

NOTE: This instrument tip and handle should be kept in the open position when sterilized.

Warranty

This instrument is warranted for its lifetime against defects in material and workmanship.

The warranty does not cover reinsulation, sharpening and refurbishing, or damage caused by misuse or failure to care for the instrument as described in the package insert. It does not cover instruments if they have been repaired, refurbished or sharpened by anyone other than SILEX MEDICAL LLC.

This product warranty is in lieu of all other warranties, whether express or implied, including any warranty or merchantability or fitness for a particular purpose. The liability and remedy stated in this product warranty will be the sole liability of SILEX MEDICAL and the sole remedy available to the user for this product, whether in contract or in tort (including negligence) or otherwise, and SILEX MEDICAL will not be liable to user for any incidental or consequential damage arising out of its handling and use.

The terms of this warranty may not be modified without Silex's express written consent.

To returned an instrument for repair, simply obtain a return authorization number from SILEX MEDICAL SERVICE DEPARTMENT and send it to our address below. We will repair the instrument or replace it at our option and return it to you.

Service: Call in the United States 1-877-694-2211 X 2

Ordering Information:

Phone: 1-877-694-2211
Fax: 1-860-621-3070
E-mail: sales@silexmedical.com

Distributed by:

SILEX MEDICAL LLC
24B Robert Porter Road
Southington, CT 06489
Phone: 1-877-694-2211
Fax: 1-860-621-3070
Visit us at: www.silexmedical.com

SILEX-IFU REV. B

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SILEX-IFU REV. B



Signature® Laparoscopic Instruments



CAUTION: PLEASE READ ALL INSTRUCTIONS PRIOR TO USE

INSTRUCTIONS FOR USE

Intended Use

The Laparoscopic Grasper/Dissector with monopolar electrosurgical foot switch connector is intended to be used to grasp/dissect and cauterize adventitial tissue from vessels, ducts and other structures and to create tissue planes between various ducts and arteries during laparoscopic surgery.

The Laparoscopic Scissors with monopolar electrosurgical foot switch connector is intended to be used to cut and cauterize adventitial tissue between various ducts and arteries during laparoscopic surgery.

The Endoscopic Non-Electrosurgical 5mm and 10mm Fan Retractors, 10mm Babcock Clamp, 10mm Extractor are intended to be used in endoscopic surgeries as manipulators to lift, move, clamp, extract and retract structures or adventitial tissue.

Caution

These instruments are not compatible with bipolar cautery cables and generators. They are intended only for monopolar cautery usage.

Activating this device when not in contact with target tissue or when not in position to deliver energy to target tissues for fulguration may cause capacitive coupling. Capacitive coupling could cause burns and increases risk of shock to patient.

Rx Only CAUTION: U.S. FEDERAL LAW RESTRICTS THIS PRODUCT TO BE USED BY OR ON THE ORDER OF A PHYSICIAN.

Warnings & Precautions

1. Check for proper grounding of instrument and patient prior to use.

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- Laparoscopic procedures should be performed only by physicians having adequate training and familiarity with laparoscopic techniques. Refer to current medical literature relative to technique, complications and hazards prior to performing any laparoscopic procedure. An understanding of monopolar electrosurgery is necessary to avoid the potential of gas embolism.
- A thorough understanding of the principles and techniques of electrosurgery is necessary to avoid shock and burn hazard to the patient, operator and operating room personnel.
- The instrument tip when energized by an electrosurgical generator has the potential to burn, cut and coagulate tissue. Care should be taken when using this device as contact with surrounding tissue in the field can produce excessive tissue burn. Verify compatibility of instrumentation and ensure that electrical isolation or grounding is not compromised and that the patient is properly grounded at all times. Use lowest dial setting to achieve desired surgical effect. Check ground and connectors before increasing generator setting. Increase generator setting slowly if more current is desired.
- Do not energize the instrument unless it is visible through the laparoscope.
- When using electrosurgery generators be sure to follow the manufacturer's recommendations for patient and staff safety. The patient should be grounded by use of a grounding pad, which is properly connected to the electrical generator. Care should be taken when handling the electrosurgery instrument so as not to burn the patient and surgical drapes. A review of current literature on the particular procedure is suggested prior to surgery.
- To minimize potential for patient injury due to capacitive coupling between the active electrosurgical instrument within the peritoneum, the following precautions should be taken:
 - Consider use of all metal cannula system, (2) insert the electrosurgical instrument through a large sized cannula (i.e., a 5mm electrosurgical instrument should be inserted through a 10mm cannula), (3) Avoid activation of electrosurgical instrument when the tip is not in contact with target tissue.
- Prior to each use inspect the laparoscopic instrument for defects. If damage is evident, do not use the instrument; return to SILEX MEDICAL LLC for repair/replacement.

Instructions for Use of Grasper/ Dissector/Scissors

- Prior to use, clean and sterilize instrument as per instructions.
- Inspect instrument for any signs of defects.
- Under laparoscopic visualization, insert instrument through appropriate sleeve, advancing until desired depth is obtained.
- Actuate handle to grasp, cut, move, etc. (See No. 1.)

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Instructions for Use of Electrosurgical Capable Instruments

- Refer to generator manufacturer's instructions prior to use.
- Apply grounding pad to patient and properly connect to generator.
- Attach monopolar electrosurgical active cord to electrosurgical connection on the instrument's handle and adjust the power, using lowest dial setting to achieve the desired surgical effect. Check ground and connectors before increasing generator setting. Increase generator setting slowly if more current is desired.

Cleaning/Maintenance

- Rinse the instrument and wash for 1 minute in warm soapy water after each use.
- Immerse instrument in freshly prepared enzymatic detergent solution (see note below on how to prepare it) for 2 minutes and use a soft-bristled brush to clean gross amounts of soil off the devices
- Rinse in clean water. Do not use saline which may cause corrosion.
- Clean instruments by immersing them in warm water in the ultrasonic cleaning unit for five (5) minutes using freshly made enzymatic detergent solution
- Force water through shaft using one of these three methods in order to ensure thorough removal of foreign matter from the shaft
 - Flush water from tip, through shaft, out of flush port until fluid runs clear.
 - Affix tubing to instrument, seating the tubing firmly onto the port, apply suction until fluid runs clear.
 - Fill a 60cc disposable syringe with water and affix the syringe to the flush port until it seats firmly. Force the fluid through the instrument by compressing the syringe. Repeat as necessary until the fluid runs clear.
- Visually inspect the instrument.
- Lubricate the instrument with an instrument milk or mineral oil prior to sterilization.
- Rinse in clean water for 1 minute and wipe dry.

NOTE 1: To prepare an enzymatic detergent solution use 1/8 oz. per gallon of Steris Prolystica 2X Concentrate Enzymatic Cleaner (the minimum effective concentration) and warm water.

NOTE 2: We do not recommend the use of glutaraldehyde or other disinfecting agents with these instruments.

Sterilization

Open flush port cap prior to sterilization. Each institution is responsible for determining the efficacy of the sterilization schedule used to sterilize this laparoscopic instrument. The following is provided for informational purposes: This instrument can be sterilized by standard autoclaving. The device should be wrapped in a lint-free surgical towel or qualified autoclave package and sterilized using standard steam gravity sterilization for 30 minutes at 250°F (121°C).

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