

Spinal Elements PSO Instrument Instructions

Part List

Catalog Number	Description	UDI
69100-000	Spinal Elements Osteotomy Instruments Tray	00190776405991
69101-015	Adjustable Vertebral Body Retractor, 15mm	00190776406004
69101-020	Adjustable Vertebral Body Retractor, 20mm	00190776406011
69101-030	Adjustable Vertebral Body Retractor, 30mm	00190776406028
69102-006	Straight Osteotome, 6mm	00190776406035
69102-010	Straight Osteotome, 10mm	00190776406042
69102-013	Straight Osteotome, 13mm	00190776406059
69103-025	Triangle Shaver, 25°	00190776406066
69103-030	Triangle Shaver, 30°	00190776406073
69103-035	Triangle Shaver, 35°	00190776406080
69105-025	Angular Template, 25°	00190776406097
69105-030	Angular Template, 30°	00190776406103
69105-035	Angular Template, 35°	00190776406110
69106-205	Posterior Wall Kerrison, 5mm x 20mm	00190776406127
69107-007	Right Angle Vertebral Body Osteotome, 7mm x 7mm	00190776406134
69108-520	Posterior Vertebral Body Punch, 5mm x 20mm	00190776406141
69108-525	Posterior Vertebral Body Punch, 5mm x 25mm	00190776406158
69108-830	Posterior Vertebral Body Punch, 8mm x 25mm	00190776406165

INTENDED USE

- The Spinal Elements PSO Instruments are intended to be used during a pedicle subtraction osteotomy procedure outlined by the Spinal Elements PSO Surgical Technique.

INTENDED USER PROFILE

- Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques. The physician's education, training, and professional judgement are necessary to determine the most appropriate device and treatment option.
- 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

- Manual medical tools comprising fixed assemblies, simple hinged instruments and simple assemblies generally composed of medical grade stainless steels and silicone rubber.
- Instrument case and trays may consist of different materials including stainless steels, aluminum, and nylon.
- Devices are supplied NON-STERILE and must be inspected, cleaned, lubricated, and sterilized before each use.
- Devices require terminal sterilization per these Instructions for Use (IFU).
- 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.
- 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.
- Lubrication of any articulating or actuating related mechanisms is required prior to use to prevent difficulty in manipulation.
- 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.

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	Enzymatic Detergent pH 6.0-8.0 i.e. MetriZyme, EndoZime, Enzol - Validated with Enzol enzymatic detergent at 1 oz per gallon of tap water Neutral Detergent pH 6.0-8.0 i.e. Liqui-nox, Valsure - Validated with Valsure neutral detergent at 1oz per gallon of tap water
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

- 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) 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.
- 5) 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.
- 6) 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.
- 7) 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.
- 8) 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.
- 9) 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.
- 10) 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.
- 11) Dry the device using an absorbent cloth. Dry any internal areas with filtered, compressed air.
- 12) Visually inspect the device for soil including all actuating mechanisms, cracks, crevices, and lumens. If not visibly clean, repeat steps 4-12.

AUTOMATED CLEANING

Note: All devices must be manually pre-cleaned prior to any automated cleaning process, follow steps 1-8. Steps 9-12 are optional but advised.

- 13) 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 (1 oz / gallon)
Wash 1	02:00	63°C / 146°F	Neutral Detergent (1/4 oz / gallon)
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

- 14) Dry excess moisture using an absorbent cloth. Dry any internal areas with filtered, compressed air.
- 15) Visually inspect the device for soil including all actuating mechanisms, cracks, crevices and lumens. If not visibly clean, repeat steps 4-8, 13-15.

DISINFECTION

- Devices must be terminally sterilized (See § Sterilization).
- Avalid instruments are compatible with washer/disinfector time-temperature profiles for thermal disinfection per ISO 15883.
- Load the devices in the washer-disinfector according to the manufacturer's instructions, ensuring that the devices and lumens can drain freely.
- The following automated cycles are examples of validated cycles:

Phase	Recirculation Time (min.)	Water Temperature	Water Type
Thermal Disinfection	1	>90°C (194°F)	RI/DO Water
Thermal Disinfection	5	>90°C (194°F)	RI/DO Water

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 an approved method.
- **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.

Note: The following catalog instruments are manufactured and supplied by Spinal Elements, Inc. These instruments were validated within the Avalign instrument set and can be placed in the set for sterilization according to the steam sterilization parameters identified below.

Catalog Number	Description
10070-000	Nerve Retractor
10080-000	Mallet

Cycle Type	Temperature	Exposure Time	Pulses	Drying Time
Prevacuum	132°C (270°F)	4 minutes	4	45 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.
- Water droplets and visible signs of moisture on sterile packaging/wrap or the tape used to secure it may compromise the sterility of the processed loads or be indicative of a sterilization process failure. Visually check outside wrap for dryness. If there are water droplets for visible moisture observed the pack or instrument tray is considered unacceptable. Repackage and re-sterilize the packages with visible signs of moisture.

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 autoclavable lubricant only on the connecting elements and moving parts.
- Discard damaged, worn or non-functional devices. No special measures are necessary with regard to disposal. Dispose of device per healthcare facility biohazardous waste protocols.

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 and ISO 17665-1 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

- **Notice to Patient and User:** Any serious incident that has occurred in relation to the medical devices should be reported to the manufacturer.













Manufactured by:
Avalign Technologies, Inc.
 8727 Clinton Park Drive
 Fort Wayne, IN 46825 USA
 1-877-289-1096
www.avalign.com
product.questions@avalign.com



Distributed by:
Spinal Elements, Inc.
 3115 Melrose Drive, Suite 200
 Carlsbad, CA 92010
 877-774-6255

Symbols Glossary

Symbol	Title	Symbol	Title
	Manufacturer & Date of Manufacture		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		Medical Device
	Distributor		Unique Device Identifier