

Instruments and Accessories

User Manual

for da Vinci Xi and da Vinci X Systems



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Rx only

End of section

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Chapter 1 General Information

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1.1 How to Use this Manual

This Instruments and Accessories User Manual provides instructions for use and limitations on use for instruments and accessories used with the following systems:

- Da Vinci Xi Surgical System, Model IS4000, (referred to in this manual as the da Vinci Xi System, or the system)
- Da Vinci X Surgical System, Model IS4200 (referred to in this manual as the da Vinci X System, or the system)

 **Note:** All da Vinci instruments and accessories are compatible with both the da Vinci Xi and the da Vinci X systems.

 **Note:** Not all technologies may be commercially available in all geographies.

This manual is not a reference for surgical techniques. It is intended to be kept with the system with which it is used. See the applicable system user manual for more information on connecting the instruments to the system. For cleaning, disinfection, and sterilization of reusable instruments, accessories and components, refer to the appropriate Reprocessing Instructions User Manual.

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.

 **WARNING:** Be sure to read and understand all information, particularly caution and warning information, found in the applicable user manuals before using these products. Failure to properly follow all instructions, including instructions supplied with accessory devices like electrosurgical units and the applicable user manuals for the da Vinci system may lead to injury and result in improper functioning of the device.

-
- i** **Note:** Read [Knowing What Applies – Organization of this Manual](#) on page 8 to understand what portions of this manual apply to any specific instrument or accessory. If information specific to an instrument or accessory is not included in this manual, Intuitive supplies it with that instrument or accessory.
-

Non-sterile

- i** **Note:** Intuitive devices ship non-sterile unless otherwise indicated in the device's labeling. Clean and sterilize reusable devices before each use, unless they are not used within the sterile field.
- i** **Note:** Use standard sterile technique for proper handling and cleaning of components that enter the sterile field.
-

Knowing What Applies – Organization of this Manual

- i** **Note:** This manual describes both EndoWrist and Single-Site instruments and accessories. Unless otherwise specified, the information applies to both suites of instruments and accessories. For specific information on instruments and accessories not covered in this manual, see the user documentation distributed with those products.
-
- This chapter (General Information) applies to all instruments and accessories supplied by Intuitive.
 - [Chapter 2 Overview of da Vinci Instruments](#) on page 13 provides general information and troubleshooting that applies to all da Vinci instruments, including scissors, scalpels, graspers, needle drivers, clip appliers, monopolar and bipolar electrocautery instruments. This chapter also provides information specific to EndoWrist and Single-Site instruments.
 - [Chapter 3 Overview of Single-Site Surgery](#) on page 35 provides information specific to Single-Site surgery.
 - [Chapter 4 Large and Medium-Large Clip Appliers](#) on page 58 provides information specific to the Large and Medium-Large Clip Appliers.
 - [Chapter 5 Small Clip Applier](#) on page 61 provides information specific to the Small Clip Applier.
 - [Chapter 6 Using Electrosurgical Units \(ESUs\)](#) on page 64 provides general information that applies to all cautery instruments, including electrosurgical unit settings, energy activation cables and cautery cords.
 - [Chapter 7 Monopolar Instruments and Related Accessories](#) on page 87 provides information specific to all Monopolar instruments and related accessories.
 - [7.3 Monopolar Curved Scissors Instrument](#) on page 90 provides information specific to the Monopolar Curved Scissors instrument.
 - [7.4 Permanent Cautery Instrument](#) on page 94 provides information specific to the Permanent Cautery instrument.
 - [Chapter 8 Bipolar Instruments and Related Accessories](#) on page 95 provides information specific to Bipolar instruments.
 - [Chapter 9 EndoWrist Suction Irrigator](#) on page 98 provides information specific to the EndoWrist Suction Irrigator Instrument.
 - [Chapter 10 Single-Site Suction Irrigator](#) on page 105 provides information specific to the Single-Site Suction Irrigator Instrument.

- [Chapter 11 Cannulas, Obturators, Reducer, and Cannula Seals](#) on page 107 provides information specific to cannulae, obturators, reducers, cannula seals and related accessories.
- [Appendix A Reprocessing Preparation in the Operating Room](#) on page 130 provides information on reprocessing preparation in the operating room.
- [Appendix B Symbols Defined](#) on page 131 provides information about symbols that may appear on packaging and labels for instruments and accessories.
- [Appendix C Natural Rubber Latex](#) on page 136 provides information about products referenced in the manual that are not made with natural rubber latex.
- [Appendix D Sterilization Methods](#) on page 137 provides information about sterilization methods used for single-use instruments and accessories.
- [Appendix E Intended Use/Indications for Use](#) on page 138

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, and general information regarding Intuitive or our products and services.

In the U.S.

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

If the system requires maintenance or service, call our Customer Service line. In the U.S., call 1.800.876.1310, where phones are staffed 24 hours a day, seven days a week.

If you have questions regarding the use, cleaning, sterilizing, or storing of Intuitive devices used with the da Vinci Xi System or the da Vinci X System, contact Intuitive Customer Service at the phone number above.

Manufacturer



Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086 U.S.A.
www.intuitive.com



Note: Manufacturer information may vary for some items manufactured by an Original Equipment Manufacturer (OEM) partner. Such items are specified in the relevant sections.

1.2 Limitation on Use – Limited License

Intuitive da Vinci instruments and accessories are provided pursuant to a limited license to use only with the Intuitive da Vinci Xi System (Endoscopic Instrument Control System, Model IS4000) and the da Vinci X System (Endoscopic Instrument Control System, Model IS4200). Upon expiration of the instrument's or accessory's programmed maximum number of uses, this limited license expires. Any repair, refurbishment, reconditioning, or servicing of Intuitive instruments and accessories is strictly prohibited and results in expiration of limited license.

1.3 Important Regulatory Information

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.



Note: The da Vinci system, instruments, and accessories are not intended specifically to control, diagnose, monitor or correct a defect of the heart, central circulatory or central nervous system through direct contact with those parts of the body.

Serious Incident Reporting

Serious incident means any incident that directly or indirectly led, might have led, or might lead to any of the following:

- the death of a patient, user, or other person,
- the temporary or permanent serious deterioration of a patient's, user's, or other person's state of health,
- a serious public health threat.

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report the incident to the manufacturer and its authorized representative and to your national authority.

In Europe

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Direct: +33.1.77.68.88.45
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33600 Pessac, France

Supplemental Information for da Vinci

This section includes clinical benefits information and intended use/indications for use for the da Vinci instruments and accessories.

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.

Intended Use/Indications for Use

For Intended Use/Indications for Use of da Vinci Instruments and Accessories, see [Appendix E Intended Use/Indications for Use](#) on page 138.

For Intended Use/Indications for Use of da Vinci systems, see the applicable system user manual.

1.4 General Instructions**Proper Care and Handling**

Proper care and handling is essential for satisfactory performance of surgical instruments and accessories. Use care when handling devices during setup and operation. Examine the instrument or accessory, including all of its components, thoroughly before and after each use. If any abnormality is found (such as dents), do not use the instrument or accessory. Use the device for its intended purpose only.

Do not expose instruments to X-rays, radioactive rays or strong electromagnetic waves. Otherwise, the instrument may be damaged, making it unrecognizable to the system.

Storage Between Uses

After removing products from their packaging, store Intuitive instruments, accessories or components in a clean, dry, dark place. Care must be taken to protect the instrument tips from damage.

Disposal

When disposing of Intuitive instruments, accessories, or any of their components, follow all applicable national and local laws and guidelines.

End of section

Chapter 2 Overview of da Vinci Instruments

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Note: All da Vinci instruments and accessories in this manual are compatible with both the da Vinci Xi and the da Vinci X systems, unless otherwise specified.

2.1 Introduction

This chapter contains general instructions for use specific to da Vinci instruments. The following sections provide general information such as part numbers and device names, intraoperative information, and troubleshooting. Specific information on individual types of instruments can be found in each specific instrument chapter (for example, for large and medium-large clip appliers, see [Chapter 4 Large and Medium-Large Clip Appliers](#) on page 58).

Note: This chapter describes both EndoWrist and Single-Site instruments and associated accessories. Unless otherwise specified, the information applies to both suites of instruments and accessories. For specific information on instruments and accessories not covered in this manual, see the user documentation distributed with those products.

Note: Da Vinci instruments ship non-sterile, unless otherwise indicated in the instrument’s labeling. Clean and sterilize reusable Instruments before use. For details see the Reprocessing Instructions User Manual.

Note: Pay attention to all, warnings, and cautions, and follow all instructions related to the setup and docking of instruments and accessories on the system. See the applicable da Vinci user manual to position the Patient Cart before starting any procedure.

2.2 Instruments Overview

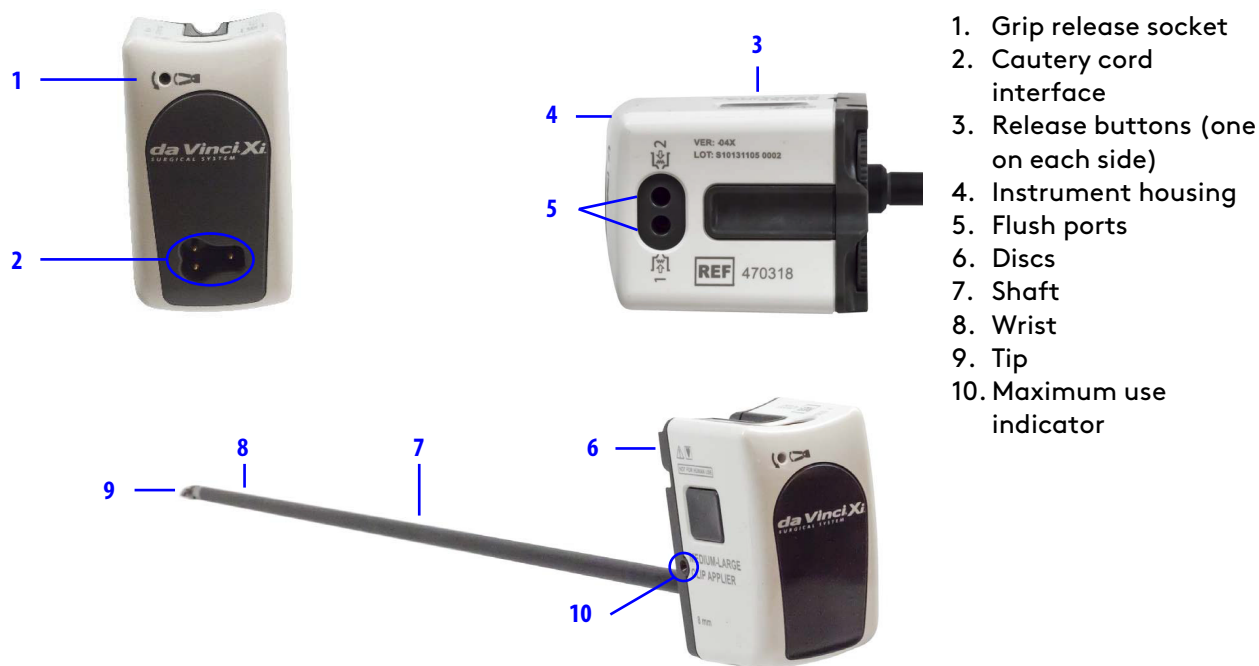
Intuitive designs instruments to give surgeons natural dexterity and range of motion. This allows for greater precision when operating in a minimally invasive environment.

Instrument Features

Da Vinci instruments consist of the following components:

- **Instrument housing (Figure 2.1 4):** The instrument housing engages with the instrument sterile adapter and includes the:
 - **Release buttons (Figure 2.1 3):** The two release buttons, one on each side of the housing, are used to release the instrument from the sterile adapter for removal.
 - **Flush ports (Figure 2.1 5):** Two flush ports are used for instrument reprocessing. See the Reprocessing Instructions User Manual for cleaning and sterilization instructions.
 - **Grip release socket (Figure 2.1 1):** Access hole for grip release wrench used to open or move grips manually during a system fault. For more information on grip release, see the applicable system user manual.
 - **Cautery Cord interface [electrosurgical instruments only] (Figure 2.1 2):** Bipolar or Monopolar (depending on instrument type) cautery cords can be plugged into this connection interface.
 - **Discs (Figure 2.1 6):** The discs connect to the instrument wrist and translate the movements of the hand controls from the Surgeon Console.
 - **Maximum use indicator (Figure 2.1 10):** An indicator on the instrument housing that turns red when the instrument has reached its maximum uses. For more information on viewing remaining uses, see the applicable system user manual.
 - **Shaft (Figure 2.1 7):** The shaft inserts through the cannula and rotates as controlled by the movements of the hand controls.
- **Wrist [if applicable] (Figure 2.1 8):** The articulating wrist provides a wide range of movements.
- **Tip (Figure 2.1 9):** The instrument tip (also called grip, jaw, or end effector). Examples include graspers, cautery hooks, and blades.

Figure 2.1 da Vinci Xi instrument



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

Refer to the applicable system user manual for more information on connecting the instruments to the system.

General Warnings and Cautions

-
-  **WARNING:** Use proper handling, cleaning, and sterilization of components within the sterile field to prevent breach of sterility.
-
-  **WARNING:** Unless it is stated, do not use da Vinci instruments on cartilage, bone, or hard objects. Doing so may damage the instrument and make it impossible to remove from the cannula or cause components to fall in the patient.
-
-  **WARNING:** Do not grasp tissue with instruments not intended to grasp tissue, as tissue injury may result. For example, do not grasp tissue with clip appliers, which are made to hold and apply plastic ligation clips, or needle drivers, which are made to hold metallic needles.
-
-  **WARNING:** Improper use or handling of any components that could get hot could lead to burn injuries.
-
-  **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:** Surgery should only be performed when the vision system provides sufficient visualization to safely perform surgical tasks.
-
-  **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:** Unexpected motion can occur when instruments collide, resulting in instrument damage, or patient injury. Ensure there is adequate room for instruments to move inside the patient and for the arms outside the patient to move without contacting the patient during the procedure. Ensure that the patient-side assistant can see all arms during the procedure and can alert the surgeon when the arms are close to contacting the patient.
-
-  **WARNING:** Instrument and cannula configurations that are electrically isolated from the body wall have the potential to enable the unintended transfer of monopolar energy.
-
-  **WARNING:** Do not use one instrument to clean another inside the patient to prevent instrument damage and components left in the patient.
-
-  **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.
-

-
-  **WARNING:** Prior to removing a grasping instrument (for example, ProGrasp) from the cannula, release all tissues and approved third-party devices from the grips to avoid jamming between the device and cannula. Removing an instrument while grasping objects could cause jamming and make it impossible to remove the instrument from the cannula. It is recommended to visualize the instrument tip under endoscopic view for removal.
-
-  **WARNING:** Avoid contact between instruments intraoperatively and do not use one instrument to apply force to another instrument inside the patient, because tissue injury could result.
-
-  **WARNING:** To clean debris from an instrument, first remove the instrument from the patient and system to prevent damage to the instrument resulting in fragments in the patient.
-
-  **WARNING:** Do not use an instrument to clean debris from another instrument intraoperatively. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip.
-
-  **WARNING:** Clean and sterilize the instruments immediately after each use to ensure proper cleaning and sterility. Do not allow debris to dry on or inside the instrument intraoperatively before instrument processing. In order to keep the instrument from drying when soiled, keep the instrument in water or an enzymatic bath between the surgical procedure and instrument processing. The instrument may also be flushed through the main flush port with sterile water during use to minimize buildup of internal deposits of bio-material.
-
-  **WARNING:** Keep instruments moist during intraoperative use to ensure particulates (for example, tissue, bodily fluids, etc.) do not dry on the instrument. Failing to do so may result in difficulty in removing those particulates during sterile reprocessing and may cause patient infection or immunologic reaction.
-
-  **WARNING:** Follow proper instrument and accessory cleaning procedures, to prevent infection.
-
-  **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:** All instructions, precautions, and contraindications found with the Hem-o-lok ligating clips apply when clips are applied with the EndoWrist and Single-Site clip appliers.
-
-  **WARNING:** Do not apply prolonged energy to an instrument when it is not in contact with tissue to prevent patient harm.
-
-  **WARNING:** Do not use instruments repaired, refurbished, reconditioned, or serviced by a third party to prevent device malfunction or injury to the patient or staff.
-
-  **WARNING:** Use only the instruments and accessories approved by Intuitive and listed in the user manuals or compatibility documents. System compatibility, safety, and performance with non-approved instrumentation cannot be guaranteed, and could result in tissue injury or damage to the instrument or equipment.
-
-  **CAUTION:** Avoid fire hazards, trip hazards, and alternate site burns when setting up energy instruments, to prevent user or patient injury.
-

-
-  **CAUTION:** Da Vinci instruments and accessories should only be used by surgeons trained in minimally invasive surgery.
-
-  **CAUTION:** Instruments may exhibit non-intuitive motion due to a lever press or external collision; unexpected instrument movement may cause tissue injury.
-
-  **CAUTION:** Da Vinci instruments and accessories should be handled and operated by trained personnel.
-
-  **CAUTION:** Handle instruments with care. Avoid mechanical shock or stress that can cause damage to the instruments, because tissue injury could result.
-
-  **CAUTION:** Da Vinci instruments are designed and manufactured for a specific surgical function. Use of an instrument for a task other than the instrument's designed use (such as off-label use) may result in a damaged instrument or patient injury.
-
-  **CAUTION:** Avoid collisions or contact between the endoscope arm and instrument arms to prevent patient tissue damage.
-
-  **CAUTION:** Prior to using compatible third party devices with the da Vinci Xi System or the da Vinci X System, read all associated instructions for use.
-
-  **CAUTION:** Always have a backup instrument available to complete the surgical procedure in case of instrument failure.
-
-  **CAUTION:** Only use the instruments as directed.
-

Inspection Before Use

Before use, all instruments should be visually inspected for damage or irregularities. Do not use the instrument if damage or abnormalities are observed. Examples of damage include:

- Broken cables or wires
- Scratches, cracks or broken parts on the instrument shaft
- Cracks or missing pieces where the grips attach to the shaft
- Broken, bent, misaligned or gouged instrument tips
- Cracked or broken pulleys near the instrument tips
- Cracks or missing pieces on the outer components surrounding the pulleys
- Loose tip or grips
- Broken lever guards (if applicable)

2.3 Intraoperative Use

General Precautions for Intraoperative Use of Instruments

-
-  **WARNING:** Make sure that the instrument moves smoothly in and out of the cannula. Do not force the instrument through the cannula, because the instrument could be damaged such that components fall in the patient.
-

-
-  **WARNING:** Do not use an instrument to clean debris from another instrument inside the patient. This may result in damage to the instruments or other unintended consequences, such as disconnection of the instrument tip, which could result in patient injury. To clean an instrument intraoperatively, remove the instrument from the system, and wipe the instrument tip with moist sterile gauze.
-
-  **WARNING:** Do not manipulate instruments that are outside of the field of view. This may damage the instruments or injure tissue inside or outside the field of view.
-
-  **CAUTION:** Da Vinci instruments must be used with the appropriate size and type Intuitive cannula, because tissue injury or instrument damage could result. See [Chapter 11 Cannulas, Obturators, Reducer, and Cannula Seals](#) on page 107 for details.
-
-  **CAUTION:** Do not remove the cannula assembly and instrument from the body simultaneously because this may damage the surrounding tissues and the instrument.
-
-  **Note:** If instruments cannot be manipulated in a precise and controlled manner, or if instrument motion appears to be non-intuitive, carefully remove the instrument and return the instrument to Intuitive Surgical. Contact Intuitive Customer Service immediately.
-
-  **Note:** If, while operating, you move the hand controls and no instrument motion occurs, there may be an interference between instruments or arms, or between an arm and the patient. Resolve the interference before proceeding with the surgery.
-
-  **Note:** In order to minimize residual soil on the instrument, keep the tips and wrist moist during intraoperative use.
-
-  **Note:** For further details and instructions on instrument installation, insertion, and removal, see the applicable system user manual.
-

For details on intraoperative use of Single-Site instruments and accessories, see [3.3 Intraoperative Use](#) on page 39.

For details on intraoperative use of cannulae, see [11.8 Cannula System Intraoperative Use](#) on page 126.

Instrument Installation onto Patient Cart Arm

-
-  **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:** Properly use Instrument Release Kit to release instrument jaws from tissue during system faults or power losses, to prevent patient injury.
-
-  **WARNING:** The instrument may not be immediately visible when being moved from the cannula into the patient. Move the endoscope to visualize the instrument and use caution when inserting instruments into the patient to avoid tissue injury.
-

 **WARNING:** Make sure that the instrument moves smoothly in and out of the cannula. Do not force the instrument through the cannula, because the instrument could be damaged such that components fall in the patient.

 **WARNING:** During instrument insertion using Single-Site instruments, including during Guided Tool Change, avoid excessive force because the tip could move beyond the intended position, or the instrument could be damaged due to flexibility of the shaft, resulting in patient injury.

 **WARNING:** Do not use excessive force while inserting an instrument during Guided Tool Change to avoid tissue injury.

 **WARNING:** Do not manipulate instruments that are outside the surgeon's field of view, to prevent patient tissue damage.

 **Note:** When using Guided Tool Change with Single-Site instruments, there could be a small lateral offset in the tip position of the newly inserted instrument due to the flexibility of the instrument shaft.

For information on the 8 mm Instrument Introducer (for use with EndoWrist instruments), see [8 mm Instrument Introducer](#) on page 31.

Instrument Insertion

Follow the steps below to install instruments onto the Patient Cart arm.

 **WARNING:** Inserting an instrument into the cannula without closing the grips can damage the cannula seal resulting in loss of insufflation or fragments in patient.

 **WARNING:** Inserting or removing an instrument without straightening the wrist can damage the instrument resulting in fragments in patient.

1. **Before** installing the instrument onto the sterile adapter and into a cannula, make sure the wrist is straight and close the tips (if applicable). This will ensure easy insertion into the cannula and prevent damage to the instrument. Do not fully close the Clip Applier, as this would prematurely lock the clip.
2. Insert the instrument tip straight down into the cannula and press the instrument housing into the sterile adapter. The instrument is engaged when an audible tone sounds and a solid blue LED light is illuminated.
3. Use caution and view the instrument tip with the endoscope when manually inserting an instrument into the patient.

Additional Notes for Single-Site Instrument Insertions

- Due to the flexibility of the instrument shaft, support the instrument housing and shaft during insertion. Use care when inserting the instrument into the cannula to avoid catching the tip on the seal or cannula bowl, bending the shaft excessively or puncturing the arm drape with the instrument tip. Use the integrated flex strips to provide clearance for the instrument during insertion.
- When requesting an instrument exchange, refer explicitly to the Patient Cart arm number, instead of “right” or “left”.



Note: In the 3D viewer, Tool Association icons are not available for Single-Site instruments.



Note: When Single-Site instruments are placed through a curved cannula, it is not necessary to use the built-in, 5 mm cap on the 5 - 10 mm Single-Site Cannula Seal (PN 478161) to maintain insufflation. Use of the cap can lead to increased friction.

Instrument Removal



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 the instrument, break or disconnect the tip, or bend the shaft, which could result in patient injury.



WARNING: When swapping arms, be sure to safely and effectively swap to unassociated arms to prevent tissue injury.



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



WARNING: Use the instructions to manually open instrument jaws to release tissue to prevent injury.



WARNING: Manually open the instrument jaws when an Instrument Release Kit is not available and provide instructions on how to do so, to prevent patient tissue injury.



WARNING: Single-Site instrument jaws may close upon removal. Before requesting an instrument exchange, pull the instrument end effector away from tissue, close the grips (if applicable), and straighten the wrist (if applicable) to avoid damaging tissue or the instrument upon removal from the cannula.

CAUTION: Instrument removal during a procedure should be performed only when the Surgeon Console operator is informed of the removal and has the instrument in full view and not grasping tissue or any other element that may lead to injury (for example, suture).

Removing Instruments from the Patient Cart Arm

Follow the steps below to remove instruments from the Patient Cart arm.

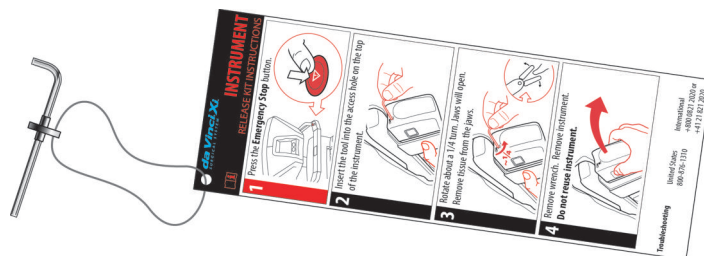
1. Make sure the surgeon is ready before removing an instrument.
2. Ensure that the tips are not grasping tissue before removing an instrument.
3. Straighten the instrument wrist and close the grips under endoscopic vision before removing the instrument through the cannula.
4. Clearly communicate with the surgeon which instrument is about to be removed. Identify the instrument by both name and arm number.
5. Confirm that the surgeon is ready for the instrument to be removed.
6. Squeeze the release buttons on the instrument housing and pull the instrument straight up and out through the cannula.

Note: For further details and instructions on instrument installation, insertion, and removal, see the applicable system user manual.

Manual Grip Release

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 in the Instrument Release Kit (PN 381216) shown in Figure 2.2 allows the patient-side operator to manually release the grips.

Figure 2.2 Instrument Release Kit



WARNING: Do not use the grip release wrench on a non-faulted system without first pressing the Emergency Stop button. Failure to observe this warning may result in unintended instrument motion, damage to the grip release mechanism, or patient injury.

WARNING: In case of system failure while the instrument is grasping tissue, the grips (jaws) can be opened manually by inserting the grip release wrench, and following the Grip Release instructions in the *da Vinci Xi System User Manual* or the *da Vinci X System User Manual* to prevent patient harm.

-
-  **WARNING:** Use visualization of the surgical site when inserting the grip release wrench, opening jaws, clearing jaws from tissue, and removing instruments from the system, to prevent patient injury.
-
-  **WARNING:** The direction of rotation is indicated on the Instrument Release Kit tag. Rotating the wrench in the incorrect direction or over-rotating can lead to tissue injury through unintended instrument motion or damage to the manual grip release mechanism.
-
-  **WARNING:** The Instrument Release Kit (PN 381216) must be individually sterile-wrapped, labeled, and placed in the Vision Cart drawer. Surgeon and OR staff must always know where the sterile-wrapped Instrument Release Kit is located in case it is needed to manually release an instrument to prevent patient injury.
-
-  **WARNING:** To prevent tissue injury, use only the Instrument Release Kit (PN 381216) with da Vinci Xi and da Vinci X instruments.
-
-  **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 patient injury.
-
-  **WARNING:** Follow the grip release tool instructions to manually open the instrument jaws when the system is in a faulted or unpowered state, to prevent patient injury.
-
-  **CAUTION:** During grip release when using Single-Site instruments, tissue or objects may move as the grips are released, due to the flexibility of the shaft.
-
-  **Note:** Visualization is needed during the use of the grip release wrench.
-
-  **Note:** For further details and instructions on grip release, see the applicable system user manual.
-
-  **Note:** When using Single-Site instruments, if grip motion is still not observed after confirming the system is in a faulted state and the grip release wrench has been turned counter-clockwise (approximately 1/4th turn), follow the steps in the [Troubleshooting Single-Site Instruments with Closed Grips](#) on page 22.
-

Troubleshooting Single-Site Instruments with Closed Grips

This section explains how to troubleshoot da Vinci Xi Single-Site grasping instruments if the grips become fixed in the closed position while gripping tissue, and when correctly following the Instrument Release Kit procedure does not release the grips. The grips can become fixed in the closed position due to a break at the proximal end, as described in [Single-Site Instrument Breaks](#) on page 23.

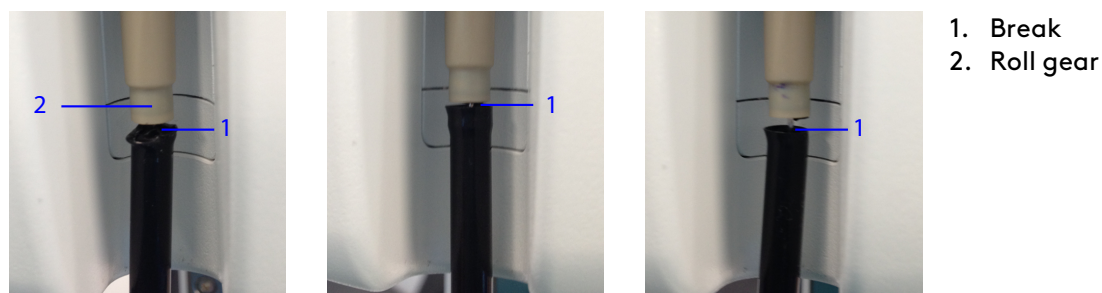
Applicable instruments include:

- 5 mm Medium-Large Clip Applier (PN 478053)
- 5 mm Maryland Dissector (PN 478050)
- 5 mm Cadiere Forceps (PN 478055)
- 5 mm Fundus Grasper (PN 478058)
- 5 mm Crocodile Grasper (PN 478059)
- 5 mm Bipolar Maryland (PN 478080)
- 5 mm Fenestrated Bipolar Forceps (PN 478093)
- 5 mm Curved Needle Driver (PN 478088)

Single-Site Instrument Breaks

An instrument can break where the shaft meets the roll gear either from prior mishandling or when excessive force is applied when inserting an instrument through the cannula (Figure 2.3).

Figure 2.3 Examples of breaks at the roll gear and instrument shaft junction



If the instrument breaks, bends or separates at the location where the shaft and roll gear meet, the open and close mechanism on the instrument grips can become damaged, causing the grips to remain fixed in a closed position. If the shaft completely separates from the roll gear, it is possible that the Instrument Release Kit may also not work.

Note: Damage may be hidden by the black outer shaft covering, or there may be damage to components inside the housing. The break may not be as obvious as those shown in Figure 2.3.

Manually Opening Grips

If the grips cannot be opened from the hand controls at the Surgeon Console or by using the Instrument Release Kit due to damage to the shaft and/or roll gear, the grips can be opened manually.

WARNING: Keep a grip release kit available for use during procedure to prevent patient injury from a closed and unresponsive instrument jaw on vital tissue prior to instrument removal.

WARNING: Only use the grip release 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.

WARNING: When using the grip release wrench from the Instrument Release Kit, hold the Patient Cart arm and instrument steady before inserting and turning the wrench, to prevent possible patient injury.

