

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Electrical Hot Biopsy Forceps
Manufactured by SterilMed, Inc.
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Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

These devices are reprocessed electrical hot biopsy forceps from various original equipment manufacturers (OEM.) The reprocessed hot biopsy forceps are intended to be used endoscopically in conjunction with monopolar electrosurgical current to obtain gastrointestinal tissue biopsies for microscopic examination, and for the removal of sessile polyps.

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

Electric hot biopsy forceps consist of a proximal handle, containing an electrosurgical plug connected via a coil, spring or rod mechanism to the biopsy cup or alligator forceps at the distal tip. These devices are covered with a fluorinated ethylene polymer electrical insulation. The electrosurgical plug on the handle is used for connection to the appropriate electrosurgical unit.

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

Reprocessed hot biopsy forceps 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 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. These instruments are not intended to be used when gastrointestinal mucosal biopsy and polypectomy are contraindicated, including but not limited to, coagulopathy and insufficiently prepped bowel.
2. These instruments are not intended to be used on patients with bleeding disorders.
3. These instruments are not intended to be used endoscopy is contraindicated, e.g., acute abdominal peritonitis, toxic megacolon, or active colitis.

WARNINGS AND PRECAUTIONS

1. The operator of the device should have adequate training and a thorough understanding of the use and applications of electric hot biopsy forceps.
2. Inspect the packaging and device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Do not exceed 35 watts when using the following models: 60101, 60102, 60103, 60104, 60107, 60108, 60109, 60110, 60113, 60114, 60115, 60116, 60119, 60120, 60121, and 60122.
4. The operator and assistant should wear protective gloves to prevent accidental burns.
5. Hemorrhage from inadvertent damage of organs and vessels may result from the use of this device; therefore, the physician is advised to pay close attention to the general principles of proper hemostasis during the procedure, as well as to inspect the biopsy area prior to conclusion of the procedure.
6. Failure to isolate the tissue to be biopsied or the polyp to be removed by pulling it away from the mucosal wall may result in fulguration of normal mucosa and/or perforation.
7. There is a chance of breakage and subsequent retention of the jaw. The decision to retrieve the small jaw requires a careful comparison of the risks and benefits of retrieval versus the risks and benefits of allowing the small object to remain.
8. The forceps should be held with the index finger and middle finger comfortably resting on the collar ridge or in the distal opposing loops and the thumb in the proximal loop. When other methods of operation are used, such as pushing on the thumb loop with the palm of one's hand, the resulting force may be so excessive as to cause jaw damage.
9. The forceps should be advanced slowly. To help prevent injury or perforation, always view through the endoscope when advancing the forceps.
10. If difficulty is experienced when inserting the forceps through the angulated portion of the scope, it may be necessary to reduce the angle slightly to allow the smooth passage of the forceps. The forceps should not be forced through the scope channel.
11. The biopsy samples should be taken under direct visualization. This will help prevent inadvertent damage to internal organs and body structure.

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12. Do not try to withdraw a partially open forceps through the scope. Pull the forceps back to the channel opening and then withdraw the scope and forceps together.
13. Lower the scope elevator before withdrawing forceps.

POTENTIAL ADVERSE EVENTS

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

1. Acute and delayed hemorrhage
2. Localized or systemic infections
3. Bowel perforation
4. Thermal injury
5. Burns
6. Any other risks associated with the methods and medications utilized in surgical procedures may cause adverse events.

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.

Open product using appropriate sterile technique when needed for use.

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 and literature and rely on training and practical experience.

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 back for reuse.

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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. 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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