

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Electrosurgical Electrodes**  
**Manufactured by SterilMed, Inc.**  
**11400 73<sup>rd</sup> Avenue North**  
**Maple Grove, MN 55369**  
**Toll Free 1-888-541-0078/ Fax 763-488-3350**  
**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 electrosurgical electrodes from various original equipment manufacturers (OEM). Reprocessed electrosurgical electrodes are intended for precision cutting or dissecting and cauterizing soft tissue. These devices are most commonly used in surgical procedures for which minimal tissue necrosis, bleeding, and surgical field smoke is desired.

Each OEM packaged 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 electrosurgical electrodes are monopolar electrosurgical instruments consisting of a tungsten tip, stainless steel housing, and several layers of insulation.

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 electrosurgical electrodes have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices are 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 .

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

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## CONTRAINDICATIONS

These instruments are not intended for use in the:

1. Central nervous system
2. Central circulatory system.

## WARNINGS AND PRECAUTIONS

SterilMed electrosurgical electrodes are reprocessed for single use only and must be returned for reprocessing prior to another use.

1. The user of the device should have adequate training and a thorough understanding of the use and applications of this device.
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. Verify appropriate compatibility of all equipment and accessories prior to use.
4. Never use a scratch pad to wipe needle.
5. Use with legally marketed generators compatible with monopolar electrosurgical devices.
6. Prior to use, inspect the needle for damage. The insulation is subject to wear and can puncture if misused or improperly handled. Perforations and other types of deterioration can result in unwanted tissue damage during use. **Do not use** if damage is apparent.
7. Handle by sleeve portion only. Do not bend or straighten.
8. Injury may occur if the metal shaft contacts tissue. Push needle into handpiece collet ensuring there is no gap at the needle/handpiece junction.
9. Do not use forceps or pliers to remove needle from handpiece.
10. *Important:* Use low wattage, initially starting out at 3-5 watts, and gradually increase until tissue drag stops. Use shallow, wisp-like strokes to achieve the best action.

## 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 upon appropriate training and experience.

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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, and routine sterilization. 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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