

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Laparoscopic Electric Instruments**  
**Manufactured by SterilMed, Inc.**  
**11400 73<sup>rd</sup> Avenue North**  
**Maple Grove, MN 55369**  
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**www.SterilMed.com**

**Caution: Federal law restricts this device to sale by or on the order of a physician.**

## INDICATIONS FOR USE

These devices are reprocessed laparoscopic electric instruments from various original equipment manufacturers (OEM). Laparoscopic Electric Instruments are designed for use in minimally invasive procedures, open surgical procedures to facilitate coagulation, transection, resection, mobilization, and dissection of tissue.

Each OEM provided an Instructions for Use (IFU) document with the original device. The health institution that wishes the device to be reprocessed should retain this original document.

## DEVICE DESCRIPTION

These devices consist of a variety of instruments including:

1. Dissectors (straight or curved)
2. Endoscopic Scissors (curved, hooked, metzenbaum)
3. Forceps (cutting and dissecting)
4. Extractors
5. Graspers
6. Shears

Devices are reprocessed under contract with the health institution that previously used the device; the devices are used by the health institution, sent to SterilMed for reprocessing, and returned for reuse.

Reprocessed laparoscopic electric instruments have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from an owner, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor and ensure the number of times reprocessed.

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**This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.**

## **CONTRAINDICATIONS**

1. Use in contraceptive coagulation of fallopian tissue.
2. Use when minimally invasive techniques are contraindicated.
3. Procedures associated with the use of these devices should be performed only by persons having adequate training and familiarity with applicable techniques. Consult literature relative to techniques, complications, and hazards prior to performing any procedure.

## **WARNINGS AND PRECAUTIONS**

1. The user of the device should have adequate training and a thorough understanding of the use and applications of these devices.
2. Inspect the packaging, and device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Equipment may vary with each manufacturer. Verify appropriate compatibility of all equipment and accessories prior to use.
4. A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both the patient and medical personnel and damage to the device or other medical instruments.
5. Ensure insulation and grounding is not compromised.
6. Do not immerse electrosurgical instruments in liquid.
7. Do not use monopolar cautery instruments as bipolar instruments.
8. Do not apply electrosurgical current directly to staples or clips.
9. Damage may occur if cutting of staple or clip is attempted.
10. Do not introduce or withdraw instruments with blades/jaws open through a trocar sleeve.
11. Do not exceed 35-40 watts of power when using these devices.

### **Tripolar Cutting Forceps**

1. Do not depress the knife actuation lever unless cutting is desired. This device contains a surgically sharp knife blade. Actuation of the lever will expose the knife blade.
2. Do not extend knife blade during electrosurgical coagulation.
3. This device can deliver an electric shock or burn when connected to an active electrosurgical unit.

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### **Cutting and Dissecting Forceps**

1. Do not exceed wattage specifications for applicable modes when using these devices.
2. These devices are for bipolar use only.
3. Ensure active electrodes are in the field of view during energy applications.
4. Ensure tissue is completely dissected before engaging cutting blade.
5. All exposed metal components at distal end of these devices may coagulate contacting material. Ensure all exposed metal is within the field of view and contacting tissue intended to be coagulated during the application of electrosurgical energy.
6. These devices are not compatible with some generators and trocars. Refer to the original manufacturer information and verify trocar compatibility prior to use.

### **Endoscopic Scissors**

1. All exposed metal components at distal end of these devices may coagulate contacting material. Ensure all exposed metal is within the field of view and contacting tissue intended to be coagulated during the application of electrosurgical energy.
2. This device may not be compatible with some generators and trocars. Refer to the original manufacturer information and verify trocar compatibility prior to use.

## **POTENTIAL ADVERSE EVENTS**

The following potential risks may be associated with the use of these devices during operative procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery. Adverse events may include the following:

1. Shock
2. Perforation
3. Electric or Thermal Burns
4. Tip Detachment

## **GENERAL INSTRUCTIONS AND INFORMATION**

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Remove the device from the sterile packaging using proper sterile technique.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment. For specific information on clinical studies, individualization of treatment, patient counseling, and procedural use of this reprocessed device, refer to the medical literature and rely on training and practical response.

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If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

## **METHODS TO TEST REPROCESSED DEVICES**

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, routine sterilization, and functional testing. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

*\* Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:*

*\* Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.*

*Instructions for Use can be found at [www.SterilMed.com](http://www.SterilMed.com). Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.*

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