



Indications for Use

AVALIGN retractors are devices intended to provide minimally invasive access to the spine by ensuring the placement, positioning of the retractor down to the lamina, with its attachment to a flexible arm to provide a self locking method of access to the spinal site through which tubes, endoscopes and surgical instruments can be manipulated.

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

Instructions for Use

Warning:

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

Attention:

Risk of damage - The retractor is a precision device. Careful handling is important for the 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 retractor and accessories must be controlled. Please confirm prior to use.

Final preparation for use:

Place the retractor in the compatible position and secure the locking mechanism respectively. Confirm once again to ensure that the device is secure and ready for use according to indication.

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 performance of any neurosurgical procedure. Before using the product, all instructions regarding its safety features as well as surgical techniques must be read carefully. The sterile retractor with the shaft is inserted into the body. The retractor 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 adapter(s) and accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users.

Cleaning: Clean the instrument externally with a soft sponge and a soft brush. Unscrew the retractor adapter(s) before decontamination. Screw the adapter(s) on, only immediately before the next usage of the retractor. Be sure that the threading is completely dry.

Sterilization: Autoclave sterilization: Use steam autoclave sterilization only. Standard autoclave cycle. Steam sterilize at 270°F 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 280°F or 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. Please clean the retractor individually and separately from other instruments. Do not clean in an ultrasonic bath to avoid risk of damage.

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 retractor 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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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.