To manually open the grips:

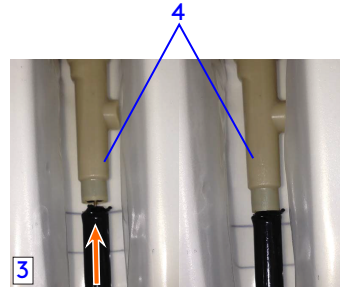
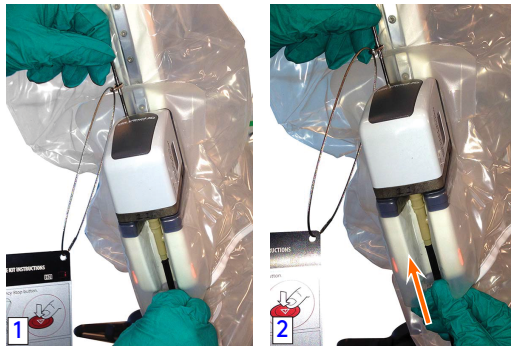
1. Make sure that the grips are open (from the hand controls).
2. Verify that the Emergency Stop button was pressed, and the system is still in a faulted state.
3. Verify that the grip release tool is in place in the housing, and carefully turn the tool counterclockwise (approximately 1/4th turn) until it engages and can no longer turn. Keep the tool engaged during the following steps ([Figure 2.4](#)).

Figure 2.4 Keep the grip release tool engaged while manually opening the grips



4. Under visualization, have the patient-side assistant grasp the instrument shaft below the break (Figure 2.5 1) and manually pull the shaft back toward the instrument housing (Figure 2.5 2) to reduce the gap between the broken components (Figure 2.5 3).

Figure 2.5



1. Grasp the instrument shaft below the break
2. Pull the shaft toward the housing
3. Reduce the gap between separated components
4. Roll gear

If the black outer shaft covering or other components inside the housing are blocking the shaft from being pulled back toward the housing, a slight twisting motion of the roll gear (the tan color piece) may help to move the obstruction (Figure 2.6). Use forceps to twist the roll gear while holding the shaft firmly in place. Do not rotate the shaft.

Figure 2.6 Using forceps, twist the roll gear while holding the shaft in place



1. Roll gear



Note: Twisting the roll gear should only be performed under endoscopic view, as the instrument grips may also twist.



CAUTION: During grip release when using Single-Site instruments, tissue or objects may move as the grips are released.

5. Under visualization, clear the tissue from the grips. If needed, adjust the Patient Cart arm to position the instrument away from the tissue. Support the arm before clutching, to prevent unintended instrument motion.
6. After the tissue is cleared from the grips, squeeze the release levers on the sides of the instrument housing and pull the instrument out. Do not re-use 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 manually opening the instrument grips, either with the Instrument Release Kit, or by following the steps above, handle the instrument using standard biohazard safety precautions, and return the affected instrument to Intuitive by contacting Customer Service.

Instrument Cable Management

Always maintain sterility of the instrument cables during all modes of use. Intuitive recommends use of atraumatic clamps to secure the cables to the sterile drapes. Do not hang the instrument cable over the arm as it may get caught or damaged and limit the arm.

 **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.

 **WARNING:** Do not place 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:** Drape tears due to interactions between arms and instruments could cause breach of sterility.

 **WARNING:** Do not drape cables through or over the Patient Cart arms, to prevent unintended motion of instruments or endoscopes which may result in patient injury.

 **Note:** Use clamps or other sterile methods to manage energy cables to avoid contamination of the cables and to reduce force exerted on the instruments.

2.4 EndoWrist Instrument Overview

Device Description

EndoWrist Instruments are multiple-use endoscopic instruments to be used in conjunction with the da Vinci Xi System and the da Vinci X System. EndoWrist Instruments have 8 mm diameter rigid shafts. The total length of the shaft is approximately 21 inches (53 cm) for EndoWrist Instruments. For a list of all 8 mm EndoWrist instruments, see [Table 2.1](#).

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

 **WARNING:** Do not activate Harmonic Ace when the system is faulted to prevent patient harm due to insufficient seal.

 **WARNING:** Do not attempt a robotic activation of Harmonic Ace while a laparoscopic instrument is connected to a generator. Doing so could cause patient harm if the instrument is in contact with tissue or operator.

 **WARNING:** Only use a compatible ultrasonic hand piece for Harmonic Ace, to prevent tissue injury from instruments not functioning or performing as expected.

 **CAUTION:** Instruments described in this manual are compatible with ONLY the da Vinci Xi System and the da Vinci X System.

 **CAUTION:** Refer to and follow the third-party instructions for use for approved third-party accessories (for example, seal and tube set). Failure to follow the instructions for use may result in loss of insufflation, which may cause procedure delay or patient injury.



CAUTION: Connecting third-party accessories to the cannula may result in reduced range of motion of instruments due to interference between the accessories and instrument carriage.

Table 2.1 EndoWrist Instruments

Instrument Description/Name		Part Number (PN)
Monopolar Cautery Instruments		
8 mm Monopolar Curved Scissors		470179
8 mm Permanent Cautery Hook		470183
8 mm Permanent Cautery Spatula		470184
Bipolar Cautery Instruments		
8 mm Maryland Bipolar Forceps		470172
8 mm Fenestrated Bipolar Forceps		470205
8 mm Curved Bipolar Dissector		470344
8 mm Micro Bipolar Forceps		470171
8 mm Long Bipolar Grasper		470400
Needle Drivers		
8 mm Large Needle Driver		470006
8 mm Mega™ Needle Driver		470194
8 mm Large SutureCut™ Needle Driver		470296
8 mm Mega SutureCut Needle Driver		470309
Graspers		
8 mm Black Diamond Micro Forceps		470033
8 mm ProGrasp Forceps		470093
8 mm Tenaculum Forceps		470207
8 mm Tip-up Fenestrated Grasper		470347
8 mm Resano Forceps		470181
8 mm Small Graptor™ (Grasping Retractor)		470318
8 mm Long Tip Forceps		470048
8 mm Cadiere Forceps		470049
8 mm Cobra Grasper		470190

(continues on next page)

Table 2.1 EndoWrist Instruments (continued)

Clip Appliers	
8 mm Large Clip Applier	470230
8 mm Medium-Large Clip Applier	470327
8 mm Small Clip Applier	470401
Specialty Instruments	
8 mm Dual Blade Retractor	470249
8 mm Atrial Retractor Short Right	470246
8 mm Cardiac Probe Grasper	470215
8 mm DeBakey Forceps	470036
8 mm Suction Irrigator	480299
Scissors	
8 mm Potts Scissors	470001
8 mm Round Tip Scissors	470007

The following table shows da Vinci Xi EndoWrist instrument compatibility with approved third-party clips and bulldog clamps.

Table 2.2 Da Vinci Xi Instrument and third-party product compatibility

Da Vinci Xi Instruments	Third-party Products
EndoWrist Large Clip Applier	WECK® Hem-o-lok® large polymer clip (PN 544240)
EndoWrist Medium--Large Clip Applier	WECK Hem-o-lok medium-large polymer clip (PN 544230)
EndoWrist Small Clip Applier	WECK Horizon Small-Wide titanium clip (PN 001201 or PN 001205)
EndoWrist ProGrasp Forceps	Clamps that are approved for use in robotic assisted applications and that can fit through standard cannulae
EndoWrist Cardiac Probe Grasper	Probes that are approved for use in robotic assisted applications and that can fit through standard cannulae

8 mm Instrument Introducer

For 8 mm, delicate tipped and sharp instruments, the reusable, 8 mm instrument introducer accessory (PN 342562, also known as the Instrument Introducer) is used to preserve the integrity of instrument tips and the 5 - 8 mm cannula seal during instrument insertion and removal. The instrument introducer ([Figure 2.7](#)) should be used when introducing the Potts Scissors and Black Diamond Micro Forceps into an 8 mm cannula with a 5 - 8 mm cannula seal.

WARNING: Ensure the proper use of the Instrument Introducer to create a path for the instrument tips through cannula seal and do not leave it in the seal while instruments are installed on the system. Failing to do so may cause damage to the instruments or cause components to fall into the patient.

Figure 2.7 Instrument Introducer



1. Before using an instrument introducer, inspect the instrument introducer for damage. If any damage, cracks or tears are observed, obtain another instrument introducer.
2. Before inserting the fine-tipped instrument into an 8 mm cannula with a 5 - 8 mm cannula seal, slide the wider end of the instrument introducer onto the instrument shaft until the tips are completely covered by the sleeve of the instrument introducer ([Figure 2.8](#)).

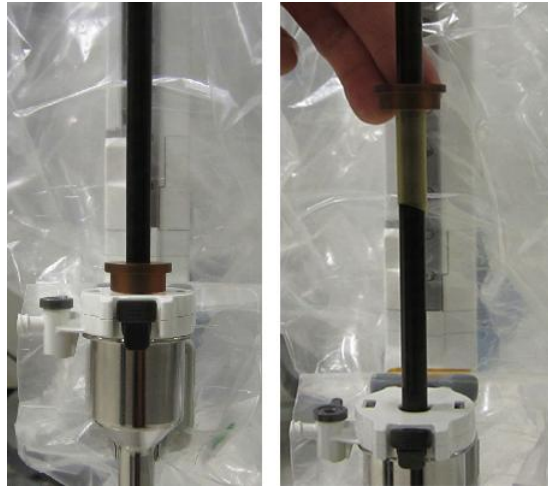
Figure 2.8 Example of instrument introducer accessory on instrument shaft



3. With the instrument introducer installed on the instrument tip, insert the instrument straight down into the cannula and seal, and slide the instrument housing into the sterile adapter.
4. To ease insertion, rotate the instrument introducer while inserting through the cannula seal. Moistening the cannula seal with saline may aid insertion.

5. After the instrument is engaged onto the Patient Cart arm, slide the instrument introducer up the instrument shaft away from the cannula seal ([Figure 2.9](#)).

Figure 2.9 Sliding the instrument introducer up the shaft



6. Immediately before removing the instrument, slide the instrument introducer back down the instrument shaft and through the cannula seal ([Figure 2.10](#)).

Figure 2.10 Sliding the instrument introducer down the shaft before instrument removal



7. Remove the instrument and the instrument introducer together.
8. Continue to use the instrument introducer accessory for all insertions of the Potts Scissors and Black Diamond Micro Forceps into an 8 mm cannula with a 5 - 8 mm cannula seal during the surgical procedure.

2.5 Single-Site Instrument Overview

Device Description

Single-Site Instruments are multiple-use endoscopic instruments to be used in conjunction with the da Vinci Xi System and the da Vinci X System. Single-Site Instruments have 5 mm diameter semi-rigid shafts. The total length of the shaft is approximately 20 in. (50.8 cm) for Single-Site Instruments. For a list of all Single-Site Instruments, see [Table 2.3](#).



CAUTION: Single-Site instruments described in this manual are compatible with ONLY the da Vinci Xi System and the da Vinci X System.

Table 2.3 Single-Site Instruments

Instrument Description/Name	Part Number (PN)
Monopolar Cautery Instruments	
5 mm Permanent Cautery Hook	478090
Bipolar Cautery Instruments	
5 mm Bipolar Maryland	478080
5 mm Fenestrated Bipolar Forceps (Bipolar Fenestrated)	478093
Needle Drivers	
5 mm Curved Needle Driver	478088
5 mm Wristed Needle Driver	478115
Graspers/Dissectors	
5 mm Maryland Dissector	478050
5 mm Cadere Forceps	478055
5 mm Fundus Grasper	478058
5 mm Crocodile Grasper	478059
Clip Appliers	
5 mm Medium-Large Clip Applier	478053
Scissors	
5 mm Curved Scissors	478057
Specialty Instruments	
5 mm Suction Irrigator	478054

The following table shows Single-Site instrument compatibility with approved third-party products.

Table 2.4 Single-Site and third-party product compatibility

Single-Site Products	Third-party Products
Single-Site Medium--Large Clip Applier	WECK Hem-o-lok medium-large polymer clip (PN 544230)
Single-Site Suction Irrigator	Stryker StrykeFlow 2 (PN 0250-070-500)
Single-Site 8 mm Endoscope Cannula	ERBE Cable for Return Electrode (PN 20194-085) ERBE NESSY® Plate 170 (PN 20193-070)

Single-Site General Warnings



WARNING: When using Single-Site instruments, excessive deflection of the instrument shaft may result in non-intuitive or uncontrolled tip motion that could result in tissue damage.



WARNING: When using wristed Single-Site instruments with roll motions, it may be possible for unexpected and non-intuitive motion of the wrist to occur that could result in tissue damage.



Note: The surgical workspace is limited to anatomy beyond the insertion depth of the curved cannulae ends. Areas that are closer to the incision site than the insertion depth of the cannulae are not accessible with the Single-Site instruments. For reference, the recommended range of surgical working depths is 17–28 cm from the incision site for the 5 x 300 mm curved cannulae, and 12–23 cm for the 5 x 250 mm curved cannulae. Always use the appropriate length cannulae for the target anatomy.

End of section

Chapter 3 Overview of Single-Site Surgery

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3.3	Intraoperative Use	39
3.4	Position the Setup Joints (da Vinci X System)	40
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3.1 Introduction

This chapter contains general instructions for use specific to the Single-Site instruments and accessories for use with the da Vinci Xi System and the da Vinci X System. The following section provides general information on setup for Single-Site surgery. Detailed information for using each type of instrument can be found in each instrument-specific chapter of this manual (for example, for large and medium-large clip appliers, see

[Chapter 4 Large and Medium-Large Clip Appliers](#) on page 58).

For information on Single-Site instruments, including intended use, device description, and general warnings and precautions, see [2.5 Single-Site Instrument Overview](#) on page 33 and [Appendix E Intended Use/Indications for Use](#) on page 138.

For information on the size, type and assembly of cannulae used with Single-Site instruments, see [Chapter 11 Cannulas, Obturators, Reducer, and Cannula Seals](#) on page 107.

Indications for Use

The Intuitive Surgical da Vinci Xi Single-Site instruments and accessories used with the da Vinci Xi Surgical System (IS4000) and the da Vinci X Surgical System (IS4200) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery, suction/irrigation and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the da Vinci Xi Single-Site Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, clip appliers, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, 8 mm endoscope cannula, flexible and rigid blunt obturators, cannula seal, and the Single-Site Port.

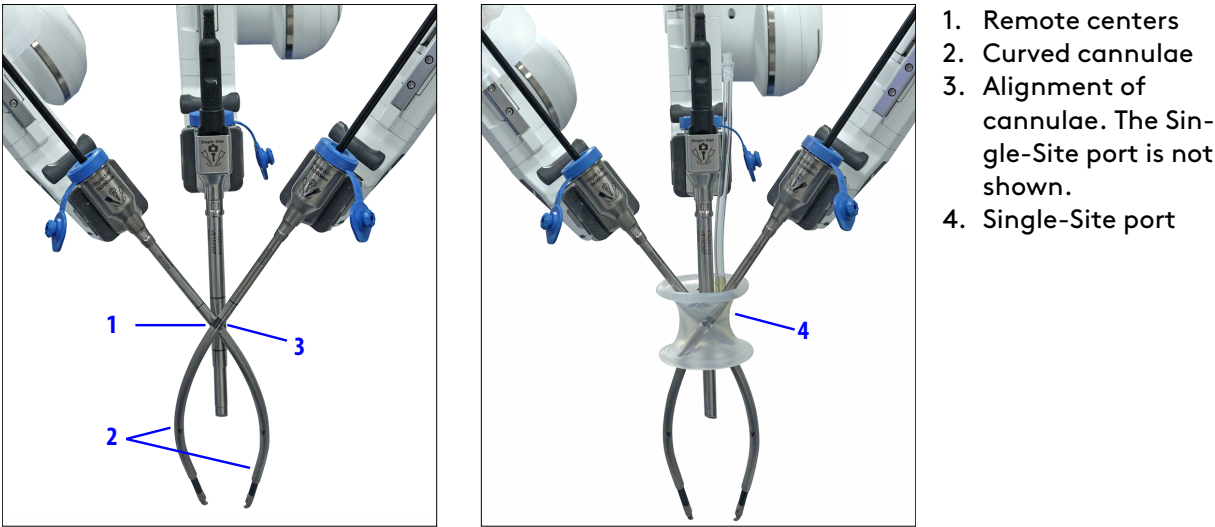


CAUTION: The safety and effectiveness of this device for use in the performance of general laparoscopic abdominal surgery or general gynecological surgery procedures have not been established. The da Vinci Single-Site instruments and accessories are only intended to be used for single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the da Vinci Single-Site instruments and the da Vinci Xi Surgical System (IS4000) and the da Vinci X Surgical System (IS4200).

3.2 Setup for Single-Site Surgery

Single-Site surgery on the da Vinci Xi System and the da Vinci X System is designed to be performed through a single skin incision using the Single-Site Port. The semi-rigid Single-Site instruments are designed to be used through curved cannulae, crossed over each other at the remote center within the Single-Site Port ([Figure 3.1](#)). See [Figure 3.2](#) for an illustration of the Single-Site Port.

Figure 3.1 Single-Site cannula configuration



This configuration enables triangulation at the surgical site while minimizing external interferences of the Patient Cart arms. To triangulate the instruments in the surgical field, you must orient the curved cannulae as indicated in [Figure 3.1](#). Each cannula is marked with an icon indicating its position relative to the other cannulae, as illustrated in [Table 3.1](#). After being docked for a procedure, cannulae should cross at their remote centers with the cannula tips pointing towards the surgical workspace (for example, target anatomy). See [Table 3.1](#) for cannulae markings and recommended arm-to-cannula configurations.

Table 3.1 Single-Site Cannula Markings and Arm Configurations

Cannula Name	Curved Cannula (Endoscope Left)	Endoscope Cannula	Curved Cannula (Endoscope Right)
Cannula Icon			
Da Vinci Xi Single-Site Patient Cart Arm Configurations	Arm 1	Arm 2	Arm 3
	Arm 2	Arm 3	Arm 4

(continues on next page)

Table 3.1 Single-Site Cannula Markings and Arm Configurations (continued)

Cannula Name	Curved Cannula (Endoscope Left)	Endoscope Cannula	Curved Cannula (Endoscope Right)
Da Vinci Xi Single-Site Patient Cart Arm Configurations	Arm 1	Arm 2	Arm 3

Note: On the da Vinci Xi System, dock arm 2 or 3 to the endoscope cannula, depending on which arm will be stowed. On the da Vinci X System, dock arm 2 to the endoscope cannula.

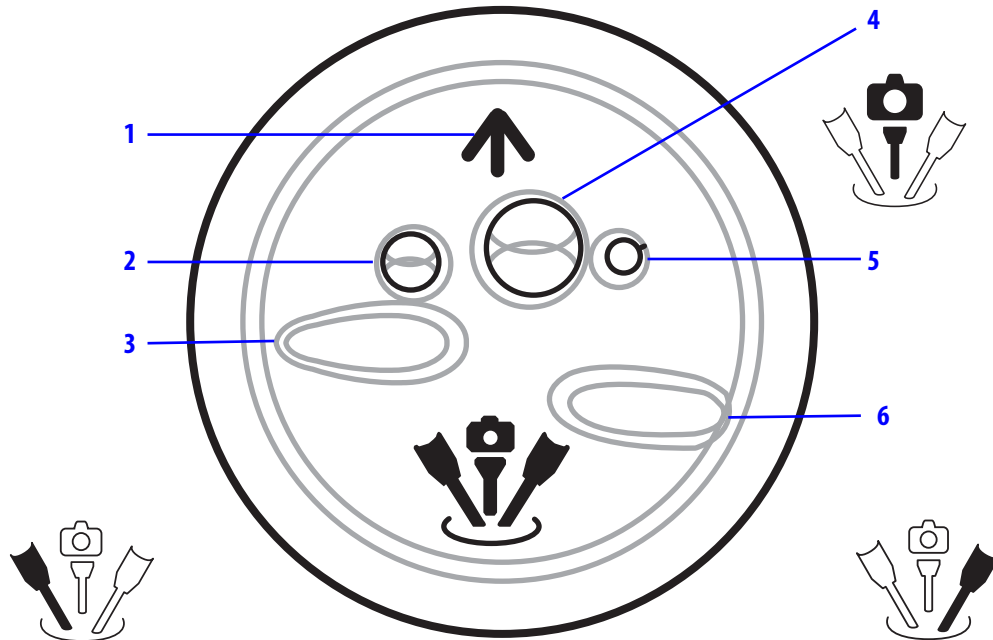
For more information on selecting and stowing a Patient Cart arm (three-arm procedure), see the applicable system user manual.

Note: The surgical workspace is limited to anatomy beyond the insertion depth of the curved cannulae ends. Areas that are closer to the incision site than the insertion depth of the cannulae are not accessible with the Single-Site instruments. For reference, the recommended range of surgical working depths is 17–28 cm from the incision site for the 5 x 300 mm curved cannulae, and 12–23 cm for the 5 x 250 mm curved cannulae. Always use the appropriate length cannulae for the target anatomy.

Single-Site Port

The Single-Site Port has four lumens to hold four cannulae and one lumen for the insufflation adapter. Each lumen, with the exception of the insufflation adapter lumen has a membrane that seals the lumen in the absence of a cannula to support insufflation of the abdomen prior to inserting cannulae. [Figure 3.2](#) illustrates the port markings and lumens.

Figure 3.2 Single-Site Port markings



1. Target anatomy arrow
2. 5 or 10 mm accessory cannula
3. Curved cannula endoscope left
4. Endoscope cannula
5. Insufflation adapter
6. Curved cannula endoscope right

i Note: The Single-Site Port for da Vinci Xi and da Vinci X is identical to the Single-Site Port for the da Vinci Si, with the exception of the lumen markings where the arm numbers have been replaced by icons corresponding to a cannula type.



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

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



WARNING: Do not use if package is damaged.

A breach in the sterile packaging of the device indicates possible contamination. Do not use the device if the packaging is not intact.



Note: The Single-Site Port (PN 478065) is sterilized with ethylene oxide (EO). It is shipped sterile and is for single use only.

Single-Site Instrument Inspection

For details on Single-Site instrument inspection, see [Inspection Before Use](#) on page 17.

Single-Site Instrument Installation onto Patient Cart Arm

For details on Single-Site instrument installation, see [Instrument Installation onto Patient Cart Arm](#) on page 18.

Single-Site Instrument Removal

For details on Single-Site instrument removal, see [Instrument Removal](#) on page 20.

3.3 Intraoperative Use

The following sections describe the recommended steps to place the Single-Site Port, insert curved and straight cannulae, and dock the system for Single-Site surgery.

- da Vinci Xi System: Patient Cart setup joints are positioned automatically. For more information on Patient Preparation or Patient Cart use for all surgery (including Single-Site surgery), refer to the *da Vinci Xi System User Manual*.
- da Vinci X System: Patient Cart setup joints are positioned manually.
 - For information on manually preparing the Patient Cart for Single-Site surgery, follow the setup instructions in section [3.4 Position the Setup Joints \(da Vinci X System\)](#) on page 40.
 - For information on Patient Preparation or Patient Cart use for Multi-Port surgery, refer to the *da Vinci X System User Manual*.



CAUTION: Always keep the tips of the instruments in view during use. Avoid large, sweeping motions during endoscope control that cause the instrument tips to leave the surgical view. Large cannula motions may generate excessive forces on the patient body wall, damage the port or cannulae, or result in loss of insufflation.



CAUTION: Interaction between the assistant cannula/instrument and the Single-Site cannulae/instruments should be limited whenever possible. Assistant should use the minimum amount of force necessary to achieve adequate visualization and exposure. Assistant interactions may generate excessive forces on the patient body wall, damage the port or cannulae, or result in loss of insufflation.



CAUTION: Keep all Intuitive seals and stopcocks closed. Check for leaks in system prior to changing insufflation tubing. Failure to identify leaks in system may result in loss of insufflation which may cause procedure delay or patient injury.

3.4 Position the Setup Joints (da Vinci X System)

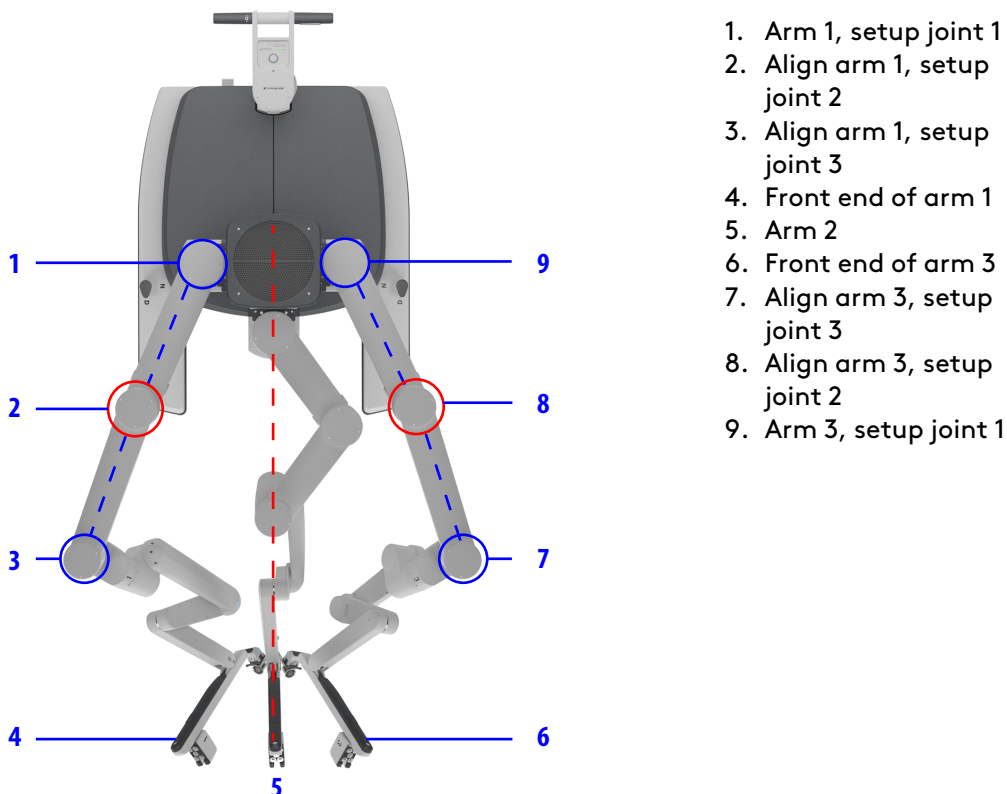
On the da Vinci X System, proper positioning of the setup joints maximizes range of motion for the Patient Cart arms and minimizes external collisions. Follow these steps:

1. Align arm 2 (used for the endoscope) with the Patient Cart column.
2. Set the **sweet spot** (optimal position) to maximize range of motion for arm 2. For details on setting the sweet spot, refer to the *da Vinci X System User Manual*.

3. For arms 1 and 3, position the setup joints as follows (Figure 3.3):
 - a. Straighten the second setup joint up to its rotation limit. There should be little or no bend in the second setup joint.
 - b. Rotate the third setup joint inward toward arm 2.

Note: Arm 4 not shown.

Figure 3.3 Align setup joints on the da Vinci X System



4. Position all arms high enough to clear the patient.

3.5 Place the Single-Site Port

This section describes the recommended steps to place the Single-Site Port. For more information on Patient Preparation or Patient Cart use, refer to the applicable system user manual.

Follow the steps below to place the Single-Site Port:

1. Prepare the port by connecting the stopcock to the insufflation adapter using sterile technique.
2. Create a midline incision within the umbilicus of approximately 1.5 cm to 2.5 cm using standard surgical technique.

An alternate port site or alternate skin incision may be used according to surgeon preference.

3. Using an atraumatic clamp such as a 9.25 in. (23.5 cm) curved Mayo-Guyon or Rochester-Pean, grasp and clamp the Single-Site Port approximately 13 mm (~1/2 in.) above its lower rim, so that it is folded. Make sure the curve of the clamp is above the lower rim of the folded port, and that the insufflation adapter barb is between the folds of the port and not caught in the clamp.
4. Lubricate the lower part of the port and clamp by wetting it with a sterile solution (for example, saline or sterile water).
5. Have an assistant provide counter traction using Army-Navy retractors within the incision.
6. Insert the leading edge of the folded port into the incision with a downward motion. As you begin to insert the port, follow the curve of the clamp as it enters the abdomen.
7. Once the entire lower rim of the port is inside the abdomen, hold the port in place with your free hand as you gently release and remove the clamps and retractors.
8. Point the arrow on the port toward the target anatomy; grasp its upper rim and gently rotate it within the incision.
9. Using sterile technique, connect standard insufflation tubing from the insufflation device to the stopcock to establish pneumoperitoneum.

3.6 Insert Cannulae

This section describes the recommended steps to insert curved and straight cannulae and dock the system. For more information on Patient Preparation or Patient Cart use, refer to the applicable system user manual.

For details on Single-Site cannulae, obturators and cannula seals, see [Chapter 11 Cannulas, Obturators, Reducer, and Cannula Seals](#) on page 107.

General Warnings and Cautions



WARNING: Insert curved cannula only under endoscopic visualization and use care to avoid injury to the patient.



WARNING: Once the da Vinci Xi System or the da Vinci X System is positioned, cannulae are placed in the patient and Patient Cart arms are attached to the cannulae, the surgical table **MUST NOT BE MOVED** in any way. Serious injury could result.

If intraoperative OR table movement is necessary, undock the da Vinci Xi System or the da Vinci X System, move the OR table, and re-dock the system.



WARNING: Excessive side loading of Single-Site instruments or use of damaged cannulae may lead to instrument damage resulting in potential particles falling in the patient. Always operate with the appropriate length cannulae and minimize lateral forces to avoid large shaft deflections during use.



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.

