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., interbodies) 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/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:

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.

PRECAUTIONS:

1. Care must be taken when using stimulating instruments near vital organs, nerves, or blood vessels.
2. 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.
3. 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.

REPROCESSING OF REUSABLE INSTRUMENTS – Important information for 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.
- 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”.
- It is recommended to rinse the device components with water that meets specifications for AAMI TIR34 “Water for the reprocessing of medical devices” for example, DI/RO water.

Instrument Preparation:

- Cleaning, inspection, lubrication, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be cleaned prior to lubrication and sterilization.
- All instrument hinged, rotating, and articulating parts (e.g., screwdrivers) must be lubricated prior to sterilization with a water soluble and sterilizable lubricant intended for surgical instruments (Hinge-Free® for example).

Cleaning Instructions for all Reusable Instruments:

- Instruments must be cleaned prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Disconnect all removable handles/knobs prior to cleaning.
- 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 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 functioning.
- Clean the instruments, trays and inserts using only recommended cleaning solutions. Use of caustic solutions (caustic soda) will damage the instruments.
- 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. **Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the step until clean.**

Cleaning of Instruments, Container, and Trays:

- All solutions for cleaning must be prepared per the manufacturer's instructions.
- Instruments provided in a set, must be removed from the set for cleaning. Instrument trays, containers, and lids must be thoroughly cleaned separately until visually clean.
- Ensure instruments are in the fully extended, open position throughout cleaning. Disconnect Quick Connect handles from the shafted instruments prior to cleaning.
- Pay special attention during cleaning to complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes.
- Use of water with high mineral content should be avoided.

Manual Cleaning Steps for Reusable Instruments (Required)

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 with alkaline detergents.
- Inspect instruments for any other damage, wear and/or corrosion.

STERILIZATION / RESTERILIZATION OF REUSABLE INSTRUMENTS:

- All instruments that are provided non-sterile must be cleaned and sterilized before use. Instruments must be sterilized using the appropriate cycle parameters in the tables below.
- Alphatec perforated trays have been validated to achieve sterility using FDA cleared sterilization accessories (container 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 achieve sterility using FDA cleared sterilization wrap. Perforated container/tray configurations must be double wrapped in sterilization wrap to allow steam to penetrate and make direct contract with all surfaces.
- Do not stack trays during sterilization.

Sterilization Parameters

Method	Cycle Type	Minimum Temperature	Exposure Time	Minimum Drying Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes (followed by a 15 mins cool down period)

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, fax, or letter. 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. To request a surgical technique manual or for additional information regarding the *SafeOp Accessories*, please contact Customer Service at Alphatec Spine, Inc. +1 (800) 922-1356. or 760-431-9286.

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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