

Reprocessed by



## Instructions for Use Reprocessed Arthroscopic Shavers

### Reprocessed Device for Single Use


**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- **STERILE**

#### Explanation of Icons

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 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

**REF** Ascent Product Code

 Do Not Reuse

 See Instructions For Use

# Reprocessed Arthroscopic Shavers

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## Arthroscopic Shaver Description

Arthroscopic shavers can be used to abrade, cut and excise tissue and bone; remove loose fragments; and, shave away debris in arthroscopic surgeries, as well as surgeries of the jaw and sinuses.

The arthroscopic shaver components reprocessed by Ascent Healthcare Solutions include a bur or blade at the end of a long rod that rotates within a long hollow stainless steel housing. The housing has a window cut out on one side of the distal end, allowing the bur to cut one structure, while the adjacent one is still protected by the housing on the opposite side of the bur or blade. This system attaches to a motorized handpiece that drives the internal bur or blade inside the outer housing and provides suction to pull the cut tissue and/or bone away from the surgical site.

## Indications for Use

Reprocessed arthroscopic shavers are indicated for use in orthopedic surgical procedures of the joints, jaw or sinuses where the cutting and removal of soft and hard tissue or bone is needed in patients requiring orthopedic surgery.

## Contraindications for Use

Reprocessed arthroscopic shavers are contraindicated for:

- Any surgical or arthroscopic procedure where an appropriate solution is not used as an irrigant.
- When there is not adequate joint space or distention for a complete arthroscopic inspection.
- On obese patients.
- On patients exhibiting ankylosis or instability.
- On patients with a varus or valgus deformity that is severe enough to cause instability, severely restrict the range of motion, or cause extreme malalignment (15° varus, 30° valgus).
- Intracortical abrasion arthroplasty on individuals who do not qualify for high tibial osteotomy or total knee replacement.
- Synovectomy in patients who have progressed beyond the phase of synovial proliferation or in patients when the articular cartilage is eroded because of advanced rheumatoid arthritis.
- When the size or model of the cutter is inappropriate for the surgery.

## Warnings

- These instruments are only intended for use by individuals with adequate training and familiarity with the arthroscopic or endoscopic surgical procedures employed.
- The use of these instruments requires a thorough understanding of the techniques and principles of electro-surgical procedures. Inappropriate use may result in shock and burn hazards to both patient and physician or damage to medical equipment.
- Cutters are most effective when driven at speeds below 3000 RPM. Operation of cutters at speeds above 6000RPM can generate excessive particulates.
- Do not allow the arthroscopic shaver to come into contact with staples, clips or any metal object to avoid damage to the blade and possible patient injury.
- The tip of the bur or cutter must be irrigated periodically (general recommendation: once a minute) to cool the blade and prevent excised tissues from accumulating.
- Do not run the instrument without appropriate suction for the duration of the process.
- Employing instruments when the working end is not fully visible can result in unintended tissue damage. Great care should be taken to avoid injury to healthy tissue and cartilage during arthroscopic procedures.
- Blood vessels extend into the cortical layer of subchondral bone. Therefore, bones should not be abraded deeper than 1 to 2 mm into the cortex and cancellous bone should not be abraded.

## Precautions

- Do not run burs without irrigation or damage to the instrument will result.
- Do not apply excessive pressure or “side-load” the blade during use. Side-loading does not improve the performance of the instrument, can dull the blade, and/or produce metal particulates.
- If using instruments from different manufacturers, verify compatibility of instruments before use to avoid complications during surgery.
- Become familiar with specific arthroscopic shaver and blade models prior to using in a surgical procedure to avoid damage to the patient, operator or instrument.
- Careful handling of the instrument is necessary to avoid damage or breakage as a result of excessive force.

## Adverse Reactions

None.

## Reprocessed Arthroscopic Shavers

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### Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Before beginning the procedure, verify compatibility of all instruments and accessories.
3. Plug in and set up the generator according to the instructions in the manufacturer's manual.
4. Select an arthroscopic shaver with size, blade and function most appropriate for the procedure.
5. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the instrument if the sterility has been compromised. If the package is damaged or if it was opened and the instrument was not used, return the instrument and package to Ascent Healthcare Solutions.
6. Do not attempt to resterilize.
7. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
8. Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted. Return the instrument and packaging to Ascent Healthcare Solutions if it is not in acceptable condition for surgery.
9. Insert bur or blade into the motor drive or motorized handpiece.
10. Prepare the patient preoperatively according to standard procedures.
11. Follow a suitable surgery protocol.

### Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then 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.