-
-  **WARNING:** Unexpected motion can occur when instruments collide, resulting in instrument damage, or patient injury. Ensure there is adequate room for instruments to move inside the patient and for the arms outside the patient to move without contacting the patient during the procedure. Ensure that the patient-side assistant can see all arms during the procedure and can alert the surgeon when the arms are close to contacting the patient.
-
-  **CAUTION:** Unintended instrument tip motion can occur when the instrument carriage and accessories connected to the corresponding cannula bowl, resulting in patient injury.
-
-  **CAUTION:** Avoid excessive tension on the port, which may cause the port to lose insufflation. Excessive tension can be caused by using the port clutch after docking.
-
-  **CAUTION:** To avoid damage to the Single-Site Port, all cannulae are to be inserted using blunt obturators.
-
-  **Note:** Properly rotate the stopcock and remove the seal, to prevent tissue injury to procedure delay.
-
-  **Note:** If, while operating, you move the hand controls and no instrument motion occurs, there may be an interference between instruments or arms, or between an arm and the patient. Resolve the interference before proceeding with the surgery.
-
-  **Note:** If interferences 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 or improperly placing remote centers while you adjust the set up joint positions.
-
-  **Note:** If interferences between the arms occur, ensure that the instruments are still fully engaged on the arm.
-
-  **Note:** Once the Patient Cart arms are docked, the port clutch button should only be used to reposition the remote center. If the port clutch button is used, use care to prevent sliding the cannulae out of the port site.
-
-  **Note:** Be aware that the cannulae are curved and for use with specific Patient Cart arms either to the left or right of the endoscope. See [Table 3.1](#).
-

Guidelines for Cannula Insertion and Placement

Before Proceeding with Cannula Insertion

1. Select the appropriate cannula, obturator, and seal. Using sterile technique, attach the appropriate sterile cannula seal to the cannula. Ensure that the seal is visibly seated around the circumference of the cannula bowl.

2. Insert the obturator fully into the cannula. Ensure that the obturator is seated firmly against the seal, the latches are fastened over the rim of the cannula, and the tip of the obturator appears at the distal end of the cannula tube. Dip the cannula assembly into sterile saline.

 **Note:** Always lubricate cannulae by dipping in sterile saline before inserting through the Single-Site Port.

 **Note:** Always hold the Single-Site Port in place when inserting or removing cannulae through the port to prevent port displacement.

Patient Safety

For patient safety during insertion of Single-Site cannulae, it is important to:

- Ensure that the patient is positioned to shift organs away from the port placement site and that an adequate level of insufflation has been achieved, before introducing the cannulae.
- Place and dock the endoscope cannula and insert the endoscope so that you can do the following:
 - Insert curved cannulae under endoscopic visualization.
 - Upon insertion of each cannula, maintain continuous control of the cannula tip until docked.

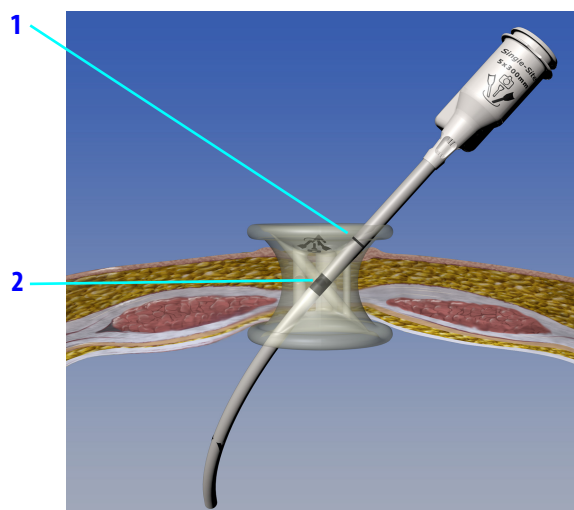
Cannula Placement

The remote center of **all** cannulae docked to the system, including the endoscope cannula, must be placed within the boundaries of the Single-Site Port. The remote center is designated by a thick black ring marked on the cannula tube. For reference, the thick black ring is in the center of the port when the top line (proximal black ring) is aligned with the top surface of the port ([Figure 3.4](#)).

Remote center placement, endoscope control and patient-side assistance all contribute to increased cannula loading and may result in potential cannula damage.

 **CAUTION:** Ensure that the remote centers of all cannulae are within the boundaries of the Single-Site Port. Failure to position the remote centers appropriately may generate excessive forces on the patient body wall, damage the port or cannulae, or result in loss of insufflation.

 **CAUTION:** Verify the placement of the remote center of the cannula to prevent potential damage to the cannula or tissue injury.

Figure 3.4 Curved cannula placement

1. Top line (proximal ring) coincident with the top of the port
2. Remote center band placed in middle of port

**Correct placement:**

- Top line aligned with top of port
- Remote center band within port

**Incorrect placement:**

- Top line NOT aligned with top of port
- Remote center band NOT contained within port

Endoscope Cannula

Follow the steps below to insert and dock the Single-Site endoscope cannula.

1. With the Single-Site Port inserted and the abdomen insufflated, dip the Single-Site endoscope cannula in sterile saline and insert the endoscope cannula into the endoscope lumen of the port using the blunt obturator. Apply continuous, controlled pressure during insertion through the port. When the cannula is at the correct insertion depth, the top line on the cannula will be level with the top of the Single-Site Port.
2. Remove the blunt obturator and insert the endoscope through the Single-Site endoscope cannula to manually assess the anatomy using the endoscope.
3. Make final patient positioning adjustments as needed; for example, reverse Trendelenburg for cholecystectomy or Trendelenburg for hysterectomy.

4. To further assess or move tissue, insert the Single-Site 5 mm accessory cannula and corresponding blunt obturator into the assistant lumen of the Single-Site Port. Proceed with tissue assessment using a 5 mm laparoscopic grasping instrument inserted through the accessory cannula. Use the built-in reducer cap of the 5 -10 mm Single-Site Cannula Seal (PN 478161) with the 5 mm laparoscopic instrument to maintain insufflation. For details on the cannula seal, see [Single-Site Cannula Seal](#) on page 124.



Note: When using monopolar cautery through the accessory cannula, ensure that the patient neutral pad (grounding pad) cable is connected to the patient neutral pad cable receptacle on the endoscope cannula and to a patient neutral pad (commonly referred to as a grounding pad), previously attached to the patient. For details, see [Connect Patient Neutral Pad Cable to Endoscope Cannula](#) on page 54.

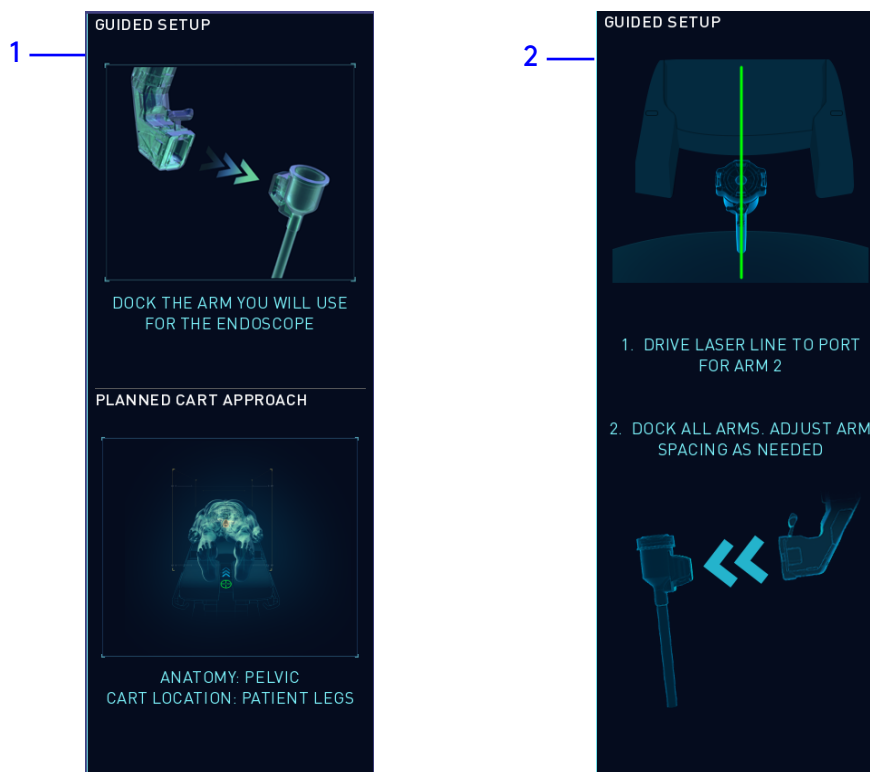
5. After tissue assessment, remove the laparoscopic instrument, accessory cannula, and endoscope and prepare to dock the endoscope cannula.
6. With only the endoscope cannula inserted in the Single-Site Port and the patient in final positioning, a non-sterile person uses the Patient Cart Drive to move the Patient Cart into the sterile field for docking.

For more information on positioning the Patient Cart, follow the steps in the applicable system user manual.

7. Proceed with positioning the Patient Cart until the laser line(s) are aligned with the Single-Site endoscope cannula. The da Vinci Xi System uses two laser lines and the da Vinci X System uses one laser line.

The Vision Cart touchscreen gives guidance for docking.

Figure 3.5 Dock initial endoscope arm (examples)



1. Da Vinci Xi Vision Cart touchscreen
2. Da Vinci X Vision Cart touchscreen

Note: On the da Vinci Xi System, dock arm 2 or 3 to the endoscope cannula, depending on which arm will be stowed. On the da Vinci X System, dock arm 2 to the endoscope cannula.

8. Identify the arm that will be used for the Single-Site endoscope cannula.
 - Da Vinci Xi: Use either arm 2 or arm 3.
 - Da Vinci X: Use arm 2.

Position the arm and dock it to the endoscope cannula. Docking for Single-Site follows the standard docking process for the system. See the applicable system user manual for details on docking.

9. Ensure that there is adequate spacing (about a fist's spacing) between the Patient Cart arm LEDs to enable movement without interference with adjacent arms or the patient. See the applicable system user manual for details on spacing the arms.

10. After the Single-Site endoscope cannula is docked, insert the endoscope, stabilize the endoscope cannula, and proceed as follows:
 - Da Vinci Xi: Proceed with targeting the patient anatomy. Follow the instructions in [Targeting on the da Vinci Xi System](#) on page 48.
 - Da Vinci X: Targeting functionality is not available. Continue to the instructions in the [Curved Cannulae](#) on page 50, which describes how to insert the cannulae into the Single-Site Port.

 **Note:** Ensure that the tubing and fittings (for example, insufflation and/or smoke evacuation) have adequate clearance to the patient after docking, final patient positioning, and throughout the procedure.

Targeting on the da Vinci Xi System

 **Note:** Targeting functionality is not available on the da Vinci X System.

Targeting for Single-Site surgery on the da Vinci Xi System aligns the Patient Cart boom and patient clearance joints to prepare for docking the Single-Site curved cannulae. During targeting, when the Single-Site endoscope cannula is docked, the patient clearance joint on the undocked inner arm (arm 2 or arm 3) will adjust to prepare the inner arm for docking the curved cannulae. After the curved cannulae are docked, the patient clearance joint on the docked inner arms can be manually adjusted to any position to optimize arm alignment and patient clearance.

1. In the following situations, adjust the patient clearance joint manually, while monitoring the patient:
 - If targeting does not complete, attempt to complete targeting by following the targeting steps in the *da Vinci Xi System User Manual* or by manually adjusting the patient clearance joint prior to docking the curved cannula.
 - If targeting is skipped, manually adjust the patient clearance joint prior to docking the curved cannulae.
 - If the patient clearance joint does not adjust during targeting due to an interference, clear the interference and check patient clearance. Then use the patient clearance buttons on the arm to adjust the patient clearance joint.

See [Figure 3.6](#) for Vision Cart touchscreen guidance and [Figure 3.7](#) for an example of proper patient clearance joint rotation.

Figure 3.6 Target patient anatomy and align the port Target Anatomy Arrow on da Vinci Xi Vision Cart touchscreen

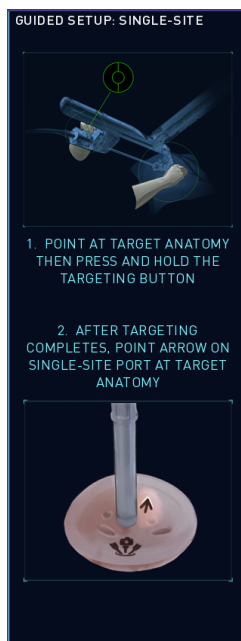
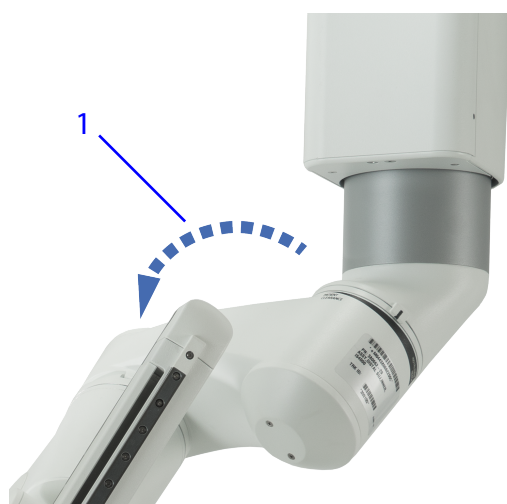


Figure 3.7 Example of patient clearance joint position on da Vinci Xi



1. Direction of patient clearance joint rotation

2. After targeting is complete, check that the Target Anatomy Arrow (Figure 3.2) on the Single-Site Port is still pointing at the target anatomy. If slight adjustment is needed, place the endoscope arm insertion access perpendicular to the body wall. Then grasp the upper rim of the port and gently lift and rotate the port within the incision.

See the *da Vinci Xi System User Manual* for details on targeting.

Curved Cannulae

Curved Cannula Length Selection

The 5 x 300 mm cannulae should always be used if intraoperative space permits. Do not adjust the remote center placement to create more intraoperative distance. If more intraoperative distance is required between the 5 x 300 mm cannulae and the target anatomy, perform the following steps under direct vision:

- Undock all arms and adjust patient positioning
- Adjust retraction of target anatomy
- Change to the shorter cannulae (5 x 250 mm)



CAUTION: Do NOT adjust the remote center placement to increase intraoperative distance. Improperly placed remote centers may generate excessive forces on the patient body wall, damage the port or cannulae, or result in loss of insufflation.



Note: Maintain visualization of the curved cannulae while docking the Patient Cart arms. If necessary, adjust the camera position to keep cannulae in the field of view.



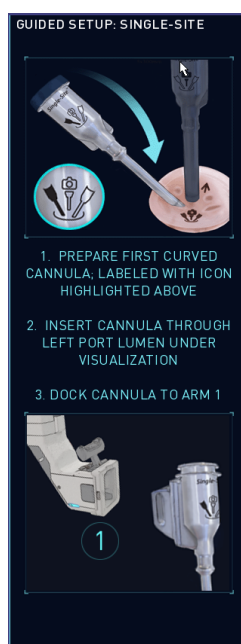
Note: To maintain control of the curved cannula tip after insertion, immediately dock each cannula after insertion.

Curved Cannula Insertion

Follow the steps below to insert and dock the Single-Site curved cannulae.

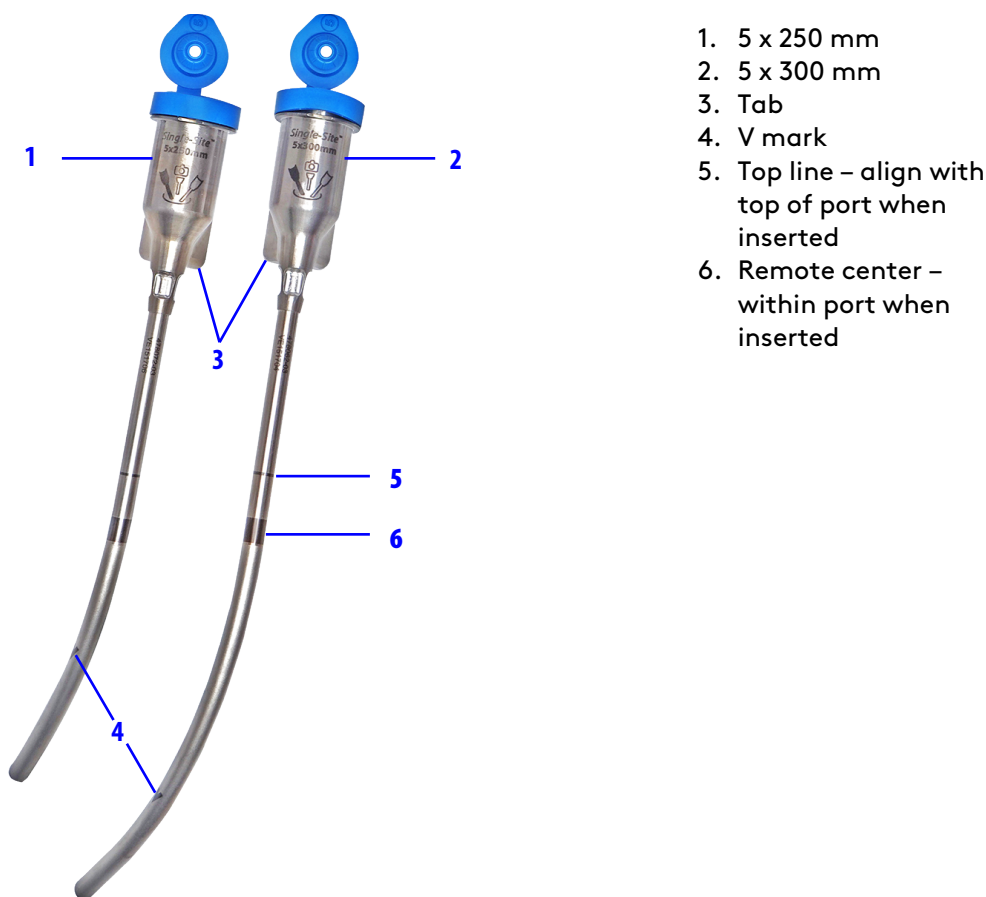
1. Prior to inserting the curved cannula, position the endoscope so that the curved cannula can be visualized upon entry into the abdomen. For example, with a 30° endoscope in the down position, extend the endoscope just within the tip of the endoscope cannula and position the endoscope shaft roughly perpendicular to the Single-Site Port so that the buttons on the endoscope housing face the lumen where the cannula will be inserted.
2. Begin the process of inserting the curved cannula by using the 5 x 300 mm Single-Site curved cannula (Endoscope Left). Ensure that the proper cannula is selected ([Figure 3.8](#)), is dipped in sterile saline before insertion into the port and that the 5 - 10 mm Single-Site Cannula Seal and appropriate blunt obturator are properly installed onto the cannula before proceeding.

Figure 3.8 Ensure that the proper cannula is selected (Vision Cart touchscreen)



3. Start inserting the cannula in the designated port lumen with the cannula icon facing toward the ceiling. As soon as the "V" mark reaches the top of the port, the tip of the obturator becomes visible below the bottom of the port in the endoscopic view. Lift and rotate the bowl of the cannula away from the endoscope to bring the tip into view if it is not immediately visible in the endoscopic view.

Figure 3.9 Single-Site curved cannulae



4. With the cannula tip in view on the Vision Cart touchscreen, continue inserting toward the target anatomy. While inserting the cannula, rotate the endoscope back to its original position, and tilt the endoscope view towards the target anatomy.
5. Continue to insert the cannula until the top line on the cannula shaft (Figure 3.9) is level with the top of the Single-Site Port.
6. With the 5 x 300 mm cannula inserted, observe the location of the tip and the "V" on the cannula shaft to assess which cannula length is appropriate to access the target anatomy. The "V" indicates the approximate location of where the tip of the 5 x 250 mm cannula would be when inserted. If the 5 x 250 mm cannula length is more appropriate, remove the 5 x 300 mm cannula and replace it with the 5 x 250 mm cannula following the steps above.

7. With the appropriate length cannula inserted correctly, hold the cannula in position as you proceed to docking the cannula.

 **Note:** Maintain visualization of the curved cannulae while docking the Patient Cart arms. If necessary, adjust the camera position to keep cannulae in the field of view.

 **Note:** To maintain control of the curved cannula tip after insertion, immediately dock each cannula after insertion.

8. Press the port clutch button or use the “Grab and Move” feature to move the Patient Cart arm within 5–8 cm (2–3 in.) of the cannula. Check and adjust the arm height in relation to the cannula using the port clutch button.
9. Use the instrument clutch button to adjust the angle of the arm so that it matches the angle of the cannula fin. Matched alignment is the key to successful docking.
10. While holding the cannula still in one hand, use the other hand to press the port clutch button to bring the arm in close proximity to the cannula fin.
11. Dock the cannula by pressing the cannula mount lever, inserting the cannula fin and releasing the cannula mount lever.
12. Remove the obturator and repeat insertion and docking steps for the remaining curved cannula. The Vision Cart touchscreen will continue to give guidance for docking the remaining arm.

 **Note:** After the curved cannulae are docked, the Patient Cart arm carriages will lower to facilitate insertion of Single-Site instruments.

13. After the curved cannulae are docked, check the arm alignment:
 - Da Vinci Xi: The patient clearance joint on the docked inner arms can be manually adjusted to any position for proper arm alignment and patient clearance.
 - Da Vinci X: The setup joints can be manually adjusted for proper arm alignment using the port clutch button. Ensure that there is still a straight line between setup joints 1, 2, and 3 on arms 1 and 3.

For more information on arm clutching, docking, patient clearance, or the “Grab and Move” feature, see the applicable system user manual.

Accessory Cannula

Follow the steps below to insert the Single-Site accessory cannulae.

1. With the endoscope installed and curved cannulae inserted and docked, if assistance is required for the surgical procedure, reposition the endoscope arm so that it is perpendicular to the Single-Site Port and does not impede the pathway of the accessory lumen.
2. Select the appropriate Single-Site accessory cannula and ensure that it is dipped in sterile saline before insertion into the port and that the 5 - 10 mm Single-Site Cannula Seal and appropriate blunt obturator are properly installed onto the cannula before proceeding.
3. After insertion of the accessory cannula, remove the blunt obturator and reposition the endoscope arm so the tips of the curved cannulae are visible on the Vision Cart touchscreen.

- Note:** Before proceeding, ensure that the accessory cannula Luer port is connected to an insufflator or smoke evacuation device, or is plugged with a Luer cap.

Connect Patient Neutral Pad Cable to Endoscope Cannula

- WARNING:** For Single-Site surgery, to avoid stray energy, ensure that a patient neutral pad is affixed to the patient and connected to the Single-Site endoscope cannula with a sterile patient neutral pad cable.

- Note:** The patient neutral pad attached to the Single-Site endoscope cannula is to be used in addition to the patient neutral pad attached to the generator. Intuitive does not provide or sell patient neutral pads or cables. Obtain them from a third party supplier.

Inspect the patient neutral pad cable for damage or irregularities before and after each use. Visually inspect the cords for physical damage including:

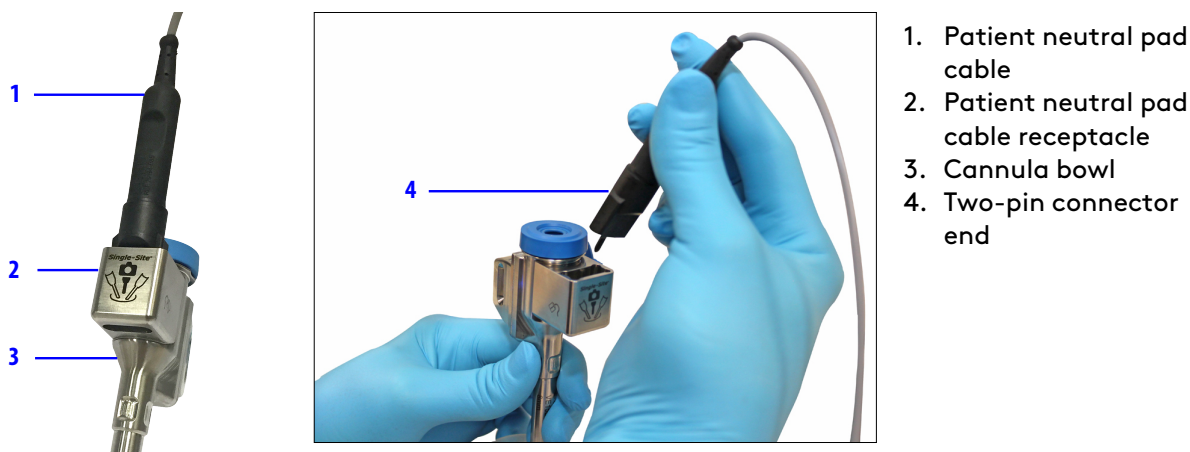
- Cracked, broken, or otherwise distorted parts
- Broken or significantly bent connector contacts
- Punctures, cuts, nicks, abrasions, unusual bumps, or significant discoloration

1. Before beginning surgery and using monopolar energy, use a compatible sterile patient neutral pad cable to connect the Single-Site endoscope cannula to a compatible patient neutral pad previously placed on the patient.

See [Table 2.4](#) for compatible patient neutral pads and cables.

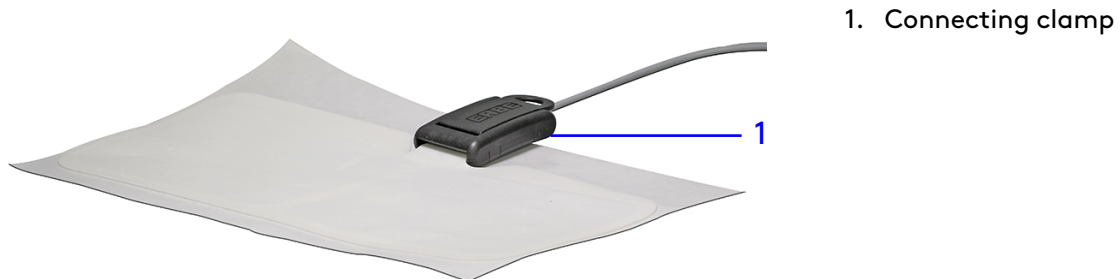
2. Insert the standard two-pin connector end of the patient neutral pad cable into the patient neutral pad cable receptacle located on the bowl of the endoscope cannula ([Figure 3.10](#)).

Figure 3.10 Connect the patient neutral pad cable (example)



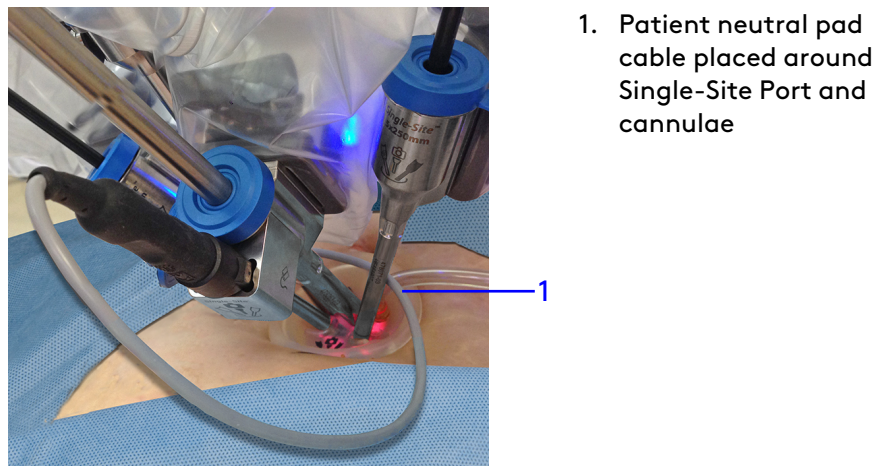
3. Attach the connecting clamp of the patient neutral pad cable to the patient neutral pad according to the manufacturer's instructions ([Figure 3.11](#)). See [Table 2.4](#) for cable and pad part numbers.

Figure 3.11 Connect the clamp to the patient neutral pad (example)



Note: For improved cable management throughout the procedure, place the patient neutral pad cable around the Single-Site Port and cannulae ([Figure 3.12](#)). This helps to retain the connection of the cable in the receptacle, and minimizes the length of cable that is free to move during the procedure. Do not place the patient neutral pad cable between cannulae, as it may get caught or damaged.

Figure 3.12 Placement of the patient neutral pad cable (example)



Release Tension and Check Cannula Placement

1. Before beginning surgery, ensure that the curved cannula tips are under direct visualization, and then release any tension built up on the Single-Site Port from the docking process. To release tension:

Da Vinci Xi:

- Simultaneously activate the port clutch buttons on any two of the docked arms to clutch all docked arms and adjust the port tension or position.

Da Vinci X:

- a. Surgeon: Grasp both the rim of the Single-Site Port and the port clutch button on one of the docked arms.
 - b. Assistant: Control the port clutch button on the other docked arm and the port clutch button on the endoscope arm (arm 2).
 - c. Surgeon and Assistant: Depress the port clutch buttons simultaneously, relieving any tension created on the body wall and/or the Single-Site Port during docking. Then release the port clutch buttons simultaneously.
2. Ensure that the remote centers of the cannula are properly placed by verifying that the top line on the cannula shafts ([Figure 3.9](#)) are coincident with the top of the port.

Cannula and Port Removal

i Note: Always hold the Single-Site Port in place when inserting or removing cannulae through the port to prevent port displacement.

1. Detach the cannula from the system, holding the cannula in place by hand.
2. While maintaining endoscopic visualization of the tip, first remove the curved cannula (endoscope right) and then the curved cannula (endoscope left) from the Single-Site Port.
3. Disconnect the patient neutral pad cable from the endoscope cannula and place it in the sterile tray for reprocessing, then remove the endoscope cannula from the Single-Site Port.

To remove the patient neutral pad from the patient, refer to the patient neutral pad manufacturer's instructions.

4. After all cannulae are removed, grasp the outer rim of the Single-Site Port and remove it gently from the incision.

i Note: Shield the incision site during port removal to prevent splatter.

3.7 Automatic Hand Control Associations

The da Vinci Xi System and the da Vinci X System recognize when Single-Site cannulae and instruments are installed correctly, and automatically assigns the Surgeon Console hand controls to compensate for the cannulae crossing at the remote center and restore intuitive control.

Arm Swap and Arm/Instrument Status

In the 3D viewer arm and instrument/endoscope status pod, after the curved cannulae are docked, the arm number, instrument name and status for each instrument switch to reflect the position in which the instrument is installed on each arm (Figure 3.13):

- When the surgeon looks into the 3D viewer, an arm swap message appears, requiring the arm swap pedal to be pressed in order to acknowledge an understanding of which hand control is associated to each instrument. The arm/instrument status areas to the left and right of the endoscope status area switch to the opposite sides of the screen.
- The instrument at the left side of the screen is re-associated with the left hand control and the instrument at the right side of the screen is re-associated with the right hand control.

Figure 3.13 Single-Site arm swap example



For details on hand control assignment, see the applicable system user manual.

