

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Stone Retrieval Baskets
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 stone retrieval baskets from various original equipment manufacturers (OEM). Reprocessed Stone Retrieval Baskets are used to entrap and remove renal stones and calculi via a rigid or flexible endoscope during transurethral or fluoroscopic percutaneous urologic procedures.

Each OEM provides 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

Stone retrieval baskets are devices that are inserted through an ureterscope or cystoscope and consist of a handle, shaft, sleeve, and catheter with an expandable wire basket or grasping forceps that serves as the stone capturing mechanism. These devices are available in a variety of lengths, tip designs, and basket configurations.

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 stone retrieval devices 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.

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

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There are no known absolute contraindications for this device. However, the following warning is listed as a “relative contraindication” in the Original Manufacturer’s Instructions for Use:

1. Some stones may be too large to remove endoscopically with a stone retrieval basket. To avoid stone impaction, fluoroscopy or x-ray should be used to determine the size of the stone. Do not use the grasping forceps if stone is too large to be removed endoscopically or held in the basket or grasping forceps.

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of procedures associated with stone retrieval baskets.
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. Do not rotate open basket or grasping forceps in ureter.
5. Kinks in the sheath will hinder the mechanical operation of the basket.
6. It is recommended that the ureter be pre-dilated before endoscopy and stone retrieval to prevent stone impaction when retracting the stone.
7. Use of the device is restricted to physicians or those under their direct supervision trained in urologic endoscopic procedures.
8. Use fluoroscopy or x-ray to determine the size of the Stone and avoid stone impaction. Do not use basket or grasping forceps if stone is too large to be removed.
9. Do not use excessive force if resistance is encountered while attempting to withdraw the basket or forceps into the sheath or sheath through the endoscope.
10. Care should be exercised to prevent perforation or trauma of the linings and associated tissue of vessels or ducts.
11. This device must not come in contact with any electrified instrument.
12. This device should not be fired upon by a pulsed dye laser if used in laser surgery.
13. A laser fiber can be passed through the hole at the proximal end of the handle. The fiber can then be carefully advanced through the basket or grasping forceps inner sheath until the aiming beam can be seen on the entrapped stone. At this point the laser can be fired.
14. The laser should never be set beyond the OEM’s specified millijoules.
15. Do not fire the laser directly into the basket or grasping forceps wires.
16. Do not probe the stone with laser fiber. Do not exert excessive force against the stone with the laser fiber. Maintain constant irrigation throughout lithotripsy to reduce heat build up within the basket or grasping forceps.

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POTENTIAL ADVERSE EVENTS

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

1. Hemorrhage
2. Ureteral evulsion
3. Edema
4. Entrapment of calculi too large to be removed
5. Inability to disengage from irretrievable stone
6. Kidney perforation
7. Ureteral evulsion
8. Ureteral perforation
9. Basket or grasping forceps inversion

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 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 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.

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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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