

# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Powered Arthroscopic Accessories**  
**Manufactured by SterilMed, Inc.**  
**11400 73<sup>rd</sup> Avenue North**  
**Maple Grove, MN 55369**  
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**www.SterilMed.com**

**Caution: Federal law restricts this device to sale by or on the order of a physician.**

## INDICATIONS FOR USE

Reprocessed powered arthroscopic accessories are intended for use in operative large and small joint arthroscopic procedures and Functional Endoscopic Sinus Surgery (FESS). These accessories are indicated for resection of soft, osseous and cartilaginous tissue, and bone in large and small articular cavities and FESS.

Powered arthroscopic accessories are variable-speed instruments consisting of shavers, burrs, drill bits, and saws, used for cutting of soft tissue, cartilage and bone. The fields of application include orthopedics, otolaryngology, spinal and plastic/reconstructive surgical procedures.

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

Powered arthroscopic accessories are variable-speed instruments consisting of shavers, burrs, drill bits, and saws, used for cutting of soft tissue, cartilage and bone. These accessories include various straight, curved, rotating, mini and irrigating blade and burr designs. Blades have various diameters, lengths, and cutting window configurations. Burrs are of various lengths, diameters, and shapes. These accessories are designed to run in conjunction with a control console, motor drive unit, foot or hand switch, and a suction /irrigation system under endoscopic/video visualization.

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..

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Reprocessed powered arthroscopic accessories 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 an additional reprocessing prior to use.**

## **CONTRAINDICATIONS**

1. Arthroscopic blades should not be used on patients without adequate joint space or distension for arthroscopic inspection.
2. Abrasion arthroplasty may not be effective in treating heavy patients or those with ankylosis, instability, or expectations beyond the relief of pain.
3. Varus or valgus deformity is not in itself a contraindication in patients with good range of motion and without gross instability or extreme misalignment (15° varus, 30° valgus).
4. Intracortical abrasion arthroplasty may be contraindicated in patients not qualifying for high tibial osteotomy or total knee replacement.
5. Synovectomy is contraindicated when the disease has progressed beyond the phase of synovial proliferation, and advance rheumatoid arthritis when erosion of the articular cartilage is present.

## **WARNINGS AND PRECAUTIONS**

1. The user of the device should have adequate training and a thorough understanding of the use and applications of powered arthroscopic accessories.
2. Inspect the packaging, and arthroscopic accessories 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 cutters, shavers, or burrs 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.
8. Excessive pressure may cause cutters, shavers, or burrs to bend or break which may in turn cause harm to the patient and / or operating room staff.
9. Do not operate the cutter, shaver, or burr at RPMs in excess of those recommended.

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10. Do not operate without the flow of irrigation. Periodic irrigation of the tip of the burr or cutter 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.

## **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 fluid

## **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 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.

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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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