English EN

Disc Preparation Surgical Instruments Instructions

INTENDED USE

- The Disc Preparation Surgical Instruments are intended to offer a comprehensive set of surgical instruments to prepare the intervertebral disc space for interbody spinal fusion.

INTENDED USER PROFILE

- 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.

DEVICE DESCRIPTION

- Surgical instruments comprising fixed assemblies, simple hinged instruments and simple assemblies generally composed of medical grade stainless steels, titanium, aluminum and silicone rubber.
- 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.

WARNINGS

- 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.
- **For the Frazier Suction Tubes, disassemble and remove stylet before cleaning.**
- 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.
- 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

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.

Reprocessing Instructions

TOOLS AND ACCESSORIES

Water	Cold Tap Water (< 20°C / 68°F) Warm Water (38°- 49°C / 100°- 120°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 Automated Washer

POINT-OF-USE AND CONTAINMENT

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 lumens, surfaces, crevices, sliding mechanisms, hinged joints, and all other hard-to-clean design features.
2) Suction or flush lumens with a cleaning solution immediately after use.
3) Follow universal precautions and contain devices in closed or covered containers for transport to central supply.

MANUAL CLEANING

4) Disassemble all devices as warranted per manufacturer's instructions.
5) Rinse devices under cold running tap water for a minimum of 3 minutes while wiping off residual soil or debris. Actuate moveable mechanisms and flush all lumens, cracks and/or crevices while rinsing.
6) Prepare an enzymatic cleaning solution per manufacturer's instructions including dilution/concentration, water quality and temperature. Immerse devices and soak for a minimum of 10 minutes. While in the solution, use a soft, bristle brush to remove all traces of blood and debris from the device, paying close attention to threads, crevices, seams, and any hard to reach areas.
    a. If the device has sliding mechanisms or hinged joints, actuate the device while scrubbing to remove trapped soil.
    b. If the device contains a lumen, use a tight-fitting nylon brush or pipe cleaner while pushing in and out with a twisting motion to facilitate removal of debris; ensure the full diameter and depth of the lumen is accessed. Flush the lumen, three times minimum, with a syringe containing a minimum solution of 60mL.
7) Remove devices and rinse/agitate in cold tap water for a minimum of 3 minutes. Actuate moveable mechanisms and flush all lumens, cracks and/or crevices while rinsing.
8) Prepare a neutral detergent cleaning solution per manufacturer's instructions including dilution/concentration, water quality and temperature. Immerse devices and soak for a minimum of 5 minutes. While in the solution, use a soft, bristle brush to remove all traces of blood and debris from the device, paying close attention to threads, crevices, seams, and any hard to reach areas.
    a. If the device has sliding mechanisms or hinged joints, actuate the device while scrubbing to remove trapped soil.
    b. If the device contains a lumen, use a tight-fitting nylon brush or pipe cleaner while pushing in and out with a twisting motion to facilitate removal of debris; ensure the full diameter and depth of the lumen is accessed. Flush the lumen, three times minimum, with a syringe containing a minimum solution of 60mL.
9) Remove devices and rinse/agitate in cold tap water for a minimum of 3 minutes. Actuate moveable mechanisms and flush all lumens, cracks and/or crevices while rinsing.
10) Prepare an enzymatic cleaning solution using hot water per manufacturer's recommendations in an ultrasonic unit. Sonicate the devices for a minimum of 15 minutes using a minimum frequency of 40 kHz. It is recommended to use an ultrasonic unit with flushing attachments. Devices with lumens should be flushed with cleaning solution under the surface of the solution to ensure adequate perfusion of channels.
11) Remove devices and rinse/agitate in ambient DI/RO water for a minimum of 4 minutes. Actuate moveable mechanisms and flush all lumens, cracks and/or crevices while rinsing. 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.
12) Dry the device using an absorbent cloth. Dry any internal areas with filtered, compressed air.

13) Visually inspect the device for soil under magnification including all actuating mechanisms, cracks, crevices, and lumens. If not visibly clean, repeat steps 4-13.
14) Submerge device in 2-3% hydrogen peroxide. The appearance of bubbles confirms the presence of hemoglobin. Repeat steps 5-14 if bubbles appear. Adequately rinse device with DI/RO water.

AUTOMATED CLEANING

Note: All devices must be manually pre-cleaned prior to any automated cleaning process, follow steps 1-9. Steps 10-14 are optional but advised.

15) Transfer the devices to an automatic washer/disinfector for processing per the below minimum parameters.

