DAVINCI | SP™

intuitive.com

Instruments and Accessories
User Manual

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

EC REP Intuitive Surgical, Sàrl
Chemin des Mûriers 1
1170 Aubonne, Switzerland

PN 553415-03 REV. A 2019.11

Trademarks

Intuitive, Intuitive Surgical, da Vinci, da Vinci SP, EndoWrist SP, EnergyShield, EntryGuide, are trademarks or registered trademarks of Intuitive Surgical, Inc. Product names are trademarks or registered trademarks of their respective holders.

Rx only

Contents

1 General Information

1.1 How to Use this Manual

This User Manual provides instructions for use and limitations on use for instruments and accessories used with the da Vinci SP® Surgical System model SP1098 (referred to in this manual as da Vinci SP System). It is not a reference for surgical techniques. This User Manual is to be used in conjunction with the *da Vinci SP System User Manual*, *da Vinci SP Reprocessing Instructions for Accessories*, *da Vinci SP Reprocessing Instructions for Instruments*, *da Vinci SP Reprocessing Instructions for Camera*, and *da Vinci SP Reprocessing Instructions Appendices*. These documents provide general information that applies broadly to use of the da Vinci SP System, instruments and accessories. Additional information related to the use of the da Vinci SP System, instruments and accessories is available as follows:

- **Addenda:** Information related to new features, corrections, optional accessories, training information, updated references, or new part numbers may be provided as addenda to the da Vinci SP User Manuals.
- **Supplements:** Supplements to the da Vinci SP User Manuals provide additional information specific to the types of surgical procedures that are cleared for a particular market. For information on specific types of surgical procedures, refer to the appropriate supplement that is available for your market.

Prior to use of this User Manual, ensure access to the latest revision of all applicable addenda and supplements.

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 such as generators and the applicable user manuals for the da Vinci SP System may lead to injury and result in improper functioning of the device.

Note: Read Knowing What Applies: Organization of this Manual (page 2) 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 Surgical supplies it with that instrument or accessory.

Non-Sterile

Note: Intuitive Surgical devices ship non-sterile unless otherwise indicated in the device's labeling. Clean and sterilize reusable devices before each use, unless a particular device is not used within the sterile field.

Note: Use standard sterile technique for proper handling and cleaning of components that enter the sterile field.

Knowing What Applies: Organization of this Manual

- Chapter 1 General Information (the chapter you are reading now) applies to all da Vinci SP instruments and accessories supplied by Intuitive Surgical. Includes general precautions.
- Chapter 2 EndoWrist SP Camera provides general information for the EndoWrist SP® Camera, and da Vinci SP® Camera Sheath installation and removal instructions.
- Chapter 3 EndoWrist SP Instruments provides general information that applies to all EndoWrist SP® instruments including Instrument Sheath installation and removal instructions.
- Chapter 4 Medium-Large Clip Applier provides specific instrument information and instructions for use.
- Chapter 5 Monopolar Curved Scissors provides specific instrument information including tip accessory installation and removal instructions.
- Chapter 6 Monopolar Cautery Instrument provides specific instrument information including tip accessory installation and removal instructions.
- Chapter 7 Bipolar Instruments provides general instrument information.
- Chapter 8 Using the Electrosurgical Unit (ESU) with Monopolar and Bipolar Instruments provides general information on the ERBE VIO® dV 2.0, EnergyShield® Monitor, use of the monopolar and bipolar instruments, energy activation settings and troubleshooting.
- Chapter 9 da Vinci SP Port Accessories provides general information for the port accessories and instructions for use.
- Appendix A: Reprocessing Preparation in the Operating Room provides information on reprocessing preparation in the operating room.
- Appendix B: Symbols Defined provides information about symbols that may appear on packaging and labels for instruments and accessories.
- Appendix C: Natural Rubber Latex provides information about products referenced in the manual that are not made with natural rubber latex.
- Appendix D: Intended Use Statements provides information about the specific intended use of individual da Vinci SP instruments and accessories.

- Appendix E: Sterilization Methods provides information about sterilization methods used for single-use Intuitive Surgical products referenced in this manual.

1.2 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 Surgical or our products and services.

In the U.S.

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

In Europe

Intuitive Surgical, Sàrl
Chemin des Mûriers 1
1170 Aubonne, Switzerland
Toll free: +800.0821.2020
Direct: +41.21.821.2020
Fax: +41.21.821.2021

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. In Europe, call +41.21.821.2020.

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

1.3 Limitation on Use: Limited License

Intuitive Surgical da Vinci SP instruments and accessories are provided pursuant to a limited license to use only with the Intuitive Surgical da Vinci SP System (Endoscopic Instrument Control System, Model SP1098). 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 Surgical instruments and accessories is strictly prohibited and results in expiration of limited license.

1.4 Indications for Use/Intended Use

For information on specific indications for use and intended use of the da Vinci SP Surgical System, refer to the appropriate da Vinci SP supplement. For information on specific intended uses of each instrument and accessory, see Appendix D: Intended Use Statements in this manual.

1.5 General Warnings and Cautions

WARNING: When instruments (camera and surgical) are not in use, they need to be placed in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

WARNING: Do not use instruments, cameras, or accessories that have been reprocessed with single-use accessories installed. Inadequate sterilization may occur when these single-use accessories, such as the MCS Tip, monopolar cautery tip, sheath, SP Cannula Seal, or EntryGuide™ (also known as Entry Guide), are installed during reprocessing.

CAUTION: Use only the instruments and accessories approved by Intuitive Surgical. System compatibility with non-approved instrumentation cannot be guaranteed.

CAUTION: EndoWrist SP instruments and accessories should be handled and operated by trained personnel.

Cautions for Single-Use Items

CAUTION:  **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.

CAUTION:  **Do not use if package is damaged.**

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

1.6 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 Surgical 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 Surgical instruments, accessories, or any of their components, follow all applicable national and local laws and guidelines. Do not dispose of cameras.

End of section

2 EndoWrist SP Camera

2.1 Introduction

This chapter contains general information for the EndoWrist SP® Camera (also referred to as endoscope) and da Vinci SP® Camera Sheath. For further information on the camera, refer to the *da Vinci SP System User Manual*.

Intended Use

For intended use of the camera and associated accessories, see Appendix D: Intended Use Statements.

General Warnings and Cautions

WARNING: Do not use instruments, cameras, or accessories that have been reprocessed with single-use accessories installed. Inadequate sterilization may occur when these single-use accessories, such as the MCS Tip, monopolar cautery tip, sheath, SP Cannula Seal, or EntryGuide™ (also known as Entry Guide), are installed during reprocessing.

WARNING: The EndoWrist SP camera and instruments must be used with the appropriate SP Cannula, SP Cannula Seal, and Entry Guide. Refer to Chapter 9 da Vinci SP Port Accessories for details.

CAUTION: All EndoWrist SP surgical instruments and the camera must be covered with sheaths designed specifically for use with the da Vinci SP System before surgical use.

CAUTION: Always have a backup camera and instruments available to complete the surgical procedure in case of failure.

CAUTION: Handle the camera carefully. The camera is delicate and can be broken if dropped or struck. Adhere to the sterilization, inspection, and connection requirements.

CAUTION: Handle the camera cable carefully. If bent sharply or kinked, it can damage the internal fibers. Damage to the camera cable can occur through repetitive actions during use in surgical or cleaning procedures. Such damage can substantially reduce the amount of light transmitted through the cable.

Device Description

The camera is an articulated instrument that includes a small stereo three-dimensional (3D) camera with a 73-degree field-of-view (FOV) located at the distal end of the shaft. The camera acquires 3D video from the surgical site in high definition (HD). The HD video is processed by the system electronics in the Vision Cart and displayed on the Surgeon Console 3D viewer and Vision Cart touchscreen.

The surgeon controls the camera with a single hand control (master). The camera does not feature shaft roll, but the elbow and wrist joints enable the surgeon to move the camera tip (at the distal end) to choose a vantage point to visualize the surgical scene.

The camera consists of the tip, wrist, forearm, elbow, shaft, housing, release buttons, cable, and connector (Figure 2.1).

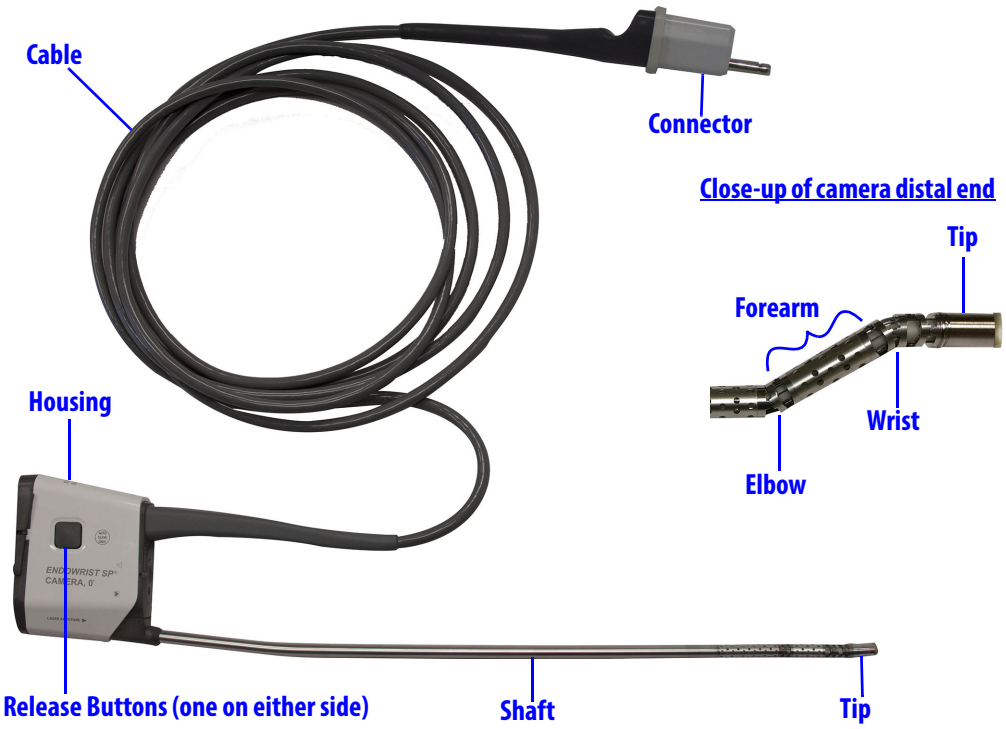

Figure 2.1 Camera

2.2 Preoperative Preparation

Inspection Before Use

WARNING: Do not use cameras with any defects or signs of damage, including damage to the glass surface at the cable connector end, glass surface at the distal tip, or cables. Serious injury or surgical complications may occur to the patient.

WARNING: Do not use a camera that has been reprocessed with a sheath installed. Inadequate sterilization may occur when single-use accessories are installed during reprocessing.

Note: By design, the camera shaft has a slight bend near the housing. This is not a defect. (See Figure 2.1.)

Before each use, the camera should be inspected for any physical damage or irregularities.

- Prior to each procedure, thoroughly inspect the camera for mechanical or optical defects.
- Visually inspect the exterior of the device for cleanliness, paying special attention to the tip. There should be no visual contamination of the device (for example, adherent soil). If the device has any residual contamination, do not use it.
- Thoroughly inspect the camera for mechanical or optical defects. Remove the camera from the sterilization tray.
- Inspect the glass surfaces at the distal tip and at the cable connector end. These areas should be clean and free of any deposits, residues or haze to ensure a bright and clear image.
- Inspect camera surfaces carefully for any irregularities or damage: sharp edges, cracks, dents, corrosion or mechanical defects.
- Inspect the camera cable for any cuts, damage or defects.

da Vinci SP Camera Sheath Overview

The da Vinci SP® Camera Sheath (PN 430020) is specifically designed to cover the camera and must be installed on the camera prior to surgical use. The Camera Sheath is supplied sterile and is for single use only; do not reuse the Camera Sheath. Always install the Camera Sheath (Figure 2.2) in the sterile field.

Figure 2.2 Camera Sheath

Camera Sheath Installation

WARNING: Inspect the Camera Sheath for damage throughout use. Examples of damage include tears or cuts in the sheath material. If damage is observed, remove and replace the Camera Sheath to prevent thermal hazards or other risks.

CAUTION: All EndoWrist SP surgical instruments and the camera must be covered with sheaths designed specifically for use with the da Vinci SP System before surgical use.

CAUTION: After the sheath is installed on a camera or instrument, do not reuse the sheath on another camera or instrument.

CAUTION: Use caution when installing and removing the sheaths to avoid camera shaft, elbow, or wrist damage. Use gloves with sufficient grip to aid with installation and removal of the sheath.

Note: Use care when placing the sheath onto the camera to prevent damage to the glass surface at the distal tip or camera distal joints.

1. Remove the Camera Sheath (Figure 2.2) from the sterile packaging using sterile technique.
2. Straighten the distal end of the camera shaft (Figure 2.3 A). Slide the connector end of the sheath onto the shaft and slide the sheath down the shaft (Figure 2.3 B).

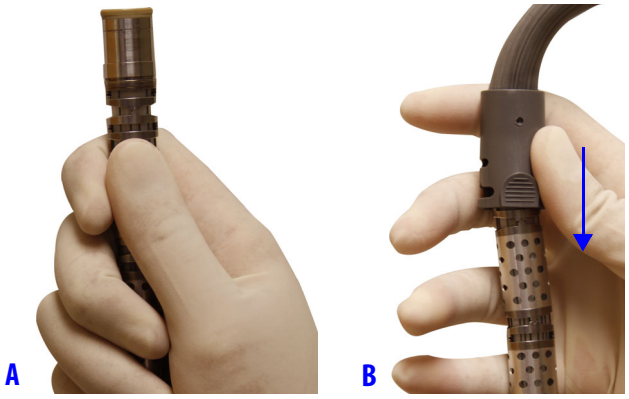

Figure 2.3 Straighten the distal end of the camera (A) and slide the sheath onto the shaft (B)

3. Press down the connector on the sheath until it is over the flanges on the base of the camera shaft, and there is a tactile and audible click (Figure 2.4).

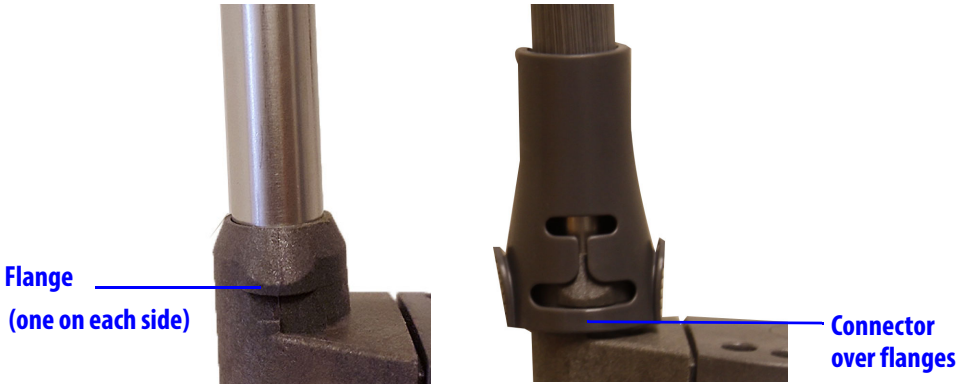

Figure 2.4 Connector over the flanges on the base of instrument shaft

4. With one hand, wrap your fingers around the joints to stabilize the camera tip and hold your thumb over the black band on the distal end of the sheath (as shown in Figure 2.5). Slide the black band down until your thumb contacts the camera lens and the band is past the distal ridge.

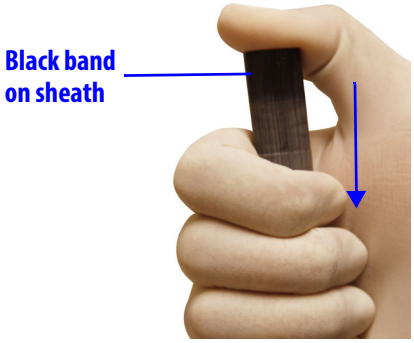

Figure 2.5 Hold thumb over black band and push black band down onto distal tip

5. Confirm that the sheath is correctly installed by ensuring that the black band of the sheath rests between the two ridges (as shown in Figure 2.6 and Figure 2.7 C). If the sheath is incorrectly installed, adjust the position of the black band or remove and reinstall the sheath.

