AVALIGN
German Specialty Instruments Division

Indications for Use

AVALIGN rongeurs are devices intended to access, cut and bite soft tissue and bone during surgery involving the spinal column.

Caution: **Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician.**

Warning: **If this 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!**

Instructions for Use

Warning:
Remove all protective caps and sheaths carefully. Prior to surgical use, rongeur must be cleaned, lubricated, decontaminated, sterilized and inspected. Instruments are reusable and supplied as non-sterile.

Attention:
Risk of damage - The rongeur is a precision device. Careful handling is important for accurate functioning of the product. Improper external handling (e.g. bending, banging, dropping, etc.) can cause product malfunction.

Control function before use:
Before using, the general functioning and preparation of the rongeur and accessories must be controlled. Please confirm prior to use.

Operation:
Neurosurgical procedures should be performed only by persons having adequate training and familiarity with neurosurgical techniques. In addition, consult medical literature relative to techniques, complications and hazards prior to performing any neurosurgical procedure. Before using the product, all instructions regarding its safety features as well as surgical techniques must be read carefully. The sterile shafted rongeur is inserted into the body. The rongeur must be operated only by trained personnel. Please observe general operating room technique.

Cleaning:
Clean the instrument externally with a soft sponge and a soft brush. If appropriate, take the instrument apart prior to decontamination.

Maintenance:
Attention: Apply lubricant only on the connecting elements (locking mechanism) and moving parts.

Repair: To ensure that all repairs are completed according to the manufacturer's specifications, the precision rongeur should be repaired by AVALIGN or by an authorized service agency only.

Warranty: All AVALIGN products are guaranteed to be free from defects in material and workmanship at the time of shipping. All of 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.

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Decontamination / Cleaning / Sterilization

Decontamination:
Take the device with the adapter(s) and accessories to the decontamination area. Clean, decontaminate, and sterilize the device, adapter(s), and accessories following the instructions in the IFUs.

Warning - Risk of infection!: Before use, the entire device, including its accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create serious risk of infection in patients and/or users.

If RING Klean is used please follow the instructions. Two sizes are available in single use, non-sterile.
Place rings over both shaft ends of the instrument and roll it up to the horn. Rings are cut off and discarded after cleaning and before sterilization.

Follow the processing instructions below for all instruments, including ClearFlush® Kerrison Rongeurs.

Processing Instructions
When reprocessing Avalign Rongeurs, we recommend that you use the following practices and procedures in conjunction with your institution's published guidelines and policies. During cleaning, wear appropriate eye and face protection, as well as gloves and other protective clothing, to protect against exposure to blood borne pathogens, as recommended by OSHA in its Bloodborne Pathogens Standard.

WARNING
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Cleaning and Maintenance: Every surgical instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Sterilize all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument.
Special attention must be paid to slots, stops, ends, hollow tubes and other highly inaccessible areas. Do not use damaged instruments. Cleaning and rinsing must take place immediately after each use for best results. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilization.

Tools and Accessories:

Water	Cold Tap Water (<20°C/ 68°F) Warm Water (38°-49°C/ 100°-120°F) Hot Tap Water (> 40°C/ 104°F) Deionized (DI) or Reverse Osmosis (RO) Water (ambient)
Cleaning Agents	Neutral Enzymatic Detergent pH 6.0-8.0 i.e. MetriZyme, EndoZime, Enzol
Accessories	Assorted Sizes of Brushes and/or Pipe Cleaners with Nylon Bristles Sterile Syringes or equivalent Absorbent, Low Line Disposable Cloths or equivalent Soaking Pans
Equipment	Medical Compressed Air Ultrasonic Cleaner (Sonicator) Automated Washer

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Point of Use and Containment:

1. Follow health care facility point of use practices. Keep devices moist after use to prevent soil from drying and removed excess soil and debris from all surfaces, crevices, sliding mechanisms, hinged joints, and all other hard-to-clean design features
2. Follow universal precautions and contain devices in closed or covered containers for transport to central supply.
3. All devices must be cleaned in the completely open and disassembled (i.e. taken apart) configuration.

