AVALIGN
German Specialty Instruments Division

INSTRUCTIONS for USE and REPROCESSING

Indication:
All surgical instruments comprising fixed assemblies, simple hinged surgical instruments, and simple assemblies, including those containing stainless steel, titanium and aluminium. Non-sterile device.

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

WARNING: Single Use Devices are to be sterilized and used only once.

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!

Cleaning preparation before use

Warning - Risk of infection!
Before the initial use and before every further usage, the entire device, including its accessories must be decontaminated. An inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or the user.

Warning:
Any variation between what is suggested here and your facility's policies and procedures or those indicated by your sterilizer manufacturer should be brought to the attention of the appropriate responsible persons at your facility for direction before cleaning and sterilizing your instruments. Prior to use, all instruments should be inspected to insure proper function and condition. Do not use instruments if they do not perform satisfactorily. Fading of color-anodized aluminium instruments may be accelerated if cleaning and sterilization recommendations below are not followed.

Remove all protecting caps and sheats carefully. Before beginning to use the instrument, the instrument must be cleaned, lubricated, decontaminated, sterilized and inspected before use in surgery.

For all Lowsley Prostatic Retractors, inject cleaning fluid through the flush port, which allows the cleaning fluid to pass freely along the walls of the lumen and base/end. Cleaning fluid exits at the distal tip of the device. The lumen chamber at the base is flared to enhance the flow of solution. Ultrasonic cleaning of this device is not recommended.

Limitations on reprocessing
Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

Attention:
Risk of damage – The surgical instrument 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.

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Control function before use:
Before using, the general functioning and preparation of the instrument and accessories must be controlled. Please check before start-up.

Operation:
Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques. In addition, 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 as well as surgical techniques must be read carefully.
The sterile instrument is inserted into the body. The instrument must be operated only by trained personnel. Please observe general operating room technique.

Cleaning / Sterilization

Point of Use
• Excess soil should be removed as soon as possible after use with a disposable cloth, wipe, or gauze.

Containment and Transportation
• It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

Preparation for Cleaning and Sterilization
• Disassembly of simple assemblies is necessary to allow more complete cleaning and sterilization.
• Disassembly should not require any mechanical tooling (i.e. screwdriver, pliers, etc.).
• Follow cleaning instructions below before sterilization.

Manual (Required if Automatic washer/disinfector method is not utilized)
- All instruments must be cleaned in the completely open and disassembled (i.e. takenapart) configuration.
- Prepare neutral pH enzymatic detergent as per vendor's directions. High alkaline detergents are not recommended for aluminum instruments. Enzol® enzymatic detergent is recommended at a preparation of 1 oz./gallon using lukewarm water.
- Fully immerse device in the prepared detergent per labeling instructions. Allow device to soak for a minimum of 1 minute.
- Actuate all movable parts during the soak time to allow complete penetration of detergent to hard to reach areas.
- Scrub the device, using a soft bristled brush (may also include a syringe and pipe cleaner), paying particular attention to movable parts, crevices, lumens, and other hard to reach areas until all visible soil has been removed.
- In addition 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.
- In addition, for lumen devices, 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).
- Rinse all surfaces, crevices, and lumens in running reverse osmosis deionized (RO/DI) water for a minimum of 3 minutes to remove any residual detergent or debris.
- In addition, 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.

- Dry the instrument with a clean, soft cloth.
- Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure.

Cleaning: Automatic
- All instruments must be cleaned in the completely open and disassembled (i.e. takenapart) configuration.
- Prepare neutral pH enzymatic detergent as per vendor's directions. High alkaline detergents are not recommended for aluminum instruments. Enzol® enzymatic detergent is recommended at a preparation of 1 oz./gallon using lukewarm water.
- Fully immerse device in the prepared detergent per labeling instructions. Allow device to soak for a minimum of 1 minute.
- Actuate all movable parts during the soak time to allow complete penetration of detergent to hard to reach areas.
- Scrub the device, using a soft bristled brush (may also include a syringe and pipe cleaner), paying particular attention to movable parts, crevices, lumens, and other hard to reach areas until all visible soil has been removed.
- In addition 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.
- Clean devices within a washer/disinfector utilizing the equipment and detergent manufacturers instructions.
- Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure.
- Rinse with distilled or deionized water to remove residual solution.

Inspection and Function Testing
- Check for smooth movement of hinge. Locking mechanisms should be free of nicks.
- Instruments with broken, cracked, chipped or worn parts, or tarnished surfaces should not be used, but should be repaired or replaced immediately.
- Stained or discolored instruments should be cold soaked in Kool Kleen, or a cold soak stain & rust remover, following the detergent manufacturer's instructions.
- Lubricate the instrument before autoclaving with Instra-Lube, or a steam permeable instrument lubricant.

Packaging
Instruments can be wrapped in sterilization wrap, according to manufacturers instructions.

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

Autoclave sterilization:
Sterilization of instruments may be accomplished by Autoclave.
Time and temperature parameters required for sterilization vary according to type of sterilizer, cycle design, and packaging material.
- Testing should be conducted by each healthcare facility to ensure that the specific configuration of instrument sets is acceptable for the sterilization process.
- Do Not sterilize instruments at temperatures over 141°C (285°F).
- All ring handled instruments must be autoclaved in the fully open position to prevent cracking of the box lock.

- All instruments must be sterilized in the completely open and disassembled (i.e. taken-apart) configuration. Note that applicable instrument disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.).
- All flush ports shall remain in the fully open position.
- All devices shall be positioned to allow steam contact of all surfaces.
- All instruments with concave surfaces shall be placed so that the surfaces will drain water.
- Always verify parameters with sterilizer manufacturer's written instructions.
- The use of "flash" sterilization is not recommended, as it may shorten the life of instruments.

Parameters for Wrapped Instruments in Steam Sterilization

	Temperature	Exposure	Drying
Gravity Displacement	**132°C(270°F)**	**15 Minutes**	**30 Minutes**
Prevacuum/Dynamic Air-Removal	**132°C(270°F)**	**4 Minutes**	**15 Minutes**
135°C(275°F)	**3 Minutes**	**15 Minutes**	

Storage

- After sterilization, instruments should remain in sterilization wrap and be stored in a clean, dry cabinet or storage case.
- Care must be taken to protect the jaws from 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 instrument is repaired by an authorized service agency only.

Regardless of age, if any instrument needs service, return it to your authorized service center. All instruments must be cleaned and sterilized prior to sending. For repairs outside the U.S., please contact your local distributor.

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 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 originals.

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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 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.