End of section

Chapter 4 Large and Medium-Large Clip Appliers

Contents

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4.2	Intraoperative Use	59

i **Note:** This chapter describes both EndoWrist and Single-Site instruments and associated accessories. Unless otherwise specified, the information applies to both suites of instruments and accessories. For specific information on instruments and accessories not covered in this manual, see the user documentation distributed with those products.

4.1 Introduction

This section contains instructions for use specific to the EndoWrist Large Clip Applier and the EndoWrist and Single-Site Medium-Large Clip Appliers with the Weck Hem-o-lok Polymer Locking Ligation Clips.

⚠ **WARNING:** Do not grasp tissue with instruments not intended to grasp tissue, as tissue injury may result. For example, do not grasp tissue with clip appliers, which are made to hold and apply plastic ligation clips.

Weck Hem-o-lok Ligating Clips

⚠ **WARNING:** All instructions, precautions, and contraindications found with the Hem-o-lok ligating clips apply when clips are applied with the EndoWrist and Single-Site clip appliers.

i **Note:** Hem-o-lok ligating clips are manufactured by Teleflex Medical.

i **Note:** Hem-o-lok ligating clips are supplied sterile. DO NOT re-sterilize ligating clip cartridges.

⚠ **CAUTION:** The clip must be latched to ensure proper ligation of the vessel or tissue. Inspect the ligation site after application to ensure proper closure of the clip. The manufacturer recommends ligation of the renal artery, in procedures other than laparoscopic donor nephrectomy (See [Appendix E Intended Use/Indications for Use](#) on page 138), with more than one clip on the patient side with a minimum distal artery cuff of 2–3 mm beyond the distal clip. Application of a second clip on all other vessels should be dictated by the surgeon's judgment. Security of the closure should be confirmed after ligation. The Hem-o-lok Polymer Ligating Clip is not designated for use as a tissue marker. Before applying a clip, verify the structural size and condition of the vessel or structure and use the proper clip size. Ligating clip systems differ in closure characteristics according to clip design and other variables. It is the responsibility of the user to select structures for the application of clips and confirm clip security after placement, and after the use of other surgical devices in the immediate area of the application.

4.2 Intraoperative Use

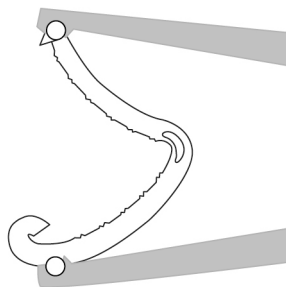
Precautions for Intraoperative Use

-  **WARNING:** Load the Clip Applier with the compatible clip sizes for each instrument, according to the instructions, to prevent components falling into patient.
-  **WARNING:** Inspect the grips for damage, bent components, or misalignment before use. If damage is observed, replace the instrument. Instrument could be damaged from mishandling during use or processing. Do not attempt to close the jaw down on a vessel or anatomic structure without a clip properly loaded into the jaws. Closure of empty jaws on a vessel or structure may result in patient injury.

Instructions for Intraoperative Use

1. Use only the compatible Weck Hem-o-lok clip cartridge. Intuitive does not assume responsibility for unsatisfactory results caused by the use of any instrument and clip that are not compatible.
2. To load the clip applier, ensure that the instrument jaws are fully open. Grasp the instrument at the intersection point of the two jaws in order to secure the wrist during clip loading. Carefully insert the jaws into the cartridge slot, making sure the jaws are perpendicular to the base of the cartridge. Gently press the applier over the clip until there is an audible click. Slightly rocking the jaws back and forth may assist in loading the clip. Do not force the applier into the cartridge or onto the clip. The applier should enter and withdraw from the cartridge easily.

Figure 4.1 Clip loaded in clip applier



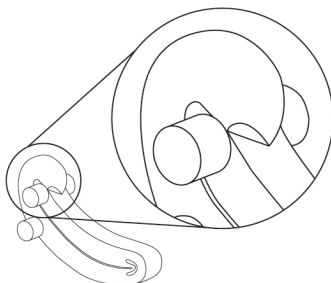
3. Remove the clip applier from the cartridge and confirm that the clip is securely held within the jaws.
4. Close the jaws until the tips of the clip are touching but the clip is not closed. Insert the tip of the instrument through the appropriate Intuitive cannula (8 mm or Single-Site curved) and engage the instrument in the sterile adapter.

 **Note:** To enter following mode during clip application, first ensure the corresponding hand control (master) is at least 90 percent open. Then, continue to open or slightly roll the hand control to enter following mode. This control is used to prevent closing the hand control and compressing the clip, which could reduce its effectiveness or cause the clip to fall out of the instrument altogether when the surgeon opens the hand controls after a small closure.

5. Once the instrument is inserted and in the surgeon's control, orient the single tooth of the clip as shown (Figure 4.1). This allows the user to visually confirm encapsulation of the structure being ligated. Position the clip around the tissue to be ligated in a manner that provides clear visualization of the locking mechanism (Figure 4.2).

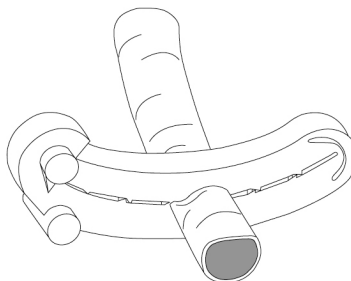
i **Note:** Avoid excess tissue in the locking mechanism of the clip. Squeeze the hand controls closed until the jaws close and the clip locks shut. Open the hand controls and withdraw from the ligation site (Figure 4.3).

Figure 4.2 Clip locked detail



6. Before instrument removal, make sure that the instrument jaws are in the open position (to free them from tissue) and that the wrist is approximately straight to ensure smooth release of the instrument from the sterile adapter.

Figure 4.3 Clip applied to vessel



End of section

Chapter 5 Small Clip Applier

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5.2	Intraoperative Use	61

i **Note:** For general information related to all instruments, see Chapter 2 Overview of da Vinci Instruments on page 13.

5.1 Introduction

This section contains instructions for use specific to the Small Clip Applier. The Small Clip Applier instrument is designed for use with Weck Horizon Small-Wide clips (Weck PN 001201 or PN 001205).

i **Note:** Order the clips required for the Small Clip Applier instrument (Weck PN 001201 or PN 001205) directly through Weck. Intuitive does not distribute this product.

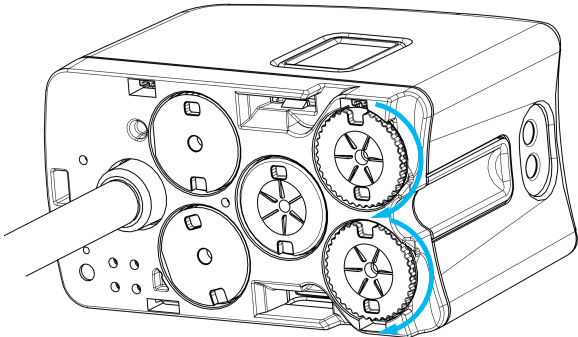
5.2 Intraoperative Use

Instructions for Intraoperative Use

Loading and Firing a Small Clip Applier instrument

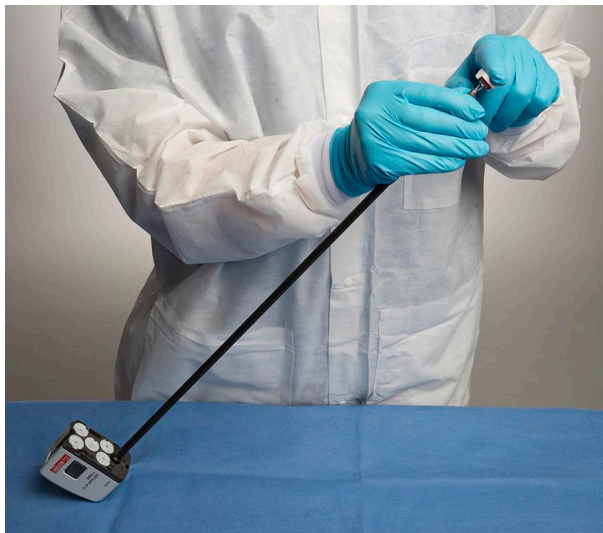
1. Before inserting the clip, drive the instrument grips (jaws) open by rotating the discs clockwise (Figure 5.1).

Figure 5.1 Location of discs



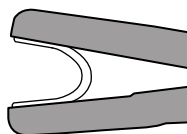
2. Rest the instrument housing on the back table. Lift the instrument shaft 45 degrees from the table top, straighten and stabilize the instrument wrist, and deliver the clip cartridge to the instrument jaws (Figure 5.2).

Figure 5.2 Positioning the instrument for loading the clip



3. Holding the instrument wrist completely straight, firmly press the clip into the jaws. Do not press too hard with the instrument or the clip cartridge while loading the clip, as excessive pressure will damage the instrument jaws.
4. A final visual inspection of the instrument tip is recommended prior to insertion to ensure that the clip is properly aligned with each instrument jaw (Figure 5.3).

Figure 5.3 Clip (titanium) loaded in clip applier



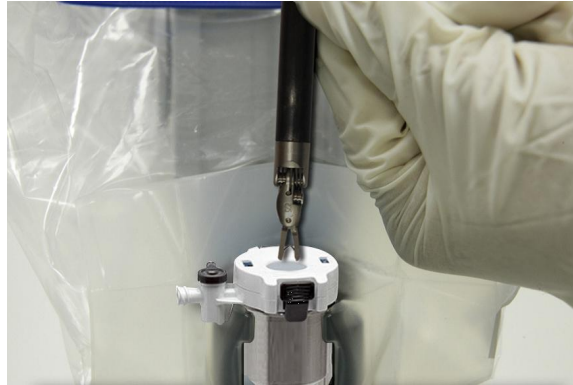
CAUTION: If excessive motion of the wrist or grips occurs during clip loading or instrument insertion, the clip should be removed and a new clip should be inserted. If the wrist moves significantly, the grip action may be affected and the clip could become slightly compressed. This could result in the clip falling out of the grip and into the patient during insertion or engagement.



Note: After loading the clip, do not touch or squeeze the jaws. Touching or squeezing the jaws may result in the clip falling out.

5. Keep the wrist straight while loading the instrument onto the Patient Cart arm (Figure 5.4).

Figure 5.4 Keep the instrument shaft and instrument wrist straight when installing the instrument



Note: To enter following mode during clip application, first ensure the corresponding hand control (master) is at least 90 percent open. Slightly roll the hand control to enter following mode. Do not move the hand control closed in any manner to activate following mode. This hand control technique is used to prevent compression of the clip, which could reduce its effectiveness or cause the clip to fall out of the instrument altogether.

6. When using the system to close a clip, the hand control should be completely closed at a moderate to fast speed. If the hand control is not adequately closed, there may be a larger clip gap than required.

End of section

Chapter 6 Using Electrosurgical Units (ESUs)

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Note: This chapter describes both EndoWrist and Single-Site instruments and associated accessories. Unless otherwise specified, the information applies to both suites of instruments and accessories. For specific information on instruments and accessories not covered in this manual, see the user documentation distributed with those products.

6.1 Introduction

The following sections contain information regarding the Monopolar and Bipolar Cautery Cords and use of the integrated ERBE VIO® dV (VIO dV) and non-integrated Electrosurgical Units (ESU) that are compatible with the da Vinci Xi and the da Vinci X systems. For details specific to non-integrated ESUs, see [6.8 Non-integrated ESU](#) on page 81.

6.2 Monopolar and Bipolar Cautery Cords

This section provide details specific to the Monopolar and Bipolar Cautery Cords (also referred to as cords). The reusable cords are supplied non-sterile and require cleaning and sterilization before use. The cords are re-usable for a maximum of twenty (20) re-use cycles. For more information regarding cleaning and sterilization, refer to the Reprocessing Instructions User Manual.

General Warnings and Precautions



WARNING: Ensure proper instrument connections to prevent delivery of energy to unintended patient tissue.

Compatible ESUs

The Monopolar and Bipolar Cautery Cords are compatible with the following ESUs:

- ERBE VIO dV
- Medtronic ForceTriad (non-integrated ESU)

Device Description

Reusable Monopolar and Bipolar Cautery Cords are designed to be used as accessories in conjunction with Electrosurgical Unit (ESU) generators during surgical and other medical procedures.

- The blue Bipolar Cautery Cord (PN 470384) connects to bipolar instruments.
- The green Monopolar Cautery Cord (PN 470383) connects to monopolar instruments.

Figure 6.1 Monopolar and Bipolar Cautery Cords

Bipolar cord ends



Generator connector



Instrument connector

Monopolar cord ends



Generator connector



Instrument connector

Instructions for Use

1. Prepare the ESU to be used with the instrument and cord as indicated in the ESU's instruction manual.
2. Connect the cord's generator connector ([Figure 6.1 Monopolar and Bipolar Cautery Cords](#) on page 65) to the corresponding port on the ESU.
3. Connect the cord's instrument connector ([Figure 6.1 Monopolar and Bipolar Cautery Cords](#) on page 65) to the instrument housing.

Inspection

Inspect cords for damage or irregularities before and after each use. Visually inspect the cords for physical damage including:

- Cracked, broken, or otherwise distorted parts
- Broken or significantly bent connector contacts
- Punctures, cuts, nicks, abrasions, unusual bumps, or significant discoloration

6.3 Electrosurgical Units (ESUs)

General Precautions and Warnings

-
-  **WARNING:** Improper setup or inadvertent activation of energy instruments could lead to patient harm.
-
-  **WARNING:** Improper setup of ESU may result in energy delivery being unavailable.
-
-  **WARNING:** Use the lowest possible power setting for the minimum time necessary to achieve the desired effect, to prevent patient tissue injury.
-
-  **WARNING:** Do not attempt to activate a da Vinci Xi instrument via an auxiliary footswitch.
-
-  **WARNING:** Only use third-party generators that are validated for use with the surgical system to prevent unintended energy delivery to patient tissue.
-
-  **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 connect the VIO dV or a non-integrated ESU to the same AC power outlet as the Vision Cart, as this could potentially overload the circuit.
-
-  **CAUTION:** Refer to the individual electrosurgical unit (ESU) manufacturer's user manual for operating instructions.
-
-  **CAUTION:** Follow proper procedure for setting up third-party generators, including connecting to the system and connecting to power. Not doing so could lead to patient injury.
-
-  **Note:** If it is desired to concurrently use two instruments of the same energy type (that is, two monopolar or two bipolar), the VIO dV can be used for both, or the VIO dV can be used for one and a third-party ESU can be used for the other. Only one monopolar and one bipolar instrument can be supported on third-party ESUs at any given time.
-

6.4 Integrated ERBE VIO dV 1.0 and VIO dV 2.0 Overview

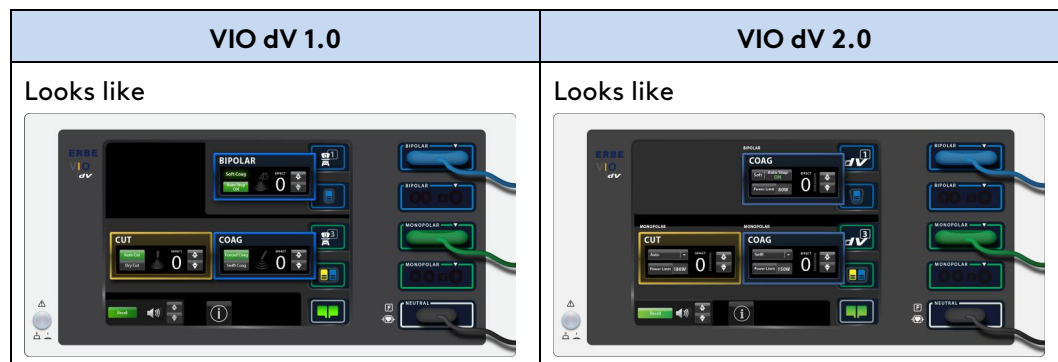
The ERBE VIO dV (VIO dV) is an integrated Electrosurgical Unit (ESU) that can be used with da Vinci Xi and laparoscopic instruments. This section provides general information specific to use with the da Vinci Xi System and the da Vinci X System and instruments. For further information, including warning and caution information, see the *ERBE VIO dV User Manual*.

-
-  **WARNING:** Do not perform the generator self-test inside the patient. This is to prevent patient harm due to pieces of the instrument falling into patient and not retrieved.
-
-  **WARNING:** Do not connect the generator PMED cable in any configuration other than instructed, to prevent patient injury.
-
-  **WARNING:** Only use compatible generators for Harmonic Ace, to prevent tissue injury or user confusion.
-

WARNING: Do not contact an activated Harmonic instrument with metal, plastic instruments, or plastic objects, to prevent damage to the instrument tip resulting in patient harm.

CAUTION: Ensure the compatibility of instruments with generator, to prevent burns to unintended tissue structures.

Two versions of the generator are available, VIO dV 1.0 and VIO dV 2.0:



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.

6.5 VIO dV 1.0

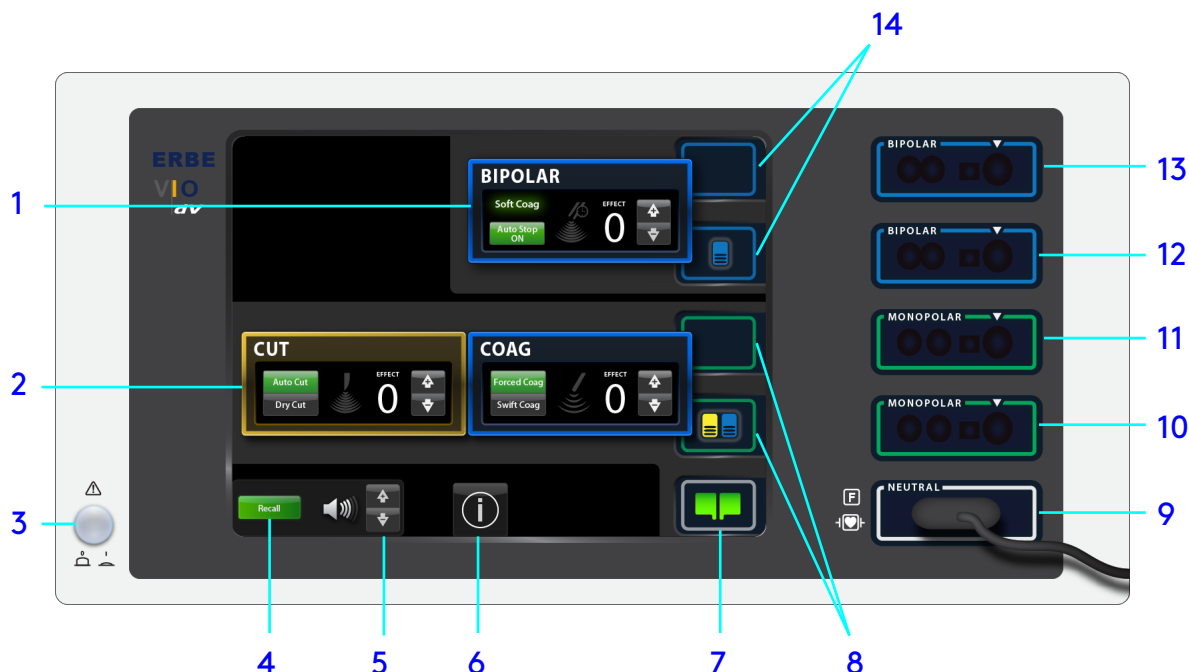
VIO dV 1.0 – Overview

ESU Screen Features

- **Power button:** The button that turns the ESU on/off.
- **Volume control:** Up/down selection buttons that adjust the volume settings.
- **Recall:** A button that displays when the ESU is first powered on that enables use of previous ESU settings.
- **Help menu:** A menu that provides descriptions of the CUT & COAG modes and explanations for the icons on the ESU screen.
- **Patient neutral pad status (NESSY):** An indicator that provides information about the safety status of the patient neutral pad. When the indicator is green, a valid patient neutral pad is properly connected. When the indicator is red, a valid patient neutral pad is not properly connected.
- **Bipolar ports (1 and 2):** The ports that are used to connect bipolar instruments to the ESU.
- **Monopolar ports (1 and 2):** The ports that are used to connect monopolar instruments to the ESU.
- **Neutral port:** The port used to connect a patient neutral pad (also referred to as neutral electrode) to the ESU to enable monopolar energy.
- **Mode pods (Bipolar and Monopolar):** The mode pods display settings and selection buttons for applicable instruments.

- Control assignment indicators (Bipolar and Monopolar): The control assignment indicators (also referred to as assignment indicators) contain icons that show how instruments can be activated.

Figure 6.2 VIO dV 1.0



1. Bipolar mode pod COAG
2. Monopolar mode pods CUT & COAG
3. Power button
4. Recall
5. Volume control
6. Help menu
7. Patient neutral pad status (NESSY)
8. Assignment indicators (monopolar)
9. Neutral port
10. Monopolar port 2
11. Monopolar port 1
12. Bipolar port 2
13. Bipolar port 1
14. Assignment indicators (bipolar)

Loading Screen

Press the power button on the lower left side of the ESU to turn it on. The loading screen appears.

Main screen

The main screen (Figure 6.3) defaults to bipolar mode with the Effect set to 0. The monopolar settings are disabled until a valid patient neutral pad is properly connected to the Neutral port. The patient pad status icon turns green when a valid patient neutral pad is properly connected, and the monopolar settings illuminate. For further details on patient neutral pads and settings, see the *ERBE VIO dV User Manual*.

Figure 6.3 Main screen with default settings displayed



VIO dV 1.0 - Selecting Settings

Once the VIO dV is powered on and a valid patient neutral pad is properly connected, the default effect settings will be zero and must be increased to activate energy. Settings can be selected by recalling previous monopolar and bipolar settings, or by manually adjusting the settings. With either selection method, set the effect as low as possible relative to the desired surgical effect.

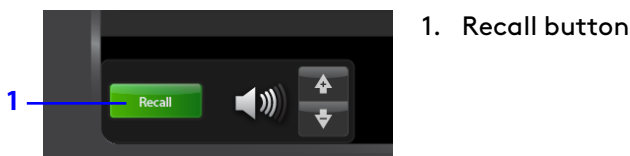
For further information on the available settings, see the applicable da Vinci system user manual, and the *ERBE VIO dV User Manual*.

Recall Previous Settings

Note: Recalling previous settings is only possible after the ESU is initially powered on, and before settings are manually adjusted.

To load the previous monopolar and bipolar settings, touch the Recall button (Figure 6.4). The Recall button disappears and the previous settings are applied. The settings can then be used or manually adjusted as needed.

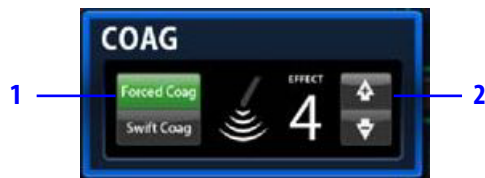
Figure 6.4 Recall button



Manually Adjust Mode and Effect Settings

To select new settings, touch the desired mode. The selected mode is shown in green (Figure 6.5). Set the desired effect using the effect selection arrows.

Figure 6.5 Mode and effect settings



1. Mode selection
2. Effect selection

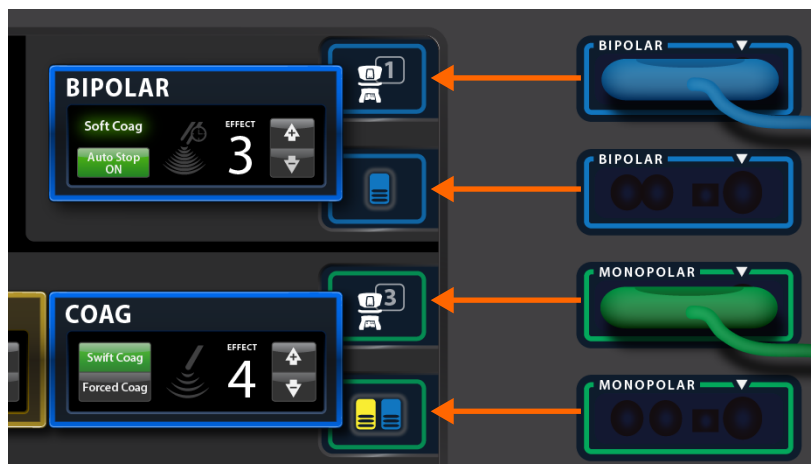
VIO dV 1.0 - Control Assignment Indicators

The control assignment indicators (also referred to as assignment indicators) contain icons that specify how the instruments connected to the ports can be activated. Each port is associated with the adjacent assignment indicator (as shown by the arrows in Figure 6.6). If a da Vinci Xi instrument is connected to the associated port, the icon indicates the following:

- whether or not the instrument is completely connected and,
- if connected, the arm on which the connected instrument is installed.

If a da Vinci Xi instrument is not installed, the icon indicates whether or not the port can be activated from the auxiliary footswitch. For more information, see the *ERBE VIO dV User Manual*.

Figure 6.6 Control Assignment indicators on VIO dV 1.0



Assignment Indicator Icon Descriptions

The following table describes the icons that appear in the monopolar and bipolar control assignment indicators.



WARNING: Activation of the incorrect instrument activation pedal could result in unintended instrument function, causing tissue injury.

Table 6.1 Control Assignment Indicator Icons

Icon	Meaning
	Good da Vinci Xi instrument connection (monopolar or bipolar) A da Vinci Xi instrument is properly connected to the port and installed on a da Vinci Xi or da Vinci X Patient Cart arm. The number indicates the arm on which the connected instrument is installed. Activation of a da Vinci Xi instrument is possible.
	Incomplete da Vinci Xi instrument connection (monopolar or bipolar) There are two possible scenarios: • There is not a proper connection between the VIO dV and the da Vinci Xi instrument installed on the Patient Cart arm, or • The da Vinci Xi instrument connected to the VIO dV is not properly installed on the Patient Cart arm. Activation of the da Vinci Xi instrument is not possible until the connection is completed. If using the VIO dV and non-integrated ESU at the same time • The VIO dV and non-integrated ESU are both connected and powered on.
	Non- da Vinci Xi instrument local activation only • No da Vinci Xi instrument connected. Activation of a da Vinci Xi instrument is not allowed. • Connected monopolar laparoscopic instrument can only be activated by switches on the instrument (that is, local fingerswitches). • If this icon appears in the monopolar port 2 or bipolar port 2 assignment indicator, the monopolar or bipolar foot pedal is not connected.
	For bipolar port 2 only • No da Vinci Xi instrument connected. Activation of a da Vinci Xi instrument is not allowed. • Connected bipolar laparoscopic instrument can be activated by auxiliary bipolar footswitch.
	For monopolar port 2 only • No da Vinci Xi instrument connected. Activation of a da Vinci Xi instrument is not allowed. • Connected monopolar laparoscopic instrument can be activated by auxiliary footswitch. • Connected monopolar laparoscopic instrument can be activated by switches on the instrument (that is, local fingerswitches).

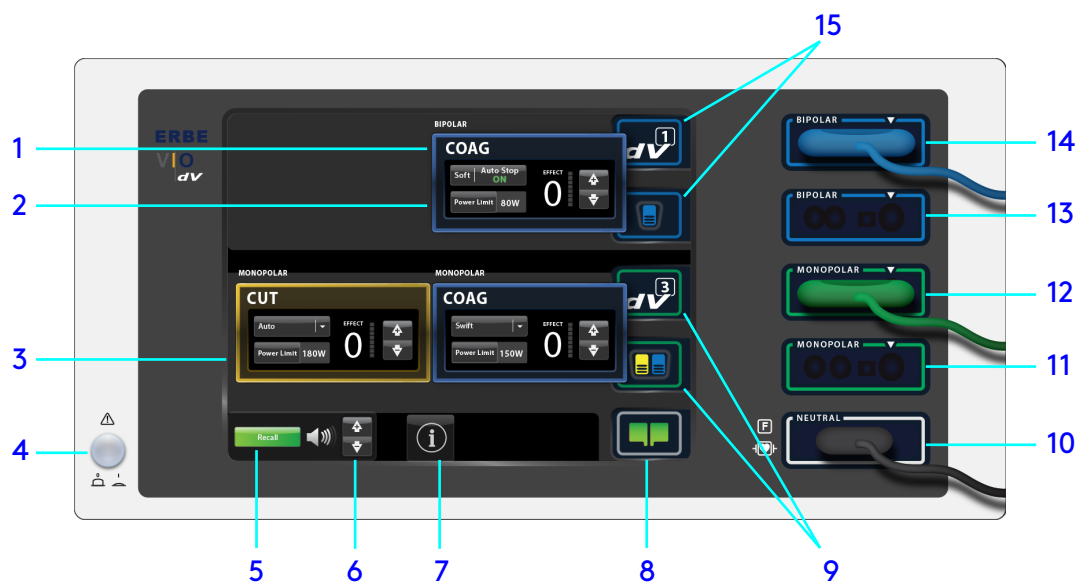
6.6 VIO dV 2.0

VIO dV 2.0 - Overview

ESU Screen Features

- **Power button:** The button that turns the ESU on/off.
- **Volume control:** Up/down selection buttons that adjust the volume settings.
- **Recall:** A button that displays when the ESU is first powered on that enables use of previous ESU settings.
- **Help menu:** A menu that provides descriptions of the CUT and COAG modes and explanations for the icons on the ESU screen. An error log is also available.
- **Patient neutral pad status (NESSY):** An indicator that provides information about the safety status of the patient neutral pad. When the indicator is green, a valid patient neutral pad is properly connected. When the indicator is red, a valid patient neutral pad is not properly connected.
- **Bipolar ports (1 and 2):** The ports that are used to connect bipolar instruments to the ESU.
- **Monopolar ports (1 and 2):** The ports that are used to connect monopolar instruments to the ESU.
- **Neutral port:** The port used to connect a patient neutral pad (also referred to as neutral electrode) to the ESU to enable monopolar energy.
- **Mode pods (Bipolar and Monopolar):** The mode pods display settings and controls for applicable instruments. Only the selected mode's settings are displayed.
- **Power Limit selection and display:** The button that enables users to select a limit on the maximum power delivered for fine-tuned control over tissue effect in each mode; the selected power limit is displayed. Effect can also be adjusted in the power limit window for iterative testing of settings.
- **Control assignment indicators (Bipolar and Monopolar):** The control assignment indicators (also referred to as assignment indicators) contain icons that show how instruments can be activated.