Figure 2.6 Ridges on the camera tip

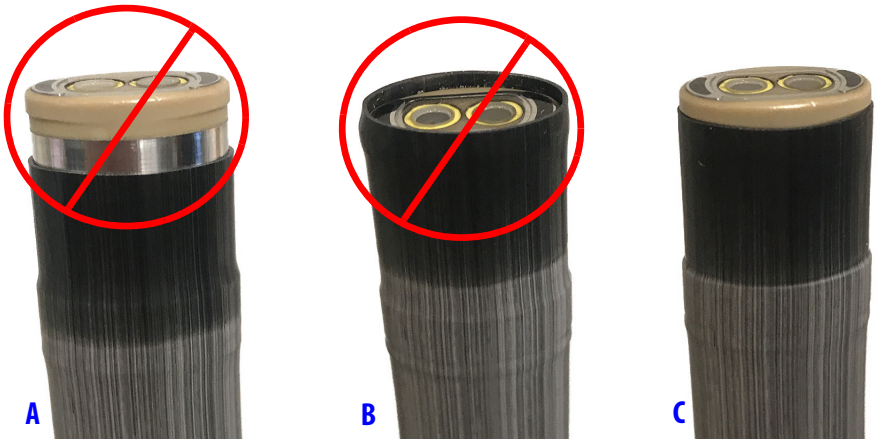

Figure 2.7 Examples of incorrect installation (A and B) and correct installation (C)

2.3 Intraoperative Use

For information on intraoperative use (installation, insertion, and removal of the camera), refer to the *da Vinci SP System User Manual*.

2.4 Postoperative Instructions

Camera Sheath Removal

⚠ **CAUTION: Use caution when installing and removing the sheaths to avoid camera shaft, elbow, or wrist damage. Use gloves with sufficient grip to aid with installation and removal of the sheath.**

Remove the sheath from the camera immediately after each procedure.

1. Press the clips on both sides of the sheath connector and pull up to disengage from the flanges at the base of the shaft (Figure 2.8).

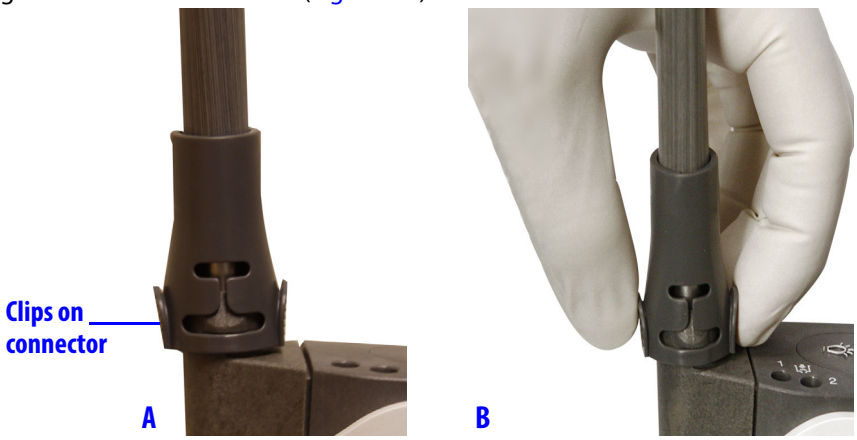

Figure 2.8 Press the clips on the connector

2. With your thumb and index finger, pinch the black band on the sheath and gently twist and push to remove it from the camera tip (Figure 2.9). When the sheath is completely loosened, hold the sheath from the black band and pull it off of the shaft. If needed, sterile gauze or less slippery gloves may be used to more firmly grasp the sheath while twisting.

Figure 2.9 Pinch the black band, then twist and push

Disposal

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

Do not dispose of cameras. Contact Intuitive Surgical Customer Service to exchange expired cameras.

Note: For more information on reprocessing the camera, refer to the *da Vinci SP Reprocessing Instructions*.

End of section

3 EndoWrist SP Instruments

3.1 Introduction

This chapter contains general instructions for use specific to the EndoWrist SP® instruments (also referred to as 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.

Intended Use

For intended use of the instruments and associated accessories, see Appendix D: Intended Use Statements.

CAUTION: Endoscopic instruments are designed and manufactured for a specific surgical function. Use of an instrument for a task other than that for which it is intended may result in a damaged or broken instrument.

General Warnings and Cautions

WARNING: Do not use instruments, cameras, or accessories that have been reprocessed with single-use accessories installed. Inadequate sterilization may occur when these single-use accessories, such as the MCS Tip, monopolar cautery tip, sheath, SP Cannula Seal, or EntryGuide™ (also known as Entry Guide), are installed during reprocessing.

WARNING: Unless it is stated, do not use EndoWrist SP instruments on cartilage, bone or hard objects. Doing so may damage the instrument and make it impossible to remove it from the SP Cannula.

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: The EndoWrist SP camera and instruments must be used with the appropriate SP Cannula, SP Cannula Seal, and Entry Guide. Refer to Chapter 9 da Vinci SP Port Accessories for details.

CAUTION: Handle instruments with care. Avoid mechanical shock or stress that can cause damage to the instruments.

CAUTION: Prior to using compatible third party devices with the da Vinci SP System, read all associated instructions for use.

CAUTION: Always have a backup camera and instruments available to complete the surgical procedure in case of instrument failure.

CAUTION: Clean and sterilize the instruments immediately after each use. 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 biological material.

Warning for Grasping Instruments

The following warning applies to all grasping EndoWrist SP instruments, such as the Needle Driver, Fenestrated Bipolar Forceps, Maryland Bipolar Forceps, Medium-Large Clip Applier, Round Tooth Retractor and Cadiere Forceps.

WARNING: In case of system failure while the instrument is grasping tissue, the grips can be manually opened by first pressing the instrument disengage button on the instrument drive and then turning the Grip Release Dial on the instrument housing to release the grips from tissue.

For troubleshooting information, see the *da Vinci SP System User Manual*.

Device Description

Note: Instruments and accessories contain metal components. Ensure that patients do not have metal allergies.

Note: Use only EndoWrist SP instruments. Other Intuitive Surgical instruments are not compatible with the da Vinci SP system.

EndoWrist SP instruments are multiple-use endoscopic instruments to be used only in conjunction with the da Vinci SP System. Table 3-1 and Table 3-2 list the EndoWrist SP instruments and accessories.

Table 3-1 EndoWrist SP Instruments

Description/Name	Part Number (PN)
Monopolar Instruments	
6 mm Monopolar Curved Scissors (MCS)	430004
6 mm Monopolar Cautery Instrument	430007
Bipolar Instruments	
6 mm Maryland Bipolar Forceps	430010
6 mm Fenestrated Bipolar Forceps	430011
Needle Drivers	
6 mm Needle Driver	430006
Clip Appliers	
6 mm Medium-Large Clip Applier	430005
Grasping Instruments	
6 mm Round Tooth Retractor	430002
6 mm Cadiere Forceps	430009

Table 3-2 EndoWrist SP Instrument Accessories

Description/Name	Part Number (PN)
MCS Tip	430035
Cautery Hook Tip, 5 mm	400156
Cautery Spatula Tip, 5 mm	400160
Instrument Sheath	430012
EnergyShield Monopolar Cautery Cord	430068
Bipolar Cautery Cord	470384

Device Overview

The EndoWrist SP instruments consist of the following components:

- **Instrument housing (Figure 3.1 A):** The instrument housing engages with the instrument sterile adapter and includes:
  - **Flush ports (Figure 3.1 B):** The flush ports are used for instrument reprocessing. See the *da Vinci SP Reprocessing Instructions* for cleaning and sterilization instructions.
  - **Grip Release Dial (Figure 3.1 C):** The Grip Release Dial is rotated to manually open the instrument tips. For troubleshooting information, see the *da Vinci SP System User Manual*.
  - **Cautery cord interface [electrosurgical instruments only] (Figure 3.1 D)**: The cautery cord interface is used to connect the Bipolar Cautery Cord or EnergyShield Monopolar Cautery Cord (depending on instrument type).
  - **Release buttons (Figure 3.1 E):** The release buttons (located on each side of the housing) are used to release the instrument from the sterile adapter.
- **Shaft (Figure 3.1 F):** The shaft inserts through the EntryGuide™ SP Cannula Insert (also referred to as Entry Guide) and rotates as controlled by the movements of the hand controls. The instrument shafts are 6 mm in diameter and approximately 22 in. (55 cm) in total length.
- **Tip (Figure 3.1 G):** The instrument tip (for example, graspers, cautery hooks, scissor blades).
- **Forearm (Figure 3.1 H)**: The distal section of the instrument shaft between the elbow and the wrist.
- **Elbow (Figure 3.1 I):** The articulating elbow offsets the distal shaft (also referred to as the forearm) to enable positioning of the instrument tip and to create space between the instruments deployed inside the body.
- **Wrist (Figure 3.1 J):** The articulating wrist bends to orient the instrument tip.

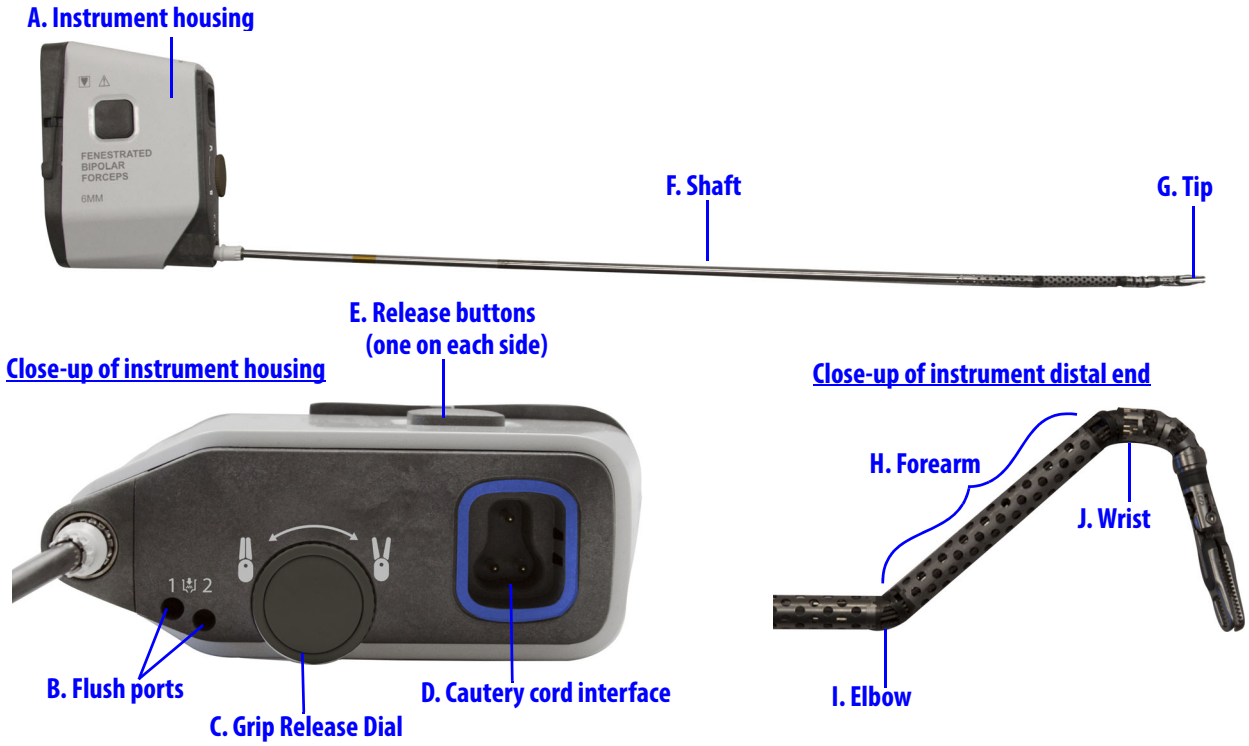

Figure 3.1 EndoWrist SP instrument

3.2 Preoperative Preparation

Inspection Before Use

WARNING: Do not use instruments that have been reprocessed with single-use accessories (for example, MCS Tip, monopolar cautery tip, sheath) installed. Inadequate sterilization may occur when these single-use accessories are installed during reprocessing.

WARNING: Inspect instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification.

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 or frayed 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
- Broken wrist or elbow joint segments
- Loose tip or grips

da Vinci SP Instrument Sheath Overview

The da Vinci SP® Instrument Sheath (Figure 3.2) is specifically designed to cover the EndoWrist SP instruments and must be installed on the instruments prior to surgical use. The Instrument Sheath is supplied sterile and is for single use only; do not reuse the sheath. Install the sheath onto instruments before installing instrument tip accessories (Hook, Spatula and MCS Tip).

Figure 3.2 Instrument Sheath

Instrument Sheath Installation

WARNING: Inspect the Instrument Sheath for damage throughout use. Examples of damage include tears or cuts in the sheath material. If damage is observed, remove and replace the Instrument Sheath on any instrument (monopolar or other) to prevent stray cautery or other risks.

CAUTION: The camera and instruments must be covered with sheaths designed specifically for use with the da Vinci SP System.

CAUTION: After the sheath is installed on a camera or instrument, do not reuse the sheath on another camera or instrument.

CAUTION: Use caution when installing and removing the sheaths to avoid instrument shaft, elbow, or wrist damage. Use gloves with sufficient grip to aid with installation and removal of the sheath.

Note: Ensure that the instrument tip is free from lubricant prior to installing the Instrument Sheath.

Note: Before use, each instrument requires installation of an Instrument Sheath. Install the sheath onto instruments before installing instrument tip accessories (Hook, Spatula and MCS Tip).

1. Remove the Instrument Sheath from the sterile packaging using sterile technique.
2. Straighten the instrument shaft (Figure 3.3 A) and fully close instrument jaws (if applicable). Slide the connector end of the sheath onto the shaft (Figure 3.3 B).

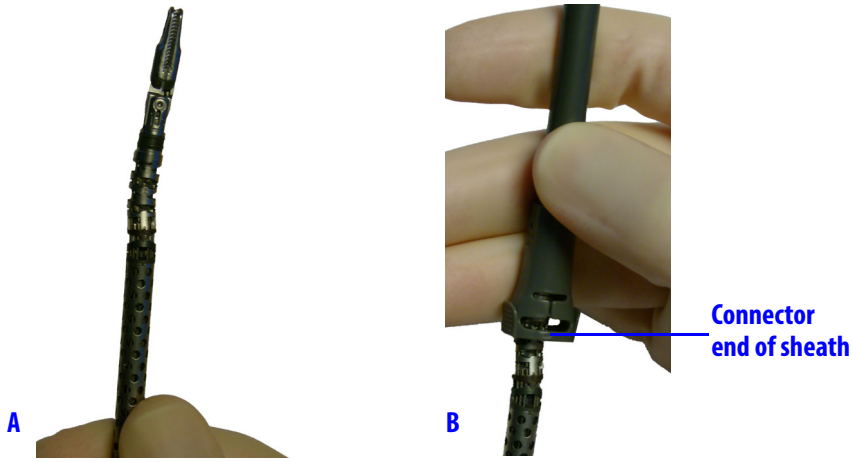

Figure 3.3 Straighten the shaft (A) and slide the sheath onto the shaft (B)

3. Pull the sheath down the shaft toward the instrument housing. Press down the connector end of the sheath until it is over the flanges on the base of the instrument shaft, and there is a tactile and audible click (Figure 3.4 A and B).

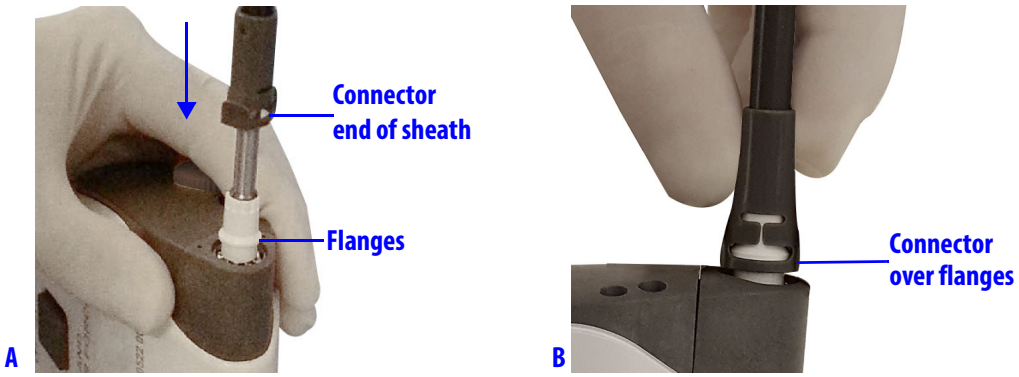

Figure 3.4 Pull sheath down the shaft toward housing (A) until it is over the flanges on instrument shaft (B)

4. Pull the distal end of the sheath over the instrument tip (Figure 3.5).

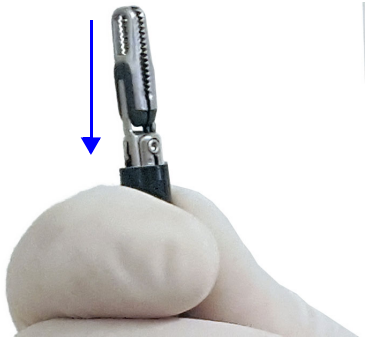

Figure 3.5 Pull sheath over the instrument tip

5. Confirm correct installation of the sheath.

Instruments with permanent tips:

- Confirm that the horizontal line below the IS logo on the instrument tip is visible just above the end of the sheath to ensure proper seating (Figure 3.6 B).

