ATEC LIGHT CABLE SYSTEM LIF
INSTRUCTIONS FOR USE

GENERAL INFORMATION:
The ATEC Light Cable System is compatible with xenon lamp light sources with a power rating up to 300 watts. Using a light source more than this power rating may result in cable failure. This is a single use device. Please dispose of it properly once the procedure is complete.

INTENDED USE:
The fiber optic cable transmits illumination from a light source to the surgical site.

WARNINGS/CAUTIONS/PRECAUTIONS:
1. Never look into the output end while it is connected to a light source. Always turn off the light source prior to removing the cable. The light source connector may become hot during use. Never rest the cable and or patient or bedding. To prevent cable damage, any Xenon light source should have a minimum of 90% IR filtering.
2. Do not sterilize or reprocess this device. Reuse of this product could lead to cross-infection and or material degradation as a result of the decontamination process.
3. Avoid stretching the cable, forming configurations involving sharp angles or kinks, or contact with sharp objects. Do not place objects on the cable that could crush it. Keep the optical faces from contacting the floor and free of fingerprints, foreign matter, and scratches. Handle the cable by the strain reliever when removing it from a light source. Remove the cable from service immediately if a puncture is found in the outer sheathing.
4. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
5. Follow Occupation Safety and Health Administration (OSHA) standards or Universal Precautions for blood borne pathogens.
6. The device has a defined shelf life. Do not use beyond the use-by-date listed on the carton/pouch label.

PREOPERATIVE/INTRAOPERATIVE MANAGEMENT:
1. Always review the instructions for use and caution/warning notices.
2. The surgeon should be thoroughly familiar with the proper operation of the power surgical instruments and accessories prior to use.
3. Inspect package prior to use for signs of damage or tampering.

STORAGE CONDITIONS:
- Expiration date of the product is printed on the shelf box label and tray label for each unit.

INSPECTION:
- Inspect the device and packaging for signs of damage, including scratches or punctures to the sterile barrier.

STERILIZATION AND RESTERILIZATION:
This device is delivered in a sterile packaged state via Ethylene Oxide.

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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