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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SafeOp™ Accessories (With A Use-By Date)

INSTRUCTIONS FOR USE

Sterile and Non-Sterile

GENERAL INFORMATION:

The *SafeOp Accessories* include various sterile and non-sterile devices provided packaged with a use-by or expiry date. Accessories that are supplied sterile are sterilized via ethylene oxide (EO), are single use, and should be discarded after use. Accessories that are supplied non-sterile such as SafeOp™ system Surface Electrodes should NOT be sterilized and are single-use accessories which should be discarded after use.

The Arcus™ Stimulating Targeting Needle is a single use instrument used to initiate or "target" the pedicle in conjunction with other MIS instruments (e.g., k-wire or guide wire). Arcus is offered with an impaction type handle with either a diamond or bevel tip. The distal shaft and tip are made of conductive materials, so the instrument can act as a stimulation electrode.

SafeOp Accessories also include 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).

Rhythmlink® Sticky Pad™ Surface and Subdermal Needle Electrodes:

INTENDED APPLICATIONS

EEG [Electroencephalography], EP [Evoked Potentials], IONM [Intraoperative Neurophysiological Monitoring], ICU [Intensive Care Unit], NCS [Nerve Conduction Studies], PSG [Polysomnography] and Ambulatory.

INDICATIONS:

The *SafeOp Accessories* are utilized in spine surgical procedures to assist in location of 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:

- Sterile 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.
- 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.
- The long-term effects of cutaneous electrodes for electrical stimulation and/or recording are unknown.
- Use caution if electrodes are applied over areas of skin that lack normal sensation.
- Replace self-adhesive electrodes if they no longer stick firmly to skin.

- If replacing surface electrodes on a patient due to poor contact or incorrect positioning, carefully remove the remaining gel from the patient prior to applying the new electrodes.
- Your patient may experience skin irritation beneath the surface electrodes applied to skin. The adhesive may irritate the skin when removed from the skin. It is a strong adhesive and should be removed from the skin with care.
- Needle electrodes may cause bruising or bleeding in patients using blood thinners or who have blood dyscrasias. Do not move or wiggle electrodes excessively after placement.

PRECAUTIONS:

- Care must be taken when using stimulating instruments near vital organs, nerves, or blood vessels.
- 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.
- 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.
- Alphatec distributes Rhythmlink® Sticky Pad™ surface and subdermal needle electrodes manufactured by Rhythmlink International, LLC. Subdermal Needles are for professional use only and should only be used in compliance with accepted industry standards. Rhythmlink International, LLC is not responsible for injury, infection or other damage resulting from the use or misuse of this product. Product is sterile only if packaging is unopened. When selecting a Subdermal Needle Electrode, it is important to choose the appropriate length and diameter.

PACKAGING AND STORAGE:

Inspect each package upon receipt to ensure it is intact. Examine accessories carefully prior to use for completeness such that all components are included and to confirm there is no damage. Do not use devices if package is opened, damaged, or past the use-by or expiry date. Damaged packages or products should be returned to Alphatec.

Rhythmlink® subdermal needle electrodes include Single Needles: one Electrode per pouch and Paired Needles: two electrodes per pouch. Rhythmlink® needle electrodes may be stored at ambient temperatures in a clean, dry location. All sterile accessories are intended for single use only. This product should NOT be re-sterilized.

SafeOp surface electrodes are provided in various quantities within a single pouch. Electrodes are offered with multiple pad configurations: three conductive pads per backing, two conductive pads per backing, and a single conductive pad per backing. SafeOp wet gel surface electrodes are provided non-sterile and must be stored at room temperature (10°C to 32°C or 50°F to 90°F) in a clean, dry location. This product should NOT be sterilized.

Rhythmlink® Sticky Pad™ surface electrode is provided non-sterile and must be stored at room temperature (10°C to 40°C or 50°F to 104°F) in a clean, dry location. This product should NOT be sterilized.

Vermed TenderTrode™ solid gel electrodes are provided non-sterile and must be stored at room temperature (10°C to 32°C or 50°F to 90°F) in a clean, dry location. This product should NOT be sterilized.

PREOPERATIVE AND INTRAOPERATIVE MANAGEMENT

General Electrode Instructions:

- Inspect the patient's skin prior to electrode application to assure that the skin is healthy, intact, clean, and dry.

- Remove the backing or needle coverings from the electrodes prior to placing on the patient.
- Anchor all electrodes with medical tape.
- For all electrodes a swab (e.g., '2x2' size) may be placed under the cable connector if it appears that cushioning is needed. Adhesive tape can be placed over the connector or cables to provide strain relief.
- A ground electrode must be placed for all recordings.
- A Rhythmlink® subdermal needle electrode or Sticky Pad™ surface electrode patch may be used for current return (e.g., for a bipolar stimulating probe) which connects to the touch proof green connector.

SafeOp Surface Electrodes:

The wet gel electrodes are designed to adhere to the patient and perform as intended for up to 24 hours. These electrodes are used for both acquisition and stimulation, including somatosensory evoked potentials and electromyography. The double pad blue colored electrodes are used for electrical stimulation, while the white triple, double and single pad electrodes are used for signal acquisition. One white double pad electrode is intended for acquisition at the C5S position and works with the single pad electrode applied to the forehead position (reference for the C5S electrode).

- The wet gel electrodes are designed to require minimal skin preparation. However, Alphatec recommends preparing the skin with NuPrep® skin prep gel and wiping any residual gel from the skin before applying the electrodes for optimal recordings. Do not apply over an ionic skin prep such as a polyvinyl-pyrrolidone mixture.
- In all cases of using surface electrodes, it is important to firmly attach the electrode to the patient using the adhesive foam around the conductive portion of the electrode. Do not press over the well gel area; instead provide a firm distributed pressure with the palm of the hand or press over the perimeter of the electrode to promote adhesion.

Rhythmlink® Sticky Pad™ Surface Electrodes:

Rhythmlink® Sticky Pad™ can be identified by the silver Mylar backing. For best results prepare the site as follows: Remove excess hair, oils, and dirt. Wash the site with warm soapy water and dry the area completely. Use light sand paper prep to lightly scrub area and wipe with alcohol prep then let dry. Remove the Mylar backing from the electrode and place the electrode on the prepared site. To assure good contact apply pressure in the center of the electrode and move to the edges. Upon completion of the recording, remove electrode by pulling directly on the electrode. DO NOT PULL ON THE CABLE. Clean any remaining hydrogel with clean soapy water.

Rhythmlink® Subdermal Needle Electrodes:

Prior to use, remove Needle sheath. Subdermal needle electrodes are typically applied after anesthesia induction has occurred. Subdermal needle electrodes should be inserted after cleansing the skin with a non-ionic disinfectant such as isopropyl alcohol. Prior to use, remove Needle sheath. When introducing Electrode into patient, do not insert up to the hub. If needle bends before, during or after insertion, do not straighten or re-insert. Discard and replace with a new electrode. This product is single-patient use only and should not be sterilized or reused. Discard electrode after use.

- Reuse of this device may cause cross contamination and has NOT been validated for multiple uses.
- Re-sterilization of this device may cause unknown malfunctions. EO re-sterilization has not been validated for this device and may contribute to excessive EO gas residuals.

Vermed® TenderTrode™:

Vermed TenderTrode™ solid gel electrodes are prewired and can be used for up to 24 hours.

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.

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