electrical connection via a wall outlet, as opposed to battery power.
Arms	The four arms of the Patient Cart that support instruments and endoscope.
Endoscope rotation indicator	Shows the orientation of the endoscope with respect to the floor. It appears in the endoscope status area of the touchscreen display and the 3D viewer display.
Electrosurgical unit (ESU)	Generator that provides energy to electrosurgical instruments.
CF or Type CF	An IEC 60601-1 classification for patient applied parts. Type CF is the most stringent classification, being required for those applications where the applied part is in direct conductive contact with the heart or other applications as considered necessary.
CAUTION	A caution alerts the reader about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.
Cart drive enable switches	Move (drive) the Patient Cart.
Circulating nurse (non-sterile user) vs. scrub nurse (sterile user)	A scrub nurse is prepared to work within the sterile surgical field (sterile user) while a circulating nurse is not (non-sterile user).
Clutch (verb)	To finger clutch is to disengage the hand control from its associated instrument so the hand can be repositioned.

(continues on next page)

Table J.1 Glossary (continued)

Term	Meaning
Clutch (noun)	As in the finger clutch (sliding button on each hand control), which allows clutching that hand control separately.
Console	See **Surgeon Console**
DICOM	Digital Imaging and Communications in Medicine (DICOM) is a standard for storing and transmitting medical images enabling the integration of medical imaging devices such as scanners, servers, workstations, printers, network hardware, and picture archiving and communication systems (PACS) from multiple manufacturers.
Docking	Attaching cannulae to the Patient Cart at the start of a surgery.
Endoscope	Provides the live video image to the system; sometimes called a “scope” as an abbreviation.
Endoscope Controller	See **Light Source**
Endoscope port	The port that will be used as the primary endoscope port for the procedure.
EndoWrist Instruments	Instruments with a wrist located near the tip.
Fault, faulting	The system generates a fault when it detects an anomaly. The transition from a working state to either a soft-locked or brake-locked state.
Flex	A joint that allows for the arm spacing to be adjusted.
Foot pedal	A pedal or switch located on the footswitch assembly of the Surgeon Console.
Footswitch panel	Located at the base of the Surgeon Console, containing all of the foot controls.
Generator (Electrosurgical)	Generator that provides energy to electrosurgical instruments. See Electro-surgical unit (ESU).
Head sensor	Infrared sensor on either side of the view port of the Surgeon Console, located above the 3D viewer.
Helm	The control center located at the back of the Patient cart. Includes the touchpad, handlebars, joysticks, and cart drive enable switches.
Illumination System or Endoscope Controller	See **Light Source**
IR radiation	Infrared radiation

(continues on next page)

Table J.1 Glossary (continued)

Term	Meaning
Instrument	Any one of several tools used to affect the procedure in the patient once attached to an arm and inserted into the patient. Instruments include, for example, Large Needle Drivers, DeBakey Forceps and Round Tip Scissors.
Left-Side pod	The appendage on the left side of the Surgeon Console armrest that provides ergonomic adjustment controls.
LED	Light emitting diode
Light source	Endoscope Controller illumination system. The da Vinci system has a single light source integrated in the Vision Cart and attached to the endoscope by the endoscope integrated connector. It provides illumination inside the body for vision.
Hand control (masters)	The control arms and grips in the Surgeon Console that the surgeon grasps and moves. The surgeon's movements are translated to the instruments and endoscope attached to the arms.
MIS	Minimally Invasive Surgery
Notes	User information to emphasize an important point.
PACS	Picture Archiving and Communication Systems (PACS) is a medical imaging technology which provides economical storage and convenient access to images from multiple modalities (source machine types).
Patient Cart (PSC)	The part of the system that is located on the patient-side and consists of the column and boom that support the setup joints that in turn support the arms.
Patient Cart arms (arms)	The arms of the Patient Cart that support instruments and endoscope, and manipulate the instruments and endoscope according to surgeon's movement of the hand controls. Also referred to as arms.
Port Hopping	The ability of the user to install the endoscope on any of the four arms.
Positioning Laser	Positioning guide that projects downward from the Patient Cart.
Remote Center	A fixed point in space around which the arms move, indicated by the thick black band on cannulae. Remote center technology enables the system to maneuver instruments and endoscopes in the surgical site while exerting minimal force on the patient's body wall.
Right-Side pod	The appendage on the right end of the Surgeon Console armrest that provides the Power button and the Emergency Stop buttons.
Scope	Endoscope
Screen	The monitor display, located in the 3D viewer and/or the touchscreen display.

