

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed ENT Shavers
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

Reprocessed ENT Shavers are intended for use with a reusable handpiece and are designed for the removal soft tissue and bone in various ENT, head and neck, and otoneurological procedures.

Sinus Applications:

- Polypectomy
- Ethmoidectomy/Sphenoethmoidectomy
- Septoplasty
- Antrostomy
- Endoscopic DCR
- Frontal Sinus Trephination and Irrigation
- Frontal Sinus Drill Out
- Septal Spur Removal
- Trans-Sphenoidal Procedures

Head and Neck Procedures

- Rhinoplasty
- Lipodebridement in the Maxillary and Mandibular Region
- Soft Tissue Shaving
- Acoustic Neuroma Removal

Nasopharyngeal and Laryngeal Procedures

- Tonsillectomy
- Tracheal Procedures
- Adenoidectomy
- Laryngeal Lesion De-Bulking
- Laryngeal Polypectomy

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Otology Procedures

- Mastoidotomy
- Mastoidectomy

Original equipment manufacturers (OEMs) provide an Instruction for Use Document for each original device. The health institution that wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTION

ENT shavers accessories are variable-speed instruments used for cutting of soft tissue, cartilage and bone. The blades have various diameters, lengths, and cutting window configurations. These devices are designed to run in conjunction with a control console, motor drive unit, foot or hand switch, and a suction /irrigation system.

Reprocessed ENT shavers have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from a health care facility, 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 an additional reprocessing prior to use.

CONTRAINDICATIONS

There are no known contraindications for this device.

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of ENT shavers.
2. Inspect the packaging, and the shaver prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Equipment may vary with each manufacturer. It is necessary to verify appropriate compatibility of all equipment and accessories prior to use.
4. Do not let fluids enter console; this can result in sparks and possible combustion and loss of power.
5. Do not contact the shavers with metal objects as this may cause the device to break or shed metal.
6. Excessive “side-loading” on the blade during use does not improve cutting performance, and in extreme cases, may result in wear and degradation of the inner blade.
7. Do not stall instruments; this may damage the shaver system.

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8. Excessive pressure may cause the shavers to bend or break which may in turn cause harm to the patient and / or operating room staff.
9. Do not operate the shaver RPMs in excess of those recommended.
10. Do not operate without the flow of irrigation. Periodic irrigation of the tip of the shaver is recommended to provide adequate cooling of the blade and to prevent accumulation of excised materials in the surgical site.
11. Do not change the accessory while the hand piece is running.
12. Keep the cutting tip of the shaver away from loose clothing and fingers.
13. Confirm appropriate anatomical landmarks and intended surgical site before operating the shaver.
14. Use of this device is dependent on patient needs and intended applications. Sharp cutting instruments such as these are capable of removing significant tissue and bone and inducing bleeding.
15. The cutting end should be carefully applied only to appropriate anatomical landmarks and intended surgical sites. Employ adequate visualization. In the event of lack of visualization, discontinue application of the device.
16. Control bleeding at the surgical site that could compromise patient safety during the procedure
17. Ensure the shaver is fully engaged with microresector and verify the tip is fully engaged with the outer cannula.

POTENTIAL ADVERSE EVENTS

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

1. Lacerations of cartilage
2. Tissue tears with excessive bleeding

GENERAL INSTRUCTIONS AND INFORMATION

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 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 that their materials remain substantially equivalent 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 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 at 1-888-541-0078.

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