

# Axis Spine Technologies

## ALIF Cleaning and Sterilization

### Instructions Guide

#### 1. Instructions

This guide applies only to Axis Spine Technologies Surgical Instruments supplied with the Axis Spine Technologies ALIF (AST-ALIF) system.

The instructions provided are given as guidance for medical device processing and have been validated by the manufacturer for preparing reusable AST-ALIF instruments for reuse.

These instructions are provided in accordance with AAMI TIR12, ANSI/AAMI ST98, ANSI/AAMI ST79, and ISO 17664 and are intended to supplement a hospital's existing instrument cleaning and disinfecting protocols.

Individuals using these instructions should be qualified personnel with appropriate training and competency in accordance with local procedures, guidelines, and standards.

It is the responsibility of the healthcare facility to ensure that processing is performed using appropriate equipment, materials and personnel at a defined processing area. This will include the handling of devices during transportation, processing and storage prior to surgical use. Any deviation by the healthcare facility from these instructions should be evaluated for effectiveness and potential adverse consequences.

These instructions must be used prior to sterilizing the devices.

#### 2. Warnings and Precautions

Neutral pH enzymatic cleaning agents are recommended for use on all Axis Spine Technologies instruments except as follows: do not use saline, environmental disinfectants (including chlorine solutions) or surgical antiseptics (such as iodine- or chlorhexidine-containing products). Do not use cleaning materials that will scratch instruments such as steel wool, abrasive cleaners or wire brushes. Please note that highly alkaline conditions (pH>10) can damage components/devices made out of aluminum materials such as some sterilization cases & trays.

Always follow the instructions provided by the manufacturer of cleaning solutions and/ or equipment used in cleaning Axis Spine Technologies surgical instruments.

Instruments should always be thoroughly inspected before each use and after a cleaning cycle for damage or wear. All reusable instruments are subjected to repeated stresses related to bone contact, impaction, routine cleaning, and sterilization processes. Instruments should be carefully inspected before each use to ensure that they are fully functional. Long, narrow lumens, blind holes, moving and intricate parts require particular attention during cleaning and inspection. Scratches or dents can result in instrument breakage or soft tissue injury. Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument. Damaged or non-functional instruments should be returned to your Axis Spine Technologies representative for replacement.

Damaged or non-functional instruments should be cleaned and sterilized per these guidelines prior to being returned to Axis Spine Technologies.

Any stainless steel or polymer instruments that may have been exposed to transmissible pathogenic agents, such as but not limited to Creutzfeldt-Jakob Disease (CJD) should be processed according to the health care facility's prion decontamination protocol. Contact the Center for Disease Control and/ or the World Health Organization for the most recent information on the transmission and deactivation of CJD or any other known transmissible pathogenic agents.

Always wear personal protective equipment (PPE) when cleaning and processing Axis Spine Technologies Surgical Instruments as defined by the health care facility's policies and procedures.

It remains the responsibility of the processor to ensure that the reprocessing is actually performed using the equipment, materials and trained personnel in the reprocessing facility achieves the desired result. This normally requires validation and routine monitoring of the process at the reprocessing facility.

### **3. Limitations on Reprocessing**

Repeated processing as defined in this document and the cleaning and sterilization instructions, as defined in the "Instructions For Use" (IFU), should have only minor effects on the reuse and device life for devices listed on this document.

End of instrument life is determined by wear and damage due to surgical use and handling and is determined through the inspection of each instrument after the reprocessing cycle. Evidence of damage and wear on a device may include but is not limited to:

- Excessive Wear
- Damage
- Cracks
- Improper functioning
- Corrosion (i.e. rust, pitting)
- Discoloration
- Excessive scratches
- Devices with unrecognizable markings.

Instruments determined to be end of life should be returned to your Axis Spine Technologies representative for replacement.

Non-sterile implants must be discarded following patient use. Any implant with evidence of damage, such as due to handling or processing must be discarded.

### **4. Instructions**

All instruments must first be thoroughly cleaned using the following validated methods described below before sterilization and introduction into a sterile surgical field.

#### **4.1 Point of Use**

Immediately after the surgical procedure, remove as much debris as possible from each instrument

using a water moistened gauze pad, exchanging the gauze pad if it becomes soiled. Instruments should be soaked immediately after use; soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately, wrap them in a moist towel to prevent desiccation.

Gross soil can be removed using sponges, cloths, or soft brushes which will not scratch the surface of the instruments. Flush all lumened devices with water (or detergent solution) to prevent the drying of soil and/or debris to the inside.

Surgically used devices may be considered bio-hazardous and should be safely transported to a designated processing area in accordance with local policies. Instruments should be cleaned as soon as possible at a designated processing area.

