SAFEOP™ ACCESSORIES (RECOMMENDED FOR STEAM STERILIZATION)

INSTRUCTIONS FOR USE

Non-Sterile Only

GENERAL INFORMATION:

The SafeOp Accessories are surgical instruments that provide electrical stimulation to the body to locate and identify nerves in either open, minimally invasive, or percutaneous procedures. These surgical instruments are compatible with common FDA cleared neuromonitoring platforms as they are connected via a compatible clip or probe depending on the system. The neuromonitoring capability provides the surgeon with spinal nerve location, proximity, and integrity information. This information assists the surgeon during targeting, bone preparation, and placement of orthopedic implants such as intervertebral fusion devices (e.g., interbody implants) and bone screws (e.g., pedicle screws).

All instruments are offered non-sterile to be steam sterilized by the end user per the recommended steam sterilization parameters below in this instructions for use (IFU). Single use instruments are disposable devices that are intended for one use on a single patient during a single procedure. Single use devices should NOT be reused or reprocessed after use. For reusable instruments proper cleaning must be performed prior to sterilization to achieve effective decontamination/sterilization. Follow *CLEANING* and *STERILIZATION AND RESTERILIZATION* sections below in this IFU.

INDICATIONS FOR USE:

The SafeOp Accessories are utilized in spine surgical procedures to assist in location of the nerves during or after preparation and placement of implants (intervertebral fusion cages and pedicle screw fixation devices) in open and percutaneous minimally invasive approaches.

WARNINGS/CAUTIONS/PRECAUTIONS:

1. All instruments that are provided non-sterile must be cleaned and sterilized prior to surgery. See *CLEANING* and *STERILIZATION* sections in this IFU.
2. Single use instruments 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.
3. Electrocautery on a patient who is being monitored may cause interference with the neuromonitoring. Be sure to follow the electrocautery manufacturer's instruction for proper placement and connection of the return electrode to avoid shock and/or burns at the electrode sites.
4. Care must be taken when using stimulating instruments near vital organs, nerves, or blood vessels.
5. Incorrect handling of these instruments may render them unsuitable for their intended use, cause corrosion, dismantling, distortion, breakage, or cause injury to the patient or user. Do not use the drills and taps at high speeds.
6. All instruments are made of biocompatible materials but are not intended to be implantable. As such, in the event an instrument breaks, no fragment may remain in the patient as this could cause post-operative complications such as allergies, infection, or complications that could potentially require further intervention.

RECOMMENDATIONS:

Alphatec recommends the following maximum stimulation parameters:

- Max Current: 40 mA
- Max Voltage: 380 V
- Max Pulse Width: 200 µs
- Max Frequency: 20 Hz
- Max RMS Current: 2.53 mA

REPROCESSING OF REUSABLE INSTRUMENTS

General Information for all Reusable 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. All reusable instruments that have been taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into the sterile surgical field.
- 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 microorganisms.
- 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.
- The validated cleaning and sterilization reprocessing steps provided in these instructions are considered recommended guidelines. The user is ultimately responsible for verifying adequate cleanliness of the devices. Any reprocessing methods used aside from those recommended for Alphatec Spine devices should be validated by the user prior to implementation.
- Equipment, materials, and personnel differ between hospitals; therefore, validation and routine monitoring of the process are normally required at a reprocessing facility.

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.

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 Reusable Instruments

Step 1	Rinse devices in ambient temperature tap water to remove excess soil.
Step 2	Submerge instrument in enzyme solution such as *Polystica*® 2X Enzymatic or equivalent. Actuate the instrument while it is submerged and soak for a minimum of 10 minutes.
Step 3	Actuate and scrub the instrument using a soft bristled brush 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 hard-to-reach areas and repeat 3 times.
Step 4	Rinse instruments in Deionized / Reverse Osmosis water for a minimum of 1 minute.
Step 5	Submerge and actuate instruments in a cleaning solution such as *Prolystica*® 2X Alkaline (pH 11.2) or equivalent and sonicate for a minimum of 10 minutes.
Step 6	Thoroughly rinse instruments with Deionized / Reverse Osmosis water to remove all detergent residues.
Step 7	Dry instruments with clean, lint free cloth or filtered compressed air.

Automatic Washer Cleaning Steps for Reusable Instruments

Important - Manual Cleaning Steps 1 and 2 are required before performing the Automated Washer / Disinfector Cycle Steps.

Step 1	Follow steps 1 and 2 of the Manual Cleaning Steps for Instruments.
Step 2	Thoroughly rinse instruments in ambient temperature tap water to remove detergent residuals.
Step 3	Place instruments in fully extended open position into washer and process using the cycle parameters described in Steps 4 – 8.
Step 4	PreWash, cold tap water, for a minimum of 2 minutes.
Step 5	Enzyme wash (such as *Prolystica*® 2X enzymatic or equivalent), hot tap water, for a minimum of 1 minute.
Step 6	Detergent wash (such as *Prolystica*® 2X Alkaline (pH11.2) or equivalent), Hot tap water (66°C/150°F minimum), for a minimum of 2 minutes.
Step 7	Rinse 2x, hot tap water, for a minimum of 15 seconds.
Step 8	Purified Water rinse, Hot (66°C/150°F minimum), for a minimum of 10 seconds.
Step 9	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.
- Drill bits and taps should be inspected after processing.
- Inspect instruments for any other damage, wear and/or corrosion.
- When necessary, dispose of products in accordance with national regulations and approved hospital practices for surgical instrument disposal.

STERILIZATION AND RESTERILIZATION:

- All reusable instruments are provided non-sterile and must be steam sterilized prior to use using validated cycle parameters in the table below. Each facility should ensure its processing system can effectively apply validated cycle parameters such that equivalent sterility assurance levels are achieved. It is the responsibility of the healthcare facility to qualify their sterilizers' maximum load capacity and determine what effect the loading pattern of the sterilizer has on the sterilization of the devices.
- 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 contact with all surfaces.
- Do not stack trays during sterilization.
- Sets have been validated in standard configurations. No additional items should be added to the set for sterilization.

- Certain devices are packaged non-sterile as a single device to be steam sterilized by the end user. Without stacking, place the device in a container basket or use hospital-provided FDA-cleared sterilizers and accessories (e.g., sterilization wraps, sterilization pouches, sterilization trays). Confirm the container basket or sterilizer/accessories are acceptable for use with the ATEC device by referring to the specifications outlined in basket/sterilizer/accessory instructions for use. Verify sterilization can be achieved following the recommended sterilization cycle specifications (time and temperature).
- It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature). Recommended sterilization parameters are provided below.

Sterilization Parameters

Set Type	Cycle Type	Temperature	Exposure Time	Minimum Drying Time	Minimum Cool down Time
Instruments Only	Pre-vacuum	270°F (132°C)	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.

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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