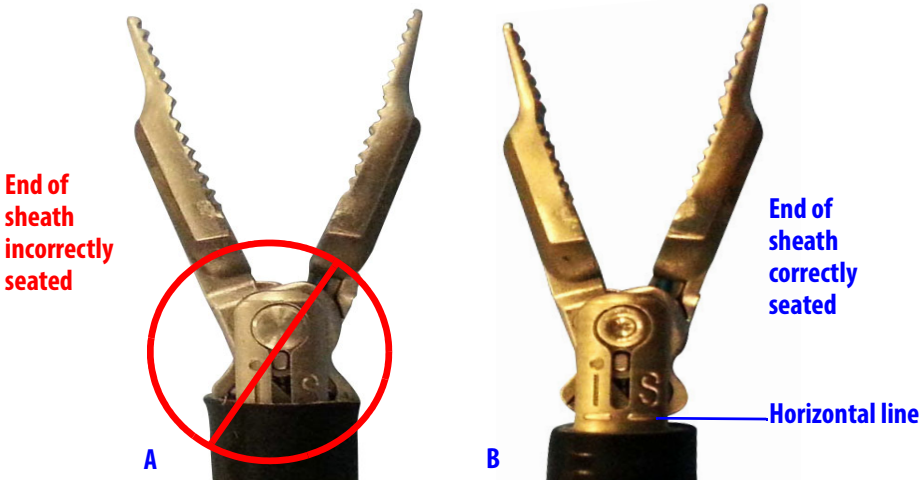

Figure 3.6 Example of incorrect (A) and correct (B) Instrument Sheath installation

Instruments with removable tips:

- Confirm that the instrument tip connector is fully visible to ensure proper seating on the end of the sheath (Figure 3.7 B and Figure 3.8 B).

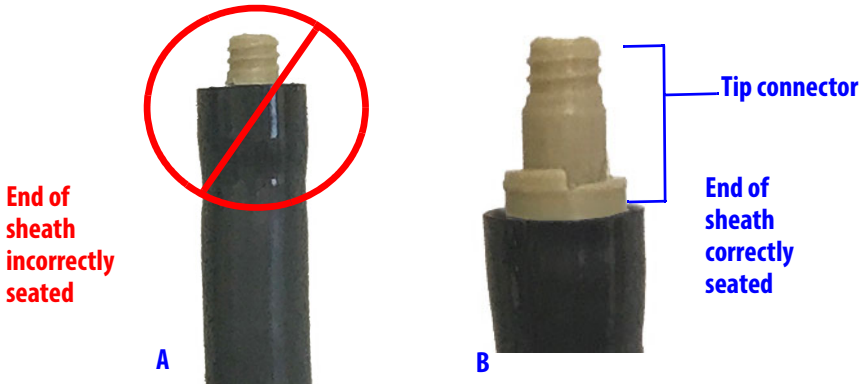

Figure 3.7 Instrument Sheath incorrectly (A) and correctly (B) installed on the Monopolar Cautery Instrument

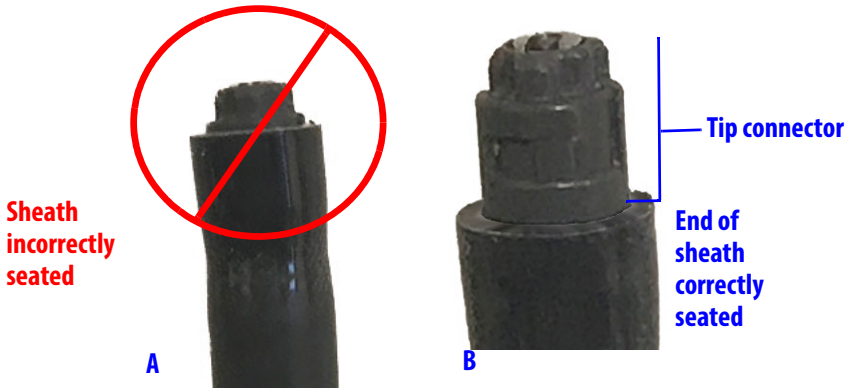

Figure 3.8 Instrument Sheath incorrectly (A) and correctly (B) installed on the Monopolar Curved Scissors

Note: Refer to individual instrument chapters for further instrument preparation instructions.

3.3 Intraoperative Use

For information on intraoperative use (installation, insertion, and removal of the instruments), refer to the *da Vinci SP System User Manual*.

3.4 Postoperative Instructions

Remove the monopolar cautery tip and MCS Tip before removing the instrument sheath.
For monopolar cautery tip removal instructions, see 6.4 Postoperative Instructions on page 34.
For MCS Tip removal instructions, see 5.4 Postoperative Instructions on page 29.

Instrument Sheath Removal

CAUTION: Use caution when installing and removing the sheaths to avoid instrument shaft, elbow, or wrist damage. Use gloves with sufficient grip to aid with installation and removal of the sheath.

Remove the sheath from the instrument after each procedure.

1. Press the clips on both sides of the sheath connector and push up to disengage from the flanges on the base of the instrument shaft (Figure 3.9 B).

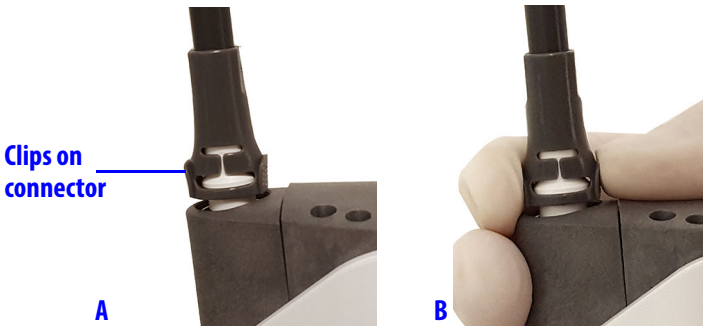

Figure 3.9 Press the clips on the connector

2. Hold the sheath and slide up towards the distal end of the instrument shaft until the sheath is fully removed (Figure 3.10 A).

   If needed, pinch the distal tip and gently twist and push to remove it from the instrument shaft (Figure 3.10 B). Sterile gauze may be used to more firmly grasp the sheath while twisting.

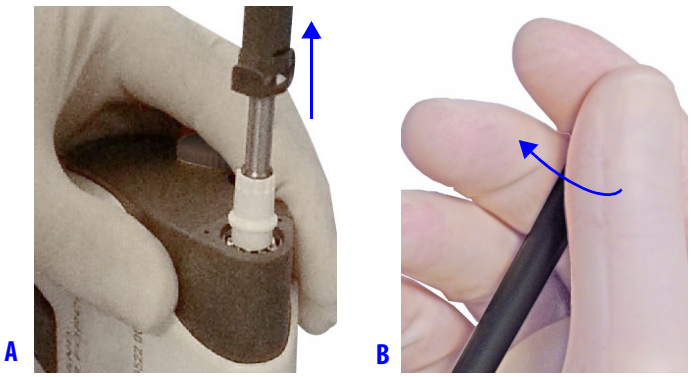

Figure 3.10 Slide sheath toward distal end of instrument shaft (A) and pinch and gently twist the sheath tip (B)

3. Dispose of the sheath. Do not reuse the sheath on another instrument.

Disposal

When disposing of Intuitive Surgical instruments, accessories, or any of their components, follow all applicable national and local laws and guidelines. Do not dispose of cameras.

Note: For more information on reprocessing the EndoWrist SP instruments, refer to Appendix A: Reprocessing Preparation in the Operating Room and the *da Vinci SP Reprocessing instructions*.

End of section

4 Medium-Large Clip Applier

Note: For general instrument information, see Chapter 3, EndoWrist SP Instruments, starting on page 13.

4.1 Introduction

This section contains instructions for use specific to the EndoWrist SP Medium-Large Clip Applier.

Compatibility Information

The EndoWrist SP Medium-Large Clip Applier compatibility with third-party products is shown in Table 4-1.

Table 4-1 EndoWrist SP Instrument and third-party product compatibility

EndoWrist SP Instrument	Third-party products	Part Number (PN)
Medium-Large Clip Applier	Weck® Hem-o-lok® Medium-Large Polymer Ligating Clips	544230

Hem-o-lok Ligating Clips

Hem-o-lok Ligating Clips are manufactured by Teleflex Medical and are supplied sterile. DO NOT re-sterilize ligating clip cartridges.

WARNING: All instructions, precautions, and contraindications found with the Hem-o-lok Ligating Clips apply when clips are applied with the EndoWrist SP Medium-Large Clip Applier.

Indications

Hem-o-lok Ligating Clips are intended for use in procedures involving ligation of vessels or tissue structures. Surgeons should apply the appropriate size clip for the size of the vessel or tissue structure to be ligated such that the clip completely encompasses the vessel or tissue structure.

Contraindications

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.

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. Teleflex Medical recommends ligation of the renal artery, in procedures other than laparoscopic donor nephrectomy (see Contraindications page 22), 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 Litigating Clips are 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 Preoperative Preparation

Use only the compatible Hem-o-lok Ligating Clips cartridge. Intuitive Surgical does not assume responsibility for unsatisfactory results caused by the use of any instrument and clip that are not compatible. For information on compatible clips, refer to Table 4-1.

CAUTION: Inspect the jaws for damage, bent components, or misalignment before use. If damage is observed, replace the instrument. Instrument could be damaged from mishandling during use or reprocessing.

1. Rotate the Grip Release Dial on the instrument housing and fully open the instrument jaws, then grasp the instrument at the intersection point of the two jaws to stabilize the jaws during clip loading.
2. Carefully insert the jaws into the clip cartridge slot, making sure the jaws are perpendicular to the base of the cartridge. Gently press the jaws over the clip until there is a tactile and audible click.

   Slightly rocking the jaws back and forth may assist in loading the clip. Do not force the instrument into the cartridge or onto the clip. The instrument should enter and withdraw from the cartridge easily (Figure 4.1).

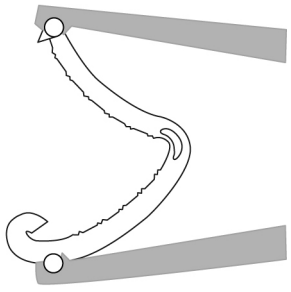

Figure 4.1 Clip loaded in clip applier

3. Remove the instrument from the cartridge and confirm that the clip is securely held within the jaws.

4.3 Intraoperative Use

CAUTION: Do not attempt to close the jaws 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.

1. Prior to installing the instrument, rotate the Grip Release Dial to close the jaws until the tips of the clip are touching but the clip is not closed. Refer to the *da Vinci SP System User Manual* for instructions on installing instruments.

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 control after a small closure of the hand control.

2. After the instrument is inserted past the SP Cannula and in the surgeon's control, position the clip around the tissue to be ligated. During application, 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).

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

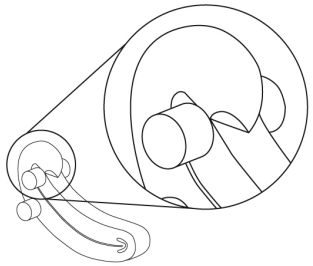

Figure 4.2 Clip locked detail

3. Before instrument removal, make sure that the instrument jaws are free of tissue.

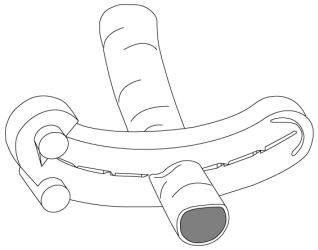

Figure 4.3 Clip applied to vessel

4.4 Postoperative Instructions

For postoperative instructions, refer to 3.4 Postoperative Instructions on page 20.

End of section

5 Monopolar Curved Scissors

Note: For general instrument information, see Chapter 3, EndoWrist SP Instruments, starting on page 13.

5.1 Introduction

The EndoWrist SP Monopolar Curved Scissors is a multiple-use endoscopic instrument that is used with a single-use Monopolar Curved Scissors Tip (MCS Tip).

General Warnings and Cautions

WARNING: Connect instrument tips and cautery cords (monopolar and bipolar) only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

WARNING: Do not re-use or re-sterilize the MCS Tip.

WARNING: Failure to install the MCS Tip properly may result in:

- **Imprecise tip movement**
- **MCS Tip falling off**
- **Electrical arcs and alternate site burns**

WARNING: Use care not to twist the MCS Tip when carefully cleaning the Monopolar Curved Scissors intraoperatively. Twisting may cause the MCS Tip to loosen.

WARNING: If damage or other flaws are observed on the instrument, do not use the instrument. Contact Intuitive Surgical Customer Service. In the U.S., call +1.800.876.1310. Examples of damage include:

- **Cracks, deformations, or burn marks on the tip connector**
- **Bends or scratches of the instrument shaft**
- **Broken or frayed cables**
- **Broken cautery cord interface**

CAUTION: The EndoWrist SP Monopolar Curved Scissors instrument must always be used in conjunction with the MCS Tip.

CAUTION: If the MCS Tip becomes loose during use DO NOT use another instrument to remove the accessory inside the patient. Close the MCS blades, remove the instrument from the SP Cannula, and replace the MCS Tip with a new one.

5.2 Preoperative Preparation

This section describes information specific to installing the MCS Tip. Refer to Preoperative Preparation on page 16, for general preoperative instrument information.

WARNING: Inspect the MCS Tip periodically during use. If any damage or tears are observed, replace the MCS Tip with a new one and continue to use the instrument. Examples of damage to the tip cover include punctures, tears or cuts. Examples of damage to the blades include nicks, gouges, or bent or loose blades.

MCS Tip Overview

The single-use Monopolar Curved Scissors Tip (MCS Tip) is designed for use with the Monopolar Curved Scissors and must be installed prior to surgical use. The MCS Tip (with installation tool, Figure 5.1) is provided in a sterile pouch and should be installed in the sterile field.

Figure 5.1 Monopolar Curved Scissors Tip (MCS Tip) with installation tool

Before installing the MCS Tip, confirm that the Instrument Sheath is installed on the Monopolar Curved Scissors (see Instrument Sheath Installation on page 17).

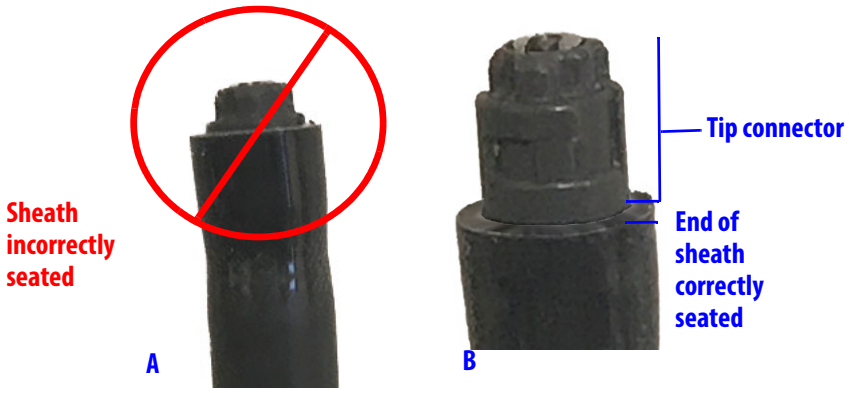

Figure 5.2 Instrument Sheath incorrectly (A) and correctly (B) installed on the Monopolar Curved Scissors

Install the MCS Tip

1. Remove the MCS Tip from the sterile packaging using sterile technique. Straighten the instrument shaft by hand (Figure 5.3).

Figure 5.3 Straighten instrument shaft

2. Rotate the Grip Release Dial on the instrument housing clockwise to extend the pin from the distal end of the instrument shaft. Identify the white stripe on the instrument shaft (Figure 5.4 A and B).