(continues on next page)

Table J.1 Glossary (continued)

Term	Meaning
Sterile adapter	Interface device that allows the sterile barrier to be maintained between the arm and the endoscope or instrument attached to the arm. There are two types of sterile adapters: a cannula sterile adapter, and an instrument sterile adapter. They are not interchangeable.
Surgical workspace	The area within the patient that the instruments will be required to reach to complete all surgical tasks throughout the procedure.
Surgeon Console (SSC)	The part of the system consisting of a structure that supports the hand controls and the 3D viewer.
Target anatomy	The center of the surgical workspace boundary.
Targeting	Adjusts the Patient Cart while maintaining remote center placement.
TilePro	A feature that allows display of the 3D image of the operative field and up to two additional images provided by auxiliary inputs.
Touchpad	The touchpad in the center of the Surgeon Console armrest and on the Patient Cart Helm.
Touchscreen	The touchscreen monitor mounted on the Vision Cart.
View port	The recessed area near the top of the Surgeon Console where the surgeon inserts their head to view the 3D viewer display. It includes the fixed eyepieces of the 3D viewer, infrared head sensors, speakers, and contoured headrest.
Vision Cart (VSC)	The da Vinci system component that houses the central processing and vision system, including the Endoscope Controller, Video Processor, and system electronics (Core). It includes a touchscreen monitor and provides adjustable shelves for optional ancillary surgical equipment such as insufflators.
WARNING	A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury.

End of Section

This page intentionally left blank.

Index

0° Endoscope
  Description 2-7
  Hand-held use 7-12
0° tip 2-7
30° down 10-32
30° Endoscope
  Description 2-7
  Hand-held use 7-12
30° tip 2-7
30° up 10-32
3D
  TilePro F-3
3D viewer 7-3
  Activation status 10-65
  Comparison between consoles 10-67
  Confirm live image 7-7
  Description 10-2
  Display 10-47
  Messages 10-47
  Viewer mode 10-33
3D viewer display J-4
8 mm Endoscope
  Description 2-7
  Features 7-3

A

Accessory Equipment Interconnection 1-12
Account 10-37
Arm
  Control buttons 9-26
  Disable B-8
  Draping procedure 6-8
  Information 10-48
  Intraoperative management 9-39
  LED status 9-6
  Manually adjusting 9-25
  Pop-up information 10-50
  Positioning precautions 1-11
  Status 10-49
  Status pods 10-30
  Swap D-5
Arm pod quick-settings 10-32
Armrest
  Description 10-3
  Location 2-1
Audio
  Connections F-1
  Connections — auxiliary 4-10
  Inputs F-3
  Messages D-17
  Outputs F-3
  System 2-8

B

Battery
  Backup B-11
  Disposal C-7
  LED status 9-6
  Low condition B-11
Boom 2-3
  Disable B-8
Brake
  Location 2-1
  Surgeon Console ..... 3-6 – 3-7
  Vision Cart — wheel locks 3-8
Brightness
  Adjustment 10-32
  Description 7-22

C

Cable
  Connect Endoscope cable 4-7
  Connect system cables 4-4
  Endoscope cable management 7-14
  System cable layout 4-4
Cart drive enable switches
  Use 3-8
Classifications C-2
  FCC E-9
Cleaning
  Endoscope fogging and intraoperative cleaning 7-18
  Intraoperative Endoscope cleaning 7-19
  System 12-1
Clip appliers 10-43
Collisions, resolving instrument 9-41
Column 2-3
  Drape 6-2
  Draping Procedure 6-6
Comparison between consoles 10-67
Compatibility
  Electromagnetic E-7
  Electromagnetic — OnSite A-15
Compliance C-2
  Laser safety 1-10
Compliance and classifications C-2

