

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Electrical Endoscopic 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 from various original equipment manufacturers (OEM). Reprocessed endoscopic electrodes are intended to be used for vaporization, ablation, coagulation and/or resection of soft tissue in the prostate and bladder as well as when ablation and coagulation are required in gynecological and urological surgical procedures.

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

Endoscopic electrodes are manually operated instruments that are long enough to gain access to the surgical area and designed to be used as an accessory to resectoscopes. These devices are used in conjunction with an endoscope and are powered by a separate RF generator. The RF generator component is not included with this device.

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 endoscopic electrodes 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.

**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

1. Pregnancy
2. Acute or active inflammation of the cervix, endometrium, fallopian tube, ovary or peritoneum (cervicitis, endometritis, tubo-ovarian inflammatory disease, or pelvic inflammatory disease.)
3. Invasive cancer that is visible on examination.
4. Known or suspected cervical changes secondary to DES (diethylstilbestrol) intrauterine exposure.
5. Large tumors that prohibit visualization of the entire site, open surgical procedure should be considered.

## WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of endoscopic electrodes.
2. Inspect the packaging and product prior to use. Do not use if sterility appears compromised or the package/product appears damaged.
3. Equipment may vary with each manufacturer. Verify appropriate compatibility of all equipment and accessories prior to use.
4. The most effective current settings will vary based on the surgeon, the procedure, and the physical/physiological characteristics of the patient; therefore, the lowest possible current setting at which adequate cutting and/or coagulation can be achieved should be used.
5. Prevention of any electrosurgical problems during use can be accomplished by ensuring all electrical contacts (on other instruments) are thoroughly dried prior to connecting to the generator.
6. All instrument cords used during electrosurgical procedures must be inspected prior to use and upon completion of procedure. Ensure insulation is intact along the entire shaft
7. Carefully inspect the electrode prior to assembly. Do not bend or manipulate.
8. Care must be taken during endoscopic procedures not to damage instruments. Damaged instruments may result in tissue injury.
9. Do not use if there are visible signs of damage or deterioration to the electrode or contact wire.
10. Electrodes become extremely hot and may cause damage to the sheath and telescope. Use caution to avoid touching the sheath or telescope with the electrode during procedure.
11. Do not use if insulation is not intact

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## **CERVICAL TECHNIQUE GUIDANCE**

1. Larger lesions involving multiple quadrants of the cervix are more difficult to remove with either the small or large diameter loop electrodes.
2. The endocervix is commonly not included in the loop excision, and the results of endocervical curettage (ECC) do not appear to be predictive of either residual or invasive disease after loop excision procedures. If the ECC is positive for dysplasia, a standard cone biopsy should be considered.
3. Loop excision procedure performed with small diameter wire loop electrodes produce multiple small pieces of cervical tissue and provide a less acceptable tissue specimen for histopathologic analysis.

## **POTENTIAL ADVERSE EVENTS**

The following potential risks may be associated with the use of endoscopic electrodes. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Infection
2. Perforation
3. Electrical or thermal burns
4. Tip detachment, in the unlikely event a tip becomes detached it may be easily retrieved with grasping forceps.

## **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.

## **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.

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*\*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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