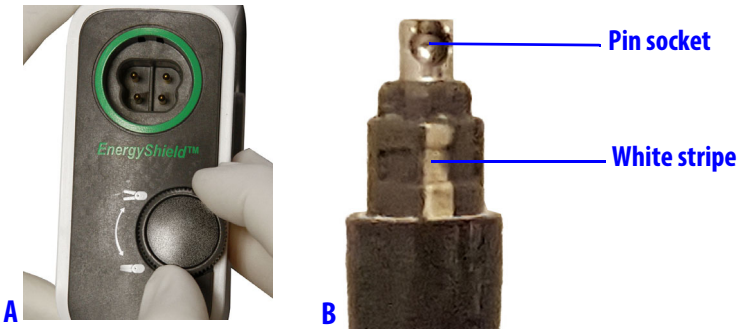

Figure 5.4 Extend pin from instrument tip and identify white stripe (A and B)

3. Grasp the MCS Tip installation tool and insert the ball end of the MCS Tip into the pin socket (Figure 5.5 B and C).

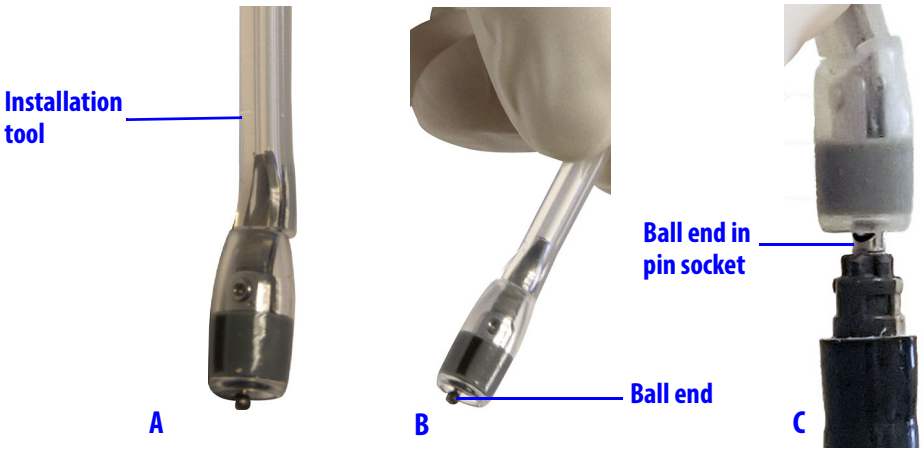

Figure 5.5 Grasp installation tool (B) and insert ball end of MCS Tip into pin socket (C)

4. Rotate the installation tool to align the black stripe on the tip cover to the white stripe on the instrument shaft, then rotate the Grip Release Dial counter-clockwise until the pin is fully retracted into the instrument shaft (Figure 5.6 A, B, and C).

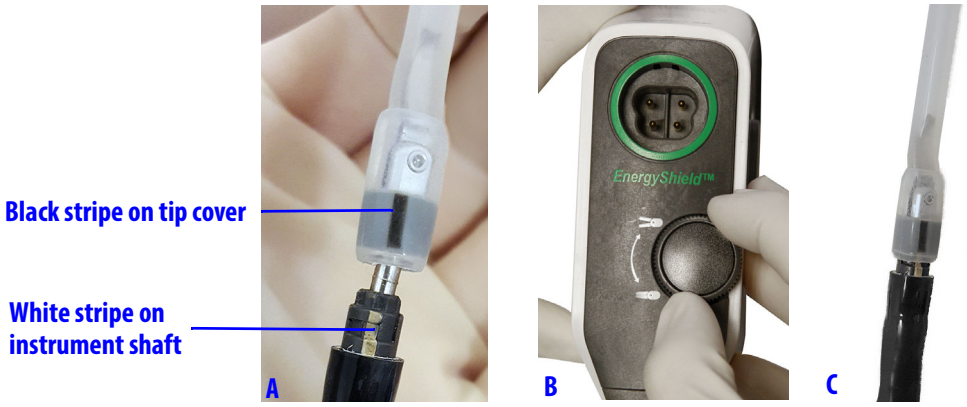

Figure 5.6 Align stripes (A), then rotate Grip Release Dial to retract pin into shaft (B and C)

5. With one hand grasping the tip cover and the other hand stabilizing the instrument joints, push the tip cover down until it is flush with instrument sheath and rotate ¼ turn clockwise until there is a tactile click to lock in place (Figure 5.7 A and B).

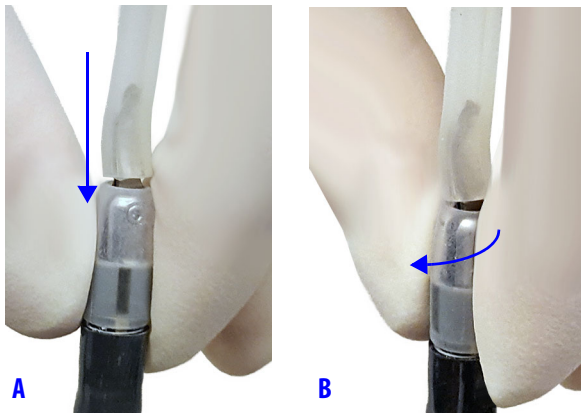

Figure 5.7 Push tip cover down (A), then rotate ¼ turn clockwise (B)

6. Remove the installation tool from the MCS Tip (Figure 5.8). If desired, retain the installation tool to aid in removing the MCS Tip after the procedure.

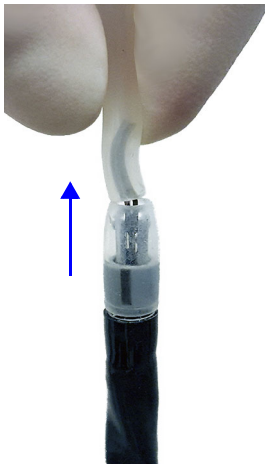

Figure 5.8 Remove installation tool from MCS Tip

7. Rotate the Grip Release Dial in both directions to confirm that the scissor blades open and close (Figure 5.9 A and B).

Figure 5.9 Rotate Grip Release Dial (A) to open and close scissor blades (B)

5.3 Intraoperative Use

This section describes information specific to troubleshooting the MCS Tip. Refer to Monopolar Instruments and EnergyShield Monitor Use on page 47, for full intraoperative use information.

MCS Tip Troubleshooting

⚠ **CAUTION: If the MCS Tip becomes loose during use DO NOT use another instrument to remove the accessory inside the patient. Close the MCS blades, remove the instrument from the SP Cannula, and replace the MCS Tip with a new one.**

If the MCS Tip becomes loose during use, perform the following steps to remove the instrument.

Surgeon

1. Close the grip on the associated hand control.
2. Use the hand control to approximately straighten the instrument joints.

Patient-side assistant

3. Retract the camera to visualize instrument removal.
4. Under endoscopic vision, clutch and retract the instrument drive to the loading position, and remove the Monopolar Curved Scissors from the instrument drive.
5. Remove the used MCS Tip, and replace with a new one.

5.4 Postoperative Instructions

This section describes information specific to MCS Tip removal. Refer to Postoperative Instructions on page 20 for full postoperative instructions.

Remove the MCS Tip

Remove the MCS Tip from the instrument after each procedure.

1. Ensure that the scissor blades are closed. If they are open, rotate the Grip Release Dial to close them.

   If desired, stabilize the instrument joints and reapply the installation tool to the scissor blades (Figure 5.10).

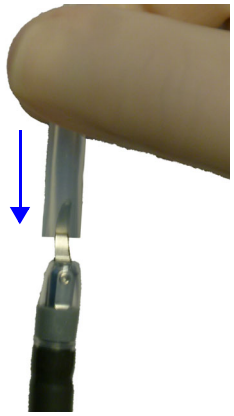

Figure 5.10 Reapply installation tool

2. Stabilize the instrument joints and grasp the tip cover. Rotate the tip cover ¼ turn counter-clockwise to unlock from the instrument shaft (Figure 5.11). If needed, use sterile gauze to more firmly grasp the tip cover while rotating.

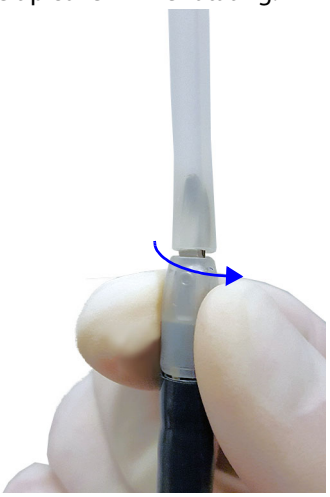

Figure 5.11 Grasp the tip cover and rotate ¼ turn counter-clockwise to unlock from the instrument shaft

3. Rotate the Grip Release Dial on the instrument housing clockwise to extend the pin from the distal end of the instrument shaft, then remove the ball from the pin socket (Figure 5.12 A and B).

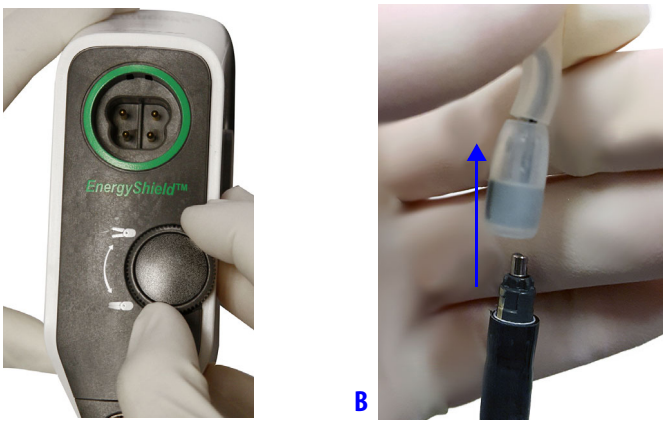

Figure 5.12 Rotate the Grip Release Dial (A), then remove the ball from the pin socket (B)

Disposal

Dispose of the single-use MCS Tip in a sharps container and according to local hospital protocol.

End of section

6 Monopolar Cautery Instrument

Note: For general instrument information, see Chapter 3, EndoWrist SP Instruments, starting on page 13.

6.1 Introduction

The EndoWrist SP Monopolar Cautery Instrument (PN 430007) is a multi-use, endoscopic instrument that is used with single-use, electrocautery tip accessories:

- Cautery Hook Tip, 5 mm (PN 400156)
- Cautery Spatula Tip, 5 mm (PN 400160)

General Warnings and Cautions

WARNING: Do not re-use or re-sterilize the hook tip or spatula tip.

WARNING: If damage or other flaws are observed on the instrument, do not use the instrument. Contact Intuitive Surgical Customer Service. In the U.S., call +1.800.876.1310. Examples of damage include:

- **Cracks, deformations, or burn marks on the tip connector**
- **Bends or scratches of the instrument shaft**
- **Broken or frayed cables**
- **Broken cautery cord interface**

WARNING: Connect instrument tips and cautery cords (monopolar and bipolar) only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

WARNING: As with any cautery 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 Monopolar Cautery Instrument to help avoid unintended contact with tissue adjacent to the area to be cauterized.

6.2 Preoperative Preparation

This section describes information specific to installing the monopolar cautery tip. Refer to Preoperative Preparation on page 16, for general preoperative instrument information.

WARNING: Inspect the hook tip or spatula tip periodically during use. If any damage or tears are observed, replace the monopolar cautery tip with a new one and continue to use the instrument. Examples of damage include scratches or nicks in the tip materials.

WARNING: The Monopolar Cautery Instrument should be cleaned and dried before installing or exchanging any monopolar cautery tip.

Monopolar Cautery Tip Overview

The single-use monopolar cautery tip (hook tip and spatula tip) is designed for use with the Monopolar Cautery Instrument and must be installed prior to surgical use (Figure 6.1). The hook tip or spatula tip (with installation tool) is provided in a sterile pouch and should be installed in the sterile field.

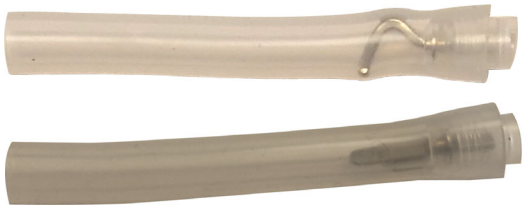

Figure 6.1 Hook tip (top) and spatula tip (bottom) with installation tools

Before installing a monopolar cautery tip, confirm that the Instrument Sheath is installed on the Monopolar Cautery Instrument (see Instrument Sheath Installation on page 17).

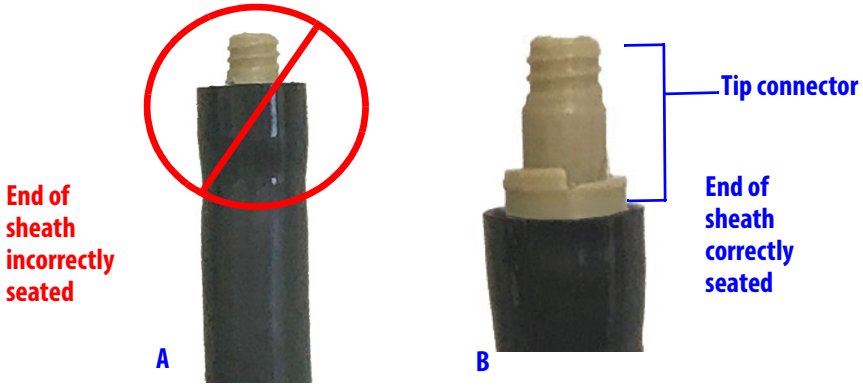

Figure 6.2 Instrument Sheath incorrectly (A) and correctly (B) installed on the Monopolar Cautery Instrument

Install the Monopolar Cautery Tip

1. Remove the monopolar cautery tip from the sterile packaging using sterile technique.
2. Straighten the instrument shaft by hand (Figure 6.3).

Figure 6.3 Straighten instrument shaft

3. Grasp the monopolar cautery tip installation tool, align and insert the metal electrode on the monopolar cautery tip into the slot on the instrument tip while stabilizing the instrument joints (Figure 6.4).

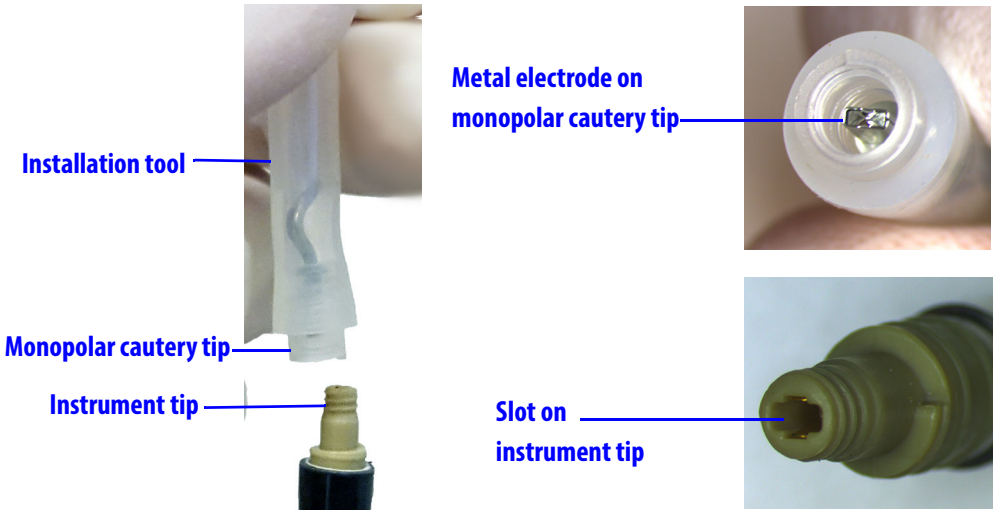

Figure 6.4 Metal electrode on monopolar cautery tip and slot on instrument tip

4. Hold the installation tool around the plastic component of the monopolar cautery tip and rotate clockwise until it is secure (Figure 6.5 A and B). Visually confirm that there is no gap between the monopolar cautery tip plastic component and the instrument to ensure it is properly connected.