Connect
Core F-4
Dual console 10-66
Electrosurgical unit . . . . . 4-8 – 4-9
Endoscope 7-8
Endoscope cable 4-7
Endoscope to Endoscope Controller 7-9
Generator 10-62
System cables 4-2
Connect system cables 4-4
Contact information B-1
Customer Service 1-2
Conversion
To non-minimally invasive technique 1-7
To open surgery B-1
Core 7-2
Audio input F-3
Audio output F-3
Connection diagram F-4
RJ-45 connector A-5
TilePro input F-3
Customer Service B-1

D

Da Vinci Update Tool 10-38
Degree of protection C-2
Deploy for draping 6-3
Guided setup 6-4
Manual 6-5
Design life E-1
Digital zoom 7-11
Description 10-33
Dimensions
Crate E-7
Physical E-6
Disable
Arms B-8
Boom B-8
Guided tool change 9-39
Hand controls B-8
Network connectivity A-5
Disabled
Activation 10-66
Disposal
Battery C-7
Instrument C-7
Docking
Description 9-17
Dual docking 9-33
Overview 9-9
Docking and arm alignment after targeting . 9-22
Drape
Remove — Patient Cart 6-19
Drape the system 6-1
Arm draping procedure 6-8
Column draping procedure 6-6
Deploy for draping 6-3
Guided setup 6-4
Guidelines 6-2
Manual deploy for draping 6-5
Overview 6-1
Sterility barrier 6-13
Dual console
Comparison between consoles 10-67
Connection 10-66
Give 10-32
Give all 10-31
Instrument control settings 10-67
Instrument status area 10-50
Pedal activation behavior 10-66
Startup 10-66
Surgery 10-66
Take 10-32
Take all 10-31
Use 10-52
Video control 10-69
Visual pointer — teaching aid 10-70
Dual docking 9-33
Dual generator
Configuration 10-62
Setup 10-62
Troubleshooting 10-65
Use 10-61
Dynamic Illumination 7-10

E

Electromagnetic compatibility
OnSite A-15
System E-7
Electrosurgery
High frequency precautions 1-8
Electrosurgical
Connection 4-9
ERBE VIO dV overview 10-51
Power specifications E-5
Electrosurgical unit J-1
Connect 4-8
EMC tables E-10
Emergency Power Off 5-4

Patient Cart B-11
Emergency Stop
Right-side pod 10-4
Emergency Stop button 2-1
Patient Cart helm B-10
Surgeon Console B-10
Endoscope 7-2
0° Endoscope 2-7
0° tip 2-7
30° Endoscope 2-7
30° tip 2-7
8 mm 2-7
Buttons 7-10
Cable management 7-14
Change settings 7-11
Connect cable 4-7
Connect to Vision Cart 7-8
Digital zoom settings 7-11
Endoscope control — dual console 10-69
Features 7-3
Focus-free setting 7-11
Fogging 7-18
Hand-held use 7-12
Haptic zoom 10-33
Horizon indicator description 7-26
Inspect 7-8
Install 7-16
Installation 7-14
Intraoperative cleaning . . . . . 7-18 – 7-19
Light apertures 7-6
Off-screen tool indicator 7-26
Orientation 7-15
Port hopping 7-16
Precautions 1-11
Procedure precautions 1-7
Removal 7-14
Rotation indicator J-1
Status 10-50
Take photo 7-28
Working distance 10-33
Endoscope control
Dual console 10-69
Endoscope Controller
Troubleshooting B-12
EndoWrist instruments
Components 9-35
Description 2-8
Install 9-36
Installation — manual 9-37
Plug and play 9-36
Remove 9-45
Environmental Specifications E-7
EPO (Emergency power off button)
Hard-cycle reset B-6
Patient Cart 5-4
Patient Cart — location 5-4
ERBE VIO dV
1.0 and 2.0 overview 10-51
Ergonomic
Controls 10-3
Setup 10-5
Event logs
Access B-2

F

Faults B-8
Finger clutch 10-44
Firefly 10-36
Flex joint
Use 9-31
Fluid leakage 9-50
Focus-free setting 7-11
Foot pedal
Activation status bar 10-47
Footswitch panel 10-4
Use 10-44

