

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Cold 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 cold biopsy forceps from various original equipment manufacturers (OEM.) The reprocessed cold biopsy forceps are intended to be used during endoscopic procedures of the gastrointestinal tract to collect tissue samples for histological examination. These forceps are advanced to the site for sampling via the operating channel of an endoscope.

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

DEVICE DESCRIPTION

Cold biopsy forceps consists of a proximal handle which is connected, via a coil, spring or rod mechanism, to the biopsy cup or alligator forceps at the distal tip. -

Reprocessed 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 and ensure the number of times the device has been 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.

CONTRAINDICATIONS

1. Contraindicated to endoscopy including, but not limited to acute abdominal peritonitis, toxic megacolon, or active colitis.
2. Contraindicated to gastrointestinal mucosal biopsy and polypectomy, including

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- but not limited to, coagulopathy and insufficiently prepped bowel.
3. Contraindicated to patients with bleeding disorders.

WARNINGS AND PRECAUTIONS

1. The device is not a “Hot Biopsy Forceps” and is not designed to be used in conjunction with electrosurgery.
2. Use of these devices requires adequate training in endoscopic procedures and a thorough understanding associated with the use and applications of cold biopsy forceps.
3. 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 homeostasis during the procedure, as a well as to inspect the biopsy area prior to conclusion of the procedure.
4. Breakage and subsequent retention of the jaw may occur with this device or similar devices. The decision to retrieve the small jaw requires a careful comparison of the risks and benefits of retrieval verses the risks and benefits of allowing the small object to remain.
5. The operator and assistant should wear protective gloves to comply with infection control principles.
6. 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.
7. Advance forceps slowly. Always maintain a view through the endoscope when advancing the forceps to preclude injury or perforation.
8. Difficulty may be 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. Do not force the forceps through the scope channel.
9. The biopsy samples should be taken under direct visualization. This will help prevent inadvertent damage to internal organs and body structure.
10. **DO NOT** try to withdraw the partially open forceps through the scope when jaws fail to close properly. Pull the forceps back to the channel opening and then withdraw the scope and forceps together.
11. Always leave the elevator in the lowered position until the forceps is in position and then raise the jaws into view for elevator equipped scopes.
12. Lower the scope elevator before withdrawing the 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

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necessitate additional medical intervention, including surgery.

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

SUGGESTED DIRECTIONS FOR USE

1. Inspect the packaging and device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
2. Inspect the forceps for kinks, fraying wire, or any other damage that may have occurred during transit. Open and close the jaw several times using the handle to confirm smooth movement. Do not use forceps if damaged.
3. Ensure that the device is compatible in shape, length and size with the endoscope being used.
4. Insert the forceps through the working channel of the endoscope with short deliberate strokes maintaining the forceps in a firmly closed position. This method will avoid damage to the scope and forceps.
5. Open the jaws carefully while visualizing the operation through the scope or on the video monitor.
6. Move the forceps forward against the tissue to be sampled and close the jaws. Carefully pull the forceps back from the wall and slowly withdraw through the scope

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.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment. For specific details in the use of cold biopsy forceps and the techniques employed in any endoscopic procedures with the biopsy, the physician should be referred to the medical 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.

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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 functionality testing. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of the 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. 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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