⚠ **CAUTION: Do not attempt to install the monopolar cautery tip by turning the metal electrode by hand or with an instrument. This will damage the instrument. Always install the monopolar cautery tip by screwing the plastic component of the monopolar cautery tip manually.**

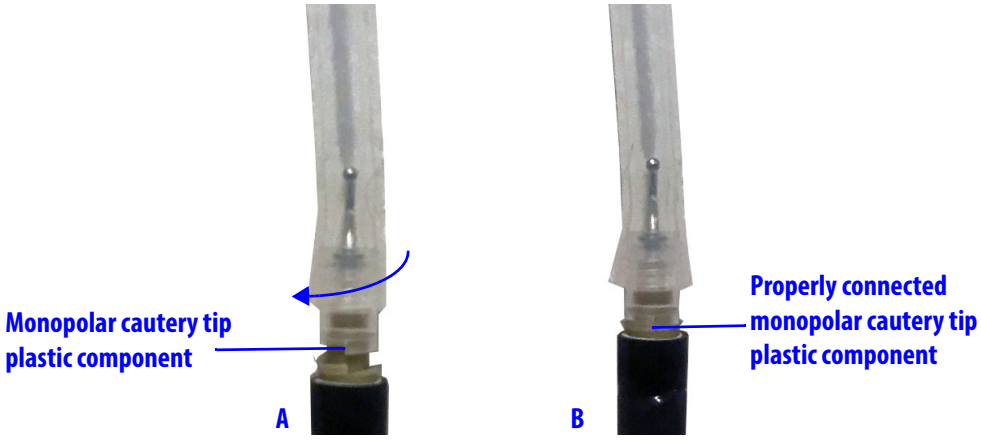

Figure 6.5 Rotate the plastic component of the monopolar cautery tip (A), and confirm it is properly connected (B)

5. Pull up on the installation tool to remove it from the monopolar cautery tip (Figure 6.6 A and B). Retain the installation tool to aid in removing the monopolar cautery tip after the procedure.

Figure 6.6 Pull up on installation tool to remove from monopolar cautery tip (A and B)

6.3 Intraoperative Use

Refer to Monopolar Instruments and EnergyShield Monitor Use on page 47, for intraoperative use information.

6.4 Postoperative Instructions

This section describes information specific to monopolar cautery tip removal. Refer to Postoperative Instructions on page 20, for full postoperative instructions.

Remove the Monopolar Cautery Tip

Remove the monopolar cautery tip from the instrument after each procedure.

CAUTION: Do not attempt to remove the monopolar cautery tip by turning the metal electrode by hand or with an instrument. This will damage the instrument. Always remove the monopolar cautery tip by unscrewing the plastic component of the monopolar cautery tip manually.

1. If desired, stabilize the instrument joints and reapply the installation tool onto the plastic component of the monopolar cautery tip (Figure 6.7).

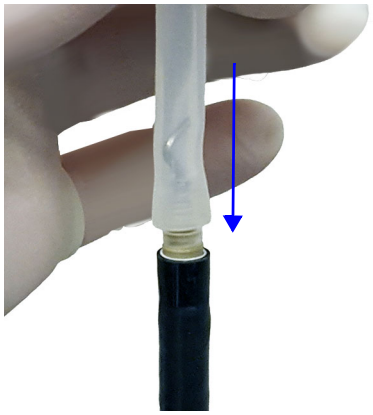

Figure 6.7 Reapply the installation tool

2. Stabilize the instrument joints. Hold the installation tool around the plastic component of the monopolar cautery tip and rotate counter-clockwise until the monopolar cautery tip disengages from the instrument (Figure 6.8 A and B).

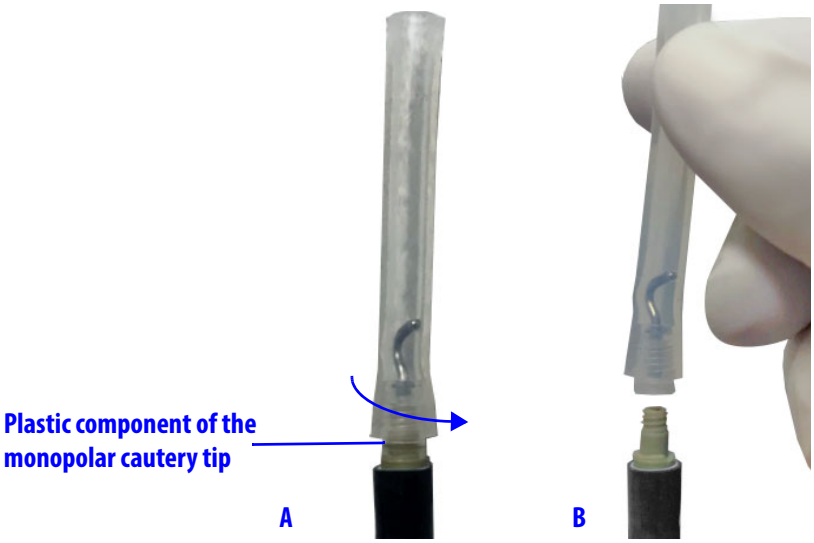

Figure 6.8 Rotate the plastic component of the monopolar cautery tip until disengaged from instrument (A and B)

Disposal

Dispose of the single-use monopolar cautery tips as biological hazardous waste and according to local hospital protocol.

End of section

7 Bipolar Instruments

Note: For general instrument information, see Chapter 3, EndoWrist SP Instruments, starting on page 13.

7.1 Introduction

The EndoWrist SP bipolar instruments are multiple-use, electrosurgical endoscopic instruments. They are designed to be used in conjunction with the da Vinci SP System and the electrosurgical unit (ESU).

Refer to 3.2 Preoperative Preparation on page 16 for general preoperative instrument information and 3.4 Postoperative Instructions on page 20 for postoperative instructions. Refer to 8.4 Bipolar Cautery on page 57 for intraoperative use information.

Compatibility Information

Bipolar instruments are not validated for use with any third-party products.

CAUTION: No EndoWrist SP instruments are validated for use with bulldog clamps.

End of section

8 Using the Electrosurgical Unit (ESU) with Monopolar and Bipolar Instruments

8.1 Introduction

The following sections contain information regarding use of the integrated electrosurgical unit (ERBE VIO® dV 2.0), EnergyShield® Monitor, set up and use of the monopolar and bipolar cautery instruments and troubleshooting.

General Warnings and Cautions

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 such as generators and the applicable user manuals for the da Vinci SP System may lead to injury and result in improper functioning of the device.

WARNING: Do not use electrosurgical instruments in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (for example, a cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

WARNING: Do not use electrosurgical instruments in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.

WARNING: Do not place instruments in contact with flammable material (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.

WARNING: Energy instrument tips may remain hot enough to cause burns after the RF current is deactivated.

WARNING: Connect instrument tips and cautery cords (monopolar and bipolar) only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

WARNING: Do not use any non-integrated ESUs as these are not approved for use with the da Vinci SP System.

WARNING: Do not use any instrument cautery cord other than those approved for use with the da Vinci SP System.

WARNING: Do not use one instrument to energize the tips of another instrument (robotic or manual laparoscopic). This may cause patient injury and damage to the instrument. Energy may flow to the patient from places other than the tip, inside or outside the field of view. Avoid close proximity to other instrument tips when energizing monopolar instruments.

WARNING: Use the lowest power setting possible for the minimum time necessary to achieve the desired effect.

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: Never increase the effect settings without first checking both the active electrode and the patient neutral pad (grounding 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: Thermal spread adjacent to target tissue may result in unintended burns to surrounding tissue.

WARNING: Inspect instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification.

WARNING: Visual inspection alone may not be sufficient to ensure that the insulation is intact. The EnergyShield Monitor must be used with monopolar instruments.

WARNING: Do not activate an electrosurgical instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.

WARNING: Do not attempt to activate an EndoWrist SP instrument via an auxiliary foot pedal.

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. To clean an instrument intraoperatively, remove the instrument from the system and wipe the instrument tip with moist sterile gauze.

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

- Ensure that the patient neutral pad is securely affixed to the patient, placed as close as possible to the operating field, and properly connected to the electrosurgical unit.
- For monopolar instruments, always use the lowest output setting that achieves the desired surgical effect. When used with the da Vinci SP System, the VIO dV limits effect settings in certain modes as shown in Table 8-1, on page 42.
- Secure and route the cautery cord to the EndoWrist SP instrument to prevent cord damage and unintended disconnection.
- Avoid patient contact with grounded metal parts.
- Place any monitoring electrodes as far as possible from the surgical electrodes or the patient neutral pad when high frequency (HF) surgical equipment and physiological monitoring equipment are used simultaneously on the same patient.
- Do not use flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen.
- Use only non-flammable agents for cleaning and disinfecting. If flammable agents are used for cleaning or disinfecting or as solvents, they must be allowed to evaporate before application of HF energy.

CAUTION: Ensure that the ESU audible output can be heard by the operating surgeon during ESU use with the da Vinci SP System.

CAUTION: Refer to the *ERBE VIO* dV *User Manual* for operating instructions and warning and caution information.

8.2 Integrated ERBE VIO dV 2.0

The ERBE VIO dV 2.0 (VIO dV) is an integrated electrosurgical unit that is used with EndoWrist SP instruments and manual instruments. This section provides general information specific to use with the da Vinci SP System and instruments. For further information, including warning and caution information, see the *ERBE VIO dV User Manual*.

Note: The da Vinci SP System requires use of a dual surface patient neutral pad with the integrated VIO dV.

Note: When using the VIO dV with EndoWrist SP monopolar instruments, the EnergyShield Monitor must be used and properly connected. See Monopolar Instruments and EnergyShield Monitor Use on page 47 for more information.

VIO dV 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. 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 manual monopolar instruments and the EnergyShield Monitor to the ESU. See Connecting the Monopolar Instruments, EnergyShield Monitor and VIO dV on page 50 for more information.
- Neutral port: The port used to connect a patient neutral pad to the ESU to enable monopolar energy. When used with the EnergyShield Monitor (for EndoWrist SP monopolar instruments), the patient neutral pad is connected through the neutral connection on the EnergyShield Monitor. See Connecting the Monopolar Instruments, EnergyShield Monitor and VIO dV on page 50 for more information.
- Mode pods (bipolar and monopolar): The mode pods display settings and selection buttons 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.

Note: The VIO dV auxiliary foot pedals (bipolar and monopolar) are connected to the VIO dV and are located in the bottom drawer of the Vision Cart.

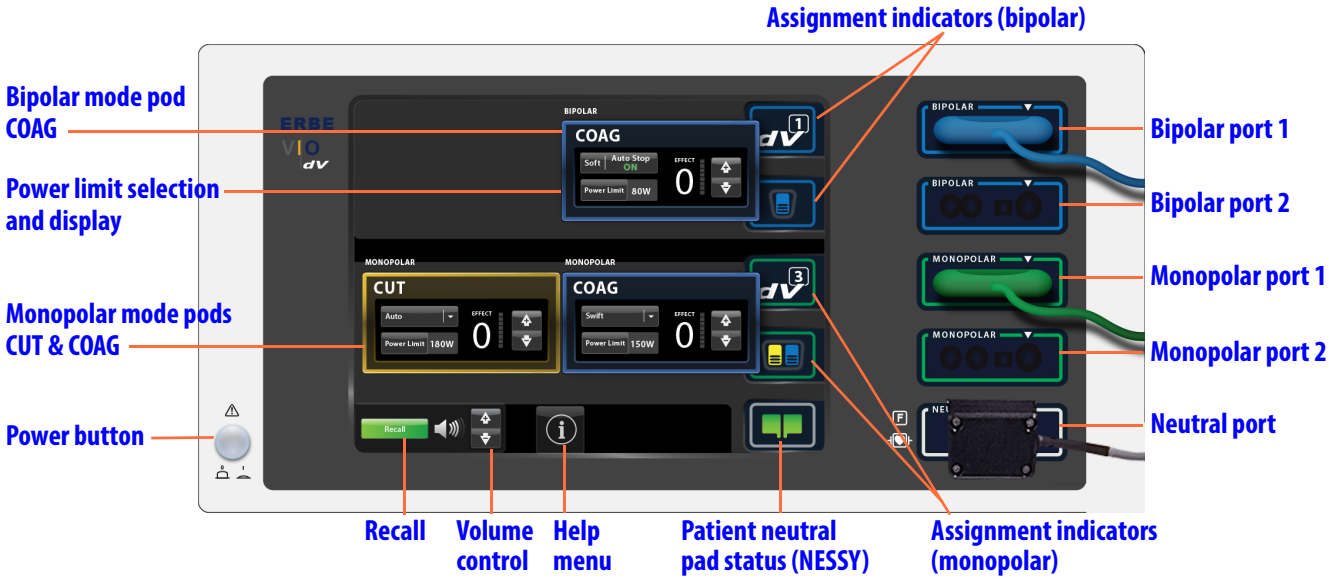

Figure 8.1 VIO dV

Loading Screen

Press the **Power** button on the lower left side of the VIO dV to turn it on. The Loading screen appears.

Main Screen

The Main screen displays the default settings shown in Figure 8.2.

Figure 8.2 Main screen with default settings displayed

Selecting VIO dV Settings

After the VIO dV is powered on, 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. When used with the da Vinci SP System, the VIO dV limits energy settings to those approved for EndoWrist SP monopolar instruments (see Table 8-1).

Table 8-1 Maximum Approved Energy Settings for EndoWrist SP Instruments

ESU	Mode	Max Effect Setting
VIO dV[a]	Monopolar, Swift Coag	5
	Monopolar, Auto Cut	7

a. All other effect settings in all other monopolar and bipolar modes are approved for use with EndoWrist SP instruments.

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. The **Recall** button disappears and the previous settings are applied. The settings can then be used or manually adjusted as needed (Figure 8.3).

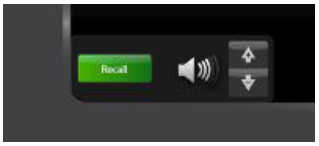

Figure 8.3 Recall button

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 8.4 and Figure 8.5).

Note: The energy settings can also be adjusted from the Surgeon Console touchpad. For more information, see the *da Vinci SP System User Manual*.

CAUTION: Changing settings on one monopolar instrument changes settings for all connected monopolar instruments. Changing settings on one bipolar instrument changes settings for all connected bipolar instruments.

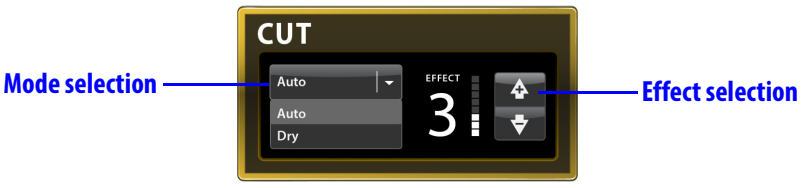

Figure 8.4 Mode and effect settings, Monopolar CUT

Figure 8.5 Mode and effect settings, Monopolar COAG

Bipolar and Monopolar Instrument Activation

Bipolar and monopolar instruments (EndoWrist SP and manual) can be activated using the specified ports (as shown with [X] in the tables below).

Table 8-2 Bipolar Instrument Activation

Port	EndoWrist SP Bipolar Instruments	Manual Bipolar Instruments (Foot pedal activated)
Bipolar Port 1	X	
Bipolar Port 2	X	X

Table 8-3 Monopolar Instrument Activation

Port	EndoWrist SP Monopolar Instruments[a]	Manual Monopolar Instruments (Foot pedal activated)	Manual Monopolar Instruments (Fingerswitch activated)
Monopolar port 1	X		X
Monopolar port 2	X	X	X

a. EndoWrist SP monopolar instruments are connected to the VIO dV through the EnergyShield Monitor.

Manually Adjust Power Limit Settings

In addition to adjusting mode and effect settings, users can adjust power limit settings (Figure 8.6). 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 changes 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.

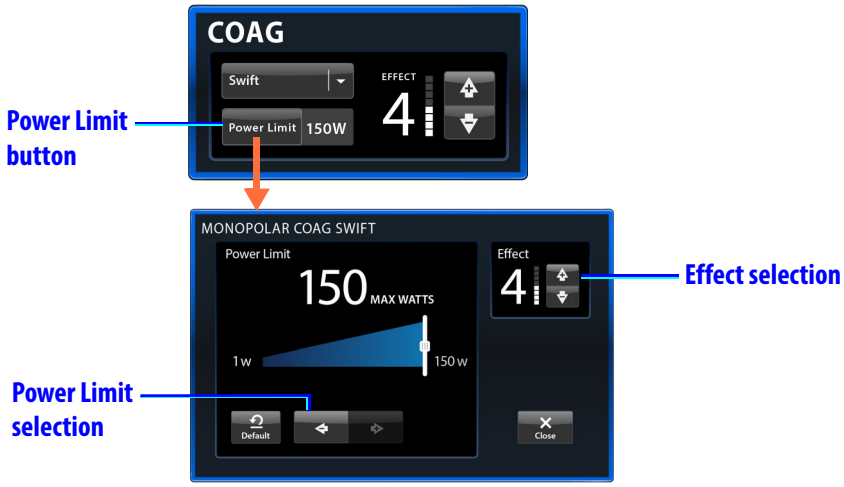

Figure 8.6 Power limit settings, Monopolar COAG example

Power limit settings can also be adjusted on the Surgeon Console touchpad. For instructions, see the *da Vinci SP 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 *da Vinci SP System User Manual*.