G

Generator
Connect 10-62
Dual 10-61
Dual generator setup 10-62
Electrosurgical unit J-1
ERBE VIO dV overview 10-51
Troubleshooting 10-65
Give
All 10-69
button 10-32
Give All 10-31
Grab and move feature 9-26
Grip release kit 9-47
Guided setup 6-4
Guided tool change 9-38
Disable 9-39
Overview 9-38
Using 9-39

H

Hand controls
Assignment description 10-67

Assignments 10-37
Comparison between consoles 10-67
Description 10-2
Disable B-8
Finger clutch 10-37, 10-44
Head-in requirement 10-42
Scaling 10-37
Haptic zoom 10-33
Hard-cycle power B-6
Head-in requirement 10-42
Helm
Controls 9-3
Emergency Stop button B-10
Indicators. 9-3
Touchpad 9-4
Horizon indicator — Endoscope status. . . . 10-50
Horizon indicatorDescription 7-26

I

Icons
On-screen D-1
Indications for Use
OnSite A-2
Information
Arm 10-48
Endoscope 10-48
Instrument 10-48
Ingress protection C-2
Install
Endoscope 7-16
Instrument 9-36
Instrument manually 9-37
Instrument using the Guided Tool Change . 9-39
Instrument
Fluid leakage. 9-50
Guided Tool Change 9-39
Install 9-36
Installation — manual 9-37
Intraoperative maintenance 9-48
Manage inventory 9-49
Plug and play 9-36
Precautions 1-11
Remove. 9-45
Status 10-49
Integrated equipment
Power specifications. E-5
IR radiation 7-8, J-2
IT requirements A-13

J

Joysticks
Enable. 9-3

L

Labels
System C-3
Laser
Class E-6
Horizontal 9-2
Indicators. 9-1
Positioning. 9-2
Safety 1-10
Specifications — Patient Cart. E-6
Latex G-1
LED
Arm status indicators 9-6
Battery status indicators. 9-6
Endoscope 7-8
Endoscope cable connection 7-8
Endoscope Controller 7-8
Laser on indicator 7-8
Status indicators 9-6
Left-side pod
Ergonomic controls 10-3
Light apertures. 7-6
Login
Help. 10-29

M

Maintenance
Intraoperative instrument. 9-48
Mode A-6
Preventive 12-1
System 12-1
Manage inventory 9-49
Manufacturer C-1
Match grips 10-42
Motor drive operation. 3-7

N

Natural rubber latex G-1
Non-minimally invasive technique conversion B-1
Non-recoverable faults B-9

O

Off-screen tool indicator 7-26
On-screen icons D-1
OnSite
  Automatic status A-5
  Common wireless devices tested A-10
  Connections A-2
  Devices known to interfere A-12
  Diagnostic steps A-7
  Diagnostics description A-6
  Disable all network connectivity A-5
  Electromagnetic compatibility A-15
  Firewall A-13
  Internet access A-13
  IT requirements A-13
  Maintenance mode A-6
  Network technology A-13
  Normal mode A-6
  Proxy server A-13
  Servicing A-6
  Standby Mode A-6
  System log retrieval A-5
  System Requirements A-2
  System service A-7
  Wired network connection A-4
  Wireless bridge data A-20
  Wireless coexistence A-9
  Wireless connection A-4
  Wireless connectivity problems A-13
  Wireless network requirements A-8
  Wireless overview A-7
Open surgery conversion B-1
OR configuration 3-2

