

Reprocessed by



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## Sustainability Solutions

### Instructions for Use Reprocessed Surgical Accessories: Drill Bits, Blades, Burs, Chisels, Rasps, Taps and Reamers

#### 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

 Product Code

 Do Not Reuse

 See Instructions For Use

## Reprocessed Surgical Accessories

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### **Surgical Accessories Description: Drill Bits, Blades, Burs, Chisels, Rasps, Taps and Reamers**

Surgical drill bits, blades, burs, chisels, rasps, taps and reamers are specially designed surgical accessories to help the surgeon cut and drill bone and bony structures

### **Indications for Use**

Reprocessed surgical accessories are indicated for use in patients requiring surgery involving bone and bony structures.

### **Contraindications for Use**

None.

### **Warnings**

- Surgical accessories like drill bits, blades, burs, chisels, rasps, taps and reamers are intended to be used only by trained medical professionals who are familiar with their use and application.
- Verify that the surgical accessories have been properly inserted and tightened before instrument activation to avoid distal migration and possible injury.
- Delicate structures close to operation site must be protected.
- Firm control of the instrument must be maintained to avoid injury to patient or operating room personnel.

### **Precautions**

#### General:

- Observe surgical accessories for damage that could impair proper operation and replace any damaged accessory immediately. Do not employ bent or damaged surgical accessories in surgery.
- To protect patient tissue, do not engage surgical accessories without using the required attachments and guards.
- Contact with metal fixtures, retractors or other parts may cause enough damage to necessitate intraoperative replacement.
- Operating room personnel should wear proper eye protection during a surgical procedure requiring the use of drill bits, blades, burs, chisels, rasps, taps and reamers.

#### Blades:

- When using slotted fixture or alignment guides, first insert the blade into the slot.
- Irrigate blades during use to prevent them from becoming hot from friction. Irrigation is necessary at all times when using blades with alignment guides or slotted cutting fixtures.
- Do not apply excessive lateral force.

#### Drills Bits and Burs:

- Drill bit breakage most often occurs when working around metallic implants (prosthetic components, internal fixations, etc.). To minimize these incidents, ensure that the tip of the drill bit does not contact an implant. In case of breakage and presence of drill bit fragments, follow the appropriate orthopedic surgery protocol.
- Avoid excessive speeds.
- Do not apply excessive lateral force.
- Carbide burs may break when performing twisting or bending cuts.
- Use a proper bur guard with medium or longer burs.

### **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 overall compatibility of all instruments and accessories to be used during the surgical procedure.
3. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the device if the sterility has been compromised. If the package is damaged or if it was opened and the device was not used, return the device and package to Stryker Sustainability Solutions.
4. Do not attempt to resterilize.
5. Remove the device from the package and place it in a sterile work area using aseptic technique.
6. Inspect the device for overall condition and physical integrity. Do not use if any damage is noted. Return the device and packaging to Stryker Sustainability Solutions if it is not in acceptable condition for surgery.
7. Insert the surgical accessory into the instrument.
8. Follow a suitable orthopedic surgery protocol.
9. Protect patient tissue during usage.

## Reprocessed Surgical Accessories

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10. Consider irrigation during saw blade usage.

### 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.

## Reprocessed Surgical Accessories

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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.

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