Figure 6.7 VIO dV 2.0



1. Bipolar mode pod COAG
2. Power limit selection and display
3. Monopolar mode pods CUT & COAG
4. Power button
5. Recall
6. Volume control
7. Help menu
8. Patient neutral pad status (NESSY)
9. Assignment indicators (monopolar)
10. Neutral port
11. Monopolar port 2
12. Monopolar port 1
13. Bipolar port 2
14. Bipolar port 1
15. Assignment indicators (bipolar)

Loading Screen

Press the power button on the lower left side of the ESU to turn it on. The loading screen appears.

Main Screen

The main screen defaults to bipolar mode with the Effect set to 0 for COAG (Figure 6.8). In the default screen, monopolar settings are disabled until a valid patient neutral pad is properly connected to the Neutral port. The patient neutral pad status icon turns green when a valid patient neutral pad is properly connected, and the monopolar settings illuminate. For further details on patient neutral pads and settings, see the *ERBE VIO dV User Manual*.

Figure 6.8 Main screen with default settings displayed



VIO dV 2.0 - Selecting Settings

Once the VIO dV is powered on and a valid neutral patient pad is properly connected, the default effect settings will be zero and must be increased to activate energy. Settings can be selected by recalling previous monopolar and bipolar settings, or by manually adjusting the settings. With either selection method, set the effect as low as possible relative to the desired surgical effect.

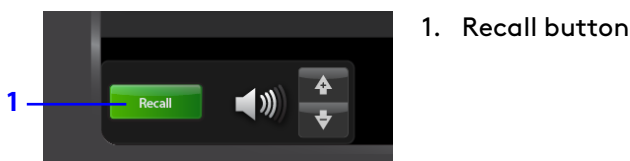
For further information on the available settings, see the applicable da Vinci system user manual, and the *ERBE VIO dV User Manual*.

Recall Previous Settings

Note: Recalling previous settings is only possible after the ESU is initially powered on, and before settings are manually adjusted.

To load the previous monopolar and bipolar settings, touch the **Recall** button (Figure 6.9). The **Recall** button disappears and the previous settings are applied. The settings can then be used or manually adjusted as needed.

Figure 6.9 Recall button



1. Recall button

Manually Adjust Mode and Effect Settings

Touch to select the mode from the drop-down menu. Set the desired effect using the effect selection arrows (Figure 6.10 and Figure 6.11).

Figure 6.10 Mode and effect settings, Monopolar CUT



Figure 6.11 Mode and effect settings, Monopolar COAG



Mode and effect settings can also be adjusted on the Surgeon Console touchpad. For instructions, see the applicable da Vinci system user manual.

Manually Adjust Power Limit Settings

In addition to adjusting mode and effect settings, users can adjust power limit settings (Figure 6.12). 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. Adjusting power limits reduces the potential range of power fluctuation.

1. Touch the **Power Limit** button to open the power limit settings window.
2. Use the left and right arrow buttons to select the required limit.

The power limit can be reset to the factory default using the **Default** button.

The effect can also be adjusted, using the effect selection arrows in this window.

3. Touch **Close** to return to the main screen.

Figure 6.12 Power limit settings, Monopolar COAG example



Power limit settings can also be adjusted on the Surgeon Console touchpad. For instructions, see the applicable da Vinci system user manual.

Presets

On the Surgeon Console touchpad, users can save up to three preferred sets of energy settings (presets) to an account. Presets include all mode, effect, and power limit settings for both monopolar and bipolar energy types.

For details on saving and applying energy presets, see the applicable da Vinci system user manual.

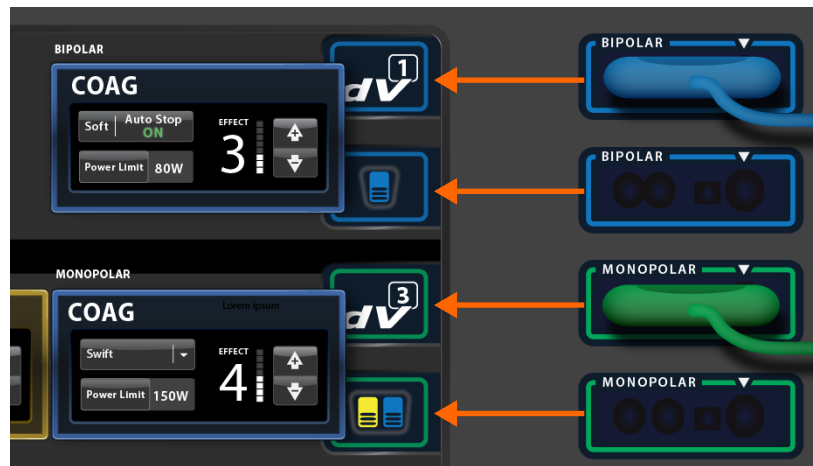
VIO dV 2.0 - Control Assignment Indicators

The control assignment indicators (also referred to as assignment indicators) contain icons that specify how the instruments connected to the ports can be activated. Each port is associated with the adjacent assignment indicator (as shown by the arrows in [Figure 6.13](#)). If a da Vinci Xi instrument is connected to the associated port, the icon indicates the following:

- whether or not the instrument is completely connected and,
- if connected, the arm on which the connected instrument is installed.

If a da Vinci Xi instrument is not installed, the icon indicates whether or not the port can be activated from the auxiliary footswitch. For more information, see the *ERBE VIO dV User Manual*.

Figure 6.13 Control Assignment indicators on VIO dV 2.0



Assignment Indicator Icon Descriptions

The following table describes the icons that appear in the monopolar and bipolar control assignment indicators.

Table 6.2 Control Assignment Indicator Icons

Icon	Meaning
	Good da Vinci Xi instrument connection (monopolar or bipolar) A da Vinci Xi instrument is properly connected to the port and installed on a da Vinci Xi or da Vinci X Patient Cart arm. The number indicates the arm on which the connected instrument is installed. Activation of a da Vinci Xi instrument is possible.
	Incomplete da Vinci Xi instrument connection (monopolar or bipolar) There are two possible scenarios: • There is not a proper connection between the VIO dV and the da Vinci Xi instrument installed on the Patient Cart arm, or • The da Vinci Xi instrument connected to the VIO dV is not properly installed on the Patient Cart arm. Activation of the da Vinci Xi instrument is not possible until the connection is completed. If using the VIO dV and non-integrated ESU at the same time • The VIO dV and non-integrated ESU are both connected and powered on.
	Non- da Vinci Xi instrument local activation only • No da Vinci Xi instrument connected. Activation of a da Vinci Xi instrument is not allowed. • Connected monopolar laparoscopic instrument can only be activated by switches on the instrument (that is, local fingerswitches). • If this icon appears in the monopolar port 2 or bipolar port 2 assignment indicator, the monopolar or bipolar foot pedal is not connected.
	For bipolar port 2 only • No da Vinci Xi instrument connected. Activation of a da Vinci Xi instrument is not allowed. • Connected bipolar laparoscopic instrument can be activated by auxiliary bipolar footswitch.
	For monopolar port 2 only • No da Vinci Xi instrument connected. Activation of a da Vinci Xi instrument is not allowed. • Connected monopolar laparoscopic instrument can be activated by auxiliary footswitch. • Connected monopolar laparoscopic instrument can be activated by switches on the instrument (that is, local fingerswitches).

6.7 VIO dV - Instrument Activation and Error Messages

This section contains information applicable to both the VIO dV 1.0 and the VIO dV 2.0.

Bipolar and Monopolar Instrument Activation

Bipolar and monopolar instruments (da Vinci Xi and laparoscopic) can be activated using the specified ports (as shown with [X] in the tables below).

Table 6.3 Bipolar Instrument Activation

Port	Da Vinci Xi Bipolar Instruments	Laparoscopic Bipolar Instruments (Foot pedal activated)
Bipolar Port 1	X	
Bipolar Port 2	X	X

Table 6.4 Monopolar Instrument Activation

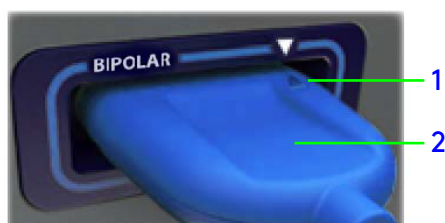
Port	Da Vinci Xi Monopolar Instruments	Laparoscopic Monopolar Instruments (Foot pedal activated)	Laparoscopic Monopolar Instruments (Fingerswitch activated)
Monopolar port 1	X		X
Monopolar port 2	X	X	X

Da Vinci Xi Monopolar and Bipolar Cautery Cord Connections for the VIO dV

Instructions for use

1. **Correctly orient the connector:** The wide depression in the connector and the molded arrow should be facing up when installing the cable into the VIO dV port ([Figure 6.14](#)).

Figure 6.14 Correct orientation of the connector with molded arrow facing up



1. Molded arrow
2. Wide depression

2. **Connect the cable to the VIO dV port:** Push the connector into the applicable port until it is fully seated ([Figure 6.15](#)).

Figure 6.15 Connectors in the correct ports



3. **Connect the cable to the da Vinci Xi instrument:** Connect the instrument side of the energy cord to the applicable da Vinci Xi instrument. See [6.2 Monopolar and Bipolar Cautery Cords](#) on page 64 for more information.

ERBE VIO dV Error Messages

Four ERBE VIO dV fault conditions related to da Vinci Xi energy instruments result in messages displayed on the Vision Cart touchscreen, in the arm and instrument status pod, and in the 3D viewer. Also, error tones sound at the Surgeon Console. Refer to [Table 6.5](#) for the message descriptions.

Table 6.5 ERBE VIO dV Error Messages on the Vision Cart Touchscreen

Instrument Type	Condition	Message	Icon
Bipolar	Energy activation has been interrupted due to detection of a short circuit condition between active and neutral electrodes on bipolar instruments. This can occur when there is not enough tissue between the jaws of the instrument and the AutoStop feature is turned ON.	C-84: Regrasp tissue or ensure jaw separation. Short detected.	
Monopolar	Energy is being activated while the patient neutral pad is not connected to the VIO dV, is defective, or has poor contact with the patient.	M-0B: Check neutral pad connection and contact with patient.	
	Energy is being activated while the patient neutral pad is not oriented in the proper direction (the long edge is not pointing toward the operating field).	M-1F: Check neutral pad orientation and contact with patient.	
Bipolar or Monopolar	Energy activation is halted when energy activation time has been exceeded.	M-1C: Max activation time exceeded.	

For further information on troubleshooting VIO dV fault conditions, see the *ERBE VIO dV User Manual*.

6.8 Non-integrated ESU

This section contains instructions for use specific to compatible electrosurgical units (ESU), energy activation cables and ESU preparation. For detailed information on a compatible non-integrated ESU, see the non-integrated ESU manufacturer's instructions.

Energy Activation Cable and Compatible ESU

The energy activation cables are designed to connect a compatible non-integrated ESU to the da Vinci Xi System and the da Vinci X System.

-  **WARNING:** Do not use any non-integrated ESU other than those compatible with the da Vinci Xi System and the da Vinci X System.
-  **WARNING:** Do not use any energy activation cable or instrument cord other than those indicated as acceptable for the ESU.
-  **WARNING:** The patient neutral pad must be properly affixed to the patient before the use of monopolar cautery, to prevent patient or operator injury.
-  **WARNING:** Make sure the electrosurgical unit (ESU or generator) is properly functioning before connecting it and using it with the system.
-  **Note:** Energy activation cables are non-sterile devices to be used outside the sterile field and do not require sterilization before use.
-  **Note:** Do not use unapproved or incompatible third-party accessories.

The following non-integrated ESU and corresponding energy activation cable are compatible with the da Vinci Xi and da Vinci X systems:

Table 6.6 Compatible ESU and Energy Activation Cable

ESU Model	da Vinci Xi/da Vinci X System Energy Activation Cable PN
Medtronic ForceTriad	371716

-  **Note:** The EndoWrist and Single-Site instruments have been evaluated for use only with the above non-integrated ESU and Energy Activation Cable.

Compatible ESU Preparation

-  **Note:** If it is desired to concurrently use two instruments of the same energy type (that is, two monopolar or two bipolar), the VIO dV can be used for both, or the VIO dV can be used for one and a third-party ESU can be used for the other. Only one monopolar and one bipolar instrument can be supported on a third-party ESU at any given time.

The VIO dV and a compatible non-integrated ESU are able to be connected to the da Vinci system and powered on at the same time.

1. Connect the energy activation cable (Figure 6.16) from the ESU to the Vision Cart. For more information on system connections, see the applicable system user manual.

Figure 6.16 Representative Energy Activation Cable



1. Connects to ESU
2. Connects to Vision Cart

2. Ensure that the ESU is properly connected to the correct EndoWrist or Single-Site instrument using the appropriate monopolar (PN 470383) or bipolar (PN 470384) instrument cord. Instrument energy cords are properly connected to the instruments when the connector completely covers the exposed pins.
3. Ensure that the cord is connected to the appropriate port on the ESU. Refer to the ESU's manual for indications and instructions in making this connection.



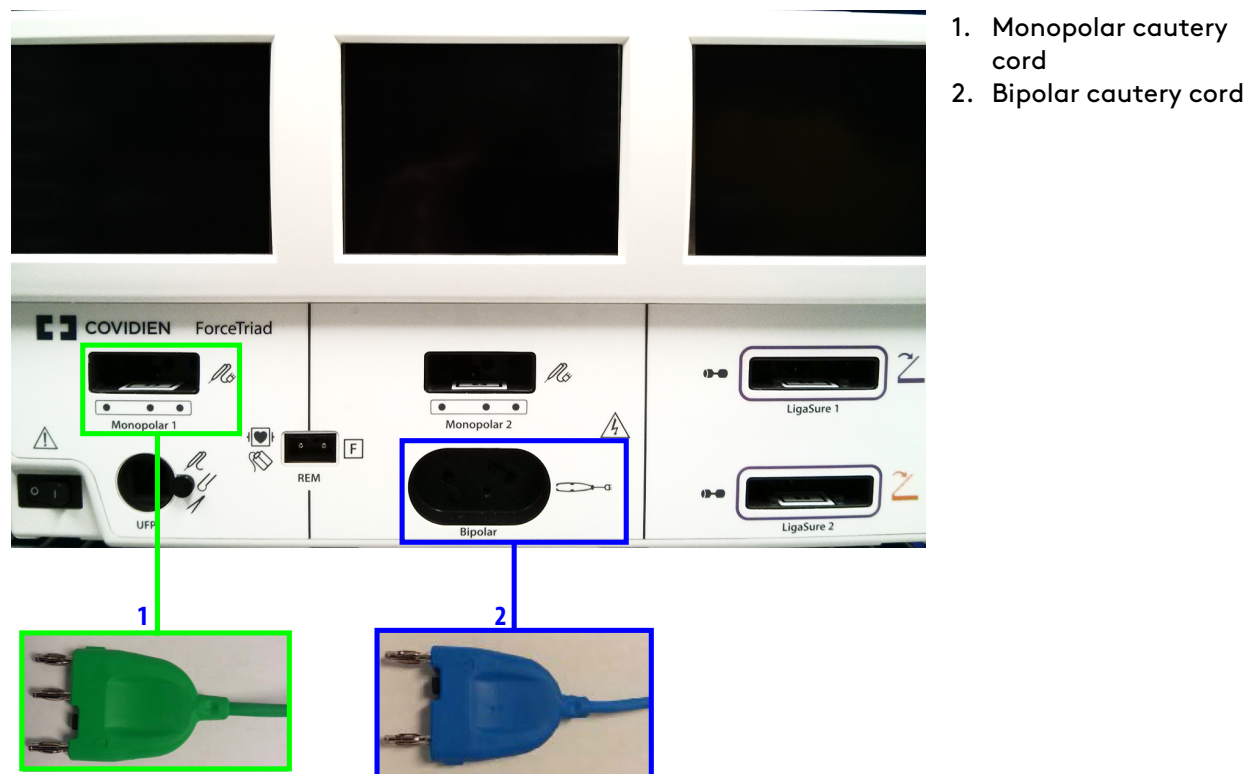
Note: Ensure that the monopolar instrument cord is plugged into the monopolar port on the ESU and that the bipolar instrument cord is plugged into the bipolar port on the ESU.

4. Turn on the ESU.

Monopolar and Bipolar Cautery Cord Connections for a Non-integrated ESU

The image below illustrates proper cautery cord connections for a non-integrated ESU, for example, Medtronic ForceTriad.

Figure 6.17 Non-integrated ESU (example, Medtronic ForceTriad)



General Maintenance - Energy Activation Cable

Cleaning the Energy Activation Cable

Wipe down the energy activation cable after each use, using a soft, lint-free cloth wetted with an anti-microbial solution of 70% isopropyl alcohol, or Cavicide. Alternatively, use Cavicide wipes. Rinsing is not required. Do not immerse cable in liquid.

Storing the Energy Activation Cable

Store the energy activation cable in a safe location off the floor to prevent damage to the cable.

6.9 Electrosurgical Unit (ESU) Settings

Monopolar Instruments

This section contains information regarding ESU settings for EndoWrist Permanent Cautery instruments, EndoWrist Monopolar Curved Scissors, and Single-Site Permanent Cautery Hook instruments. Monopolar instruments are rated for a maximum peak voltage of 3kV.

-  **WARNING:** Never increase the power or effect settings without first checking both the active electrode and the patient neutral pad and their connections. Use the active electrode or forceps only for the minimum time necessary to achieve the desired surgical effect in order to minimize the possibility of burns.
-  **WARNING:** Reduce power or effect setting if any of the following effects are observed to prevent damage to patient tissue: excessive arcing, excessive tissue charring, and excessive overheating of the instrument end effector.
-  **WARNING:** Excessive power or effect levels may result in instrument malfunction and possible patient or user injury. Reduce power or effect setting if any of the following effects are observed: excessive arcing, excessive tissue charring, excessive overheating of the tip (for example, the tip glowing red or emitting a blue plasma cloud).
-  **WARNING:** Do not use Electrosurgical Units (ESU) in the following modes above the listed power settings for the listed instrument types, doing so could result in energy delivery to unintended patient tissue.

Table 6.7 Maximum ESU Power Settings for Approved ESUs and Monopolar Cut and Coag Modes

Da Vinci Xi Instrument Type	ESU Model	Mode	Maximum Power Setting
EndoWrist and Single-Site	Medtronic ForceTriad	Pure Cut	150 Watts
Single-Site		Coag Spray	75 Watts
Single-Site		Coag Fulgurate	70 Watts
Single-Site	Integrated ERBE VIO dV	AutoCut	Effect 4

-  **WARNING:** For Single-Site surgery, to avoid stray energy, ensure that a patient neutral pad is affixed to the patient and connected to the Single-Site endoscope cannula with a sterile patient neutral pad cable.
-  **WARNING:** Set the ESU monopolar output power or effect level as low as possible to achieve adequate hemostasis.
-  **WARNING:** The da Vinci monopolar electrosurgical instruments are designed for use with a maximum peak voltage of 3kV (6kV peak-to-peak). Only compatible electrosurgical units have been tested to ensure that they do not exceed this limit. Do not attempt to use instruments with electrosurgical units that are not compatible with the da Vinci Xi System or the da Vinci X System.

 **Note:** The patient neutral pad attached to the Single-Site endoscope cannula is to be used in addition to the patient neutral pad attached to the generator. Intuitive does not provide or sell patient neutral pad cables or pads. Obtain them from a third party supplier.

 **Note:** Do not place the tips of energy instruments against patient or operator skin.

Bipolar Instruments

This section contains information regarding ESU settings for EndoWrist and Single-Site bipolar instruments. Bipolar instruments are rated for a maximum peak voltage of 500V.

 **WARNING:** Do not use bipolar instruments with a monopolar source output as this may cause damage to the instrument and harm to the patient or medical personnel.

 **Note:** Do not place the tips of energy instruments against patient or operator skin.

 **WARNING:** Excessive power or effect levels may result in instrument malfunction and possible patient or user injury. Reduce power or effect setting if any of the following effects are observed: excessive arcing, excessive tissue charring, excessive overheating of the tip (for example, the tips glowing red or emitting a blue plasma cloud).

 **WARNING:** Using Single-Site bipolar instruments with Medtronic ForceTriad Bipolar Macro mode could result in damage to instruments or injury to patients.

 **WARNING:** Set the ESU bipolar output power or effect as low as possible to achieve adequate hemostasis.

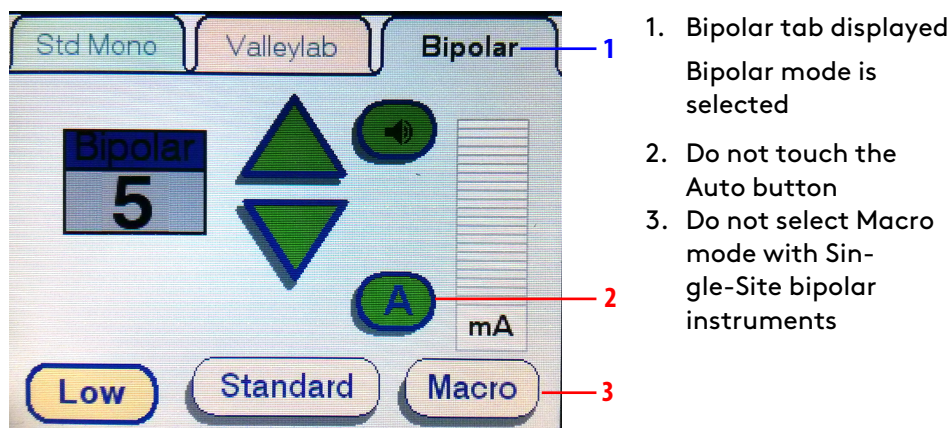
Proper ForceTriad Configuration Instructions

 **WARNING:** Ensure that Auto Start is not selected for Bipolar modes. To properly configure the Medtronic ForceTriad for use with the Surgeon Console footswitch, follow the instructions below.

 **WARNING:** To prevent damage to patient tissue, do not use Auto Start or Stop on Medtronic ForceTriad ESU.

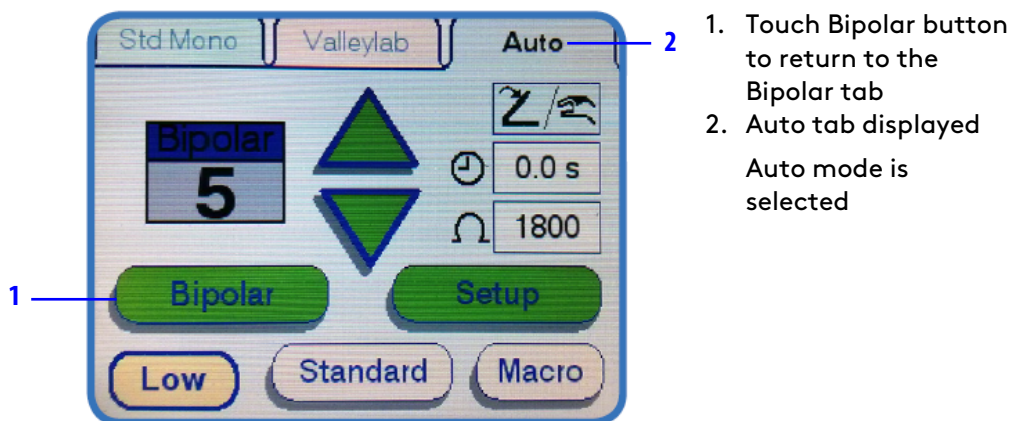
On the Medtronic ForceTriad, make sure that Auto mode is not selected. When Auto mode is off (not selected), the screen displays the **Bipolar** tab and Bipolar mode is selected (Figure 6.18).

Figure 6.18 Bipolar mode selected



If Auto mode is selected, the screen displays the **Auto** tab as shown in Figure 6.19. Touch the **Bipolar** button to return to the **Bipolar** tab and turn off Auto mode.

Figure 6.19 Auto mode selected



End of section

Chapter 7 Monopolar Instruments and Related Accessories

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 **Note:** For general information related to all instruments, see [Chapter 2 Overview of da Vinci Instruments](#) on page 13.

 **Note:** This chapter describes both EndoWrist and Single-Site instruments and associated accessories. Unless otherwise specified, the information applies to both suites of instruments and accessories. For specific information on instruments and accessories not covered in this manual, see the user documentation distributed with those products.

7.1 Introduction

This chapter provides instructions for monopolar instruments and applicable accessories and is intended to enhance the general instrument instructions in [Chapter 2 Overview of da Vinci Instruments](#) on page 13.

Monopolar Instrument Overview

- [7.3 Monopolar Curved Scissors Instrument](#) on page 90
- EndoWrist Permanent Cautery Instrument, in [7.4 Permanent Cautery Instrument](#) on page 94
- Single-Site Permanent Cautery Hook Instrument, in [7.4 Permanent Cautery Instrument](#) on page 94

7.2 Intraoperative Use

Precautions for Intraoperative Use

-  **WARNING:** Do not touch the tips of the instrument to any staples, clips, or sutures while energized. Damage to the tips may occur.
-  **WARNING:** Do not use this instrument to energize the tips of other instruments. This may damage the tips or injure tissue inside or outside the field of view. Tissue damage could occur at points near the tip or at the port site (cannula) of the energized instrument.
-  **WARNING:** Do not attempt to clean the instrument by scraping it with a sharp object such as a scalpel.
-  **WARNING:** Thermal spread adjacent to target tissue may result in unintended burns to surrounding tissue.

-
-  **WARNING:** The EndoWrist Monopolar instruments should *never* be used with an Intuitive 8 mm metal cannula inserted through any plastic cannula. This cannula configuration increases the risk of energy build up on the metal cannula, potentially leading to unintended thermal injury to the patient.
-
-  **WARNING:** The Single-Site Permanent Cautery Hook instrument should never be used with any other cannula or trocar system except the Single-Site 5 mm Curved Cannulae. Failure to use Single-Site 5 mm Curved Cannulae increases the risk of energy build up on the metal cannula, potentially leading to unintended thermal injury to the patient.
-
-  **WARNING:** As with any electrosurgical device, it is possible for energy to discharge in an area other than the instrument tip. It is important to exercise caution when using an energized EndoWrist or Single-Site Monopolar instrument to help avoid unintended contact with tissue adjacent to the area to be cauterized.
-
-  **WARNING:** Exercise caution when working with monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could result in burns to tissue in contact with any of the second instrument's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.
-
-  **WARNING:** While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. The instrument should not be used as a retractor while applying energy.
-
-  **WARNING:** Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes) to prevent patient injury.
-
-  **WARNING:** When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
-
-  **WARNING:** Aspirate fluid from the area before activating the instrument. Conductive fluids (for example, blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
-
-  **WARNING:** The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.
-
-  **WARNING:** Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
-
-  **WARNING:** Use protective eyewear, filtration masks, and effective smoke evacuation equipment in procedures where electrosurgical instruments are used to prevent carcinogenic and infection.
-

Precautions and Warnings for Endoscope Use with Monopolar Instruments

Da Vinci Xi endoscope and cannula configurations that electrically isolate the endoscope shaft from the body wall have the potential to enable the transfer of monopolar energy to tissue in contact with the endoscope shaft. This tissue contact, if it occurs, happens outside the surgeon's field of view. Observe the following warnings and caution to mitigate this risk during use of the da Vinci Xi or da Vinci X System.

-
-  **WARNING:** Do not use monopolar energy when the da Vinci Xi 8 mm endoscope is introduced through the 12 mm & Stapler cannula while using a 12 - 8 mm reducer (PN 470381-09 or lower version). Only use monopolar energy with a da Vinci Xi 12 - 8 mm reducer (PN 470381-10 or higher version) when the da Vinci Xi 8 mm endoscope is introduced through the 12 mm & Stapler cannula.
-
-  **WARNING:** Never insert a da Vinci Xi cannula into another cannula placed in the patient's body wall (double cannulation).
-
-  **WARNING:** To prevent critical burn injury, use caution when activating monopolar energy during da Vinci Xi or da Vinci X procedures in which contact between the endoscope cannula and the body wall is not assured.
-

For details on the 12 mm & Stapler cannula and the versions of the 12 - 8 mm reducer, see [12 - 8 mm Reducer Versions](#) on page 110.

Instructions for Intraoperative Use

1. Touch the target tissue to be cut or coagulated with the tip of the monopolar instrument. Make sure that the tip does not come in contact with non-target tissue.
2. Activate the ESU by depressing the associated instrument foot pedal in the Surgeon Console.
3. Once cutting or coagulating is complete, visually inspect the surgical area to ensure adequate hemostasis.

-
-  **WARNING:** To avoid inadvertent arcing from the instrument, do not fire the instrument if the tip is not in contact with the intended tissue.
-

Intraoperative Cleaning

-
-  **WARNING:** Do not use another instrument to clean tissue or char from the tip of the Monopolar Cautery Instruments.
-

If the tips are contaminated by carbonized tissue, remove the instrument and use a piece of soft gauze moistened with saline or sterile water to remove the tissue.

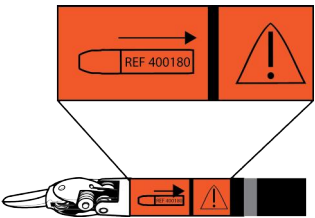
7.3 Monopolar Curved Scissors Instrument

Monopolar Curved Scissors Instrument Overview

The EndoWrist Monopolar Curved Scissors instrument is a multiple-use endoscopic instrument utilizing a single-use Tip Cover Accessory (PN 400180), to be used in conjunction with the da Vinci Xi System or the da Vinci X System.

Tip Cover Accessory

This section contains instructions for use specific to the Tip Cover Accessory for the EndoWrist Monopolar Curved Scissors.



WARNING: The Tip Cover Accessory (PN 400180) is shipped sterile and is for single use only.

WARNING:  DO NOT RE-STERILIZE.  DO NOT RE-USE.
Reprocessing and/or reuse of products intended for single use only may result in degraded instrument performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prionic pathogens.

WARNING:  Do not use if package is damaged.
A breach in the sterile packaging of the device indicates possible contamination. Do not use the device if the packaging is not intact.

Note: The Monopolar Curved Scissors Instrument must ALWAYS be used with Tip Cover Accessory (PN 400180), as shown near the tip of the instrument itself.