P

Patient Cart 2-1
  AC power switch 5-4
  Arm height joint 2-3
  Battery LED indicator 3-8
  Boom 2-3
  Boom height control 3-8
  Boom pivot 2-3
  Boom position control 3-8
  Boom rotation 2-3
  Brakes 3-7
  Cart drive enable switches
    Location 3-8
  Column 2-3
  Docking 9-9
  Drape the arm 6-1
  Drape the column 6-1
  Emergency Stop button 3-8
  EPO (Emergency power off button) 5-4
  Flex joint 2-3
  Hand controls B-8
  Helm 3-8
  LED status indicators 9-6
  Manual positioning 9-12
  Manually adjust the arms 9-25
  Microphone 2-8
  Motor drive operation 3-7
  Overview 9-1
  Patient clearance button 9-30
  Patient clearance joint 9-44
  Position for draping 3-7
  Position for surgery 3-7
  Power button 3-8
  Self-test of stowed arms 5-1
  Speakers 2-8
  Stabilization feet 3-7
  Stow 6-18
  Touchpad 3-8
  Use 9-1
Patient clearance
  Button 9-30
  Description 9-27
  Joint 9-44
  Use . . . . . 9-29 – 9-30
Pedal
  Activation 10-44
  Activation status bar 10-47
  SmartPedal™ Technology 10-46
Place ports . . . . . 8-1 – 8-2
Plug and play 9-36
Port hopping 7-16
Positioning laser
  Description 9-2
Power
  Button color indicators 5-2
  Guidelines 4-2
  Hard-cycle B-6
  Integrated equipment E-5
  Specifications — Vision Cart components . E-5
  Switch 5-4
Power button 2-1
  Patient Cart 5-1
  Surgeon Console 5-1
  Vision Cart 5-1
Power requirements
  Patient Cart 4-1
  Surgeon Console 4-1

Vision Cart 4-1
Precautions
Arm positioning 1-11
Endoscope 1-11
Endoscopic procedure 1-7
Fluid leakage 9-50
General precautions, warnings, and contraindications A-1
High frequency electrosurgery 1-8
Installation and service 1-10
Instruments 1-11
Transportation and storage 1-11
Prepare patient 8-1
Preventive maintenance 12-1
Primary pedal
Blue, left . . . . . 10-46 – 10-47
Blue, right . . . . . 10-46 – 10-47

Q

Quick-settings bar 10-30
Audio 10-31
Give all 10-31
Headset 10-31
Messages 10-31
Take all 10-31
Take photo 10-31
TilePro 10-31
VIO dV 10-31

R

Recoverable faults B-8
Remote center 8-4
Remove
Instrument 9-45
Representative uses H-1
Bench verification H-1
Human factors H-11
IS3000 and IS4000 performance data . . . H-12
IS4000 performance data H-1
Performance data H-12
Restart
Cool mode restart from individual power . B-7
During a procedure B-9
From automatic high temperature power down B-7
System B-7
Restore
Factory defaults 10-37
Image to factory defaults 10-33
Log in preferences 10-8
Saved settings 10-37
RFID modules E-16
Right-side pod
Emergency Stop 10-4
Power 10-4

S

Satisfy intended motion 10-43
Scaling 10-2
Comparison between consoles 10-67
Scope angle 10-32
Secondary pedal
Yellow, left . . . . . 10-46 – 10-47
Yellow, right . . . . . 10-46 – 10-47
Self-test
Patient Cart 5-1
Surgeon Console 5-2
settings
system 12-1
Settings tab
Account 10-37
Display 10-33
Patient Cart touchscreen 9-4
Surgeon Console touchpad 10-32
TilePro 10-35
Vision Cart 7-23
Shutdown
System 11-2
SmartPedal™ Technology 10-46
Specifications
Crate dimensions E-7
Environmental E-7
Laser — Patient Cart E-6
Power, Integrated equipment E-5
Power, main components E-4
Power, Vision Cart components E-5
System E-1
Wireless network requirements A-8
Stabilization feet 3-7
Standby mode D-4
Standby Mode
OnSite A-6
Startup sequence 5-1
Sterile adapter
Attach to arm 6-12
Cannula 6-2
Instrument 6-2
Sterile stow
Description 9-51