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
Wash 1	02:00	63°C / 146°F	Neutral Detergent
Rinse 1	02:00	Hot Tap Water	N/A
Purified Water Rinse	02:00	146°F / 63°C	N/A
Drying	15:00	194°F / 90°C	N/A

16) Dry excess moisture using an absorbent cloth. Dry any internal areas with filtered, compressed air.
17) Visually inspect the device for soil under magnification including all actuating mechanisms, cracks, crevices and lumens. If not visibly clean, repeat steps 4-9, 15-17.
18) Submerge device in 2-3% hydrogen peroxide. The appearance of bubbles confirms the presence of hemoglobin. Repeat steps 5-9, 15-18 if bubbles appear. Adequately rinse device with DI/RO water.

DISINFECTION

- Devices must be terminally sterilized (See § Sterilization).
- Avalign instruments are compatible with washer/disinfector time-temperature profiles for thermal disinfection per ISO 15883.

INSPECTION AND FUNCTIONAL TESTING

- Visually inspect devices for damage or wear, including sharp edges. Instruments with broken, cracked, chipped or worn features, should not be used, but should be replaced immediately.
- Verify device interfaces (junctions and threads) continue to function as intended without complications.
- Check for smooth movement of hinges. Locking mechanisms should be free of nicks.
- Lubricate before autoclaving with Instra-Lube, or a steam permeable instrument lubricant.

PACKAGING

- 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 or ISO 17665-1 for additional information on steam sterilization.
- **Sterilization Wrap**
  - Cases may be wrapped in a standard, medical grade sterilization wrap using the AAMI double wrap method or equivalent.
- **Rigid Sterilization Container**
  - 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

Sterilize with steam. The following are minimum cycles required for steam sterilization of Avalign devices:

1. US Sterilization Wraps:

Cycle Type	Temperature	Exposure Time	Pulses	Drying Time
Prevacuum	132°C (270°F)	4 minutes	3	30 minutes
Gravity Displacement	132°C (270°F)	15 minutes	-	30 minutes

2. US Rigid Containers:

Cycle Type	Temperature	Exposure Time	Pulses	Drying Time
Prevacuum	132°C (270°F)	4 minutes	3	30 minutes

- 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. Note: rigid sterilization containers cannot be used in gravity steam cycles.

STORAGE

- After sterilization, instruments should remain in sterilization packaging and be stored in a clean, dry cabinet or storage case.
- Care should be taken when handling devices to avoid damaging the sterile barrier.

MAINTENANCE

- Attention: Apply lubricant only on the connecting elements (locking mechanism) and moving parts.
- Discard damaged, worn or non-functional devices.

WARRANTY

- 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 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.

CONTACT

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Label Glossary

Symbol	Title and Translations	Symbol	Title and Translations
	Manufacturer		Caution
	Lot Number / Batch Code		Non-Sterile
	Catalogue Number		Federal Law (USA) restricts this device to sale by or on the order of a physician
	Consult Instructions for Use		

Part List

Part Number	Description	GTIN
48970002	Straight Cobb, 18mm	00190776140427
48970003	Straight Cobb, 22mm	00190776140434
48970004	Straight Cobb, 26mm	00190776140441
48970006	4 Degree Cobb, 18mm	00190776140465
48970007	4 Degree Cobb, 22mm	00190776140472
48970009	Straight Rake Curette	00190776140496
48970010	4 Degree Rake Curette	00190776140502
48970011	Straight Teardrop Curette	00190776140519
48970012	10 Degree Teardrop Curette	00190776140526
48970134	30 Degree Angled Teardrop Curette	00190776138219
48970013	Straight Ring Curette	00190776140533
48970014	10 Degree Ring Curette	00190776140540
48970135	30 Degree Angled Ring Curette	00190776138233
48970015	Straight 4mm Cup Curette	00190776140557
48970017	45 Degree 4mm Cup Curette	00190776140571
48970016	Straight 7mm Cup Curette	00190776140564
48970018	45 Degree 7mm Cup Curette	00190776140588
48970021	Straight Osteotome, 10mm	00190776140618
48970022	Curved Osteotome, 10mm	00190776140625
48970129	Pituitary 4mm, Non-Bayonetted	00190776141028
48970130	Pituitary 6mm, Non-Bayonetted	00190776141035
48970131	Pituitary Up-biting 4mm, Non-Bayonetted	00190776141042
48970132	Kerrison 3mm, Non-Bayonetted	00190776141059
48970133	Kerrison 5mm, Non-Bayonetted	00190776141066
48970056	Single Sided Rasp	00190776140960
48970057	Double Sided Rasp	00190776140977
48970058	Penfield 4mm, Bayonetted	00190776140984
48970059	Penfield Reverse 4mm, Bayoneted	00190776140991
48970062	Knife Handle, Bayoneted	00190776141004
48019301	Slap Hammer	00190776138271
48970098	Mallet	00190776141318
48970067	Frazier Suction 11Fr	00190776141011
48970127	Frazier Suction 14Fr	00190776141561