Sigma™ Access System
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The Sigma Access System is intended to aid the surgeon's visualization of the surgical area and allow for performance of spinal procedures. The Sigma Access System includes the following subsystems: Sigma LIF PTP™, Sigma TLIF, Sigma Medialized, Sigma ALIF, Sigma LTP™, Sigma Cervical, and Sigma LIF Corpectomy.

INDICATIONS FOR USE:
The Sigma Access System is designed to provide access and exposure to the spine for the performance of surgical procedures.

CONTRAINDICATIONS:
The Sigma Access System is contraindicated for patients with an allergy or sensitivity to instrument materials.

WARNINGS/CAUTIONS/PRECAUTIONS:
1. The instruments of the system are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections. Instruments marked single use are disposable devices, designed for single use and should not be reused or reprocessed. Reprocessing of single use instruments may lead to instrument damage and possible improper function.
2. The following statements apply to single use instruments:
    i. Inspect the packaging for signs of damage. Do not use devices if package is opened, damaged, or past the expiry date.
    ii. Do not re-sterilize instruments.
    iii. Do not use scratched or damaged devices.
3. Device components should be received and accepted only in packages that have not been damaged. Damaged or worn instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
4. Do not over-retract. To reduce risk of patient injury, only use as much retraction as necessary to provide adequate exposure and access.
5. The Tertiary Dilator (PN: 250-050) and SafeOp Stimulating Dilator Kit, Sterile - Oval (PN: AIX1335-S) have been designed to be used only with the Sigma LTP and LIF Corpectomy Access Systems. The Tertiary Dilator (PN: 100602) and SafeOp Stimulating Dilator Kit (PN: AIX1330-S) must not be used with the Sigma LTP and LIF Corpectomy Access Systems.
6. The instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
7. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times.
8. To avoid patient injury, it is critical to confirm that the Sigma ALIF Hub latches are secured to the Frame prior to placing the Frame over the exposure site.
9. To help avoid denervation of the musculature, avoid using electrocautery following dissection of subcutaneous tissue.
10. It is critical to verify that the Sigma ALIF Blade is locked to the Blade Arm **PRIOR** to locking the Hub to the track to avoid adding inadvertent tension on the vasculature.
11. To avoid patient injury, do **NOT** let go of the Sigma ALIF Independent Blade until the A-Arm is locked in place.

12. When using Sigma ALIF, do not apply tension on the bifurcation of the aorta and vena cava with the cranial Blade as this will resu`lt in tension on the branching vasculature.
13. Use caution when utilizing the Sigma ALIF Stabilization Anchors to avoid injuring surrounding tissue and/or vasculature.
14. Avoid using electrocautery in males after exposure of the disc space to avoid injury to the hypogastric plexus which may result in retrograde ejaculation.
15. When using the Sigma-C Access Screwdriver, it is important to lift the sleeve into its unlocked position while applying force to remove the Access Screw from bone.
16. Prior to docking the Exposure Guard into the Sigma-C Blade, use a secondary instrument such as a Cloward or Penfield to sweep tissue away from the lateral edge of the blade so that the Exposure Guard track is fully exposed and protected from soft tissue interference.
17. The Ancillary Blades (PN: 330-3XXX) feature 20 mm of spring-loaded distal extension. Use caution when positioning the distal tip of the device during anterior retraction in order to avoid damage to anatomy.

PREOPERATIVE MANAGEMENT:

1. Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings, and cautions, as well as functions and limitations of the instruments.
2. Careful preoperative planning should include surgical approach strategy, pre-assembly of component parts (if required), and verification of required inventory for the case.

REPROCESSING OF REUSABLE INSTRUMENTS

General Information for all Instruments:

- **Point-of-Use Processing:** To facilitate cleaning, instruments should be cleaned initially directly after use in order to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
- The cleaning process is the first step in effectively reprocessing reusable instruments. Adequate sterilization depends on thoroughness of cleaning.
- The cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorgansims.
- It is recommended that all new relevant clinical practice guidelines be followed as per the *CDC guidance, "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008."*
- It is recommended to rinse the device components with water that meets specifications for *AAMI TIR34 "Water for the reprocessing of medical devices, 2014"* for example, DI/RO water.

Instrument Preparation and Disassembly:

- Cleaning, inspection, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be cleaned prior to sterilization.
- Certain instruments may be disassembled prior to cleaning.

Cleaning of Instruments, Containers, and Trays:

- Instruments provided in a set must be removed from the set and cleaned prior to sterilization. Instrument trays, containers, and lids must be thoroughly cleaned separately until visually clean.
- Cleaning, maintenance, and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.

- Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible and verify that all actuating parts move freely. Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.
- Clean the instruments, trays and inserts using only recommended cleaning solutions. Use of caustic solutions (caustic soda) will damage the instruments.
- All solutions for cleaning must be prepared per the manufacturer's instructions.
- Use of water with high mineral content should be avoided.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
- Ensure instruments are in the fully extended, open position throughout cleaning. Disconnect Quick Connect handles/knobs from the shafted instruments prior to cleaning.
- Ensure all moving parts of instruments are cleaned at both extents of travel. Handle all products with care. Mishandling may lead to damage and possible improper function.

Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the step until clean.

Manual Cleaning Steps for Instruments (Required)

Step 1	Rinse devices in ambient temperature tap water to remove visible soil.
Step 2	Prepare enzymatic solution, such as *Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner* or equivalent, per manufacturer's recommendations and submerge device in enzyme solution. Actuate the device while it is submerged and soak for a minimum of 10 minutes.
Step 3	Actuate and scrub the device using an appropriately sized soft bristled brush, such as a *Spectrum Surgical code #M-16* or 45-542 (or equivalent), to brush any lumens for a minimum of 2 minutes. If needed, actuate at several locations to access all surfaces. Use of a syringe (minimum of 50 ml) or water jet is recommended for the hard-to-reach areas and repeat 3 times.
Step 4	Rinse devices in Deionized / Reverse Osmosis (DI/RO) water for a minimum of 1 minute.
Step 5	Prepare cleaning solution, such as *Prolystica® 2X Concentrate Alkaline Detergent,* per manufacturer's recommendations and submerge and actuate devices in cleaning solution and sonicate for a minimum of 10 minutes.
Step 6	Thoroughly rinse devices with DI/RO water to remove all detergent residues.
Step 7	Dry devices with a clean, lint free cloth or filtered compressed air.

Automatic Washer Cleaning Steps for Instruments

Step 1	Complex instruments, such as those with cannulations, lumens, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using

	a water jet or syringe with ambient temperature tap water where debris could become trapped. Place them into the Washer/Disinfector and process through a standard surgical instrument cycle.
Step 2	Prewash with cold tap water for 2 minutes.
Step 3	Enzyme wash using cleaner such as *Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner* or equivalent, per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum of 1 minute.
Step 4	Detergent wash using detergent such as *Prolystica® 2X Concentrate Alkaline Detergent* or equivalent, per manufacturer's recommendations, hot tap water (66°C/150°F minimum), for a minimum 2 minutes.
Step 5	Rinse 2 times, hot tap water (66°C/150°F minimum), for a minimum 15 seconds.
Step 6	Purified water rinse, hot (66°C/150°F minimum), for a minimum 10 seconds.
Step 7	Hot air dry (115°C/239°F minimum), for a minimum of 10 minutes.

INSPECTION:

- Inspect each instrument, container, and tray to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Inspect instruments for any other damage, wear, and/or corrosion.

STERILIZATION AND RESTERILIZATION:

- All instruments are provided non-sterile and must be steam sterilized prior to use in the provided trays using the validated cycle parameters in the table below.
- Alphatec perforated trays have been validated to achieve a sterility assurance level (SAL) of 10^{-6} using FDA cleared sterilization accessories (containers and filters). FDA cleared reusable or paper filters should be used to achieve and maintain sterility after processing.
- Alphatec perforated container/tray configurations have also been validated to a sterility assurance level (SAL) of 10^{-6} using FDA cleared sterilization wrap. Perforated container/tray configurations must be double wrapped to allow steam to penetrate and make direct contract with all surfaces.
- Do not stack trays during sterilization.
- Instrument sets have been validated in standard configurations. **No additional items should be added to the set for sterilization.**

Sterilization Parameters

Set Type	Cycle Type	Temperature	Exposure Time	Minimum Drying Time	Minimum Cool Down Time
Instrument Only Set	Pre-vacuum	132°C (270°F)	4 Minutes	45 Minutes	75 Minutes

Sterilization Notes:

- These parameters are consistent with the appropriate version of *ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."*

RETURNING INSTRUMENTS TO ALPHATEC SPINE:

All used products returning to Alphatec Spine must undergo all steps of cleaning, inspection, and terminal sterilization before being returned to Alphatec Spine. Documentation of decontamination should be included.

UDI CONSTRUCTION

To compile a unique device identifier (UDI) for reusable, reprocessed devices, the device identifier (GTIN) may be ascertained by searching for the part number in the FDA GUDID at https://accessgudid.nlm.nih.gov/. The production identifier(s) (e.g., lot number, serial number) may be found directly marked on the device.

COMPLAINT HANDLING/REPORTING:

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, e-mail, or letter, per contact information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. You may contact Customer Service directly at customerservice@atecspine.com.

For Surgical Technique Guides or additional information regarding the products, please contact your local representative or Alphatec Spine, Inc. Customer Service directly at customerservice@atecspine.com.

℞only **CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.**

For a listing of Symbols and Explanations, see **atecspine.com/eifu**

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