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 in Figure 8.7). If an EndoWrist SP instrument is connected to the associated port, the icon indicates the following:

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

If an EndoWrist SP instrument is not installed, the icon indicates whether or not the port can be activated from the auxiliary foot pedals. For more information, see the *ERBE VIO dV User Manual*.

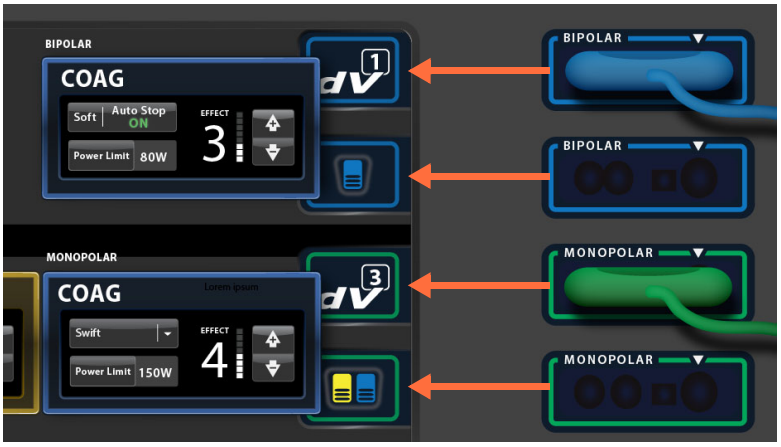

Figure 8.7 Control Assignment indicators

The numbers shown in the assignment indicator icons correspond to specific instrument drives (1, 2 or 3) on the instrument arm.

Assignment Indicator Icon Descriptions

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

Table 8-4 Control Assignment Indicator Icons

Icon	Meaning
	**Good EndoWrist SP instrument connection (monopolar or bipolar)** An EndoWrist SP instrument is connected to the port and installed on an instrument drive. The number corresponds to the instrument drive on which the connected instrument is installed. Activation of an EndoWrist SP instrument is possible.
	**Incomplete EndoWrist SP instrument connection (monopolar or bipolar)** **Monopolar** • There is a broken connection between the VIO dV, EnergyShield Monitor, and the EndoWrist SP instrument installed on the instrument drive, or • The EndoWrist SP instrument is connected to the EnergyShield Monitor and VIO dV, but is not installed on an instrument drive. **Bipolar** • The EndoWrist SP instrument is installed on an instrument drive but is not connected to the VIO dV, or • The EndoWrist SP instrument is connected to the VIO dV, but is not installed on an instrument drive. Activation of the EndoWrist SP instruments is not possible until the connection is completed and the instrument is installed onto an instrument drive.
	**Non-EndoWrist SP instrument local activation only** • No EndoWrist SP instrument connected. • Connected monopolar manual laparoscopic instrument can only be activated by switches on the instrument (such as 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 EndoWrist SP instrument connected. • Connected bipolar manual laparoscopic instrument can be activated by auxiliary bipolar foot pedal.
	**For monopolar port 2 only** • No EndoWrist SP instrument connected. • Connected monopolar manual laparoscopic instrument can be activated by auxiliary foot pedal. • Connected monopolar manual laparoscopic instrument can be activated by switches on the instrument (such as local fingerswitches).

ERBE VIO dV 2.0 Fault Conditions

Four ERBE VIO dV 2.0 fault conditions related to da Vinci SP energy instruments result in system messages displayed on the Vision Cart touchscreen, above the instrument status pod, and in the 3D viewer. Also, error tones sound at the Surgeon Console and Patient Side Cart. Refer to Table 8-5 for the message descriptions.

Table 8-5 ERBE VIO dV Fault Conditions and System Message Descriptions

Instrument Type	ERBE VIO dV 2.0 Fault Condition	System Message Description	Icon
Bipolar	C-84: 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.	Regrasp tissue or ensure jaw separation. Short detected.	
Monopolar	M-0B: Energy is being activated while the patient neutral pad is not connected to the EnergyShield Monitor, is defective, has poor contact with the patient, or when the neutral adapter is not connected to the VIO dV.	Check one or more of the following: • Dual neutral pad and connection • Contact with patient • Neutral adapter connection	
	M-1F: 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).	Check dual neutral pad orientation and contact with patient.	
Bipolar or Monopolar	M-1C: Energy activation is halted when energy activation time has been exceeded.	Timeout reached.	

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

8.3 Monopolar Instruments and EnergyShield Monitor Use

This section discusses Monopolar Instruments and EnergyShield Monitor Use:

- General Warnings and Cautions-Monopolar Instruments
- EnergyShield Monopolar Cautery Cord
- Connecting the Monopolar Instruments, EnergyShield Monitor and VIO dV
- Intraoperative Use
- Intraoperative Cleaning

General Warnings and Cautions-Monopolar Instruments

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

WARNING: Do not use one instrument to energize the tips of another instrument (robotic or manual laparoscopic). This may cause patient injury and damage to the instrument. Energy may flow to the patient from places other than the tip, inside or outside the field of view. Avoid close proximity to other instrument tips when energizing monopolar instruments.

WARNING: Do not touch the tips while electrosurgical energy is activated as this may cause severe electrical injury and/or burn to the user.

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: Do not bypass the EnergyShield Monitor while using EndoWrist SP monopolar instruments by connecting the patient neutral pad directly to the ESU. ESU operation is prevented if the patient neutral pad is not connected to the EnergyShield Monitor.

WARNING: Aspirate fluid from the area before activating the monopolar instrument. Conductive fluids (such as 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: Prior to increasing the intensity, check the adherence of the patient neutral pad and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the patient neutral pad or poor contact in its connections.

WARNING: Loss of safe contact between the patient neutral pad and the patient will not result in an alarm unless a compatible monitoring patient neutral pad is used.

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: 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: Avoid routing the monopolar and bipolar energy cords close together. Doing so may increase the risk of stray cautery from the bipolar instrument due to capacitive coupling between the cords.

CAUTION: The EndoWrist SP 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 SP System.

EnergyShield Monopolar Cautery Cord

The reusable EnergyShield Monopolar Cautery Cord (PN 430068) is intended to be used in conjunction with the VIO dV generator, EnergyShield Monitor and EndoWrist SP monopolar instruments with the appropriate connector (Figure 8.8). The cord is supplied non-sterile and requires cleaning and sterilization before use. For more information regarding cleaning and sterilization, refer to the Reprocessing Instructions.

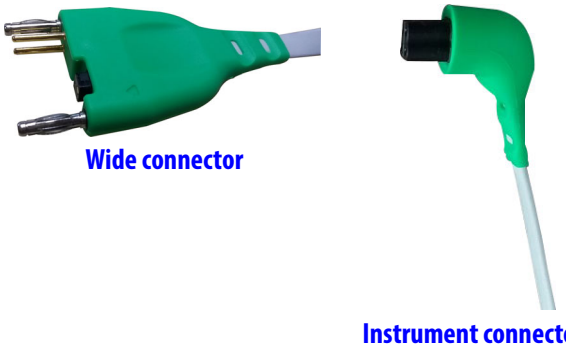

Figure 8.8 EnergyShield monopolar cautery cord connectors

Inspection

Inspect cord for damage or irregularities before and after each use. Visually inspect the cord 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
- Corrosion of connector contacts

EnergyShield Monitor Overview

The EnergyShield Monitor provides monitoring of electrosurgical energy during use of EndoWrist SP monopolar instruments, which are shielded to reduce the risks of capacitive coupling. The EnergyShield Monitor terminates energy delivery when a fault condition is detected on the connected monopolar instrument, such as:

- Loss of instrument shield integrity
- Breakdown of internal instrument insulation
- Loss of Instrument Sheath integrity (only in certain conditions)

WARNING: The EnergyShield Monitor will not detect all occurrences of damage to the monopolar instrument sheath. Inspect the Instrument Sheath for damage throughout use. Examples of damage include tears or cuts in the sheath material. If damage is observed, remove and replace the Instrument Sheath on any instrument (monopolar or other) to prevent stray cautery or other risks.

For more information on troubleshooting the EnergyShield Monitor, see EnergyShield Monitor Faults and Failure on page 54.

Connecting the Monopolar Instruments, EnergyShield Monitor and VIO dV

This section describes how the EnergyShield Monitor works with the da Vinci SP System and connects to the EndoWrist SP monopolar instruments and the VIO dV.

Note: The EnergyShield Monitor should remain powered on. When the da Vinci SP System is powered off, the EnergyShield Monitor is in a sleep state with all LEDs off. The EnergyShield Monitor will start up with the da Vinci SP System when it is powered on.

Note: The da Vinci SP System should be powered on before the monopolar cord is connected to the EnergyShield Monitor to enable the EnergyShield Monitor to complete all self-tests.

1. If not already on, power on the da Vinci SP System. The EnergyShield Monitor performs a self-test. After the self-test completes, the Instrument LED and Sheath LED illuminate blue and the Neutral Pad LED and Cord LED illuminate amber (Figure 8.9).

Figure 8.9 EnergyShield Monitor self test complete

2. Ensure that the VIO dV is plugged into the appropriate power receptacle and powered on.

3. Verify that the neutral adapter from the EnergyShield Monitor is plugged into the neutral port on the VIO dV (Figure 8.10). Confirm that the connector cannot be pushed further into the neutral port.

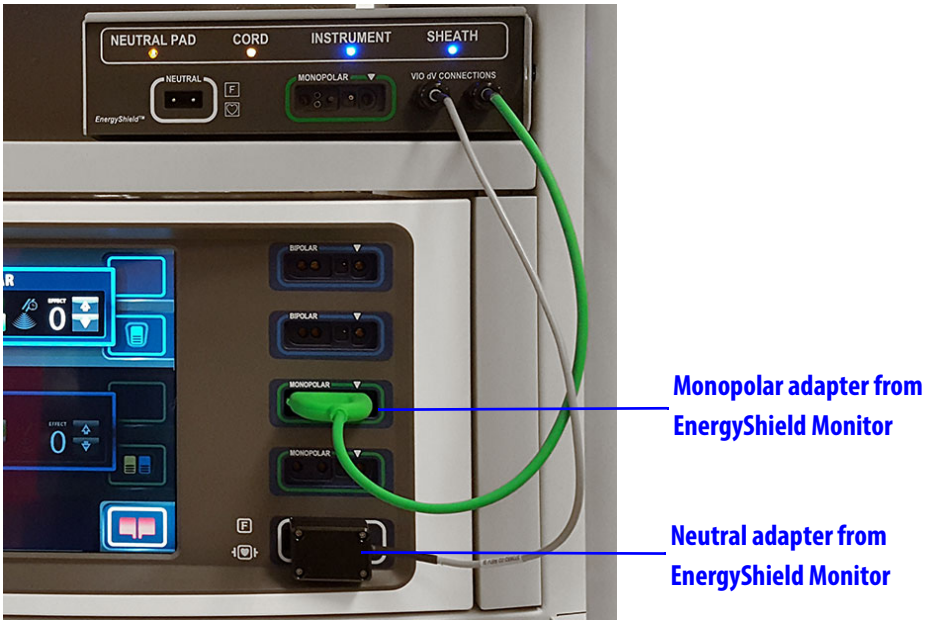

Figure 8.10 Check EnergyShield Monitor neutral adapter and monopolar adapter connections to VIO dV

Note: The neutral adapter from the EnergyShield Monitor can remain plugged into the neutral port on the VIO dV to enable use of manual instruments with the VIO dV, even in the event of an EnergyShield Monitor fault.

Note: Only monopolar port 2 can be used for manual monopolar instruments that are activated by the auxiliary foot pedal.

4. Verify that the monopolar adapter from the EnergyShield Monitor is plugged into a monopolar port on the VIO dV (Figure 8.10).
5. Remove the patient neutral pad from the package and place the pad in the preferred location on the patient. See Patient Neutral Pad Positioning on page 62 for more information.

6. Connect the patient neutral pad plug into the neutral receptacle on the EnergyShield Monitor (Figure 8.11). Verify that the Neutral Pad LED illuminates blue and the patient neutral pad icon on the VIO dV illuminates green.

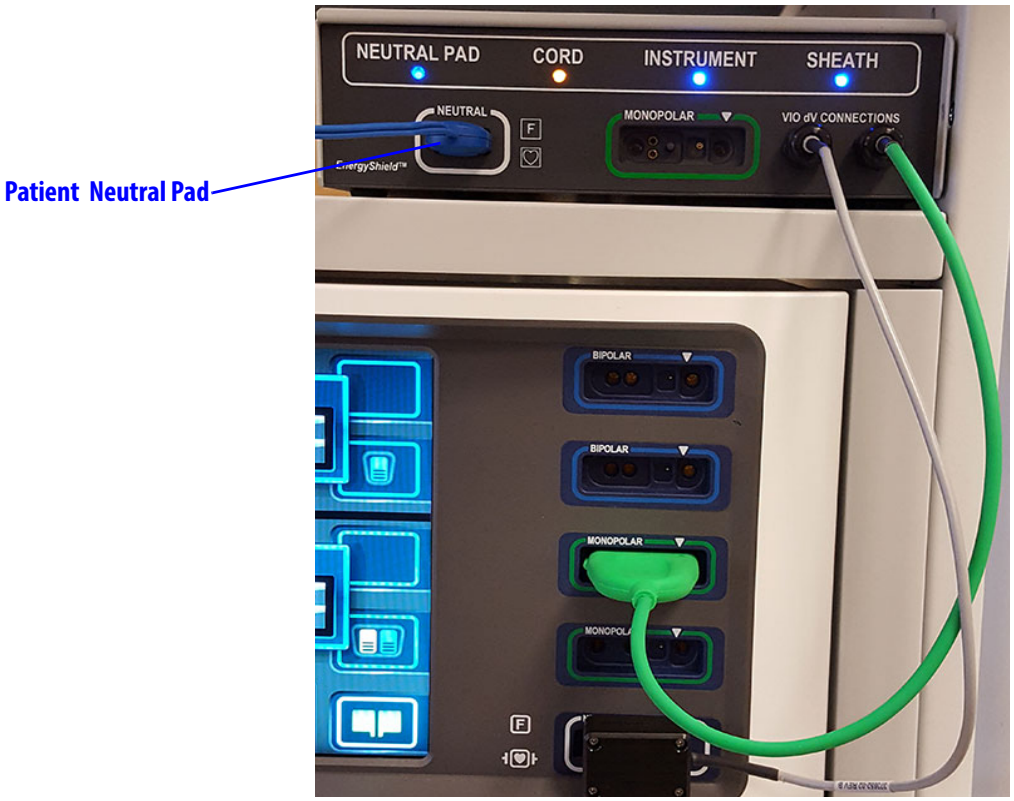

Figure 8.11 Patient pad plugged into EnergyShield Monitor

WARNING: Do not bypass the EnergyShield Monitor while using EndoWrist SP monopolar instruments by connecting the patient neutral pad directly to the ESU. ESU operation is prevented if the patient neutral pad is not connected to the EnergyShield Monitor (Figure 8.12).

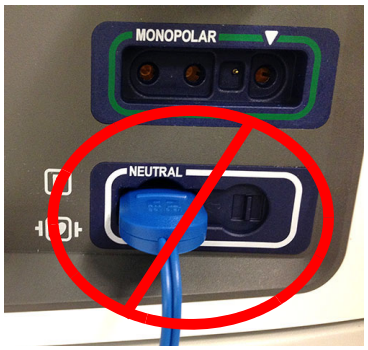

Figure 8.12 Do not connect the patient neutral pad directly to the VIO dV

7. Obtain the monopolar instrument and confirm that the cautery tip and Instrument Sheath are installed. Connect the instrument connector end of the EnergyShield monopolar cautery cord to the EndoWrist SP monopolar instrument housing. The connector is properly seated when it cannot be pushed further into the housing.

Note: It is recommended to have a backup EndoWrist SP monopolar instrument available for use to minimize procedure delay in the event of an instrument-related EnergyShield Monitor fault.

8. Align the arrow on the wide connector end of the monopolar cautery cord with the arrow above the monopolar receptacle on the EnergyShield Monitor (Figure 8.13) and plug it in. Ensure that the monopolar cautery cord is fully seated by verifying that the connector cannot be pushed further into the receptacle. When both ends of the monopolar cautery cord are properly connected to the EndoWrist SP monopolar instrument and EnergyShield Monitor, the cord LED on the EnergyShield Monitor illuminates blue (Figure 8.13).

