English EN

Avalign Vessel Dilators

INTENDED USE	Avalign vessel dilators are devices used to enlarge or calibrate vessels during coronary artery bypass or angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels, and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.
INTENDED USER PROFILE	• Surgical instruments should not be used by individuals who are not fully trained in proper cardiovascular surgical techniques • Consult relevant medical literature for the appropriate indications, techniques, and risks applicable to the corresponding cardiovascular procedure.
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. • Remove all protective caps and sheaths carefully. • Devices are critical and require terminal sterilization • Devices are not implantable.
WARNINGS 	• Read the Instructions for Use prior to using this device. • **RISK OF INFECTION**: Before use, the entire device, including its accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users. • 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. • 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.

Reprocessing Instructions

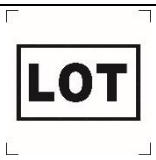
<table>
<tr><td>TOOLS AND ACCESSORIES</td><td></td><td>
<table>
<tr><td>Water</td><td>Cold Tap Water (< 20°C / 68°F)
Hot Tap Water (> 40°C / 104°F)
Deionized (DI) or Reverse Osmosis (RO) Water (ambient)</td></tr>
<tr><td>Cleaning Agents</td><td>Neutral Enzymatic Detergent pH 6.0-8.0 i.e. MetriZyme, EndoZime, 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></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) Take the device with the adapter(s) and accessories to the decontamination area. Clean, decontaminate, and sterilize the device, adapter(s), and accessories foll9owing the instructions in this Instructions for Use.
4) 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.
5) Fully immerse device in the prepared detergent per labeling instructions. Allow device to soak for a minimum of 1 minute, flushing all lumens.
6) Scrub the device, using a soft bristled brush, paying particular attention to hard to reach areas until all visible soil has been removed.
7) 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).
8) 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; flush all internal lumens at least 3 times with the running RO/DI water.
9) Dry the device with a clean, soft cloth. Filtered, compressed air may be used to aid drying.
10) 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 1-6. Steps 7-9 are optional but advised.

11) 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>Drying</td><td>15:00</td><td>194°F / 90°C</td><td>N/A</td></tr>
</table>
12) Dry excess moisture using an absorbent cloth. Filtered, compressed air may be used to aid drying.
13) 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>
</table>

<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>25 minutes</td></tr><tr><td>Gravity Displacement</td><td>132°C (270°F)</td><td>15 minutes</td><td>N/A</td><td>30 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.
CAUTION: Autoclave temperatures should not exceed 280°F</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.
Apply lubricant only on the connecting elements (locking mechanism) and moving parts.</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.
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 instruments are reusable and meet AAMI standards for sterilization.</td></tr>
<tr><td>CONTACT</td><td> 
Manufactured by:
Avalign German Specialty Instruments
626 Cooper Court
Schaumburg, IL 60173; USA
Tel: +1-877-289-1096
www.avalign.com/IFU
product.questions@avalign.com</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