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 sheats 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.

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.

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

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.

For Clear Flush Kerrison Rongeurs please follow special instructions provided.

Sterilization: Autoclave sterilization: Use steam autoclave sterilization only. Standard autoclave cycle. Steam sterilize at 270ºF for fifteen (15) minutes. Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. (Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.)
Caution: Autoclave temperatures should not exceed 280ºF, handles, insulation or other nonmetallic parts may be damaged.

Make certain that the instrument container is sealed in appropriate packaging for sterilization. Sterilize in compliance with the local guidelines for hospital hygiene.

AVALIGN instruments are reusable and meet AAMI standards for sterilization.

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.

AVALIGN German Specialty Instruments
626 Cooper Court
Schaumburg, IL 60173; USA
Tel: +1 877 289 1096
product.questions@avalign.com

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.

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Clear Flush Processing Instructions

When reprocessing Clear Flush® Flushable 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 RECOMMENDATIONS

1. **Immediately after use** For best results, and to prolong the life of the instrument, reprocess immediately after use. Place the soiled instrument in an instrument tray/container that contains sterile distilled water or an enzymatic cleaning solution to moisten the soil and prevent blood, mucus, and other debris from drying on the instrument. Do NOT use a saline solution as it might damage or corrode the instrument. Attach a 15ga blunt needle to a 50cc syringe and then fill the syringe with sterile distilled water or an enzymatic cleaning solution. Insert the blunt needle into the open flush port on the top of the instrument shaft and apply downward pressure on the needle to ensure a tight seal. Flush the instrument's internal flush channel with the jaws open to remove gross soil and debris from inside the shaft. Place the instrument back into the solution and cover the tray/container with a towel moistened with the solution.
2. **Enzymatic detergent soak**. Prior to manual cleaning, soak the instrument in an approved, neutral pH (7 or lower), enzymatic detergent solution. Use only low-foaming, non-ionizing cleaning agents and detergents. Always follow the manufacturer's instructions for use, warnings, concentrations and recommended cycles. Be sure that the solution is at the correct temperature as per the detergent manufacturer's recommendations. Completely immerse the instrument, with the jaws open, into the solution for a minimum of 5 minutes (or longer if called for on the detergent manufacturer's label).
3. **Manual cleaning.** Attach a 15ga blunt needle to a 50cc syringe and then fill the syringe with the enzymatic detergent solution. Insert the blunt needle into the open flush port on the top of the instrument shaft and apply downward pressure on the needle to ensure a tight seal. Flush the instrument's internal flush channel with the jaws open to remove gross soil and debris from inside the shaft, Clean each of the instrument's components (jaws, hinges, handles and shaft) with a clean, appropriately sized soft-bristle brush to remove all organic debris. Pay particular attention to the hinges, crevices and other hard to clean areas, Do NOT remove any screws and do NOT attempt to disassemble the instrument.
4. **Rinse.** Prior to sonication in an ultrasonic cleaning unit, rinse the instrument's components thoroughly with lukewarm water for a minimum of 1 minute to remove dislodged debris and the detergent solution Attach a 15ga blunt needle to a 50cc syringe and then fill the syringe with lukewarm tap water. Insert the blunt needle into the open flush port on the top of the instrument shaft and apply downward pressure on the needle to ensure a tight seal. Flush the instruments internal flush channel with the jaws open to remove dislodged gross soil and debris from inside the shaft. Wipe the instrument with a clean, soft cloth.
5. **Ultrasonic cleaning**. The cavitation action of ultrasonic cleaners can remove particles of debris from areas of the instrument inaccessible to a brush and is recommended as part of the reprocessing procedure. With the jaws in the open position, place the instrument in a mesh bottom instrument basket. Place the basket in the ultrasonic cleaner. Follow the recommendations of the ultrasonic cleaner manufacturer as to cycle times, cleaning solutions, suspension of the basket (e.g. the basket should not sit on the bottom of the ultrasonic cleaner), conditioning of the water, etc. Ensure that all instruments are fully submerged in the ultrasonic cleaner. Do NOT place dissimilar metals (stainless, copper, chrome-plated, etc.) in the same cleaning cycle.

6. **Rinse.** After removing from the ultrasonic cleaner, rinse all of the instrument's components thoroughly with lukewarm, neutral pH (7 or lower) water, which is controlled for bacterial endotoxins, to remove any remaining debris or ultrasonic, detergent residue that could interfere with the sterilization process. Attach a 15ga blunt needle to a 50cc syringe and then fill the syringe with lukewarm tap water. Insert the blunt needle into the open flush port on the top of the instrument shaft and apply downward pressure on the needle to ensure a tight seal. Flush the instruments internal flush channel with the jaws open to remove dislodged gross soil and remaining debris or ultrasonic detergent residue from inside the shaft. Wipe the instrument with a clean, soft cloth.
7. **Dry.** Instruments must be thoroughly dried with a clean, soft cloth. The use of pressurized air is recommended to aid in drying; especially in the flush port of the instrument. Residual moisture may contain waterborne pathogens and must be removed prior to sterilization. Additionally, any remaining moisture, especially in the internal areas may result in corrosion that can cause the instrument to 'bind-up' and shorten the life of the instrument.
8. **Visual Inspection.** Visually inspect the instrument for cleanliness, and clean off any remaining debris. Visually inspect the instrument for damage. Open and close the jaws to ensure proper operation of the instrument.
9. **Lubrication.** Use a hospital approved instrument lubricant (instrument milk) on all of the instrument's moving parts to ensure that they move freely and will not 'bind-up' during use. Attach a 15ga blunt needle to a 10cc. syringe and then fill the syringe with instrument lubricant. Insert the blunt needle into the open flush port on the top of the instrument shaft and apply downward pressure on the needle to ensure a tight seal. Flush the instrument's internal flush channel with the instrument lubricant with the jaws open. Ultrasonic cleaners remove all of the lubrication from the instrument; therefore, proper lubrication during every reprocessing cycle before sterilization will extend the useful life of the instrument. If the instrument is to be stored or if it is to be sterilized by ethylene oxide (EtO) gas, be sure it is thoroughly dried after lubrication.

STERILIZATION RECOMMENDATIONS

After following the above cleaning recommendations, Clear Flush® Flushable Rongeurs are ready for sterilization. **Independent laboratory testing, conducted under U.S. FDA REGULATIONS (21 CFR PART 58), has validated steam sterilization as an effective sterilization process for Clear Flush ® Flushable Rongeurs.** The instruments were sterilized using one pre-vacuum steam sterilization method and one gravity steam sterilization method. The instruments were validated as sterile after completing a 4 minute, 132 degree Celsius pre-vacuum sterilization cycle. The instruments were also validated as sterile after completing a 10 minute, 132 degree Celsius gravity sterilization cycle. Care should be taken to ensure that no part of the sterilization process exceeds 140 degrees Celsius.

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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