Figure 8.13 All LEDs illuminated blue

9. Confirm all four LEDs illuminate blue (as shown in Figure 8.14) before using the monopolar instrument.

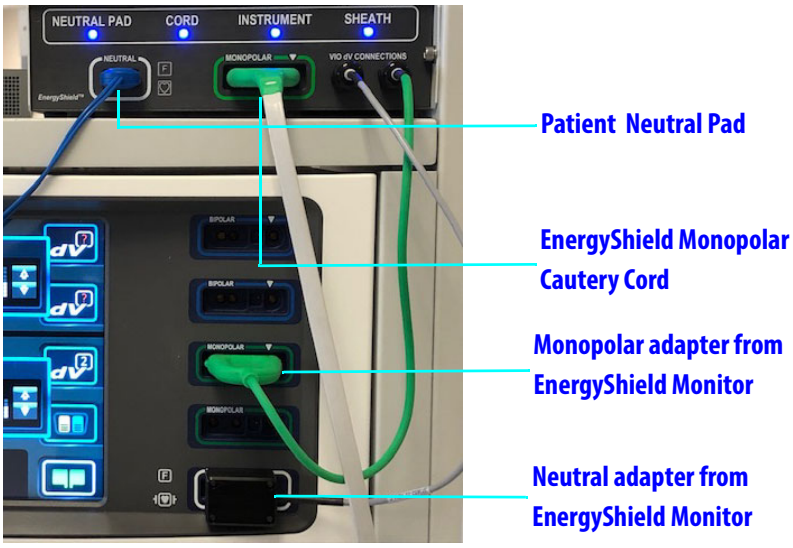

Figure 8.14 Blue LEDs confirmation

For more information on EndoWrist SP monopolar instruments, see Chapter 5 Monopolar Curved Scissors starting on page 25 and Chapter 6 Monopolar Cautery Instrument starting on page 31.

EnergyShield Monitor Faults and Failure

WARNING: The EnergyShield Monitor will not detect all occurrences of damage to the monopolar instrument sheath. Inspect the Instrument Sheath for damage throughout use. Examples of damage include tears or cuts in the sheath material. If damage is observed, remove and replace the Instrument Sheath on any instrument (monopolar or other) to prevent stray cautery or other risks.

If the EnergyShield Monitor detects a fault condition, the system emits an audible tone upon the user attempting to activate monopolar energy and upon occurrence of an instrument or a sheath fault, and the associated LED(s) on the front panel illuminate amber. During EnergyShield Monitor faults, energy activation of EndoWrist SP monopolar instruments is prevented from the Surgeon Console, but energy activation of EndoWrist SP bipolar instruments and manual instruments (footswitch or auxiliary foot pedal activated) is permitted. All system control modes (including Following mode for installed instruments) remain available during an EnergyShield Monitor fault.

If at any time the EnergyShield Monitor does not function as described, discontinue use of the EnergyShield Monitor and contact Intuitive Surgical Customer Service.

EnergyShield Monitor Faults

If an EnergyShield Monitor fault can be resolved by the user, solid amber LED(s) on the EnergyShield Monitor indicate the source of the fault (Figure 8.15). When the user attempts to activate monopolar energy in a fault condition, the system also emits a temporary audible tone and an error message displays above the instrument drive pod associated with the installed EndoWrist SP monopolar instrument (Figure 8.16).

Figure 8.15 EnergyShield Monitor

See Table 8-6 for more information to identify and resolve faults. If a cord, instrument, or sheath fault does not resolve after following the corresponding steps in Table 8-6, replace the remaining components not yet replaced (for example, cord, instrument, or sheath). If the fault does not resolve, contact Intuitive Surgical Customer Service.

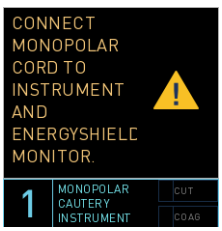

Figure 8.16 Error message above instrument drive pod example

Table 8-6 EnergyShield Monitor Faults

EnergyShield Monitor Amber LED	EnergyShield Monitor Status	Troubleshooting Steps
Neutral Pad	Dual-surface patient neutral pad not connected to EnergyShield Monitor	Ensure that a dual-surface patient neutral pad is applied to the patient. Connect the patient neutral pad to the neutral receptacle of the EnergyShield Monitor.
Cord	Monopolar cautery cord connection interrupted	Connect the monopolar cautery cord to the monopolar instrument installed on the da Vinci SP System and to the monopolar receptacle of the EnergyShield Monitor. a. If fault persists, replace the monopolar cautery cord with a backup monopolar cautery cord. If fault resolves following cord replacement, dispose of the faulty monopolar cautery cord. b. If fault persists following cord replacement, replace the monopolar instrument with a backup monopolar instrument. If fault resolves following instrument replacement, dispose of faulty monopolar instrument.
Instrument	Internal instrument insulation compromised	Replace the monopolar instrument with backup monopolar instrument. Dispose of faulty monopolar instrument.
Sheath	Instrument Sheath integrity compromised	In the event of an Instrument Sheath fault, it is recommended to inspect the surgical site, including the area outside of the surgical view, for any stray burns, as damage to the Instrument Sheath may result in stray cautery. Replace the Instrument Sheath on the monopolar instrument with a new, unused Instrument Sheath.

EnergyShield Monitor Failure

An internal EnergyShield Monitor failure that cannot be resolved by the user is indicated by all four LEDs blinking amber (Figure 8.17). A system message also displays across the top of the surgical view (Figure 8.18).

Figure 8.17 All LEDs illuminated amber

Figure 8.18 EnergyShield Monitor fault system message

If this type of EnergyShield Monitor failure occurs, the EnergyShield Monitor may be non-functional and should not be used. The system will trigger a system recoverable fault (Figure 8.19) which can be recovered to resume all system control modes and bipolar energy activation of the VIO dV, but energy activation of EndoWrist SP monopolar instruments will be prevented from the Surgeon Console. If this occurs, contact Intuitive Surgical Customer Service.

Figure 8.19 Recoverable fault message example

Intraoperative Use

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

WARNING: Use the lowest power setting possible for the minimum time necessary to achieve the desired effect.

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: 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 (EndoWrist SP or manual laparoscopic). This could result in burns to tissue in contact with any of the second instrument's metal parts or port. To exercise caution in these scenarios, the monopolar tip should be closer to the tissue than to the second instrument.

WARNING: The Monopolar Cautery Instrument should be cleaned and dried before installing or exchanging any monopolar cautery tip.

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 SP cautery instrument to help avoid unintended contact with tissue adjacent to the area to be cauterized.

WARNING: Inspect the Instrument Sheath for damage throughout use. Examples of damage include tears or cuts in the sheath material. If damage is observed, remove and replace the Instrument Sheath on any instrument (monopolar or other) to prevent stray cautery or other risks.

CAUTION: If the MCS Tip becomes loose during use DO NOT use another instrument to remove the accessory inside the patient. Close the MCS blades, remove the instrument from the port, and replace the MCS Tip with a new one.

Monopolar instruments are rated for a maximum peak voltage of 3kV (6kV peak-to-peak).

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 at the Surgeon Console.
3. After cutting or coagulating is complete, visually inspect the surgical area to ensure adequate hemostasis.

Intraoperative Cleaning

WARNING: Use care not to twist the MCS Tip when carefully cleaning the Monopolar Curved Scissors intraoperatively. Twisting may cause the MCS Tip to loosen.

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. To clean an instrument intraoperatively, remove the instrument from the system and wipe the instrument tip with moist sterile gauze.

CAUTION: Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.

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.

8.4 Bipolar Cautery

This section contains instructions for use specific to connecting the EndoWrist SP bipolar instruments with the VIO dV and bipolar instrument settings.

This section discusses the following topics:

Bipolar Cautery Cord

This section provides details specific to the Bipolar Cautery Cord (PN 470384). The reusable cord is supplied non-sterile and requires cleaning and sterilization before use. For more information regarding cleaning and sterilization, refer to the Reprocessing Instructions.

General Warnings and Cautions

WARNING: Never use the cords when there is visible evidence of damage to the exterior, such as a cracked or damaged connector.

⚠CAUTION: Connect the ESU to the EndoWrist SP instrument using the appropriate monopolar/bipolar cord. Refer to the ESU's manual for indications and instructions in making this connection. Monopolar cords may only be connected to monopolar ports, and bipolar cords to bipolar ports.

Device Description

The reusable Bipolar Cautery Cord (PN 470384) is designed to be used as an accessory to the EndoWrist SP bipolar instruments in conjunction with the VIO dV generator during surgical and other medical procedures.

Wide connector

Instrument connector

Figure 8.20 Bipolar cautery cord connectors

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
- Corrosion of connector contacts

Connecting Bipolar Instruments to the VIO dV

1. **Connect the energy cord to the EndoWrist SP instrument:** Connect the instrument connector on the energy cord to the applicable EndoWrist SP instrument. The instrument connector is properly seated when it cannot be pushed further into the instrument housing.
2. **Correctly orient the wide 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 8.21).

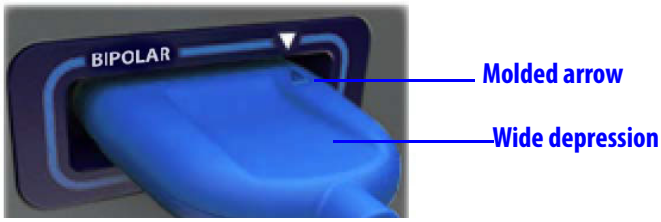

Figure 8.21 Correct orientation of the connector with molded arrow facing up

3. **Connect the energy cord to the VIO dV port:** Push the connector into the bipolar port until it cannot be pushed further and is fully seated (Figure 8.21).

For more information on EndoWrist SP bipolar instruments, see Chapter 7 Bipolar Instruments on page 36.

Intraoperative Use

Bipolar instruments are rated for a maximum peak voltage of 500V.

WARNING: Do not touch the end effectors of the instrument to any staples, clips, or sutures while energized. Damage to the end effectors may occur.

WARNING: Do not attempt to scrape off carbonized tissue with a sharp object such as a scalpel.

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

CAUTION: The EndoWrist SP bipolar electrosurgical instruments are designed for use with a maximum peak voltage of 500V. 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 SP System.

1. Grasp the tissue to be cut or coagulated using the hand control (master) on the Surgeon Console. Make sure that the jaws do not come in contact with non-target tissue.
2. Activate the ESU by depressing the associated foot pedal at 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.

WARNING: Do not use one instrument to energize the tips of another instrument (robotic or manual laparoscopic). This may cause patient injury and damage to the instrument. Energy may flow to the patient from places other than the tip, inside or outside the field of view. Avoid close proximity to other instrument tips when energizing monopolar instruments.

3. After coagulating is complete, visually inspect the surgical area to ensure adequate hemostasis.

Intraoperative Cleaning

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. To clean an instrument intraoperatively, remove the instrument from the system and wipe the instrument tip with moist sterile gauze.

CAUTION: Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.

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.

8.5 Troubleshooting

This section discusses the following topics:

- Monopolar and Bipolar Instrument Energy Delivery
- Patient Neutral Pad Positioning

Monopolar and Bipolar Instrument Energy Delivery

Table 8-7 describes troubleshooting information to help you address energy delivery issues when using the EndoWrist SP monopolar and bipolar instruments. If troubleshooting does not resolve the energy delivery issue, contact Intuitive Surgical Customer Service.

Table 8-7 Troubleshooting Monopolar and Bipolar Instrument Energy Delivery

Possible Problems	Remedy
Monopolar and Bipolar Instruments	
VIO dV not powered on or mode effect not set	• Confirm that the VIO dV is powered on. • Verify that the mode effect setting is higher than zero. Effect settings default to zero.
Cautery cord connections	• Verify all cautery cord connections. See Connecting the Monopolar Instruments, EnergyShield Monitor and VIO dV and Connecting Bipolar Instruments to the VIO dV. • Confirm that the correct cautery cord is connected to the correct instrument. See EnergyShield Monopolar Cautery Cord and Bipolar Cautery Cord. • Use an alternate port to connect the instrument to the VIO dV. • Replace the cautery cord with a backup cautery cord.
Instrument connection	• Confirm that the instrument is installed on the system. • Check the icon on the VIO dV to ensure proper instrument connection. See Control Assignment Indicators.
Incorrect foot pedal being used	• Confirm that correct pedal is being pressed at the Surgeon Console. See Bipolar and Monopolar Instrument Activation.
Activation is disabled	Confirm the following: • The VIO dV is connected to the da Vinci SP System and powered on. • The foot pedals are enabled. • The mode effect setting is higher than zero. Effect settings default to zero. • The installed instrument is inserted past the distal edge of the Entry Guide of the port. • The installed instrument is connected to the VIO dV. • The surgeon's head is in the 3D viewer. • The installed instrument is associated with a hand control.
Monopolar Instruments Only	
EnergyShield Monitor not powered on, improperly connected, or faulted	• Confirm that the EnergyShield Monitor is powered on and not faulted. See EnergyShield Monitor Faults and Failure. • Verify EnergyShield Monitor connections. See Connecting the Monopolar Instruments, EnergyShield Monitor and VIO dV.
Patient neutral pad error (red patient neutral pad status on the VIO dV)	• Confirm that a dual surface patient neutral pad is being used. • Verify patient neutral pad placement. • Verify that the patient neutral pad is connected to the EnergyShield Monitor and that the neutral adapter connection between the EnergyShield Monitor and VIO dV is secure. See Connecting the Monopolar Instruments, EnergyShield Monitor and VIO dV.
Bipolar Instruments Only	
Improper connection of instrument to VIO dV	• Confirm that the wide connector end of the bipolar cautery cord is oriented with the molded arrow side facing up, and is properly connected to the VIO dV. See Connecting Bipolar Instruments to the VIO dV.

Patient Neutral Pad Positioning

It is possible to get patient neutral pad positioning errors on the VIO dV, especially when not using the ERBE patient neutral pads. For more information on proper patient neutral pad positioning, refer to the *ERBE VIO dV User Manual*.

_____End_____

9 da Vinci SP Port Accessories

9.1 Introduction

This section contains instructions for use specific to the da Vinci SP® port accessories (da Vinci SP Cannula, da Vinci SP Obturator, and EntryGuide™ Kit) used with the da Vinci SP System.

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

Intended Use

For intended use of the port accessories, see Appendix D: Intended Use Statements.

Cautions for Single-Use Items

CAUTION:  **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.

CAUTION:  **Do not use if package is damaged.**

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

9.2 Device Description

Compatibility Information

Table 9-1 shows compatible products used with the da Vinci SP System.

Table 9-1 da Vinci SP Port Accessory Compatibility

SP Cannula PN	SP Obturator PN	EntryGuide Kit PN
SP Cannula, Circular, 25 mm x 100 mm (430036)	SP Obturator, Circular, 25 mm x 100 mm (430016)	EntryGuide Kit C.6.6.6, 25 mm x 100 mm (includes EntryGuide Cannula Insert and EntryGuide Cannula Seal) (430022)

Device Overview

- **SP Cannula:** A stainless steel component (Figure 9.1) consisting of a SP Cannula fin, insufflation port, and hollow tube (lumen).

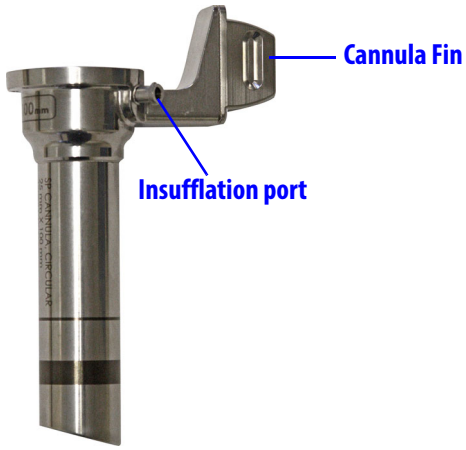

Figure 9.1 Example SP Cannula

- **EntryGuide Kit**: The single-use EntryGuide Kit consists of the EntryGuide SP Cannula Insert (also referred to as Entry Guide) and EntryGuide SP Cannula Seal (also referred to as SP Cannula Seal).

  The Entry Guide is sterile, single-use and disposable and guides the instrument and camera shafts through the SP Cannula and allows rotation of the instrument drives relative to the SP Cannula. The Entry Guide consists of three integrated instrument lumen doors and a camera lumen door which enables maintenance of insufflation while instruments are not inserted into the Entry Guide. The levers on the Entry Guide are not used during typical instrument exchange but provide a manual method to open the lumen doors (Figure 9.2).

