English EN

Drill Bit Instructions for Use and Reprocessing

INTENDED USE	• General surgical instrument for the rotary cutting of a hole to size and depth in bone or tissue.
INTENDED USER PROFILE	• Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques. • Consult medical literature relative to techniques, complications and hazards prior to performance of any surgical procedure. Before using the product, all instructions regarding its safety features must be read carefully.
DEVICE DESCRIPTION	• Surgical instruments composed of medical grade stainless steel. • Instruments are supplied NON-STERILE and must be inspected, cleaned and sterilized before each use. • Devices are critical and require terminal sterilization per FDA guidelines and the Spaulding Classification scheme. • Devices are not implantable.
WARNINGS 	• Avalign recommends thorough manual and automated cleaning of medical devices prior to sterilization. Automated methods alone may not adequately clean devices. • Devices should be reprocessed as soon as possible following use. Instruments must be cleaned separately from cases and trays. • All cleaning agent solutions should be replaced frequently before becoming heavily soiled. • Prior to cleaning, sterilization and use, all instruments should be inspected to ensure proper function and condition. Do not use instruments if they do not perform satisfactorily. • Risk of damage – The surgical instrument is a precision device. Careful handling is important for the accurate functioning of the product. Improper external handling can cause product malfunction. • Use caution when handling sharp instruments to avoid injury. • If a device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination.
CAUTION  **ONLY**	Federal U.S. Law restricts this device to sale, distribution, and use, by, or on order of a physician.
LIMITATIONS ON REPROCESSING	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.
DISCLAIMER	It is the responsibility of the reprocessor to ensure reprocessing is performed using equipment, materials and personnel in the reprocessing facility and achieves the desired result. This requires validation and routine monitoring of the process. Any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.
INSPECTION AND FUNCTIONAL TESTING	• Visually inspect devices for damage or wear. Instruments with broken, cracked, chipped or worn parts or surfaces should not be used, but should be replaced immediately. • Check that drill cutting edges are smooth and continuous, free from large cracks or chips that may impair cutting performance. • Verify mating surfaces function as intended and device interfaces with power without complications.

Reprocessing Instructions

<table>
<tr><td>TOOLS AND ACCESSORIES</td><td></td><td>
<table>
<tr><td>Water</td><td>Cold Tap Water (< 20°C / 68°F)
Hot Tap Water (> 40°C / 104°F)
Deionized (DI) or Reverse Osmosis (RO) Water (ambient)</td></tr>
<tr><td>Cleaning Agents</td><td>Neutral Enzymatic Detergent pH 6.0-8.0 i.e. MetriZyme, EndoZime, Enzol</td></tr>
<tr><td>Accessories</td><td>Assorted Sizes of Brushes and/or Pipe Cleaners with Nylon Bristles
Absorbent, Low Lint Disposable Cloths or equivalent
Soaking Pans</td></tr>
<tr><td>Equipment</td><td>Medical Compressed Air
Ultrasonic Cleaner (Sonicator)
Automated Washer</td></tr>
</table>
</td><td></td></tr>
<tr><td>POINT-OF-USE AND CONTAINMENT</td><td colspan="2">1) Follow health care facility point of use practices. Keep devices moist after use to prevent soil from drying and remove excess soil and debris from all surfaces and hard-to-clean design features.
2) Follow universal precautions and contain devices in closed or covered containers for transport to central supply.</td></tr>
<tr><td>MANUAL CLEANING</td><td colspan="2">3) Prepare neutral pH enzymatic detergent as per vendor's directions. Enzol® enzymatic detergent is recommended at a preparation of 1 oz./gallon using lukewarm water.
4) Fully immerse device in the prepared detergent per labeling instructions. Allow device to soak for a minimum of 1 minute.
5) Scrub the device, using a soft bristled brush, paying particular attention to hard to reach areas until all visible soil has been removed.
6) Prepare neutral pH enzymatic detergent in the sonicator (as per vendor directions) and sonicate the devices for a minimum of 10 minutes. Note: Enzyme solution shall be changed when it becomes grossly contaminated (bloody and/or turbid).
7) Rinse all surfaces in running reverse osmosis or deionized (RO/DI) water for a minimum of 3 minutes to remove any residual detergent or debris.
8) Dry the device with a clean, soft cloth. Filtered, compressed air may be used to aid drying.
9) Visually examine each device for cleanliness. If visible soil remains, repeat cleaning procedure.</td></tr>
<tr><td>AUTOMATED CLEANING</td><td colspan="2">Note: All devices must be manually pre-cleaned prior to any automated cleaning process, follow steps 1-5. Steps 6-9 are optional but advised.