General Cautions and Warnings

-  **WARNING:** The EndoWrist Monopolar Curved Scissors instrument must *always* be used in conjunction with the Tip Cover Accessory, to prevent patient injury.
-  **WARNING:** Do not use another instrument to clean the Tip Cover Accessory.
-  **WARNING:** Be aware of potential sources of heat, to prevent endoscope damage or burns.
-  **WARNING:** Failure to follow these precautions will result in electrical arcs from the wrist and alternate site burns.

-
-  **WARNING:** Instruments and accessories are single-use to prevent contamination risk, device malfunction, and injury to patient.
-
-  **WARNING:** Do not re-use or re-sterilize the Tip Cover Accessory.
-
-  **WARNING:** Do not use another instrument to clean the Tip Cover Accessory, to prevent energy delivery to unintended tissues resulting in patient injury.
-
-  **WARNING:** To prevent damage to the Tip Cover Accessory insulation, always straighten the instrument wrist under endoscopic visualization before removing the instrument through the cannula.
-
-  **WARNING:** During heavy intraoperative cautery application, it may be possible for tissue char to cause the blades to stick together or to reduce cutting performance. Should this occur, remove the instrument and clean the blades with moist gauze or a scrub pad.
-
-  **WARNING:** As with any electrosurgical device, it is possible for energy to discharge in an area other than the instrument tip. It is important to exercise caution when using an energized EndoWrist Monopolar Curved Scissors instrument to help avoid unintended contact with tissue adjacent to the area to be cauterized.
-
-  **WARNING:** Do not use a torn Tip Cover Accessory. Doing so may cause energy delivery from the Monopolar Curved Scissors to unintended tissues, resulting in patient injury.
-
-  **WARNING:** Exercise caution when working with monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could result in burns to tissue in contact with any of the second instrument's metal parts or its cannula. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.
-
-  **WARNING:** While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. The instrument should not be used as a retractor while applying energy.
-

Inspection Before Use

-
-  **WARNING:** If cracks or other flaws are observed on the instrument, do not use the instrument. Examples of damage include nicked, gouged, bent, or loose blades, cracks or scratches on the instrument shaft including the region to be covered by the Tip Cover, or a broken energy cord connector. Contact Intuitive Customer Service.
-
-  **WARNING:** Do not use a torn monopolar tip cover, to prevent energy delivery to unintended tissue resulting in patient injury.
-

Tip Cover Accessory Installation – Before Use

The Tip Cover Accessory is provided in a sterile pouch for a single use. Install the Tip Cover Accessory onto the instrument in the sterile field.



WARNING: Improper assembly or disassembly of instruments or accessories requiring installation could lead to tissue injury.

1. Close the scissor blades.
2. Straighten the wrist of the instrument. See [Figure 7.1](#).
3. Grasping the Tip Cover Accessory with the Installation Tool as shown in [Figure 7.1](#), slide the Tip Cover Accessory onto the distal end of the instrument until it comes to the stop. A twisting motion can be used to ease installation. The distal end of the instrument should be facing away from you during installation.

Figure 7.1 Sliding the Tip Cover Accessory onto the instrument



1. Tip cover
2. Installation tool

4. Remove the Installation Tool and retain it to aid in removing the Tip Cover Accessory after use.

Proper Installation

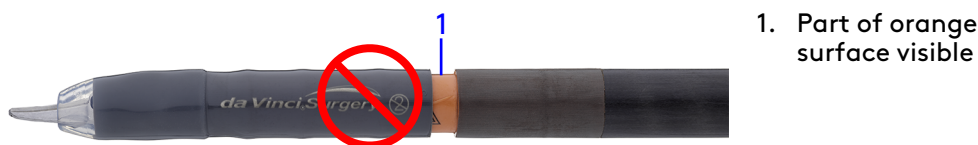
- The Tip Cover Accessory is properly installed when the orange surface is completely covered. See [Figure 7.2](#).

Figure 7.2 Properly installed Tip Cover Accessory in place



- The Tip Cover Accessory is **not** properly installed if any part of the orange surface is visible, as shown in [Figure 7.3](#).

Figure 7.3 Tip Cover Accessory not properly installed



- It is also **not** properly installed if installed beyond the orange surface and over the shaft. This causes a bulge on the shaft and may prevent it fitting through the cannula. See [Figure 7.4](#).

Figure 7.4 Tip Cover over-installed



WARNING: Failure to install the Tip Cover Accessory properly may result in:

- Improper scissor opening
- Tip Cover Accessory falling off into the patient
- Electrical arcs and alternate site burns
- Difficulty installing the instrument

Disassembly

After each clinical application, remove the Tip Cover Accessory. A twisting motion can be used to ease the removal of the Tip Cover Accessory. The Installation Tool may be reapplied to the Tip Cover Accessory to facilitate removal.

Examine the instrument thoroughly after each use. If any abnormality is detected, do not use the instrument and contact Intuitive Customer Service.

Disposal of Tip Cover Accessory

Discard the Tip Cover Accessory per institution biohazard protocol.

7.4 Permanent Cautery Instrument

This section contains instructions for use specific to EndoWrist and Single-Site Permanent Cautery instrument and related accessories.

Permanent Cautery Instrument Overview

The EndoWrist and Single-Site Permanent Cautery Instruments are multiple-use electro-surgical endoscopic instruments. They are to be used in conjunction with the da Vinci Xi System or the da Vinci X System and an external electro-surgical unit (ESU).

General Precautions and Warnings - Permanent Cautery Instrument



WARNING: Do not use damaged or broken instruments or accessories. Inspect instruments and accessories prior to use. Failure to do so may result in fragments falling into patient leading to potential conversion to an open procedure for removal, x-ray, delay in procedure, or component left in patient.



WARNING: Do not use this instrument to energize the tips of other instruments. This may damage the tip or injure tissue inside or outside the field of view. Tissue damage could occur at points near the tip or at the port site (cannula) of the energized instrument.

Inspection Before Use

Before use, examine the entire instrument for damage. If you observe cracks or other damage, or if the tip appears loose, do not use the instrument. Examples of damage include: defects on the hook or spatula tip, damage to the ceramic piece connecting the tip to the wrist, cracked or broken pulleys, cuts on the insulation over the wires, broken energy cord connector, and cracks or scratches on the shaft.

End of section

Chapter 8 Bipolar Instruments and Related Accessories

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Note: For general information related to all instruments, see Chapter 2 Overview of da Vinci Instruments on page 13.

Note: This chapter describes both EndoWrist and Single-Site instruments and associated accessories. Unless otherwise specified, the information applies to both suites of instruments and accessories. For specific information on instruments and accessories not covered in this manual, see the user documentation distributed with those products.

8.1 Bipolar Instrument Overview

This section contains instructions for use specific to EndoWrist and Single-Site Bipolar Instruments.

EndoWrist Bipolar Instruments

The EndoWrist bipolar instruments are multiple-use electro-surgical endoscopic instruments with a grasping tip to be used in conjunction with the da Vinci Xi System and the da Vinci X System and an external electro-surgical unit (ESU).

Single-Site Bipolar Instruments

The Single-Site bipolar instruments are single-use electro-surgical endoscopic instruments with a grasping tip to be used in conjunction with the da Vinci Xi System and the da Vinci X System and an external electro-surgical unit (ESU).

WARNING: The Single-Site Bipolar Maryland Instrument (PN 478080) and the Single-Site Fenestrated Bipolar Forceps (PN 478093) are sterilized with ethylene oxide (EO). They are shipped sterile and are for single use only.

WARNING:  DO NOT RE-STERILIZE.  DO NOT RE-USE.
Reprocessing and/or reuse of products intended for single use only may result in degraded instrument performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prionic pathogens.

WARNING:  Do not use if package is damaged.
A breach in the sterile packaging of the device indicates possible contamination. Do not use the device if the packaging is not intact.

8.2 Intraoperative Use

Precautions for Intraoperative Use

-
-  **WARNING:** Thermal spread adjacent to target tissue may result in unintended burns to surrounding tissue.
-
-  **WARNING:** Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
-
-  **WARNING:** When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
-
-  **WARNING:** Aspirate fluid from the area before activating the instrument. Conductive fluids (for example, blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
-
-  **WARNING:** The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.
-
-  **WARNING:** Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
-
-  **WARNING:** Use protective eyewear, filtration masks, and effective smoke evacuation equipment in procedures where electrosurgical instruments are used to prevent carcinogenic and infection.
-

Instructions for Intraoperative Use

Inspect the instrument for damage prior to use. Examples of damage include bent, broken, or loose grips, cuts on the insulation over the wires, broken energy cord connector, cracked or broken pulleys, and cracks or scratches on the instrument shaft. If any abnormality is observed, discontinue instrument use.

1. Grasp the tissue to be coagulated with the tip of the bipolar instrument. Make sure that the tips do not come in contact with non-target tissue. Activate the ESU by depressing the associated instrument foot pedal in the Surgeon Console. To coagulate tissue, the two grips of the bipolar instruments must not come in contact with each other. If the tissue is thin and no coagulation occurs, open the grips slightly, press the bipolar foot pedal, and then close the grips to cauterize the tissue. It may also be possible to coagulate very thin structures by directly applying monopolar energy to the tissue.
2. Once coagulating is complete, visually inspect the surgical area to ensure adequate hemostasis.

-
-  **WARNING:** Do not touch the tips of the instrument to any staples, clips, or sutures while energized. Damage to the tips may occur.
-
-  **WARNING:** Do not use this instrument to energize the tips of other instruments. Damage to the tips and injury to the patient may occur.
-



WARNING: Do not attempt to clean the instrument by scraping it with a sharp object such as a scalpel.

Intraoperative Cleaning



WARNING: Do not use another instrument to clean tissue or char from the tip of the Bipolar Cautery Instruments.

If the tips are contaminated by carbonized tissue, remove the instrument and use a piece of soft gauze moistened with saline or sterile water to remove the tissue.

End of section

Chapter 9 EndoWrist Suction Irrigator

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i **Note:** All da Vinci instruments and accessories are compatible with both the da Vinci Xi and the da Vinci X systems.

9.1 Overview

This section contains instructions for use specific to the EndoWrist Suction Irrigator (PN 480299). It is designed to be used with the da Vinci Xi System or the da Vinci X System.



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

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

i **Note:** The EndoWrist Suction Irrigator (PN 480299) is sterilized with ethylene oxide (EO) and ships sterile. It is for single use only and is not designed to be cleaned, disinfected, or sterilized. Therefore, validated cleaning and sterilization methods and reprocessing instructions are not available for this product.

Compatibility Information

The EndoWrist Suction Irrigator is compatible for use with the da Vinci Xi System and the da Vinci X System; it is not compatible for use with the da Vinci, the da Vinci S, and the da Vinci Si systems.

The suction tubing can be used with any wall or standalone suction system.

In addition, the EndoWrist Suction Irrigator is designed for use with a bag of irrigation fluid, pressurized using standard methods for irrigation bag pressurization in the operating room (Figure 9.1).

Figure 9.1 Pressurization Options

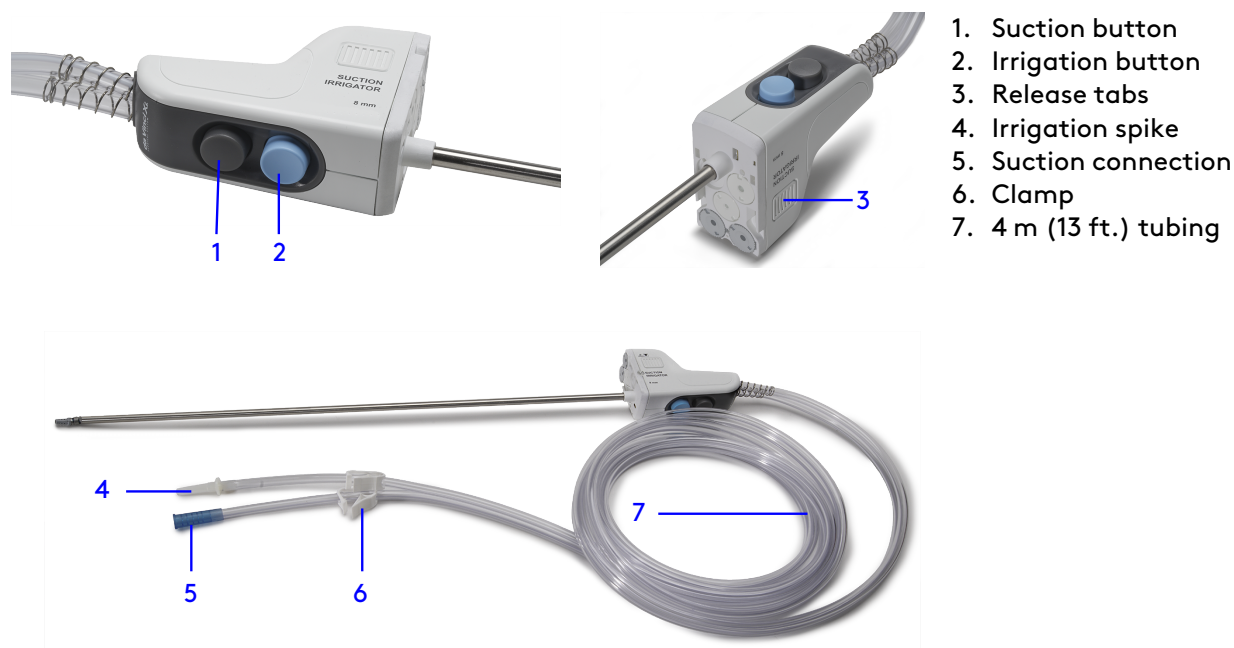


Device Description

The EndoWrist Suction Irrigator has the following features:

- It is a fully disposable instrument with an integrated tubing set (Figure 9.2).
- The surgeon can activate suction and irrigation from the Surgeon Console using the blue and yellow pedals.
- The patient-side assistant can activate the suction and irrigation valves manually when used through an assistant port, or when the instrument is attached to the Patient Cart arm. Figure 9.2 shows the location of the manual activation buttons for suction and irrigation.

Figure 9.2 EndoWrist Suction Irrigator instrument features



9.2 Instructions for Use

Inspection

The EndoWrist Suction Irrigator is for single use only and comes in a sterile package. Ensure that the packaging has no tears that could lead to contamination of the instrument.



WARNING: Do not use if package is damaged.

A breach in the sterile packaging of the device indicates possible contamination. Do not use the device if the packaging is not intact.

Instrument Setup

Instrument setup requires two people, one non-sterile and one sterile. Note which person is responsible for each of the following steps:

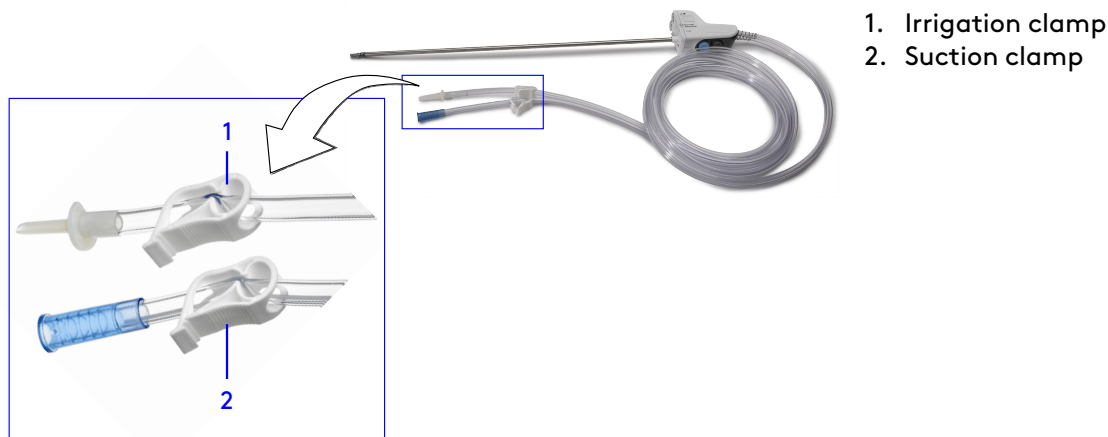
Open the Sterile Tray.

1. **Non-sterile person:** Open the sterile tray using aseptic technique and either deposit the instrument onto a sterile table, or have a sterile person remove the instrument and tube set from the tray. Remove the paper wrap from the tubing.

Connect the instrument tubing to an irrigation and a suction collecting system.

2. **Sterile person:** Pass the tubing ends off to a non-sterile person.
3. **Non-sterile person:** Clamp off the irrigation line on the instrument tubing by fully depressing the irrigation clamp provided. If desired, also clamp off the suction tubing by fully depressing the suction clamp provided.

Figure 9.3 Irrigation and suction clamps



4. **Non-sterile person:** Using aseptic technique, remove the cover from the sterile spike and spike the tubing set to the irrigation bag.



CAUTION: Ensure that the spike and the bag opening are kept sterile. Follow the manufacturer's instructions for use.

5. **Non-sterile person:** Pressurize the spiked bag using methods for irrigation bag pressurization commonly used in the operating room, or place it on an IV pole for gravity pressure.
6. **Non-sterile person:** Separate the conjoined tubing so that the suction line can independently reach the suction collecting system.

Ensure tubing clamps are open.

7. **Non-sterile person:** Connect the suction line from the instrument tubing set to the suction collecting system, open the clamp on the suction tubing, and turn on the vacuum source.
8. **Non-sterile person:** Open the clamp on the irrigation line.



CAUTION: Do not exceed an irrigation pressure of 400 mm Hg.

Prime the Instrument

9. **Sterile person:** With the end of the instrument in a basin, press both the blue irrigation button and the gray suction button to prime the instrument and tubing. Hold down both buttons until all of the air is out of the system.

Figure 9.4 Manual control buttons



1. Suction button
2. Irrigation button

9.3 Intraoperative Use



WARNING: The EndoWrist Suction Irrigator should not be used with an Intuitive 8 mm metal cannula inserted through any plastic cannula. This cannula configuration increases the risk of energy build up on the metal cannula when a monopolar instrument is activated if the EndoWrist Suction Irrigator is filled with conductive fluid, potentially leading to unintended thermal injury to the patient.



WARNING: The wrist and shaft of the EndoWrist Suction Irrigator are conductive. Exercise caution when working with monopolar instruments close to the EndoWrist Suction Irrigator. Unintended energy may be delivered from the active monopolar instrument to the EndoWrist Suction Irrigator. This may result in unintended thermal injury to tissue in contact with the EndoWrist Suction Irrigator metal parts or its cannula. Position the monopolar tip closer to the tissue than to the EndoWrist Suction Irrigator. Do not activate a monopolar instrument if the EndoWrist Suction Irrigator metal parts are submerged in conductive fluid.

-
- CAUTION:** Only a physician or medical personnel under the supervision of a physician should use the EndoWrist Suction Irrigator.
-
- CAUTION:** Intraperitoneal pressure monitoring is mandatory when using this device.
-
- CAUTION:** When the instrument is fully articulated, use caution when applying force to the end of the instrument. Excessive force may result in instrument damage.
-
- CAUTION:** Do not use this instrument to apply force to bone or other hard objects, because it may result in instrument damage.
-
- CAUTION:** Inadvertent electrosurgical energy may cause serious injury or surgical complications to the patient. It is important to ensure a full understanding of the da Vinci System energy user interface and use caution when working near critical anatomy.
-
- Note:** While the EndoWrist Suction Irrigator is not an electrosurgical instrument, the surgeon can activate it with the same pedals used to activate electrosurgical instruments. Therefore, observe the following caution.
-

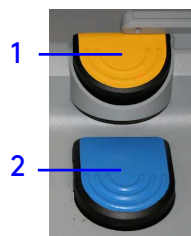
Surgeon Console Activation

-
- Note:** Before installing the instrument, manually straighten the wrist and ensure the tubing path is free from potential collisions, kinks, and has enough slack to allow for insertion and manipulation of the instrument.
-
- Note:** Be careful to maintain the sterility of the instrument tubing during all modes of use. Intuitive recommends use of atraumatic clamps to secure the tubing to the sterile drapes on the OR table or back tables.
-

To operate the instrument once installed and in following mode:

1. Press the blue pedal to activate suction (Figure 9.5).
2. Press the yellow pedal to activate irrigation (Figure 9.5).

Figure 9.5 Surgeon Console controls



1. Irrigation
2. Suction

Best Practices

-
- CAUTION:** Do not attempt to remove and re-install an instrument more than once after a self-test failed message, as this may cause further damage to the instrument. Install the backup EndoWrist Suction Irrigator and contact Intuitive Customer Service.
-
- Note:** Prior to removal, make sure the wrist is completely straight (Figure 9.6).
-

- Note:** The EndoWrist Suction Irrigator instrument has less overall range of motion at the instrument tip than other 8 mm EndoWrist instruments. In addition, the instrument does not have roll functionality.

Figure 9.6 Wrist at angle and wrist completely straight

Issue	Solution
While trying to remove the EndoWrist Suction Irrigator, the wrist gets stuck in the cannula. 	Prior to removal, the EndoWrist Suction Irrigator wrist should be completely straight. 

Figure 9.7 Clamp the tubing to stop the leak

The suction or irrigation valves remain partially open during use and typical measures for clearing the lines (that is, applying irrigation and/or suction) do not result in the valves closing.	Clamp the tubing to stop the leak or manually pull back the buttons on the instrument. Furthermore, if the valves remain partially open during a system fault, press/release the corresponding Surgeon Console pedal to fully reset the valve position. 
---	---

- Note:** Suction or irrigation can be activated at the same time as other energy instruments by pressing the associated foot pedals simultaneously.
- Note:** When not using suction, make sure that the gray suction button does not remain depressed, so as to minimize loss of pneumoperitoneum.

Patient-Side Activation

Suction or irrigation can be manually activated by pressing the gray suction button or blue irrigation button on the instrument housing. These buttons work at any time the instrument is properly attached to suction and irrigation sources, whether installed on an arm or using the EndoWrist Suction Irrigator as an independent laparoscopic instrument through a dedicated 8–12 mm assistant port. These buttons work whether or not activated from the Surgeon Console.

Note: Before inserting or removing the EndoWrist Suction Irrigator through the assistant cannula for manual use, make sure the wrist is straight.

- To activate irrigation, press the blue irrigation button (Figure 9.8).
- To activate suction, press the gray suction button (Figure 9.8).

Figure 9.8 Patient-side activation of irrigation and suction



Note: While installed on an arm, the manual suction and irrigation buttons work at all times regardless of arm status, whether or not in Follow mode, clutched, locked, or inactive. Therefore, while installed on an arm, communication between the console surgeon and assistant is important to coordinate patient-side activation of suction and irrigation.

Disposal

CAUTION: This instrument is for single use only and must be disposed of as hazardous biological waste.

Before disposing of the instrument, close the irrigation and suction clamps and detach the tubes from the irrigation and suction sources. When disposing of this product or any of its components, follow all applicable national and local laws and guidelines.

End of section

Chapter 10 Single-Site Suction Irrigator

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i Note: For general information related to all instruments, see Chapter 2 Overview of da Vinci Instruments on page 13.

10.1 Overview

This section contains instructions for use specific to the Single-Site Suction Irrigator instrument (PN 478054) for use with the Stryker® StrykeFlow™ 2 Suction Irrigation Pump. The instrument is supplied with reusable tubing and reusable tubing adapter.

Figure 10.1 Single-Site Suction Irrigator, with supplied tubing and adapter



Stryker StrykeFlow 2 Suction Irrigation Pump

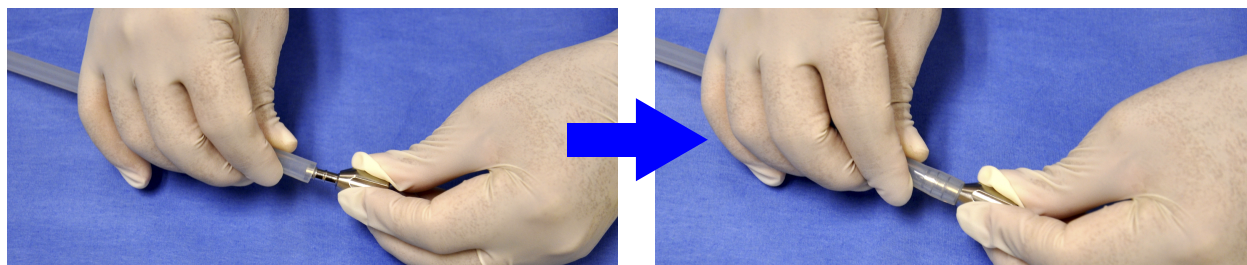
⚠ WARNING: All instructions, precautions, and contraindications found with the Stryker StrykeFlow 2 Suction Irrigation Pump apply when used with the Single-Site Suction Irrigator instrument.

10.2 Installation Before Use

The StrykeFlow 2 Suction Irrigation Pump is provided in a sterile package for a single use. Assemble the StrykeFlow 2 onto the instrument in the sterile field.

1. Insert the male end of the reusable metal tubing adapter into one end of the supplied reusable tubing (Figure 10.2).

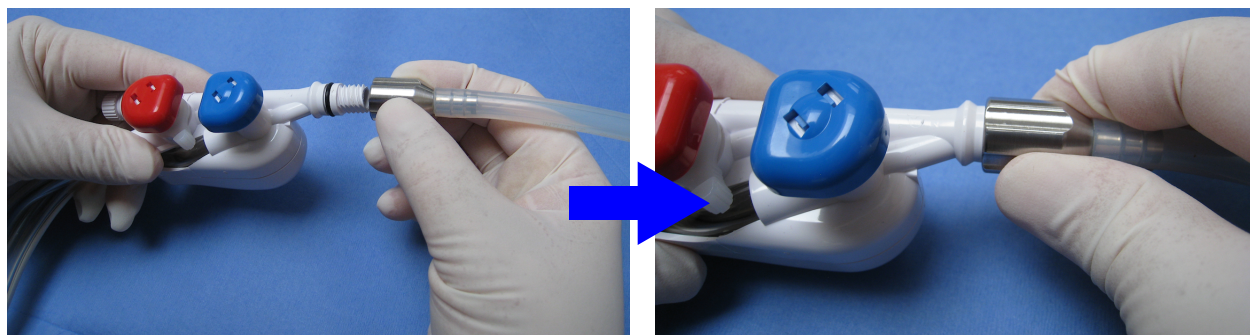
Figure 10.2 Insert adapter in tubing



2. Screw on the female end of the adapter over the threaded white plastic end of the StrykeFlow 2 Suction Irrigation Pump control assembly. Ensure that the parts are aligned properly. Hand tighten the adapter until the black O-ring is not visible (Figure 10.3).

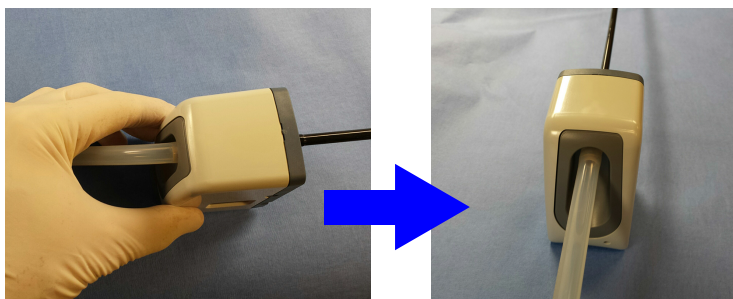
⚠ WARNING: Incorrect attachment of the reusable fitting to the plastic handpiece could result in the potential for particles that fall into the patient. Ensure proper alignment of the parts before threading.

Figure 10.3 Screw adapter onto StrykeFlow 2 Suction Irrigation Pump



3. Attach the other end of the tubing over its fitting on the rear of the instrument (Figure 10.4).

Figure 10.4 Attach tubing to rear of the Suction Irrigator instrument



10.3 Intraoperative Use

The surgeon positions the Suction Irrigator using the da Vinci Xi System and the da Vinci X System. The patient-side assistant must manually activate either suction or irrigation in cooperation with the surgeon. Press the blue button on the StrykeFlow 2 Suction Irrigation Pump to provide irrigation, and the red button to apply suction. Do not push the instrument into cartilage, bone, or other hard objects.

End of section

Chapter 11 Cannulas, Obturators, Reducer, and Cannula Seals

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Note: This chapter describes accessories associated with both EndoWrist and Single-Site instruments. Unless otherwise specified, the information applies to both suites of accessories. For specific information on instruments and accessories not covered in this manual, see the user documentation distributed with those products.

Note: All da Vinci Xi instruments and accessories are compatible with both the da Vinci Xi and the da Vinci X systems.

11.1 Introduction

This section contains instructions for use specific to the Intuitive cannulas, obturators, reducer, and cannula seals used with the da Vinci Xi System and the da Vinci X System. For components identified as having separate instructions for use, refer to those instructions.

Note: Reusable cannulae and accessories are shipped non-sterile unless otherwise indicated in the device's labeling. Clean and sterilize before use.

11.2 Cannula System Overview

- **Cannula:** A tube with a lumen which provides a single port of entry into the body for an instrument or an endoscope.
- **Obturator:** A cylinder used when inserting the cannula into the patient to prevent coring or tearing of the body wall upon insertion.
- **Cannula Seal:** Sterile, single-use disposable cap for each cannula. When attached to the cannula, the seal maintains insufflation when the cannula is empty and when an instrument is inserted.
- **12 - 8 mm Reducer:** A sterile, single-use, hollow cylinder with integrated seal that is inserted into the 12 mm & Stapler cannula to make the cannula compatible with 8 mm instruments or endoscopes.

The cannula seals provide an outlet for insufflation or smoke evacuation. The obturators attach to the cannula seal, which attaches to the cannula and facilitates the introduction of the cannula into the body cavity. The obturators have a variety of tip configurations for different mechanisms by which to enter the body cavity. The obturators are removed before the use of the cannula for instrument or endoscope access.

The Single-Site 5 mm accessory cannula provides an outlet for insufflation or smoke evacuation; an insufflation port is not included on the 5 - 10 mm Single-Site Cannula Seal. The Single-Site obturators have blunt tip configurations and fit over the 5 - 10 mm Single-Site Cannula Seal, and attach to the cannula to facilitate the introduction of the cannula through the Single-Site Port and into the body cavity. The obturators are removed before the use of the cannula for instrument or endoscope or accessory access.

For 8 mm and Single-Site accessory reprocessing information, see the Reprocessing Instructions User Manual.

For 12 mm & Stapler accessories reprocessing information, see the Reprocessing Instructions User Manual.

Cannula Lengths



Note: The da Vinci Xi System and the da Vinci X System are designed to allow the use of cannulas with different lengths and diameters; the system automatically recognizes the parameters of installed cannulas and adjusts accordingly.

