

Reprocessed by



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

 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

REF Ascent Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed Surgical Accessories

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 Ascent Healthcare 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 Ascent Healthcare 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.

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9. Protect patient tissue during usage.
10. Consider irrigation during saw blade usage.

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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.