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.

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

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

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