The cannulas come in the lengths listed in [Table 11.1](#):

Table 11.1 Cannula Lengths

Cannula	Cannula PN	Length
8 mm Cannula, Standard	470002	100 mm
8 mm Cannula, Long	470004	150 mm
12 mm & Stapler Cannula, Standard	470375	100 mm
12 mm & Stapler Cannula, Long	470389	150 mm
Single-Site 5 mm x 300 mm Curved Cannula (Endoscope Left and Right)	478062, 478061	300 mm
Single-Site 5 mm x 250 mm Curved Cannula (Endoscope Left and Right)	478072, 478071	250 mm
Single-Site 10 mm Accessory Cannula	428076	145 mm
Single-Site 5 mm Accessory Cannula	478060	110 mm
Single-Site 8 mm Endoscope Cannula	478263	100 mm

Cannula System Compatibility Information

Table 11.2, Table 11.3, Table 11.4, Figure 11.1, Figure 11.2, and Figure 11.4 present compatible products for each cannula type used with the da Vinci Xi System and the da Vinci X System.

Note: Only the cannulae, obturators, and seal listed below should be used with the da Vinci Xi System and the da Vinci X System.

8 mm Cannula System Compatibility

Table 11.2 8 mm Cannulas, Obturators, and Cannula Seal

Cannula	Cannul-a PN	Blunt Obturator PN	8 mm Bladeless Obturator (Optical) (single use) PN	Cannula Seal PN
8 mm Cannula, Standard (1)	470002	Standard 470008 (3)	Standard 470359 (5)	470361 (7)
8 mm Cannula, Long (2)	470004	Long 470009 (4)	Long 470360 (6)	

Figure 11.1 8 mm cannulas, obturators, and cannula seal example



Table 11.3 12 mm & Stapler Cannulas, Obturators, Reducer, and Cannula Seal

12 mm & Stapler Cannula	Cannula PN	12 mm & Stapler Blunt Obturator PN	12 mm & Stapler Bladeless Obturator PN	12 mm & Stapler Bladeless Obturator (Optical) (single use) PN	12 - 8 mm Reducer PN	12 mm & Stapler Cannula Seal PN
12 mm & Stapler Cannula, Standard (1)	470375	Standard 470376 (3)	Standard 470395 (5)	Standard 470403 (7)	470381 (9)	470380 (10)
12 mm & Stapler Cannula, Long (2)	470389	Long 470390 (4)	Long 470396 (6)	Long 470404 (8)		

Figure 11.2 12 mm & Stapler cannulas, obturators, reducer, and cannula seal example

Note: The 12 mm & Stapler Bladeless Obturator (Optical), Standard (PN 470403) and the 12 mm & Stapler Bladeless Obturator (Optical), Long (PN 470404) are no longer commercially available. The non-optical, reusable obturators are an alternative to PN 470403 and PN 470404.

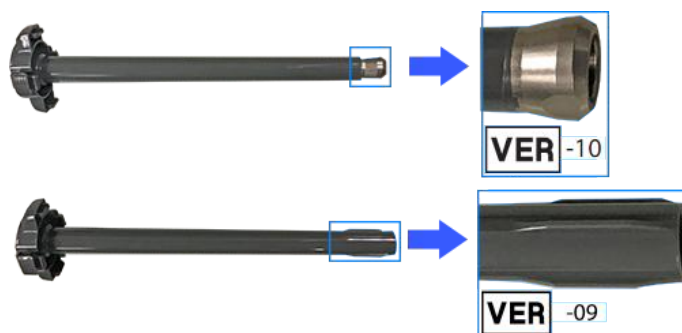
12 - 8 mm Reducer Versions

WARNING: Do not use monopolar energy when the 8 mm endoscope is introduced through the 12 mm & Stapler cannula while using a 12 - 8 mm reducer (PN 470381-09 or lower version). Only use monopolar energy with a 12 - 8 mm reducer (PN 470381-10 or higher version) when the 8 mm endoscope is introduced through the 12 mm & Stapler cannula.

The 12 - 8 mm reducer is shipped sterile and is for single use only.

This section shows the difference between versions of the 12 - 8 mm reducer: PN 470381-09 and lower, and PN 470381-10 and higher.

Figure 11.3 PN 470381-09 and 470381-10 versions



12 mm & Stapler Cannula System Compatibility

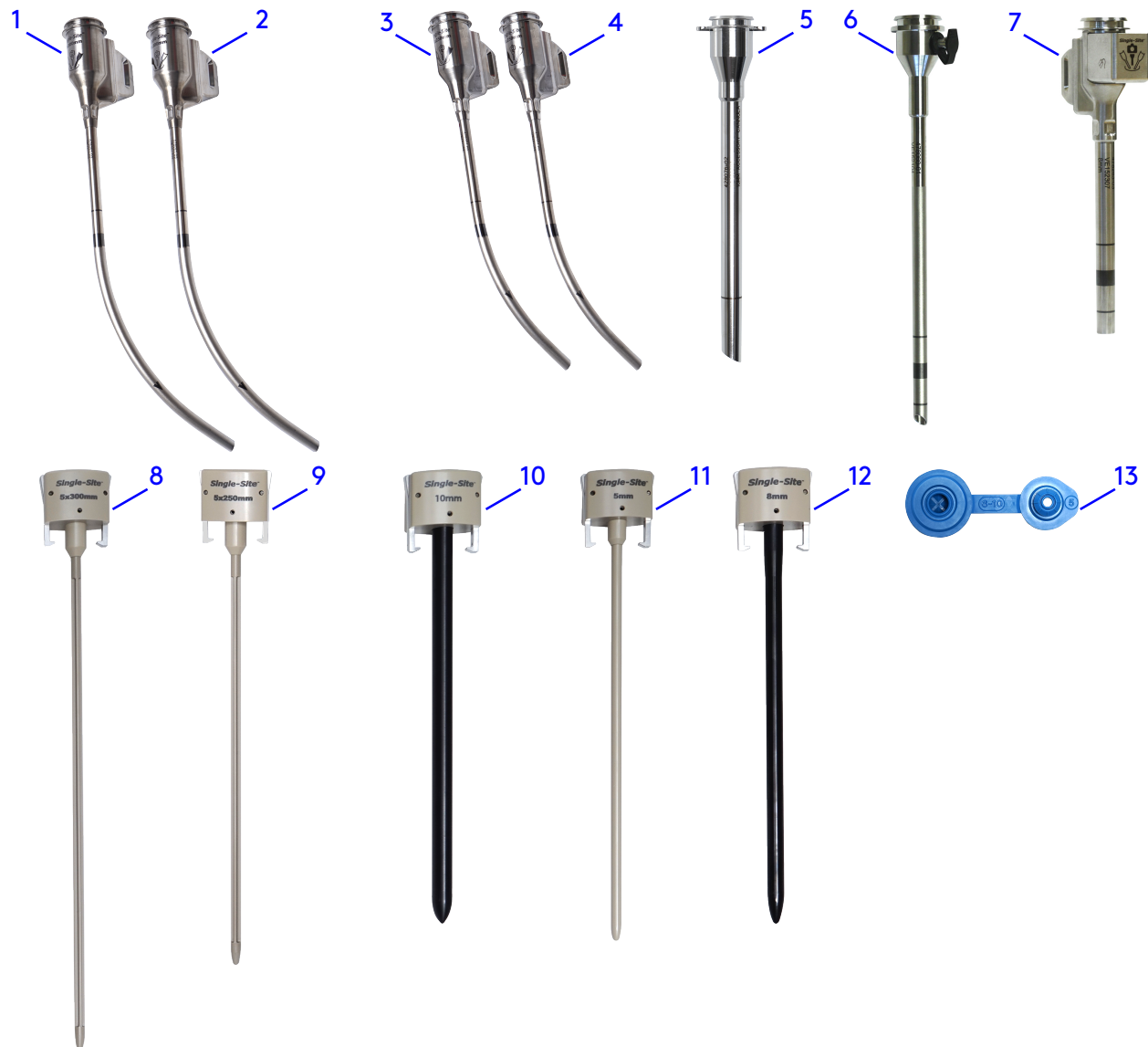
For precautions on using monopolar energy when endoscopes are introduced with the 12 mm & Stapler cannula while using the 12 - 8 mm reducer, see

[Precautions and Warnings for Endoscope Use with Monopolar Instruments](#) on page 89.

Single-Site Cannula System Compatibility

Table 11.4 Single-Site Cannulae, Obturators, and Seal

Single-Site Cannula	Cannula PN	Blunt Obturator PN	Cannula Seal PN
5 x 300 mm Curved Cannula (Endoscope Right) (1)	478061	428064 (8)	478161 (13)
5 x 300 mm Curved Cannula (Endoscope Left) (.2)	478062		
5 x 250 mm Curved Cannula (Endoscope Right) (3)	478071	428074 (9)	
5 x 250 mm Curved Cannula (Endoscope Left) (4)	478072		
10 mm Accessory Cannula (5)	428076	428084 (10)	
5 mm Accessory Cannula (6)	478060	478013 (11)	
8 mm Endoscope Cannula (7)	478263	478008 (12)	

Figure 11.4 Single-Site cannulae, obturators, and cannula seal example

Note: When Single-Site instruments are placed through a curved cannula, it is not necessary to use the built-in, 5 mm cap on the 5 - 10 mm Single-Site Cannula Seal (PN 478161) to maintain insufflation. Use of the cap can lead to increased friction.

General Precautions and Warnings

- WARNING:** The cannula must be used in conjunction with the appropriate cannula seal in order to maintain pneumoperitoneum. See [Table 11.2](#), [Table 11.3](#) and [Table 11.4](#) for cannula and seal compatibility.
- WARNING:** Ensure that the cannula or cannula seal outlet is not inadvertently blocked by patient anatomy, other instruments ports, kinked tubing, etc.

-
-  **WARNING:** Never use a double cannula (for example, an 8 mm cannula installed through the 12 mm & Stapler cannula) on the da Vinci Xi System or the da Vinci X System. This may cause instrument damage or an imbalance of the remote center, and potential injury to the patient.
-
-  **WARNING:** To prevent critical tissue injury, do not use double cannulation (placing one cannula into a larger cannula).
-
-  **WARNING:** Check the port sites throughout surgery for forces on the patient at the remote center, to prevent patient harm.
-
-  **CAUTION:** To minimize the risks associated with port placement ensure the following to prevent tissue injury:
- Appropriate patient positioning to shift organs away from the port placement site.
 - An adequate level of insufflation.
 - Obturator tip is pointing away from major vessels, organs, and other anatomic structures.
 - When possible, visualization of the entire insertion of the cannula using the endoscope is preferred.
 - Utilize continuous, controlled pressure with a deliberate rotating motion when placing the cannula and obturator.
-
-  **WARNING:** Ensure instruments inserted through the cannula are straightened before removal. Do not use excessive force when removing instruments to prevent instrument damage or patient injury.
-
-  **CAUTION:** Consider instrument length when placing ports to prevent inability to access target anatomy.
-

Complications

Potential complications associated with the use of cannulae, obturators and related accessories are the same as those associated with the use of surgical trocars and laparoscopic surgery in general. These potential complications include, but are not limited to, superficial lesions, injury to internal vessels, bleeding, hematoma, injury to the abdominal wall, infection, and peritonitis.

General Precautions and Warnings for Single-Use Accessories

 **WARNING:** Do not use another instrument to clean the Tip Cover Accessory. Doing so could tear the Tip Cover Accessory near the wrist of the Monopolar Curved Scissors, which may cause energy delivery to unintended tissues, resulting in patient injury.

 **WARNING:** Do not reuse or re-sterilize single-use accessories or instruments once they are removed from the package even if they are unused, to prevent infection.

 **WARNING:**



DO NOT RE-STERILIZE.



DO NOT RE-USE.

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



WARNING: Do not use if package is damaged.

A breach in the sterile packaging of the device indicates possible contamination. Do not use the device if the packaging is not intact.

11.3 Inspection Instructions

Before use, inspect the accessories for damage or defects.



WARNING: Do not use a damaged cannula. Damaged cannulae may abrade the instrument shaft and generate particles that may fall inside the patient.

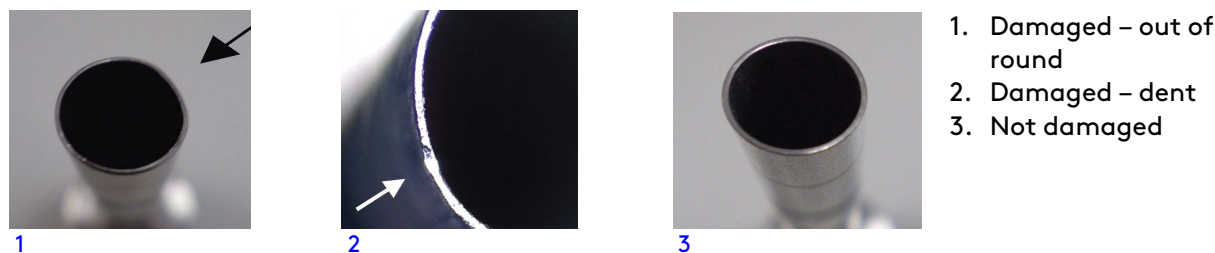


CAUTION: Do not use an obturator with visible cracks or other damage that could impact instrument alignment.

- Visibly inspect for cleanliness. Inspect the exterior of the device, paying special attention to the tip. There should be no visual contamination of the device (for example, adherent soil).
- Thoroughly inspect the device for damage.
- Hold the item up close and visually inspect for damage. Examples of damage include rough edges, dents, cracks, corruptions or an out-of-round shape that can interfere with the free insertion of instruments. The Single-Site curved cannulae were designed with a slightly oval cross section.

Figure 11.5 shows examples of cannula defects and a cannula that is not damaged.

Figure 11.5 Visual inspection examples



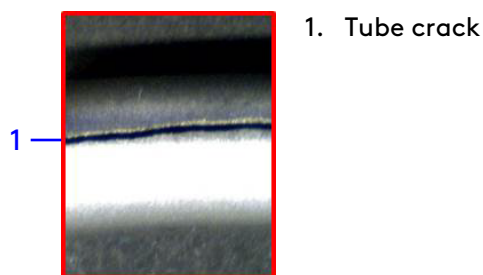
Note: Image magnification and special lighting were used in order to capture the images above. However, cannula and obturator defects can be seen under normal lighting conditions with the naked eye.

Additional Single-Site Curved Cannula Inspection

The Single-Site Curved Cannula consists of a tube attached to a bowl section that mounts to the system. The bowl section of the curved cannula contains a marking indicating the intended arm. The tube section contains additional markings including reference marks for the remote center, placement guides and product information. Visually inspect the entire tube for cracks or other tube anomalies. Pay particular attention to the area just above and below the remote center (indicated by the dark band) and at the bowl/tube interface (Figure 11.6).

Figure 11.6 Inspect cannula

Note: Visually inspect entire cannula for cracks, tube anomalies, or other damage. Pay particular attention to area below the cannula bowl and around the remote center.



Gage Pin Inspection for 8 mm Cannulas

If available, use the da Vinci 8 mm Cannula Gage Pin (PN 470397) for the 8 mm cannula inspection.

Figure 11.7 Gage pin



WARNING: Check cannulas for dents visually and with the Intuitive application-specific gage pin prior to each use. Failing to do so may permit imperfect cannulas to cause damage to the instrument, resulting in fragments in the patient.

WARNING: Follow the proper instructions on how to use the gage pin to prevent an adverse biological response.

Note: The gage pin can be sterilized using the same sterilization parameters as the reusable da Vinci EndoWrist Instruments. Refer to the Reprocessing Instructions User Manual for details.

1. Hold the cannula upright.
2. Use your thumb and index finger on the same hand to hold the gage pin above the bowl of the cannula (Figure 11.8).
3. Place your other hand under the tip of the cannula.
4. Drop the gage pin through the cannula and catch it with your hand at the cannula tip.

Figure 11.8 Inspection process

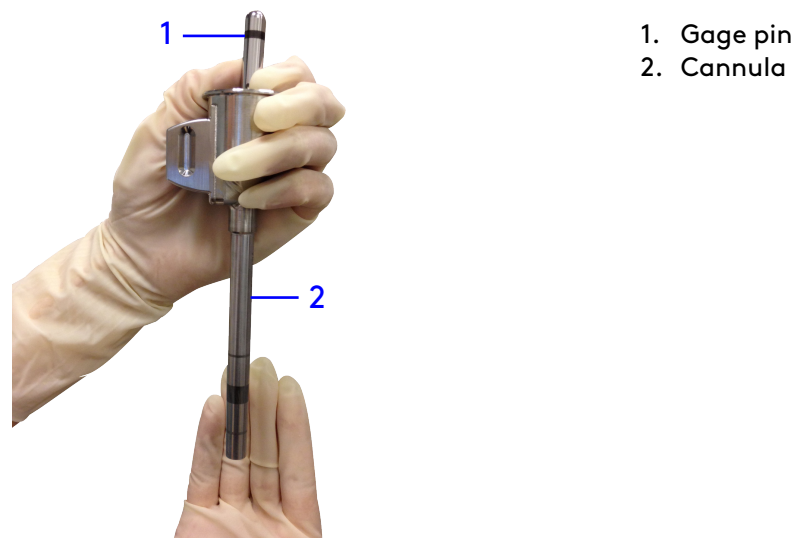


Figure 11.9 Gage pin pass and fail examples



Pass/Fail Criteria

The cannula may be used if:

- the gage pin passes through the cannula (Figure 11.9, 1)
- **and** there are no burrs or dents.

The cannula should not be used if:

- the gage pin does not pass through the cannula (Figure 11.9, 2)
- **or** there are burrs or dents.

11.4 Hasson Cone Overview

This section contains general instructions for use specific to the Hasson Cone for use with the da Vinci Xi System and the da Vinci X System.

Device Description

Hasson Cone: A device with a lumen that allows the cannula to be secured to the body wall while maintaining pneumoperitoneum (Figure 11.10).

- **Latch:** Secures the Hasson Cone to the cannula.
- **Roto-Collar™:** Allows the cannula to rotate independent of the Hasson Cone for robotic use.
- **Suture tie-downs (slot and post):** Retains 2-0 and 0 braided suture. The suture is wrapped around each post and secured in each slot.

Figure 11.10 Hasson Cones



Table 11.5 presents Hasson Cone information (name, part number, and uses).

Table 11.5 Hasson Cone Information

Hasson Cone	PN	Uses
8 mm Hasson Cone	470398	Reusable
12 mm & Stapler Hasson Cone	470399	Reusable

Compatibility

Assemble the Hasson Cone with the appropriate cannula. Table 11.6 and Table 11.7 present da Vinci Xi cannulae compatibility information.

For detailed cannula system compatibility, such as cannula lengths, obturators and cannula seals, see [11.2 Cannula System Overview](#) on page 107, [11.5 Obturator Overview](#) on page 120, and [11.6 Cannula Seal Overview](#) on page 122.

Table 11.6 8 mm Cannulas

8 mm Cannula	Cannula PN
8 mm Cannula, Standard	470002
8 mm Cannula, Long	470004

Table 11.7 12 mm & Stapler Cannulas

12 mm & Stapler Cannula	Cannula PN
12 mm & Stapler Cannula, Standard	470375
12 mm & Stapler Cannula, Long	470389

Intraoperative Use

Only a physician or medical personnel under the supervision of a physician should use Intuitive accessories.

- Using sterile technique, select and assemble the appropriate cannula, cannula seal, and blunt obturator.

For details on cannula system use, see [11.8 Cannula System Intraoperative Use](#) on page 126.

- Open the latch of the appropriately-sized Hasson Cone. Insert the blunt obturator, cannula, and cannula seal assembly into the Hasson Cone. Ensure that the tip of the cannula is flush with the tip of the Hasson Cone so instrument movement is not restricted ([Figure 11.11](#)).

Figure 11.11 Cannula inserted flush with the Hasson Cone (example)



- Cannula inserted flush with Hasson Cone

3. Close the latch, securing the Hasson Cone to the cannula.

Figure 11.12 Hasson Cone opened/closed latch (examples)

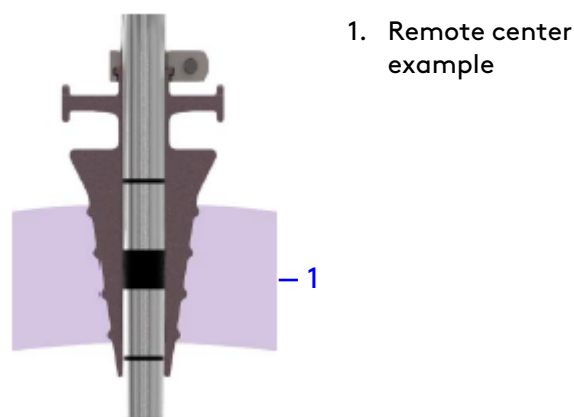


4. Make a skin incision for port placement using open surgical technique. Place two sutures into the body wall/peritoneum. These will be used to secure the Hasson Cone to the body wall.
5. Insert the Hasson Cone and cannula, cannula seal, and blunt obturator assembly into the incision.
6. Secure the Hasson Cone: pull firmly for an air-tight seal, and wrap the sutures around each post at least three times. Retain excess suture in each slot.

Insufflate the body cavity. If loss of pneumoperitoneum is experienced, adjust the Hasson Cone position and re-secure the sutures.
7. Remove the blunt obturator (leave the cannula and cannula seal assembly in place).
8. Place all remaining ports and dock each cannula to the da Vinci Xi System or the da Vinci X System Patient Cart arms, following instructions in the applicable system user manual.
9. Confirm the remote center is placed within the body wall. If needed, open the latch and move the cannula up or down within the Hasson Cone to see the remote center marking positions relative to the cone.

For detailed information on remote center, see the applicable system user manual.

Figure 11.13 Remote center example



Removal

1. Unwrap the sutures from the Hasson Cone.
2. Remove the Hasson Cone, cannula, and cannula seal assembly from the body cavity.

Reprocessing

For reprocessing information, see the Reprocessing Instructions User Manual.

11.5 Obturator Overview

i **Note:** For information on Single-Site obturators, see [Single-Site Obturators](#) on page 121.

Obturators

Obturators attach to the cannula and cannula seal assembly and facilitate the introduction of the cannula into the body cavity. The obturators have tip configurations to aid entry into the body cavity and are removed before the use of the cannula for instrument or endoscope access.

Table 11.8 presents information (name, part number and use information) for each obturator type used with the da Vinci Xi System and the da Vinci X System.

For reusable obturator reprocessing information, refer to the appropriate Reprocessing Instructions User Manual. Single-use obturators should be discarded after each use.

Table 11.8 Obturator Information

Obturator	PN	Uses
8 mm Blunt Obturator, Standard	470008	Reusable
8 mm Blunt Obturator, Long	470009	Reusable
8 mm Bladeless Obturator (Optical), Standard	470359	Single use
8 mm Bladeless Obturator (Optical), Long	470360	Single use
12 mm & Stapler Bladeless Obturator (Optical), Standard	470403	Single use
12 mm & Stapler Bladeless Obturator (Optical), Long	470404	Single use
12 mm & Stapler Blunt Obturator, Standard	470376	Reusable
12 mm & Stapler Blunt Obturator, Long	470390	Reusable
12 mm & Stapler Bladeless Obturator, Standard	470395	Reusable
12 mm & Stapler Bladeless Obturator, Long	470396	Reusable

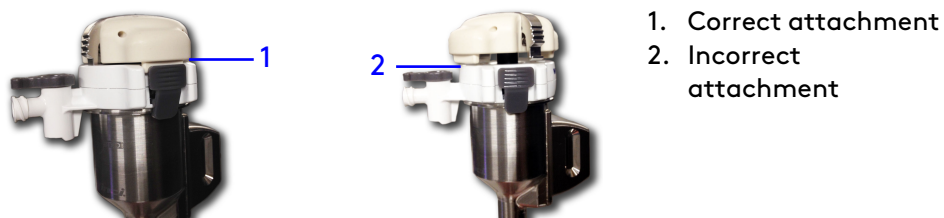
i **Note:** The 12 mm & Stapler Bladeless Obturator (Optical), Standard (PN 470403) and the 12 mm & Stapler Bladeless Obturator (Optical), Long (PN 470404) are no longer commercially available. The non-optical, reusable obturators are an alternative to PN 470403 and PN 470404.

Attaching the Obturator

⚠ WARNING: Follow the instructions in this section to ensure complete attachment of an obturator to a cannula and seal assembly. Failure to observe these instructions may result in incomplete attachment and unexpected detachment from the cannula.

When attaching an obturator to a cannula and cannula seal assembly, make sure the obturator snaps into the cannula seal or over the cannula with an audible click to ensure that it is fully engaged with the cannula seal, as shown in [Figure 11.14](#).

Figure 11.14 Correct and incorrect attachment



Removing the Obturator

To remove the obturator from a cannula, firmly squeeze the obturator latches toward each other (as shown in [Figure 11.15](#)) and pull the obturator out of the cannula and cannula seal assembly.

Note: To avoid unexpected loss of insufflation, do not remove the cannula seal.

Figure 11.15 Removing obturator



Single-Site Obturators

Single-Site obturators attach to the cannula and cannula seal assembly and facilitate the introduction of the cannula into the body cavity. The obturators have blunt tip configurations that aid entry through the port and into the body cavity, and are removed before the use of the cannula for instrument or endoscope access.

[Table 11.9](#) presents information (name, part number and use information) for each Single-Site obturator type used with the da Vinci Xi System and the da Vinci X System.

For obturator reprocessing information, refer to the appropriate Reprocessing Instructions User Manual.

Table 11.9 Single-Site Obturator Information

Obturator	PN	Uses
Single-Site 5 x 300 mm Flexible Blunt Obturator	428064	Reusable
Single-Site 5 x 250 mm Flexible Blunt Obturator	428074	Reusable
Single-Site 5 mm Accessory Blunt Obturator	478013	Reusable
Single-Site 10 mm Accessory Blunt Obturator	428084	Reusable
Single-Site 8 mm Endoscope Blunt Obturator	478008	Reusable

Attaching the Obturator



WARNING: Follow the instructions in this section to ensure complete attachment of an obturator to a cannula and seal assembly. Failure to observe these instructions may result in incomplete attachment and unexpected detachment from the cannula.

Insert the obturator into the cannula and seal assembly and ensure that the obturator is seated firmly against the cannula seal. Fasten the obturator latches over the rim of the cannula to ensure that it is fully attached.

Removing the Obturator

Unfasten the obturator latches from the rim of the cannula and pull the obturator out of the cannula and seal assembly.

11.6 Cannula Seal Overview



Note: For information on Single-Site cannula seals, see [Single-Site Cannula Seal](#) on page 124.

Cannula Seals



WARNING: Do not insert instruments through the cannula that have outside diameters less than the cannula seal diameter. This situation may cause release of gas and loss of pneumoperitoneum.



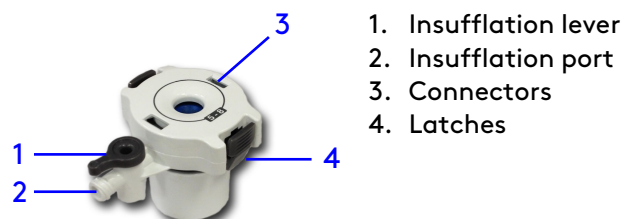
WARNING: Inserting bulky items through the cannula seal may damage the seal and generate parts that could fall into the patient, leading to patient injury.



Note: Inserting bulky items through the seal may damage the seal and cause a loss of insufflation.

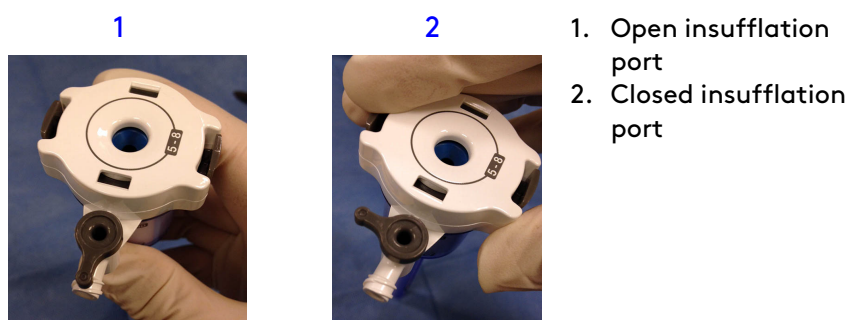
The 5 - 8 mm Cannula Seal and the 12 mm & Stapler Cannula Seal (each referred to as cannula seal) has latches on both sides to secure it into the cannula. The cannula seal is single-use and consists of an internal valve and seal to prevent gas leakage when instruments are inserted or withdrawn.

Figure 11.16 Cannula seal example



The cannula seal has an insufflation port to allow insufflating through the cannula. The lever on the port can be opened or closed to control air flow. The lever is in open position when it is straight and in line with the port and closed when it is perpendicular (in either direction) with the port.

Figure 11.17 Open and closed insufflation port



The 5 - 8 mm Cannula Seal is compatible with 8 mm da Vinci instruments and endoscopes as well as laparoscopic instruments with a diameter range of 4.7 mm (0.185 in.) to 9.4 mm (0.370 in.). Assemble the 8 mm cannula seal with the appropriate cannula.

The 12 mm & Stapler Cannula Seal is compatible with the da Vinci EndoWrist Stapler as well as laparoscopic instruments and staplers with a diameter range of 9.7 mm (0.381 in.) to 14.2 mm (0.558 in.). Assemble the 12 mm & Stapler Cannula Seal with the appropriate cannula.

Attaching the Cannula Seal

Place the cannula seal into the bowl of the cannula and push down until there is an audible click.

Removing the Cannula Seal

Firmly squeeze the latches toward each other and pull the cannula seal out of the cannula.

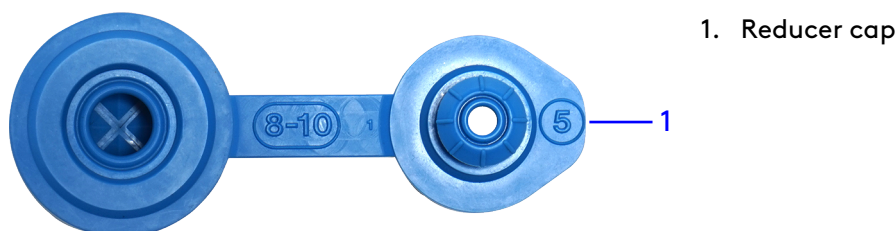
Cleaning the Cannula Seal Intraoperatively

If the cannula seal should become soiled during the procedure, gently wipe with sterile gauze moistened with sterile saline or water as needed.