Manual Cleaning:

4. Prepare neutral pH enzymatic detergent per vendor's directions. Enzol® enzymatic detergent is recommended at a preparation of 1 oz./gallon using lukewarm water.
5. Fully immerse device in the prepared detergent per labeling instructions. Allow device to soak for a minimum of 5 minutes.
6. Actuate all movable parts during the soak time to allow complete penetration of detergent to hard to reach areas.
7. Scrub the device, using a soft bristled brush (may also include a syringe and pipe cleaner), paying particular attention to movable parts, crevices, and other hard to reach areas until all visible soil has been removed.

a. For lumen devices, flush internal lumens with detergent using an appropriately sized syringe at least 7 times with a minimum of 15mL of detergent. If available, use flush ports for flushing.

8. Rinse the device with warm water.
9. Place the device into a bath of warm water and allow device to soak for a minimum of 3 minutes. Actuate all moveable parts during the entire soak time.
10. Prepare neutral pH enzymatic detergent in the sonicator (as per vendor directions) and sonicate the instruments for a minimum of 10 minutes. Note: Enzyme solution shall be changed when it becomes grossly contaminated (bloody and/or turbid).
11. Rinse all surfaces and crevices in running reverse osmosis or deionized (RO/DI) water for a minimum of 3 minutes to remove any residual detergent or debris.

a. For lumen devices, flush internal lumens a minimum of 3 times with RO/DI water (minimum of 15 mL) using an appropriately sized syringe. If available, use flush ports for flushing.

12. Dry the instrument with a clean, soft cloth. Filtered, compressed air may be used to aid drying.
13. Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure.

Automated Cleaning:

Note: All devices must be manually pre-cleaned prior to any automated cleaning process, follow steps 1-9. Steps 10-13 are optional but advised.

14. Clean devices within a washer/disinfector utilizing the equipment and detergent manufacturers' instructions per the below minimum parameters.

Phase	Time (minutes)	Temperature	Detergent Type & Concentration
Pre-wash 1	02:00	Cold Tap Water	N/A
Enzyme Wash	02:00	Hot Tap Water	Enzyme Detergent
Rinse 1	01:00	Hot Tap Water	N/A
Purified Water Rinse	00:10	146-150°F/ 63-66°C	N/A
Drying	15:00	194°F/ 90°C	N/A

15. Dry excess moisture using an absorbent cloth. Dry any internal areas with filtered, compressed air.
16. Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure.

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STERILIZATION RECOMMENDATIONS

Sterilization:

Steam sterilize using the parameters listed in the table below. Other time and temperature cycles may also be used; however, user must validate any deviation from the recommended time and temperature. (Note: Contact the manufacture of your steam autoclave to confirm appropriate temperatures and sterilization times.)
Caution: Care should be taken to ensure that no part of the sterilization process exceeds 140°C as handles, insulation or other nonmetallic parts may be damaged.

Steam Sterilization Type	Temperature (°C)/(°F)	Cycle Time (min)	Dry Time (min)
Pre-vacuum	132/270	4	30
Gravity	132/270	15	45

Hospital approved disposable paper wrap or cotton muslin wrap may be used for multiple instruments. Hospital approved paper or plastic sterilization pouches may be used to sterilize individual instruments. Make sure you use a wide enough pouch (5" or wider) so the instrument can be sterilized in the open and unlocked position. Instruments may also be sterilized in a hospital approved container or tray. Place your heavy instruments at the bottom of the set (when two layers are required). Do not overload the sterilizer chamber. Pockets may form that do not permit steam penetration. As recommended by the **Association for the Advancement of Medical Instrumentation (A.A.M.I.) Standards and Recommended Practices,** the sterilizer manufacturer's written instructions for sterilization cycle parameters should be followed at all times.

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NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING IS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY TO ACHIEVE THE DESIRED RESULT. THIS REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKEWISE, ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.