Patient Cart 6-18
Sterilization Methods I-1
Store
Blue system cables 11-2
System 11-3
Stow 9-50
Instructions — Patient Cart 9-50
Patient Cart — shutdown 11-2
Sterile 6-18
Sterile stow 9-51
Touchscreen 3-8
Vision Cart 11-2
Surgeon Console 2-1
3D viewer 7-3
3D viewer — confirm live image 7-7
3D viewer description 10-2
Armrest 10-5
Audio 2-8
Brake 3-6
Brightness 10-32
Cable connection 4-2
Dual console setup 10-60
Dual console use 10-52
Emergency Stop 10-4
Emergency Stop button 2-1
Ergonomic controls 10-3
Ergonomic setup 10-5
Footswitch panel 10-44
Hand controls 2-1
Head-in requirement 10-42
Headset 10-31
Match grips 10-42
Messages 10-2
Positioning 3-5
Power 10-4
Power button 2-1
Quick-settings bar 10-30
Rear panels 10-5
Satisfy intended motion 10-43
Self-test 5-2
Take photo 7-28
Touchpad 10-60
Use 10-1
Surgical controls
3D viewer display 10-42
Footswitch panel 10-42
Match grips 10-42
Swap
Instrument connections from VIO dV to ForceTriad 10-64
System
Audio connections F-1
Cable layout 4-4
Clean 12-1
Connect 4-1
Connect system cables 4-2
Drape 6-1
Electrosurgical connection 4-8
Faults B-8
Integrity test 5-1
Labels C-3
Maintenance 12-1
Non-recoverable faults B-9
Power connections 4-1
Power requirements E-1
Recoverable faults B-8
Restart B-7
Shutdown 11-2
Startup 5-1
Startup sequence 5-1
Store 11-3
Video connections F-1
system settings
overview 12-1

T

Take
All 10-69
Button 10-32
Take photo 7-28
Endoscope 7-28
Surgeon Console 7-28
Vision Cart 7-28
Targeting 7-12
Technical system information . . . . . C-1 – C-2
Telestration 7-29
Three-Arm Procedure 9-32
TilePro 10-31
2D and 3D F-3
3D use 10-36
Controls 10-35
TilePro QuickClick 10-35
Use 10-36
Video input F-3
Viewer mode 10-35
Touchpad 10-3
Adjust energy settings 10-63
Adjust power limit settings 10-55
Brightness 10-32
Comparison between consoles 10-67
Controls 10-7
Edit energy presets 10-57

Information icons 10-7
Surgeon Console 10-60
Unlock 10-7
Touchscreen 2-6
Telestration 7-29
Troubleshooting 10-64
Access event logs..... B-2
Activation not available..... 10-66
Contact information B-1
Dual generator..... 10-65
Endoscope Controller B-12
Faults B-7
Hard-cycle power B-6
Image quality 7-29
Non-recoverable Faults B-9
Non-responsive system B-11
OnSite servicing and diagnostics A-6
Patient Cart drive B-2
Patient Cart quick references 9-52
Power issues B-4
Quick references 2-9
Recoverable faults..... B-7
System B-1
Unexpected motion B-4
VIO dv display..... 10-53

U

Unexpected motion B-4

V

Video
Connections F-1
Input F-1
Output F-1
TilePro input F-3
Video processor 7-2
VIO dV
1.0 overview.....10-51
2.0 energy presets 10-56
2.0 overview 10-51
2.0 power limit settings 10-55
Adjust 1.0 settings — Surgeon Console touchpad 10-52
Adjust 2.0 settings — Surgeon Console touchpad 10-54
Adjust energy settings 10-54
Adjust power limit settings — Surgeon Console touchpad 10-55
Applying presets to VIO dV 10-60
Display troubleshooting..... 10-53
Editing presets 10-57
Energy controls 10-31
Open the control panel 10-54
Settings 10-51
Using two instruments of same energy type 10-53
Vision Cart.....2-1
Accessory shelves 2-7
Components 7-1
Connect system cables 4-2
Core.....7-1
Endoscope 7-1
Endoscope Controller 7-1
Event logs B-2
Positioning..... 3-8
Set up and use 7-1
Stow 11-2
System electronics (Core) 7-1
Take photo..... 7-28
Tank holders 2-7
Telestration..... 7-29
Touchscreen 7-1
Transport — Vision Cart 3-8
Video processor 7-1
VIO dV.....7-1
Wheels (locked and unlocked) — Vision Cart..... 3-8
Voice feedback..... 9-4

W

Wheel lock..... 3-9
White balance 7-30
Wireless
Bridge data A-20
Coexistence..... A-9
Connection A-4
Devices tested A-10
Network requirements..... A-8
Overview A-7
Wireless communication
Overview E-16
Wireless connectivity
Overview E-19
Quality of service..... E-20
Security E-20
Specification..... E-20
Wireless network requirements
Quality of service..... A-8
Security A-8

Specifications A-8
Working distance
Description 10-33
Enable 7-11
Set up H-4