Reprocessed by

stryker®

Sustainability Solutions

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

STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
REF	Product Code
2	Do Not Reuse
	See Instructions For Use

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Reprocessed Arthroscopic Shavers

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 Stryker Sustainability 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.
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 Stryker Sustainability 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 Stryker Sustainability 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

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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.