



Lateral Angled Discectomy Instrumentation System Instructions

<p>INTENDED USE</p>	<ul style="list-style-type: none"> The Discectomy Instrumentation System is intended to offer a comprehensive set of surgical instruments to prepare the intervertebral disc space for customer designed interbody fusion implants.
<p>INTENDED USER PROFILE</p>	<ul style="list-style-type: none"> Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques. 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 must be read carefully.
<p>DEVICE DESCRIPTION</p>	<ul style="list-style-type: none"> Surgical instruments comprising fixed assemblies, simple hinged instruments and simple assemblies generally composed of medical grade stainless steels, titanium, aluminum and silicone rubber. Instrument case and trays may consist of different materials including stainless steels, aluminum and silicone mats. Devices are supplied NON-STERILE and must be inspected, cleaned and sterilized before each use. Devices are critical and require terminal sterilization. Devices are not implantable.
<p>WARNINGS</p> 	<ul style="list-style-type: none"> Align 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, remove all protective caps carefully. All instruments should be inspected to ensure proper function and condition. Do not use instruments if they do not perform satisfactorily. The sterilization methods described have been validated with the devices in predetermined placement locations per the case and tray designs. Areas intended for specific devices shall contain only those devices. Risk of damage – The surgical instruments are precision devices. Careful handling is important for the accurate functioning of the devices. Improper external handling can cause the devices to malfunction. Use caution when handling sharp instruments to avoid injury. Wash the instrument case and trays with an aluminum safe, neutral pH detergent to avoid faded surface colors and deterioration of anodized surfaces. 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.
<p>CAUTION</p>  <p>ONLY</p>	<p>Federal U.S. Law restricts this device to sale, distribution, and use, by, or on order of a physician.</p>
<p>LIMITATIONS ON REPROCESSING</p>	<p>Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.</p>
<p>DISCLAIMER</p>	<p>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.</p>


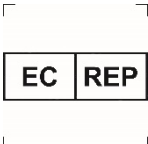





Reprocessing Instructions

TOOLS AND ACCESSORIES	Water	Cold Tap Water (< 20°C / 68°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 Lint Disposable Cloths or equivalent Soaking Pans																										
	Equipment	Medical Compressed Air Ultrasonic Cleaner (Sonicator) Automated Washer																										
POINT-OF-USE AND CONTAINMENT	<ol style="list-style-type: none"> 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, 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	<ol style="list-style-type: none"> 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 1 minute. 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. <ol style="list-style-type: none"> 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) 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). 9) 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. <ol style="list-style-type: none"> a) For lumen devices, flush internal lumens a minimum of 3 times with RO/DI water (minimum of 15mL) using an appropriately sized syringe. If available, use flush ports for flushing. 10) Dry the instrument with a clean, soft cloth. Filtered, compressed air may be used to aid drying. 11) Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure. 																											
AUTOMATED CLEANING	<p>Note: All devices must be manually pre-cleaned prior to any automated cleaning process, follow steps 1-7. Steps 8-11 are optional but advised.</p> <ol style="list-style-type: none"> 12) Clean devices within a washer/disinfector utilizing the equipment and detergent manufacturers' instructions per the below minimum parameters. <table border="1" style="margin-left: 20px; margin-top: 10px;"> <thead> <tr> <th>Phase</th> <th>Time (minutes)</th> <th>Temperature</th> <th>Detergent Type & Concentration</th> </tr> </thead> <tbody> <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>Purified Water Rinse</td> <td>00:10</td> <td>146-150°F / 63-66°C</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> </tbody> </table> 13) Dry excess moisture using an absorbent cloth. Dry any internal areas with filtered, compressed air. 14) Visually examine each instrument for cleanliness. If visible soil remains, repeat cleaning procedure. 				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
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DISINFECTION	<ul style="list-style-type: none"> • Devices must be terminally sterilized (See § Sterilization). • Aalign devices are compatible with washer/disinfector time-temperature profiles for thermal disinfection per ISO 15883. 																											

Reprocessing Instructions

INSPECTION AND FUNCTIONAL TESTING	<ul style="list-style-type: none"> • Check for smooth movement of hinges. Locking mechanisms should be free of nicks. • Devices with broken, cracked, chipped or worn parts should not be used, but should be replaced immediately. • Lubricate instruments before autoclaving with Instra-Lube, or a steam permeable instrument lubricant. 															
PACKAGING	<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ Wrap cases in a standard, medical grade sterilization wrap using a double layer wrap per the AAMI method or equivalent. • Rigid Sterilization Container <ul style="list-style-type: none"> ○ For information regarding rigid sterilization containers, please refer to appropriate instructions for use provided by the container manufacturer or contact the manufacturer directly for guidance. 															
STERILIZATION	<p>Sterilize with steam. The following are minimum cycles required for steam sterilization of Avalign devices:</p> <p>Double Wrapped Instrument Case:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Cycle Type</th> <th style="text-align: left;">Temperature</th> <th style="text-align: left;">Exposure Time</th> <th style="text-align: left;">Pulses</th> <th style="text-align: left;">Drying Time</th> </tr> </thead> <tbody> <tr> <td>Prevacuum</td> <td>132°C (270°F)</td> <td>4 minutes</td> <td>4</td> <td>30 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> </tbody> </table> <ul style="list-style-type: none"> • 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 the 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. Note: rigid sterilization containers cannot be used in gravity steam cycles. 	Cycle Type	Temperature	Exposure Time	Pulses	Drying Time	Prevacuum	132°C (270°F)	4 minutes	4	30 minutes	Gravity Displacement	132°C (270°F)	15 minutes	N/A	30 minutes
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STORAGE	<ul style="list-style-type: none"> • After sterilization, devices should remain in the sterilization packaging 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. 															
MAINTENANCE	<ul style="list-style-type: none"> • Attention: Apply lubricant only on the connecting elements (locking mechanism) and moving parts. • Discard damaged, worn or non-functional devices. 															
WARRANTY	<ul style="list-style-type: none"> • All products are guaranteed to be free from defects in material and workmanship at the time of shipping. • Avalign devices are reusable and meet AAMI standards for sterilization. Devices are designed and manufactured to meet the highest quality standards. Avalign cannot accept liability for failure of devices which have been modified in any way from their original design. 															
CONTACT	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;">  <p>Manufactured by: Avalign Technologies 8727 Clinton Park Drive Fort Wayne, IN 46825 1-877-289-1096 www.avalign.com product.questions@avalign.com</p> </td> <td style="width: 50%; vertical-align: top;"> <p>Distributed by: Orthofix Inc. 3451 Plano Parkway Lewisville, TX 75056 (214) 937-2000</p> </td> </tr> </table>	 <p>Manufactured by: Avalign Technologies 8727 Clinton Park Drive Fort Wayne, IN 46825 1-877-289-1096 www.avalign.com product.questions@avalign.com</p>	<p>Distributed by: Orthofix Inc. 3451 Plano Parkway Lewisville, TX 75056 (214) 937-2000</p>													
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Symbols Glossary

Symbol	Title and Translations
	<p>Manufacturer</p>
	<p>Authorized Representative in the European Community</p>
	<p>Lot Number / Batch Code</p>
	<p>Catalogue Number</p>
	<p>Consult Instructions for Use</p>
	<p>Caution</p>
	<p>Federal Law (USA) restricts this device to sale by or on the order of a physician</p>