Single-Site Cannula Seal

The 5 - 10 mm Single-Site Cannula Seal (referred to as cannula seal) is single-use and consists of an internal valve and seal to prevent gas leakage when instruments are inserted or withdrawn. The cannula seal has an attached reducer cap for use with 5 mm endoscopic instruments (Figure 11.18). The reducer cap is not required for use with the Single-Site instruments.

Figure 11.18 5 - 10 mm Single-Site Cannula Seal



The 5 - 10 mm Single-Site Cannula Seal is compatible with 5 mm Single-Site instruments, 8 mm da Vinci Xi endoscopes, as well as 5 mm through 10 mm laparoscopic instruments. Assemble the 5 - 10 mm Single-Site Cannula Seal with the appropriate cannula.

Attaching the Cannula Seal

Place the cannula seal onto the bowl of the cannula and push down until it is visibly seated around the circumference of the cannula bowl. If needed, install the reducer cap by folding it over the cannula seal and pushing down firmly into the seal until the reducer is completely seated against the top surface of the cannula seal.

Removing the Cannula Seal

To remove the reducer cap, firmly grip the tab on the reducer cap and pull upward while holding the cannula seal against the cannula. To remove the entire seal from the cannula, firmly grip the cannula seal and remove from the cannula bowl.

Cleaning the Cannula Seal Intraoperatively

If the cannula seal should become soiled during the procedure, gently wipe with sterile gauze moistened with sterile saline or water as needed.

11.7 Reducer

The 12 - 8 mm Reducer with integrated seal (referred to as reducer) allows the 12 mm & Stapler cannula to be used with 8 mm da Vinci instruments and endoscopes after the obturator has been removed. It is a single-use accessory and should be discarded after each use.

Attaching a Reducer

When attaching a reducer to a 12 mm & Stapler cannula, as shown in [Figure 11.19](#), make sure it snaps into the cannula seal with an audible click to ensure it is fully engaged, as shown in [Figure 11.20](#).

Figure 11.19 Attaching a reducer



Figure 11.20 Correct reducer and cannula seal attachment



1. Correct reducer and cannula seal attachment

Attaching a Reducer Cap When Using 5 mm Handheld Laparoscopic Instruments

Press the 5 - 10 mm Single-Site Cannula Seal reducer cap ([Figure 11.18](#)) firmly onto the 12 - 8 mm Reducer seal ([Figure 11.21](#)). The correct reducer cap installation is shown in [Figure 11.22](#).

Figure 11.21 12- 8 mm Reducer seal (blue)



Figure 11.22 Correct reducer cap and cannula seal attachment



Insert the 5 mm handheld laparoscopic instrument through the reducer cap.

Removing a Reducer Cap When Using 5 mm Handheld Laparoscopic Instruments

Remove the 5 mm handheld laparoscopic instrument. Pull the 5 - 10 mm Single-Site Cannula Seal reducer cap out of the reducer seal.

Removing a Reducer

Firmly squeeze the latches toward each other and pull the reducer out of the cannula through the cannula seal, as shown in [Figure 11.23](#).

Figure 11.23 Removing a reducer



Note: To avoid unexpected loss of insufflation, do not remove the cannula seal.

11.8 Cannula System Intraoperative Use

Only a physician or medical personnel under the supervision of a physician should use Intuitive accessories.

1. Remove the product from the package using standard sterile technique. To prevent damage, care should be taken not to allow the components to fall into the sterile field.
2. Ensure the reusable accessories have been appropriately sterilized according to the reprocessing instructions.
3. Using sterile technique, attach the appropriate cannula seal to the cannula.

4. Insert the obturator fully into the cannula and cannula seal assembly until latched (see [Figure 11.24](#)).

Figure 11.24 Example of cannula, cannula seal, and obturator assembly



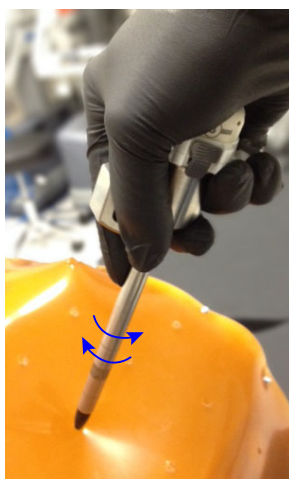
5. Make a skin incision for port placement using standard surgical technique.



Note: A skin incision that is too short will inhibit rotation of the cannula and increase resistance to insertion.

6. Position the obturator and cannula assembly in hand such that the top of the obturator is firmly supported by the palm of the hand (see [Figure 11.25](#)).
7. Before introducing the cannula, ensure that the patient is positioned to shift organs away from the port placement site and that an adequate level of insufflation has been achieved. Introduce the port through the incision and apply continuous, controlled pressure with a deliberate rotating motion of approximately 180° until the obturator and cannula tip passes through the abdominal or thoracic wall. Make sure that the obturator tip is pointing away from anatomic structures during insertion.

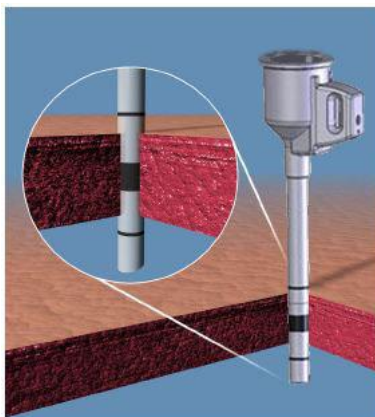
Figure 11.25 Using a rotating motion



8. When the obturator and cannula are in the body cavity, remove the obturator (leave the cannula and cannula seal assembly in place).

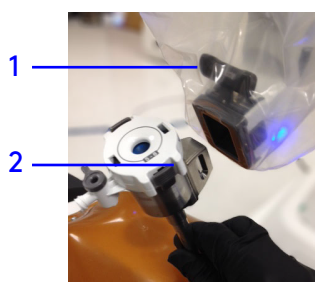
9. The remote center of the cannula (marked in black on the cannula as shown in [Figure 11.26](#)) should be placed within the boundaries of the patient body wall according to the specific procedure being performed. For thicker body wall patients, use of a long length cannula may be required to ensure the tip of the cannula remains in the body cavity during use. For more information on the remote center, see the applicable system user manual.

Figure 11.26 Illustrated example of remote center placement



10. Once all ports are placed, attach each cannula to the Patient Cart arms by (1.) pressing and holding the cannula mount lever, (2.) inserting the cannula fin, and (3.) releasing the lever ([Figure 11.27](#)). For ease of use, make sure that the cannula seal insufflation port is not facing the arm during installation to allow access for insufflation.

Figure 11.27 Securing the cannula to the arm



1. Press and hold cannula mount lever
2. Insert cannula fin
3. Release the lever

11. Insert and remove the instrument or endoscope through the cannula and cannula seal as needed intraoperatively. When using 8 mm instruments or endoscopes through a 12 mm & Stapler cannula, insert the reducer into the 12 mm & Stapler cannula and cannula seal assembly before installing the 8 mm instrument or endoscope. Remove the reducer before installing anything other than an 8 mm instrument or endoscope.
12. For cannula removal, first detach the cannula and the cannula seal assembly from the da Vinci Xi System and the da Vinci X System. Then, remove the cannula and cannula seal assembly from the body cavity.

11.9 Single-Site Intraoperative Use

For information on Single-Site intraoperative use, see [3.3 Intraoperative Use](#) on page 39.

End of section

Appendix A Reprocessing Preparation in the Operating Room

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A.1 Prime and Soak	130
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For full reprocessing information, refer to the appropriate Reprocessing Instructions User Manual.

-
-  **Note:** Carefully remove all accessories, including disposable attachments, such as removable tips or tip covers before reprocessing.
-
-  **Note:** Check the Maximum Use Indicator on the instrument housing. The indicator turns red when the instrument has reached its maximum number of clinical uses. When instruments expire, they are automatically inactivated and can no longer be used. Expired instruments must be properly disposed of.
-

When disposing of Intuitive instruments, accessories, or components, follow institution biohazard protocol and all applicable national and local laws and guidelines.

A.1 Prime and Soak

-
-  **Note:** The cleaning preparation process (as described below) must begin within 60 minutes after the procedure. Intuitive recommends starting immediately after the procedure to avoid drying of residual soil on devices.
-

Prime the instrument using a syringe with a Luer fitting to fill the Primary Flush Port with 15 mL cold water, or with enzymatic cleaner prepared in accordance with the chemical manufacturer's directions.

Soak the instruments in cold water or cleaner, or spray the instruments with a pH-neutral preparation cleaner. Alternatively, if the foregoing cannot be done, then employ a method to keep the instrument tips moist. Observe the specifications of the chemical manufacturer.

A.2 Transport to Sterile SPD or CSSD

Observe your in-house hygiene regulations, and use only suitable containers to transport devices to the sterile processing department (SPD) or central sterile supply department (CSSD).

End of section

Appendix B Symbols Defined

The following symbols may appear on packaging labels for instruments or accessories and have the meaning indicated. For a full list of symbols and icons, see the applicable system user manual.

Symbol or Icon	Meaning
	Caution: Read all warnings and precautions in instructions for use
Rx only	Federal (U.S.) law restricts this device for sale, distribution, and use by or on the order of a physician
	Manufacturer
	Date of Manufacture
	Type BF Applied Part
	Type CF Applied Part
	Non-Sterile
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Do not re-sterilize
	Do not re-use
	Do not use if package is damaged
	Keep dry
	Use by date

Symbol or Icon	Meaning
	Temperature limit
	Humidity limitation
	Non-ionizing electromagnetic radiation
	Version
	Quantity
	Batch Code
	Serial Number
	Catalogue Number
	Uses. The adjacent number indicates the number of procedures after which a device expires.
	Fires. The adjacent number indicates the number of times a device can be fired before it expires.
	Closures. The adjacent number indicates the number of times an installed clip applicator instrument can fully close its jaws before it expires.
	Contains or presence of natural rubber latex
	Peel to open

Symbol or Icon	Meaning
	Dispose of in accordance with local regulations—particularly applies to electronic components.
	MR Marking
	Double sterile barrier system
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system with protective packaging inside
	In conformance with Regulation (EU) 2017/745 European Medical Devices Regulation (MDR)
	Refer to Instruction Manual/Booklet
	Medical Device
	Authorized representative in the European Community
	Consult Instructions for Use
	Flush Port Symbol
	Direction indicator
	Open grip
	Diameter size indicator

Symbol or Icon	Meaning
	Diameter size indicator
	Diameter size indicator
	(Long) Length indicator
	(Standard) Length indicator
	For use with the EndoWrist Stapler or related accessories
	Curved Cannula (Endoscope Left) indicator
	Curved Cannula (Endoscope Right) indicator
	Endoscope Cannula indicator
	Port Marking indicator
	Target Anatomy Arrow indicator

End of section

Appendix C 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:

- Tip Cover Accessory (PN 400180)
- Energy Activation Cable (PN 371716)
- 5 - 8 mm Cannula Seal (PN 470361)
- 12 mm & Stapler Cannula Seal (PN 470380)
- 12 - 8 mm Reducer (PN 470381)
- Monopolar Cautery Cord (PN 470383)
- Bipolar Cautery Cord (PN 470384)
- Single-Site Suction Irrigator Tubing (PN 332217, provided with PN 478054)
- Single-Site Port (PN 478065)
- Single-Site 5 - 10 mm Cannula Seal (PN 478161)

End of section

Appendix D Sterilization Methods

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The following tables list the sterilization methods used for single-use instruments and accessories.

D.1 Instruments

Product	Base PN	Method of Sterilization
5 mm Bipolar Maryland	478080	Ethylene Oxide
5 mm Fenestrated Bipolar Forceps	478093	Ethylene Oxide
8 mm Suction Irrigator	480299	Ethylene Oxide

D.2 Accessories

Product	Base PN	Method of Sterilization
Tip Cover Accessory	400180	Ethylene Oxide
EndoWrist Stapler Sheath	410370	Ethylene Oxide
8 mm Bladeless Obturator (Optical), Standard	470359	Radiation
8 mm Bladeless Obturator (Optical), Long	470360	Radiation
5 - 8 mm Cannula Seal	470361	Radiation
12 mm & Stapler Cannula Seal	470380	Radiation
12 - 8 mm Reducer	470381	Radiation
12 mm & Stapler Bladeless Obturator (Optical), Standard	470403	Radiation
12 mm & Stapler Bladeless Obturator (Optical), Long	470404	Radiation
Single-Site Port for 8 mm Endoscope	478065	Ethylene Oxide
Single-Site 5 - 10 mm Cannula Seal	478161	Ethylene Oxide



Note: The 12 mm & Stapler Bladeless Obturator (Optical), Standard (PN 470403) and the 12 mm & Stapler Bladeless Obturator (Optical), Long (PN 470404) are no longer commercially available. The non-optical, reusable obturators are an alternative to PN 470403 and PN 470404.

End of section

Appendix E Intended Use/Indications for Use

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E.1 Contraindication - Weck Hem-o-lok Ligating Clips

Hem-o-lok ligating clips are not intended for use as a fallopian contraceptive tubal occlusion device. Hem-o-lok ligating clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

E.2 Contraindication - da Vinci Hasson Cones

Da Vinci Hasson Cones are contra-indicated for use in the intercostal space for thoracoscopy.

E.3 Intended Use/Indications for Use

The following tables describe the intended use/indications for use for instruments and accessories used with da Vinci Xi and da Vinci X systems that are approved in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices).

Single-Site Trocar

Instrument Name	Part Number	Intended Use/Indications for Use
5 x 300 mm Flexible Blunt Obturator	428064	The Blunt Flexible Obturators are intended to be used in endoscopic surgery to introduce a port of entry (e.g., curved cannula) to the surgical site.
5 x 250 mm Flexible Blunt Obturator	428074	The Blunt Flexible Obturators are intended to be used in endoscopic surgery to introduce a port of entry (e.g., curved cannula) to the surgical site.
10 mm Accessory Cannula	428076	The Single-Site Accessory Cannula is intended to be used in endoscopic surgery to establish a port of entry for laparoscopic instruments and surgical accessories.
Single-Site 8 mm Obturator	478008	The Single-Site Blunt Obturator is intended to be used in endoscopic surgery to introduce a port of entry (i.e., cannula) to the surgical site.
Single-Site 5 mm Accessory Obturator	478013	The Single-Site Blunt Obturator is intended to be used in endoscopic surgery to introduce a port of entry (i.e., cannula) to the surgical site.
Single-Site 5 mm Accessory Cannula	478060	The Single-Site Accessory Cannula is intended to be used in endoscopic surgery to establish a port of entry for laparoscopic instruments and surgical accessories.
Single-Site 5 x 300 mm Curved Cannula (Endoscope Right)	478061	The Curved Cannula is intended to be used in endoscopic surgery to establish a port of entry for Single-Site robotic instruments.
Single-Site 5 x 300 mm Curved Cannula (Endoscope Left)	478062	
Single-Site Port for 8 mm Endoscope	478065	The Single-Site Port is intended to be used in endoscopic surgery to maintain insufflation and provide a point of entry for robotic and laparoscopic cannulae.
Single-Site 5 x 250 mm Curved Cannula (Endoscope Right)	478071	The Curved Cannula is intended to be used in endoscopic surgery to establish a port of entry for Single-Site robotic instruments.
Single-Site 5 x 250 mm Curved Cannula (Endoscope Left)	478072	

Instrument Name	Part Number	Intended Use/Indications for Use
Single-Site 5-10 mm Cannula Seal	478161	The Single-Site Cannula Seal is intended to be used in endoscopic surgery to maintain insufflation and provide a point of entry for robotic and laparoscopic instruments, endoscopes and surgical accessories.
Single-Site 8 mm Endoscope Cannula	478263	The Camera Cannula is intended to be used in endoscopic surgery to establish a port of entry for endoscopes and surgical accessories.
10 mm Accessory Blunt Obturator	428084	The Single-Site Blunt Obturator is intended to be used in endoscopic surgery to introduce a port of entry (i.e., cannula) to the surgical site.

Bipolar

Instrument Name	Part Number	Intended Use/Indications for Use
Micro Bipolar Forceps	470171	The EndoWrist Micro Bipolar Forceps are intended to be used with the da Vinci system for endoscopic manipulation of tissue including dissection, grasping and retraction, while being able to deliver bipolar energy.
Maryland Bipolar Forceps	470172	The EndoWrist Maryland Bipolar Forceps are intended to be used with the da Vinci system for endoscopic manipulation of tissue including dissection, grasping and retraction, while being able to deliver bipolar energy.
Fenestrated Bipolar Forceps	470205	The EndoWrist Fenestrated Bipolar Forceps are intended to be used with the da Vinci system for endoscopic manipulation of tissue including dissection, grasping and retraction, while being able to deliver bipolar energy.
Curved Bipolar Dissector	470344	The EndoWrist Curved Bipolar Dissector is intended to be used with the da Vinci system for endoscopic manipulation of tissue including dissection, grasping and retraction, while being able to deliver bipolar energy. Additionally, the EndoWrist Curved Bipolar Dissector is specially designed for surgical tasks requiring dissection and tissue plane separation around vessels, lymph nodes and bronchiolar structures.
Long Bipolar Grasper	470400	The EndoWrist Long Bipolar Grasper is intended to be used with the da Vinci system for dissecting, grasping, manipulating, retracting, and coagulating tissue and vessels.
Force Bipolar	470405	The EndoWrist Force Bipolar is intended to be used with compatible systems for endoscopic manipulation of tissue, including dissection, grasping, retraction, and bipolar coagulation of tissue.

Clip Applier

Instrument Name	Part Number	Intended Use/Indications for Use
Large Clip Applier	470230	The EndoWrist Large Clip Applier is intended to be used with the da Vinci system for the application of Large Hem-o-Lok clips for ligation of vessels and tissue bundles ranging in size from 5-13 mm in diameter.
Medium-Large Clip Applier	470327	The EndoWrist Medium-Large Clip Applier is intended to be used with the da Vinci system for the application of Medium-Large Hem-O-Lok clips for ligation of vessels and tissue bundles ranging in size from 3-10 mm in diameter.
Small Clip Applier	470401	The EndoWrist Small Clip Applier is intended to be used with the da Vinci system and Weck Horizon small/wide clips for the ligation of small vessels.

Cold Scissors / Grasp / Retract

Instrument Name	Part Number	Intended Use/Indications for Use
Potts Scissors	470001	The EndoWrist Potts Scissors are intended to be used with the da Vinci system for endoscopic manipulation of tissue, including: cutting and sharp dissection.
Round Tip Scissors	470007	The 8 mm EndoWrist Round Tip Scissors is intended to be used with the da Vinci system for dissecting and cutting tissue.
Black Diamond Micro Forceps	470033	The EndoWrist Black Diamond Micro Forceps are intended to be used with the da Vinci system to manipulate small needles and fine tissue for precise tissue repair surgery.
DeBakey Forceps	470036	The 8 mm EndoWrist DeBakey Forceps are intended to be used with the da Vinci system for grasping, manipulating, and retracting tissue.
Long Tip Forceps	470048	The EndoWrist Long Tip Forceps are intended to be used with the da Vinci system to perform surgical tasks requiring atraumatic grasping, retraction and manipulation of delicate tissue structures.
Cadiere Forceps	470049	The 8 mm EndoWrist Cadiere Forceps are intended to be used with the da Vinci system for dissecting, grasping, manipulating, and retracting tissue.
ProGrasp Forceps	470093	The EndoWrist ProGrasp Forceps are intended to be used with the da Vinci system to perform surgical tasks requiring strong grasping and manipulation of various tissue types.
Resano Forceps	470181	The EndoWrist Resano Forceps are intended to be used with the da Vinci system to perform surgical tasks requiring atraumatic grasping of delicate tissue structures.

Instrument Name	Part Number	Intended Use/Indications for Use
Cobra Grasper	470190	The 8 mm EndoWrist Cobra Grasper is intended to be used with the da Vinci system for aggressively grasping, manipulating, and retracting dense or fibrous tissue.
Tenaculum Forceps	470207	The EndoWrist Tenaculum Forceps are intended to be used with the da Vinci system to perform surgical tasks that require strong grasping, retention and retraction of dense and/or fibrous tissues.
Dual Blade Retractor	470249	The EndoWrist Dual Blade Retractor is intended to be used with the da Vinci system to perform surgical tasks requiring atraumatic manipulation and exposure/retraction of soft tissue.
Small Grasping Retractor	470318	The EndoWrist Small Graptor (Grasping Retractor) is intended to be used with the da Vinci system to perform surgical tasks requiring atraumatic grasping and retracting of a variety of tissue structures.
Tip-Up Fenestrated Grasper	470347	The 8 mm EndoWrist Tip-Up Fenestrated Grasper is intended to be used with the da Vinci system to perform surgical tasks requiring atraumatic grasping and manipulation of soft tissues. Furthermore it is intended to facilitate atraumatic blunt dissection and safe passage around vessels, tissue bundles and pulmonary structures.
Atrial Retractor Short Right	470246	The EndoWrist Atrial Retractor Short Right is intended to be used with the da Vinci system to perform surgical tasks requiring atraumatic manipulation and exposure/retraction of soft tissue such as the atrial/septal heart tissue.
Cardiac Probe Grasper	470215	The EndoWrist Cardiac Probe Grasper is intended to be used with the da Vinci system to deliver and place cryogenic ablation probes used during cardiac tissue ablation procedures, to perform precise and blunt dissection of tissue and to atraumatically handle delicate tissue.

Monopolar

Instrument Name	Part Number	Intended Use/Indications for Use
Tip Cover Accessory	400180	The Tip Cover Accessory is intended to provide insulation over a section of the EndoWrist Monopolar Curved Scissors instrument so that RF energy is only available at the tip.
Monopolar Curved Scissors	470179	The EndoWrist Monopolar Curved Scissors is intended to be used with the da Vinci system for endoscopic manipulation of tissue, including: cutting, blunt and sharp dissection, electrocautery.
Permanent Cautery Hook	470183	The EndoWrist Permanent Cautery Hook is intended to be used with the da Vinci system for precise dissection and division of tissue with monopolar cautery.
Permanent Cautery Spatula	470184	The EndoWrist Permanent Cautery Spatula is intended to be used with the da Vinci system for precise dissection and division of tissue with monopolar cautery.

Needle Driver

Instrument Name	Part Number	Intended Use/Indications for Use
Large Needle Driver ¹	470006	The Large Needle Driver is intended to be used with the da Vinci X and Xi surgical systems for handling and driving needles and handling and tying suture.
Mega Needle Driver ¹	470194	The Mega Needle Driver is intended to be used with the da Vinci X and Xi surgical systems for handling and driving needles and handling and tying suture.
Large SutureCut Needle Driver	470296	The Large SutureCut Needle Driver is intended to be used with the da Vinci X and Xi surgical systems for handling and driving needles and handling, tying, and cutting suture.
Mega SutureCut Needle Driver	470309	The Mega SutureCut Needle Driver is intended to be used with the da Vinci X and Xi surgical systems for handling and driving needles and handling, tying, and cutting suture.

Needle Driver Specifications

Instrument Name	Part Number	Jaw Length (cm)
Large Needle Driver	470006	1.0 cm
Mega Needle Driver	470194	1.3 cm
Large SutureCut Needle Driver	470296	1.1 cm
Mega SutureCut Needle Driver	470309	1.1 cm

1. The Intended Use of the Large Needle Driver and Mega Needle Driver is to handle and drive needles through tissue. There are many variables around driving needles, including needle size and tip configuration, suture type, tissue type, and tissue thickness and toughness. Surgeons should choose the appropriate needle and suture combination based on their clinical application by referring to the Needle Driver specifications which shows the dimensions of the needle driver jaw length.

Single-Site

Instrument Name	Part Number	Intended Use/Indications for Use
Single Site	NA	The Intuitive Surgical da Vinci Xi Single-Site instruments and accessories used with the da Vinci Xi Surgical System (IS4000) and the da Vinci X Surgical System (IS4200) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery, suction/irrigation and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the da Vinci Xi Single-Site Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, clip appliers, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, 8 mm endoscope cannula, flexible and rigid blunt obturators, cannula seal, and the Single-Site Port.
Maryland Dissector	478050	The Single-Site Maryland Dissector is intended to be used with the da Vinci system and Single-Site instruments and accessories for dissection, grasping, manipulating, and retracting tissue.
Medium-Large Clip Applier	478052 478053	The Single-Site Medium-Large Hem-O-Lok Clip Applier is intended to be used with the da Vinci Surgical System and Single-Site instruments and accessories for the application of Medium-Large Hem-O-Lok clips for ligation of vessels and tissue bundles ranging in size from 3-10 mm in diameter.
Suction Irrigator	478054	The Single-Site Suction Irrigator is intended to be used with the da Vinci system and Single-Site instruments and accessories, including compatible sources and tubing sets for suction and irrigation, and blunt dissection of tissue.

Instrument Name	Part Number	Intended Use/Indications for Use
Cadiere Forceps	478055	The Single-Site Cadiere Forceps are intended to be used with the da Vinci system and Single-Site instruments and accessories for grasping, manipulating, and retracting tissue.
Curved Scissors	478057	The Single-Site Curved Scissors are intended to be used with the da Vinci system and Single-Site instruments and accessories for dissecting and cutting tissue.
Fundus Grasper	478058	The Single-Site Fundus Grasper are intended to be used with the da Vinci system and Single-Site instruments and accessories for grasping, manipulating, and retracting tissue.
Crocodile Grasper	478059	The Single-Site Crocodile Grasper is intended to be used with the da Vinci system and Single-Site instruments and accessories for grasping, manipulating, and retracting tissue.
Bipolar Maryland	478080	The Single-Site Bipolar Maryland is intended to be used with the da Vinci system and Single-Site instruments and accessories for dissection, manipulation, grasping, retraction and bipolar coagulation of tissue.
Curved Needle Driver	478088	The Single-Site Curved Needle Driver is intended to be used with the da Vinci system and Single-Site instruments and accessories for handling and driving needles and handling and tying sutures.
Permanent Cautery Hook	478090	The Single-Site Permanent Cautery Hook is intended to be used with the da Vinci system and Single-Site instrument and accessories for dissection and monopolar cautery.

Instrument Name	Part Number	Intended Use/Indications for Use
Fenestrated Bipolar Forceps	478093	The Single-Site Fenestrated Bipolar Forceps is intended to be used with the da Vinci system and Single-Site instruments and accessories for dissection, manipulation, grasping, retraction and bipolar coagulation of tissue.
Wristed Needle Driver	478114 478115	The Single-Site Wristed Needle Driver is intended to be used with the da Vinci system and Single-Site instruments and accessories for handling and driving needles and handling and tying sutures.

Suction Irrigator

Instrument Name	Part Number	Intended Use/Indications for Use
Suction Irrigator	480299	The EndoWrist Suction Irrigator is intended for use in all endoscopic surgical applications where the compatible da Vinci system is indicated. The EndoWrist Suction Irrigator is designed to be used in conjunction with an Intuitive Surgical da Vinci system and compatible suction and irrigation sources and tubing sets for delivering fluid to the surgical site and for evacuation and aspiration of fluids. The instrument may also be used for retraction and blunt dissection of tissue.

Trocar

Instrument Name	Part Number	Intended Use/Indications for Use
8 mm Instrument Cannula	470002	Cannulas are essentially hollow tubes that provide a path for instruments to extend into the surgical site, typically through the abdominal or chest wall of the patient.
8 mm Instrument Cannula, Long	470004	
12 mm & Stapler Cannula	470375	
12 mm & Stapler Cannula, Long	470389	
8 mm Blunt Obturator	470008	Obturers provide a means of inserting the cannulas into the surgical site by providing a tip that extends beyond the cannula's most distal point.
8 mm Blunt Obturator, Long	470009	
12 mm & Stapler Blunt Obturator	470376	
12 mm & Stapler Blunt Obturator, Long	470390	
8 mm Bladeless Obturator, Long	470360	The Bladeless Obturator (Optical) is intended to be used in endoscopic surgery to introduce a port of entry (i.e., cannula) to the surgical site.
8 mm Bladeless Obturator	470359	
12 mm & Stapler Bladeless Obturator	470403	
12 mm & Stapler Bladeless Obturator, Long	470404	
12 mm & Stapler Bladeless Obturator	470395	
12 mm & Stapler Bladeless Obturator, Long	470396	
5-8 mm Cannula Seal	470361	The seal maintains pneumoperitoneum as various surgical instruments are passed through the cannula.
12 mm & Stapler Cannula Seal	470380	
12-8 mm Reducer	470381	The Reducer is intended to support use of a da Vinci system 8 mm instrument or endoscope with the 12 mm & Stapler Cannula during a procedure.
12 mm & Stapler Hasson Cone	470399	Hasson Cones are intended to be used in endoscopic surgery to anchor a port of entry (i.e., cannula) to the patient. da Vinci Hasson Cones are contra-indicated for use in the intercostal space for thoracoscopy.
8 mm Hasson Cone	470398	
8 mm Flared/Grounded Cannula	470319	The 8 mm Flared/Grounded cannula is intended to be used with the da Vinci system to serve as a port of entry during da Vinci procedures that do not require maintenance of insufflation.

Release Kit

Instrument Name	Part Number	Intended Use/Indications for Use
EndoWrist Instrument Release Kit	381216	The EndoWrist Instrument Release Kit (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.

Additional Accessories

Instrument Name	Part Number	Intended Use/Indications for Use
8 mm Instrument Introducer	342562	The 8 mm Instrument Introducer is used to preserve the integrity of instrument tips and the cannula seal during insertion and instrument insertion and removal.
Energy Activation Cable, Covidien Force Triad	371716	The Energy Activation Cable is intended to connect the Covidien Force Triad ESU to the da Vinci system and allows the use of the foot pedals on the Surgeon Console when using the ESU.
8 mm Cannula Gage Pin	470397	The 8 mm Cannula Gage Pin is used to inspect 8 mm cannulae.
Monopolar Cautery Cord	470383	The Monopolar and Bipolar Cautery Cords are intended for connecting monopolar/bipolar electro-surgical instruments to an electro-surgical generator to provide transmission of high frequency current from the electro-surgical generator to the surgical instrument.
Bipolar Cautery Cord	470384	

End