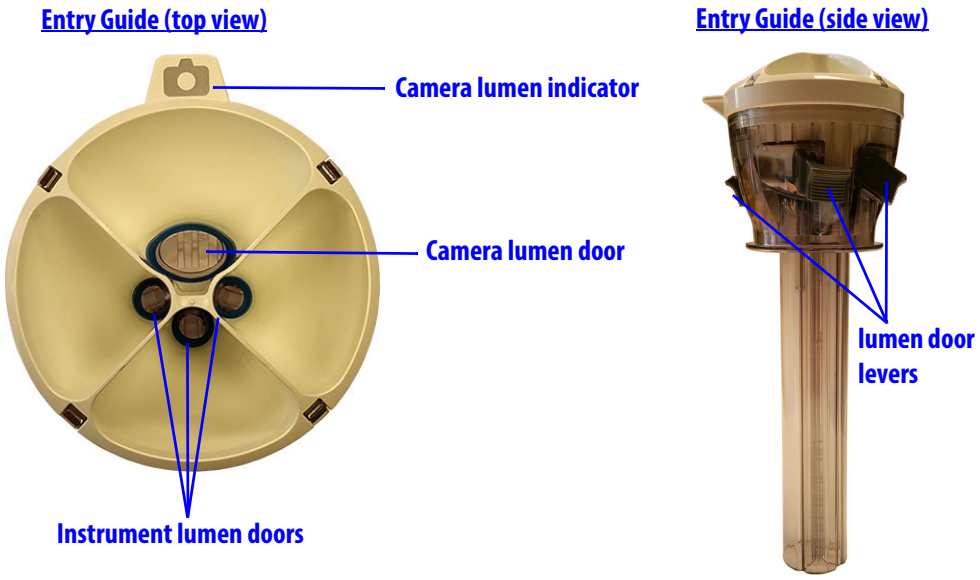

Figure 9.2 Example Entry Guide

The SP Cannula Seal is a sterile, single-use disposable cap for the SP Cannula, used to maintain insufflation with and without an obturator or Entry Guide inserted. The slider on the SP Cannula Seal is used to remove the SP Cannula Seal from the SP Cannula. The latch on the SP Cannula Seal retains the Entry Guide and obturator (Figure 9.3).

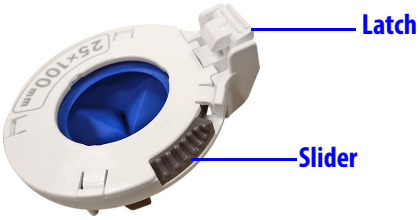

Figure 9.3 Example SP Cannula Seal

- **Obturator**: A blunt tip cylinder used when inserting the SP Cannula into the patient to prevent coring or tearing of the body wall upon insertion. The obturator (Figure 9.4) is removed before use of the SP Cannula for instrument or camera access.

Figure 9.4 Example obturator

9.3 Preoperative Preparation

Only a physician or medical personnel under the supervision of a physician should use Intuitive Surgical SP Cannulas and obturators. Before use, confirm that the SP Cannula and obturator have been appropriately sterilized and that the sterile packaging of the EntryGuide Kit is intact.

Inspection Before Use

Before use, inspect the SP Cannulas, obturators and accessories for damage or defects.

WARNING: Do not use a damaged SP Cannula. Damaged SP Cannulas may injure tissue during insertion and may abrade the Camera Sheath, Instrument Sheath or Entry Guide and generate particles that may fall inside the patient.

WARNING: Do not use SP Cannulas or obturators that have been reprocessed with single-use accessories (for example, SP Cannula Seal, Entry Guide) installed. Inadequate sterilization may occur when these single-use accessories are installed during reprocessing.

1. Carefully inspect the SP Cannula visually for damage. Examples of damage include nicks or dents in the edge of the SP Cannula tube, and dents or flat spots in the SP Cannula tube that interfere with the free insertion of the Entry Guide. Figure 9.5 shows examples of SP Cannula damage and a SP Cannula that is not damaged.

Figure 9.5 Visual inspection examples

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

CAUTION: Do not use an obturator with visible cracks or other damage.

2. Insert the obturator into the SP Cannula to inspect the inner diameter of the SP Cannula (Figure 9.6 A and B). If the obturator cannot be inserted smoothly through the SP Cannula, use a new SP Cannula.

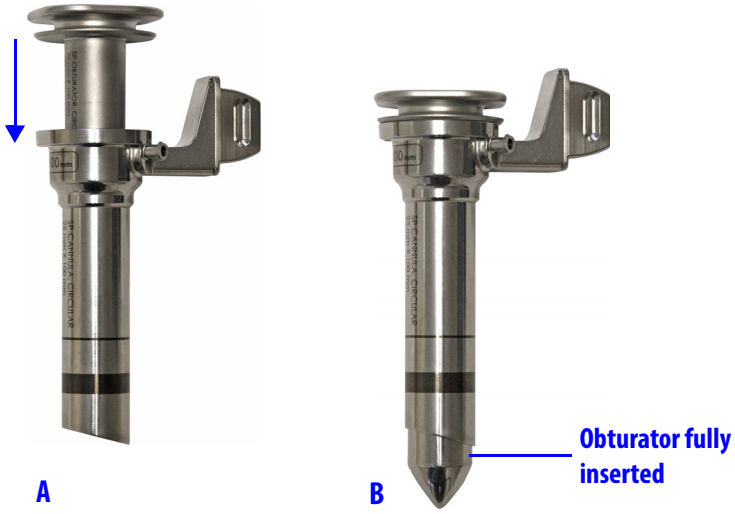

Figure 9.6 Insert the obturator (A) until it is fully inserted (B)

3. After the obturator inserts all the way, spin the obturator relative to the SP Cannula. Ensure that the obturator can make one complete revolution freely. Use Table 9-2 for pass/fail criteria when inspecting SP Cannulas.
4. Remove the obturator.

Table 9-2 SP Cannula Inspection Criteria

Pass	Fail
The obturator inserts all the way	The obturator cannot be inserted all the way
AND the obturator can spin freely at insertion depth	**OR** the obturator cannot spin freely at insertion depth
AND there are no burrs or dents	**OR** there are burrs or dents

9.4 Using the Port Accessories

The following section describes general instructions for using the port accessories. Before using the accessories, remove them from the sterile packaging using sterile technique and keep them within the sterile field.

WARNING: Follow the instructions in this section to ensure complete attachment of the SP Cannula Seal to the SP Cannula, and the Entry Guide or obturator to the SP Cannula/SP Cannula Seal assembly.

CAUTION: The Entry Guide should only be used with EndoWrist SP instruments. Do not insert hand-held laparoscopic instruments through the Entry Guide as loss of insufflation may result.

Note: The SP Cannula must be used with the SPCannula Seal and Entry Guide. Do not insert a camera or instruments through a SP Cannula without a SP Cannula Seal and Entry Guide installed.

Attaching and Removing the SP Cannula Seal

To attach the SP Cannula Seal to the SP Cannula, align the latch on the SP Cannula Seal with the SP Cannula fin and push down until the SP Cannula Seal locks into place with a tactile and audible click. Visually confirm that there are no gaps between the SP Cannula and the SP Cannula Seal (Figure 9.7 A and B).

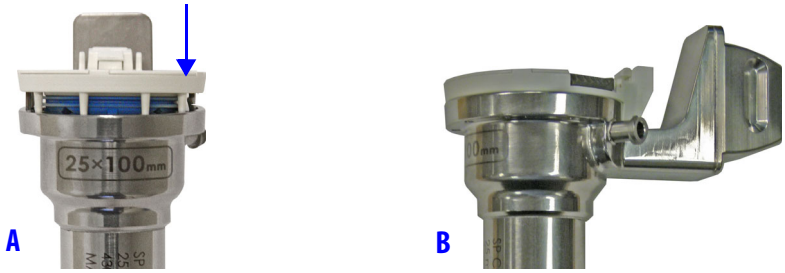

Figure 9.7 SP Cannula Seal attached to SP Cannula

To remove the SP Cannula Seal from the SP Cannula, rotate the slider on the SP Cannula Seal in a counter-clockwise direction and pull up to remove it from the SP Cannula (Figure 9.8 A and B).

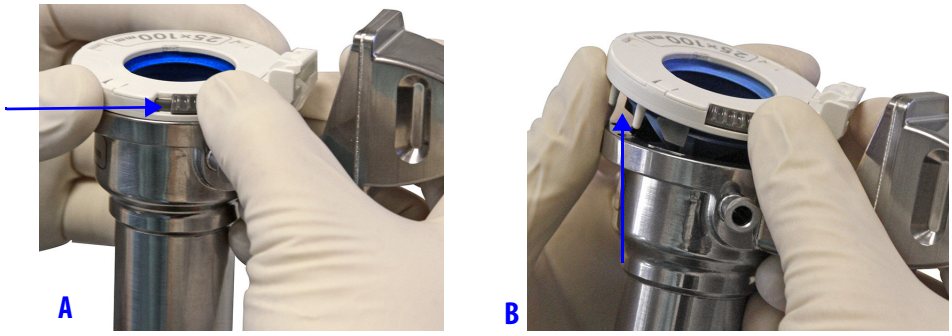

Figure 9.8 Remove the SP Cannula Seal from the SP Cannula

Attaching and Removing the Obturator

Before attaching the obturator, ensure that a SP Cannula Seal is attached to the cannula. Insert the obturator fully into the SP Cannula Seal and through the SP Cannula until the latch on the SP Cannula Seal locks the obturator into place with a tactile and audible click (Figure 9.9).

Figure 9.9 Obturator attached to SP Cannula Seal

To remove the obturator, pull back the latch on the SP Cannula Seal and gently pull the obturator out of the SP Cannula (Figure 9.10).

Figure 9.10 Remove obturator from SP Cannula Seal

Attaching and Removing the Entry Guide

Before attaching the Entry Guide, ensure that a SP Cannula Seal is attached to the SP Cannula. Insert the Entry Guide fully into the SP Cannula Seal and through the SP Cannula until the latch on the SP Cannula Seal locks the Entry Guide into place with a tactile and audible click (Figure 9.11).

Figure 9.11 Entry Guide attached to SP Cannula Seal and SP Cannula

To remove the Entry Guide, pull back the latch on the SP Cannula Seal and pull the Entry Guide out of the SP Cannula (Figure 9.12).

Figure 9.12 Remove the Entry Guide from the SP Cannula

Disposal

Dispose of the single-use Entry Guide and SP Cannula Seal as biological hazardous waste and according to local hospital protocol.

_____End of Section _____

A Appendix A: Reprocessing Preparation in the Operating Room

For full Reprocessing information, refer to the *da Vinci SP Reprocessing Instructions*.

Note: Carefully remove all accessories, including disposable attachments, such as removable tips, before reprocessing.

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

Prime and Soak

Note: The cleaning preparation process (as described below) must begin within 60 minutes after the procedure. Intuitive Surgical 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.

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 _____

B Appendix B: Symbols Defined

The following symbols may appear on instruments, accessories, and packaging labels. For a complete list of symbols and icons see the *da Vinci SP System User Manual*.

Symbol or Icon	Meaning
	Attention: Consult accompanying documents
Rx only	Federal (U.S.) law restricts this device for sale, distribution, and use by or on the order of a physician
	Manufacturer
	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
VER	Version
QTY	Quantity
LOT	Batch Code
REF	Catalog Number
EC REP	Authorized representative in the European Community
intuitive.com/IFU	Electronic Instructions for Use
	Entry Guide Camera indicator
25×100mm	Entry Guide and SP Cannula Seal Size indicator
	Entry Guide Camera and Lumen icon
LTP	Camera Leak Test Port icon
LASER APERTURE	Camera Laser Aperture icon
AUTO CLAVE ONLY	Must be sterilized only by autoclave
CE 0543	In conformance with the Medical Device Directive 93/42/EEC
	Flush Port Symbol
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified

Symbol or Icon	Meaning
	Device is not designated for human use
	Number of times the instrument can be used
	Number of closures that can be used with the clip applier

End of section

C Appendix C: Natural Rubber Latex

For the following Intuitive Surgical products containing elastomeric/pliable parts and 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:

- EndoWrist SP Camera (PN 430060)
- MCS Tip and installation tool (PN 430035)
- Cautery Hook Tip, 5 mm (PN 400156)
- Cautery Spatula Tip, 5 mm (PN 400160)
- EntryGuide Kit C.6.6.6, 25 mm x 100 mm (PN 430022)
- EnergyShield Monopolar Cautery Cord (PN 430068)
- Bipolar Cautery Cord (PN 470384)
- Instrument Sheath (PN 430012)
- Camera Sheath (PN 430020)

End of section

D Appendix D: Intended Use Statements

The following intended use statements apply to the da Vinci SP instruments and accessories. For information on specific indications for use and representative uses of the da Vinci SP Surgical System, refer to the appropriate da Vinci SP supplement.

Product	Part Number	Intended Use
EndoWrist SP Camera, 0°	430060	The EndoWrist SP Camera, 0° is intended to provide stereoscopic visualization of tissue and instruments when performing procedures with the da Vinci SP System.
Needle Driver	430006	The Needle Driver is intended to be used with the da Vinci SP System to drive needles and tie suture.
Round Tooth Retractor	430002	The Round Tooth Retractor is intended to be used with the da Vinci SP System for retracting, grasping and manipulating tissues.
Cadiere Forceps	430009	The Cadiere Forceps is intended to be used with the da Vinci SP System for dissecting, grasping, manipulating, and retracting tissues.
Medium-Large Clip Applier	430005	The Medium-Large Clip Applier is intended to be used with the da Vinci SP System for the application of Weck® Hem-o-lok® Medium-Large Polymer Ligating Clips for ligation of vessels and tissue bundles ranging in size from 3 - 10 mm in diameter.
Monopolar Curved Scissors and MCS Tip	430004 430035	The Monopolar Curved Scissors with MCS Tip is intended to be used with the da Vinci SP System for manipulating, cutting, and dissecting tissue, coagulating and transecting tissue using monopolar electrosurgical energy, and cutting suture. The MCS Tip is also intended to provide electrical insulation over a section of the Monopolar Curved Scissors instrument so that RF energy is only available at the scissor blades.
Monopolar Cautery Instrument and Monopolar Cautery Tips	430007 400156 400160	The Monopolar Cautery Instrument with the 5 mm Cautery Hook Tip or 5 mm Cautery Spatula Tip is intended to be used with the da Vinci SP System for manipulating and dissecting tissue and coagulating and transecting tissue using monopolar electrosurgical energy.
Bipolar Instruments	430010 430011	The Maryland Bipolar Forceps and Fenestrated Bipolar Forceps are intended to be used with the da Vinci SP System for dissecting, grasping, manipulating, retracting, and coagulating tissues and vessels.
Bipolar Cautery Cord	470384	The Bipolar Cautery Cord is intended for connecting bipolar electrosurgical instruments to an electrosurgical generator to provide transmission of high frequency current from the electrosurgical generator to the surgical instrument.
EnergyShield Monopolar Cautery Cord	430068	The EnergyShield Monopolar Cautery Cord is intended to conduct high frequency current from the electrosurgical generator and EnergyShield Monitor to a da Vinci shielded monopolar instrument.
SP Cannula, SP Obturator, and EntryGuide Kit	430036 430016 430022	The SP Cannula, SP Obturator, and EntryGuide Kit are intended to establish a port of entry for EndoWrist SP instruments, EndoWrist SP cameras, and compatible accessories.

Product	Part Number	Intended Use
Instrument Sheath	430012	The Instrument Sheath is intended to be used with the EndoWrist SP surgical instruments to reduce ingress of biological material into the instrument, allow smooth insertion and retraction through the Entry Guide, and provide electrical insulation over the shaft and joints of the EndoWrist SP surgical instruments to reduce the likelihood of unintended electrosurgical energy delivery.
Camera Sheath	430020	The Camera Sheath is intended to be used with the EndoWrist SP Camera to reduce ingress of biological material into the camera, reduce component surface exposure, and allow smooth insertion and retraction through the Entry Guide.
Instrument Arm Drape	430013	The Instrument Arm Drape is intended to be used with the da Vinci SP Patient Cart as a sterile barrier during clinical procedures.

End of section

E Appendix E: Sterilization Methods

This table describes sterilization methods used for single-use Intuitive Surgical products referenced in this manual.

Name	Part Number	Method
Camera Sheath	430020	Ethylene Oxide
Instrument Sheath	430012	Ethylene Oxide
MCS Tip	430035	Ethylene Oxide
Cautery Hook Tip, 5 mm	400156	Ethylene Oxide
Cautery Spatula Tip, 5 mm	400160	Ethylene Oxide
EntryGuide Kit C.6.6.6, 25 mm x 100 mm	430022	Gamma Irradiation
Instrument Arm Drape	430013	Ethylene Oxide

End