10) Clean devices within a washer/disinfector utilizing the equipment and detergent manufacturers' instructions per the below minimum parameters.
<table>
<tr><th>Phase</th><th>Time (minutes)</th><th>Temperature</th><th>Detergent Type & Concentration</th></tr>
<tr><td>Pre-wash 1</td><td>02:00</td><td>Cold Tap Water</td><td>N/A</td></tr>
<tr><td>Enzyme Wash</td><td>02:00</td><td>Hot Tap Water</td><td>Enzyme Detergent</td></tr>
<tr><td>Rinse 1</td><td>01:00</td><td>Hot Tap Water</td><td>N/A</td></tr>
<tr><td>Purified Water Rinse</td><td>00:10</td><td>146-150°F / 63-66°C</td><td>N/A</td></tr>
<tr><td>Drying</td><td>15:00</td><td>194°F / 90°C</td><td>N/A</td></tr>
</table>
11) Dry excess moisture using an absorbent cloth. Filtered, compressed air may be used to aid drying.
12) Visually examine each device for cleanliness. If visible soil remains, repeat cleaning procedure.</td></tr>
<tr><td>DISINFECTION</td><td colspan="2">• Devices must be terminally sterilized (See § Sterilization).
• Avalign devices are compatible with washer/disinfector time-temperature profiles for thermal disinfection per ISO 15883.</td></tr>
<tr><td>PACKAGING</td><td colspan="2">• Only FDA cleared sterilization packaging materials should be used by the end user when packaging the devices.
• The end user should consult ANSI/AAMI ST79 for additional information on steam sterilization.
• Sterilization Wrap
o Individual instruments may be wrapped in a standard, medical grade sterilization wrap using the AAMI double wrap method or equivalent.</td></tr>
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<table>
<tr><td>STERILIZATION</td><td>Sterilize with steam. The following minimum cycle has been validated for sterilization of Avalign devices:

Double Wrapped Instruments:
<table><tr><th>Cycle Type</th><th>Temperature</th><th>Exposure Time</th><th>Pulses</th><th>Drying Time</th></tr><tr><td>Prevacuum</td><td>132°C (270°F)</td><td>4 minutes</td><td>4</td><td>20 minutes</td></tr></table>
The operating instructions and guidelines for maximum load configuration of the sterilizer manufacturer should be followed explicitly. The sterilizer must be properly installed, maintained, and calibrated.
Time and temperature parameters required for sterilization vary according to type of sterilizer, cycle design, and packaging material. It is critical that process parameters be validated for each facility’s individual type of sterilization equipment and product load configuration.
A facility may choose to use different steam sterilization cycles other than the cycle suggested if the facility has properly validated the cycle to ensure adequate steam penetration and contact with the devices for sterilization.</td></tr>
<tr><td>STORAGE</td><td>After sterilization, devices should remain in sterilization wrap and be stored in a clean, dry cabinet or storage case.
Care should be taken when handling wrapped devices to avoid damaging the sterile barrier.</td></tr>
<tr><td>MAINTENANCE</td><td>Discard damaged, worn or non-functional devices.
Drills cannot be resharpened.</td></tr>
<tr><td>WARRANTY</td><td>All products are guaranteed to be free from defects in material and workmanship at the time of shipping.
Avalign instruments are reusable and meet AAMI standards for sterilization. All our products are designed and manufactured to meet the highest quality standards. We cannot accept liability for failure of products which have been modified in any way from their original design.</td></tr>
<tr><td>CONTACT</td><td> 
Manufactured by:
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8727 Clinton Park Drive
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Distributed by:
Millennium Surgical Corp
822 Montgomery Ave
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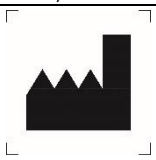
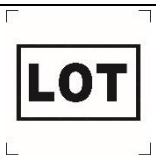
800-600-0428</td></tr>
</table>

Symbols Glossary

Symbol	Title
	Manufacturer
	Lot Number / Batch Code
	Catalogue Number
	Consult Instructions for Use
	Caution
	Federal Law (USA) restricts this device to sale by or on the order of a physician