#### 4.2 Preparation for decontamination

If applicable, disassemble instruments prior to cleaning and sterilization according to AA-03-0002 Disassembly Instructions. If not removed at the point of use then gross soil should be removed prior to cleaning.

Rinse the instruments under cool running tap water and wipe off any residual soil or debris with a disposable towel. Ensure to flush out any lumens, cracks or crevices while rinsing under running cool tap water.

#### 4.3 Cleaning: Manual

Recommended Equipment:

- Small, medium and large nylon brushes
  - Lint free disposable cloth or sponge,
  - Low foaming - Neutral pH - Phosphate-Free cleaning solution (such as MetriWash or equivalent such as Prolystica Ultra Concentrate Neutral Detergent).
1. Prepare a neutral pH enzymatic cleaning solution, such as MetriZyme, according to the detergent manufacturer's instructions. The temperature of the solution should be between 95-104°F for manual cleaning. Immerse the instruments in the enzymatic solution and activate any moving mechanisms a minimum of five times. Soak the instruments in the enzymatic solution for between 10 to 15 minutes. Change the soak solution often if grossly soiled.
  2. While still in the soak solution, use a soft non-metallic bristle brush (plastic bristles, like nylon) to thoroughly scrub all surfaces of the instruments and remove all visible soil. If applicable, use appropriately sized cleaning brushes to thoroughly scrub all lumens. Scrub for a minimum of one minute for surfaces and applicable lumens.
  3. After the enzymatic soak, rinse instruments thoroughly under running warm tap water (95-104°F), taking care to flush all lumens or crevices, for at least one minute.
  4. Immerse the instruments in the open position (if appropriate) into a fresh batch of an enzymatic cleaning solution per the manufacturer's instructions and sonicate for 10 minutes.
  5. Rinse the instruments thoroughly under running warm tap water (95-104°F), taking care to flush all lumens or crevices, for at least one minute.
  6. Rinse the instruments under running deionized water, taking care to flush all lumens or crevices, for a minimum of one minute.

7. Dry the instruments with a sterile gauze pad, clean towel, or filtered air. Open and close any applicable devices during drying. Pay special attention to any device threads, ratchets and hinges or areas where fluid can accumulate.
8. Perform a visual inspection on the instruments and verify that they are clean. If instruments are not visibly clean, repeat cleaning steps #3 – 7.
9. Verify the instruments are in proper working order prior to sterilization.

#### 4.4 Cleaning: Automated

Recommended Equipment:

- Medical grade ultrasonic cleaner (Such as Steris Caviwave Ultrasonic Cleaning System or equivalent)
- Enzymatic Cleaner that is compatible with stainless steel, plastics and soft metals including aluminum (Such as MetriZyme Enzymatic Cleaner or equivalent such as Prolystica Ultra Concentrate Enzymatic Cleaner)
- Medical grade washer / disinfectant capable of sustained wash and or rinse temperatures of 203°F / 95°C, adjustable cycle times, adjustable temperature controls, adjustable pressure controls for varying soil conditions, water filtering to adjust for water quality and automatic detergent injection to control solution concentrations (such as Steris AMSCO Reliance 444 single chamber washer disinfectant or equivalent),
- Low foaming - Neutral pH - Phosphate-Free cleaning solution (such as MetriWash or equivalent such as Prolystica Ultra Concentrate Neutral Detergent). Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.
  1. All instruments must be dismantled and manually cleaned according to section 4.1 and 4.2 above prior to any automated cleaning process to ensure best possible cleanliness and removal of debris, blood and tissue prior to sterilization.
  2. Use a low foaming, neutral pH, phosphate-free cleaning solution and prepare per manufacturer's recommendations using warm tap water in a sonication unit. Allow the instruments to sonicate for 10 minutes. Instruments should be properly placed to maximize cleaning and to avoid damage or dislodgement of instruments and components.
  3. Remove the instruments from the detergent and rinse by agitating and actuating in ambient deionized water for a minimum of 1 minute. Actuate the instruments through a full range of motion while rinsing and flush all hard to reach areas with a sterile syringe at each end of the instruments with a minimum of 60 mL.
  4. Transfer the instruments into the washer for processing. Position the instruments to allow for proper drainage. Below is the validated and recommended cycle:

Phase	Recirculation Time	Water Temperature	Detergent Type & Concentration (if applicable)
Pre-wash	2 minutes	Cold tap water	N/A
Enzyme Wash	2 minutes	Hot tap water	MetriZyme, (1 oz/gallon) or Equivalent (per manufacturer's instructions)
Rinse	1 minutes	110°F	N/A
Wash	2 minutes	135°F - set point (122-150°F)	MetriWash, (1 oz/gallon) or Equivalent (per manufacturer's instructions)
PURW Rinse	1 minutes	194°F	N/A
Drying	15 minutes	194°F	N/A

5. Dry the instruments using a clean non-linting cloth and inspect for residual moisture.

#### 4.5 Maintenance and Inspection

Visually inspect the instruments under ambient light following performance of the cleaning instructions prescribed above.

Inspect all devices for:

- Insufficient cleaning: if any residual soils are detected repeat cleaning steps until there is no remaining visible soil
- Insufficient Drying: If moisture is present drying should be repeated
- Wear or Damage: including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, cracks and wear
- Markings: devices with unrecognizable or missing markings
- Function, including but not limited to, sharpness of cutting tools, bending of flexible devices, movement of hinges/joints/box locks and moveable features such as handles, ratcheting and couplings, damaged and worn devices should be discarded.

All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.

Damaged, worn, non-functional or instruments with missing markings should be returned to your Axis Spine Technologies representative for replacement.

#### 4.6 Packaging

Place cleaned, dry devices into the specified locations within the appropriate sterilization case, if applicable.

Only legally marketed and locally approved sterilization barriers (e.g. wraps, pouches or containers) should be used for packaging sterilized devices, in compliance to the manufacturer's instructions.

#### 4.7 Storage

Packaged and sterilized instruments are only to be stored in areas that provide protection from dust, moisture, insects and extremes of temperature and humidity.

Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

### 5. Sterilization

All instruments and implants are provided non-sterile and must be sterilized prior to use. All components are sterilizable by steam (moist heat) sterilization using standard hospital practices.





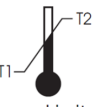


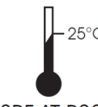







The implants and instruments can be sterilized using the provided standard open cases, small baskets, trays, and other types of accessories, especially with covers or lids, not provided by Axis Spine Technologies for a specific system should not be used.

For standard open cases, devices are to be packaged in an FDA-cleared sterilization wrap prior to placement in an autoclave.

The steam sterilizer should be validated to the requirements of any local standards and guidance such as ISO 17665-1 or ANSI/AAMI ST79. The steam sterilizer should be installed and maintained in compliance with manufacturer’s instructions and local requirements. Ensure that the steam sterilizer cycle is chosen that is designed to remove air from porous or lumened device loads in accordance with manufacturer’s instructions and does not exceed the criteria for sterilizer load. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the following validated parameters.

<b>Method:</b>	Steam
<b>Cycle:</b>	Pre-Vacuum
<b>Temperature:</b>	270°F (132°C)
<b>Exposure Time:</b>	4 Minutes
<b>Minimum Dry Time:</b>	30 Minutes
<b>Minimum Cool Down Time:</b>	40 Minutes

## 6. Symbol Translation

<b>LOT</b> LOT NUMBER			<b>STERILE</b> STERILE		
<b>REF</b> <b>REF</b> CATALOG NUMBER	DO NOT RESTERILIZE	SINGLE USE	<b>STERILE A</b> Sterile medical device processed using aseptic technique	MANUFACTURER	DISMANTLE BEFORE CLEANING
<b>QTY</b> QUANTITY	 T1— T2 Lower Limit of temperature = T1 Upper Limit of temperature = T2	 ATTENTION. SEE INSTRUCTIONS FOR USE	<b>STERILE R</b> STERILIZATION BY IRRADIATION		DATE OF MANUFACTURE
<b>SZ</b> SIZE					
<b>MADE IN</b> MADE IN	 25°C STORE AT ROOM TEMPERATURE	 PACKAGE CONTAINS FLAMMABLE LIQUID	<b>STERILE EO</b> STERILIZATION BY ETHYLENE OXIDE	<b>US REP</b> US REPRESENTATIVE	
<b>NTI</b> NEURAL TISSUE INSTRUMENT					
<b>IOM</b> NEUROMONITORING INSTRUMENTS	 KEEP AWAY FROM SUNLIGHT	 DO NOT USE IF PACKAGE IS DAMAGED	<b>LATEX FREE</b> LATEX FREE	<b>EC REP</b> AUTHORIZED EUROPEAN REPRESENTATIVE	
<b>Rx Only</b> Federal (USA) law restricts this device to sale by or on the order of a physician					
		<b>MSR</b> MEASURING DEVICE	 <b>NON STERILE</b> NONSTERILE	<b>DIST</b> DISTRIBUTED BY	UNLOCK
			<b>NONSTERILE</b> NONSTERILE	 XXXX-XX USE BY	

## 7. Manufacturer



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