



FIBER OPTIC CABLES
User Manual
ENGLISH

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
















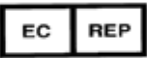


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INDICATION FOR USE

This fiber optic cable is designed to deliver illumination from a high intensity light source to a surgical headlight or surgical instrument for surgical site illumination, either standard or minimally invasive. It is compatible for use with light sources made with the following: Xenon with lamp power rating of up to 300 Watts, Halogen with lamp power rating of up to 250 Watts, or Metal Halide with lamp power rating of up to 100 Watts. Any light source used with this cable should have a minimum of 90% IR filtering to prevent cable damage during use.

TABLE OF SYMBOLS

Found on a medical grade light source, other illumination related equipment, fiber optic cables and corresponding packaging.

	Attention; Consult Accompanying Documents		Fuse
	Caution: High Voltage		Type CF Equipment
	Equipotentiality		Type BF Equipment
	Protective Earth		High Temperature
	On / Off		Brightness
	Stand-by		Motor
	System Status Display		Fan
	System		CE
	Do Not Dispose		Listed by ETL
	Push		Listed by CSA
	Hours		Part Number
	Over Temperature		Batch Code
	Intensity		Serial Number
or 	Lamp		Authorized Representative in the European Community
	Keep dry		Manufacturer

GENERAL WARNINGS

- The user should carefully study this manual before making any attempt to use the product clinically. Instructions should be followed specifically, with special attention given to warnings and cleaning instructions. This manual should also be available to the surgical team during a procedure.
- Follow the instructions in the operating manuals of other manufacturers' equipment when they are used in conjunction with this product.
- Before every procedure, carefully inspect the fiber optic cable to ensure it has been properly maintained, cleaned and sterilized (if compatible) and that it is fully functional.
- Care should be taken to follow the maintenance and cleaning instructions.
- Excessive bending of the cable should be avoided.
- Use care not to point the cable directly at the eye while in operation. The brilliant light output can cause severe eye discomfort.
- Light sources use high intensity lamps, which produce heat as well as brilliant light. The high brightness and the light output of the fiber optic cable can cause burns.

FIRE HAZARD: DO NOT DRAPE OR COVER THE LIGHT SOURCE OR THE FIBER OPTIC CABLE WHILE IT IS OPERATING.

DO NOT PLACE THE CABLE END FITTING ON A DRAPE WHILE IT IS OPERATING.

PRECAUTIONS

- Take precautions to verify that the fiber optic cable is appropriately suited for the light source. Xenon and other high illumination light sources require premium fiber optic cables in order to achieve optimal performance and prevent damage to the fibers, thereby diminishing the quality of the light output or the useful life of fiber optic cable.
- Take precautions not to touch or disconnect the cable end fitting from the turret until the light source has been "shut down" for a period of time and allowed to cool. The cable end fitting will remain hot immediately following shut down, which can cause burns.
- Take precautions to not place and rest a hot cable end fitting and/or head light on a patient or allow the system to come in contact with un-protected hands or tissue. The entire system should be allowed to cool following use. Failure to do so can cause burns and/or tissue damage.

CABLE CARE

Fiber optic cables are fine, high quality optical instruments. You can prolong the useful life by following a few guidelines:

- Avoid stretching your cable, forming configurations involving sharp angles or kinks, or contact with sharp or pointed objects. The internal light fibers are made of glass, a material that breaks under stress. Fiber breakage will result in diminished light output.
- Utilize the gown clips (if provided) to keep the headlight cable secured to the surgeon's gown for greater comfort and maneuverability. (This does not apply to instrument cables.)
- Do not use your fiber optic cable with any alterations to its original design or fabrication.
- Bundle size (aperture) of the fiber optic cable should be matched to the aperture of the instrument to obtain maximum light output.

NOTE: A larger aperture fiber optic cable will not increase light output of a smaller aperture instrument.

- Keep the optical faces from contacting the floor or other hard surfaces. The resulting scratches will diminish light output. Store the cables in sterilization trays for additional protection.
- Any inadvertent cut or puncture to the outer sheath will render the cable unsafe. It should be taken out of service immediately.

MAINTENANCE

Follow all applicable bloodborne pathogen procedures as indicated by OSHA and /or your hospital requirements when cleaning, disinfecting, and sterilizing instruments and accessories.

Cleaning (other than UltraLite® headlight cables*):

Lukewarm water with mild detergent is recommended to remove all blood and debris. (Do not use synthetic detergents or oil-based soap, as these chemicals may be absorbed into the cable and could subsequently leak out and cause tissue reactions.) Rinse thoroughly with distilled water, taking care to rinse the face of glass fiber at both ends of the cable.

Cleaning (UltraLite® headlight cables*):

Luxtec suggests the use of alcohol wipes to clean the UltraLite® and Sweatband headlight cables.

Disinfecting (other than UltraLite® headlight cables*):

Cables may be soaked briefly in disinfecting solutions without damage. Refer to the manufacturer's time specifications; however, avoid soaking cables for more than 10 minutes.

Disinfecting (UltraLite® headlight cables*):

Soaking the UltraLite® and Sweatband headlight cables in any sterilizing disinfectant should be avoided. There is a lens assembly at the light source end, which is not sealed and could allow moisture to penetrate behind the lens.

Sterilization (other than UltraLite® headlight cables*):

RECOMMENDED STERILIZATION METHODS

STEAM

Hospital Steam Sterilizer compliant to AAMI ST8

Place clean and dry cables in a steam sterilization self seal pouch or compatible container.

Temperature: 270°F (132 °C)

Exposure Time: 4.0 Minutes

Drying Time: 20.0 Minutes

ETO (ethylene oxide)

Place clean and dry cables in a ETO self seal pouch or compatible container.

ETO concentration- 100%

Exposure time – 60 minutes

Temperature- 131 °F (55 °C)

Aeration- 8 hours minimum

STERIS SYSTEM

Place clean and dry cables in a self seal pouch or compatible container.

Steris 20™ Sterilant Concentration

Place a Peracetic acid Chemical Indicator and cable in tray and secure lid.

Place tray into the STERIS SYSTEM I®

Exposure Time: 12.0 Minutes

CIDEX PLUS® 28 day Solution

Clean and dry the cable taking care not to scratch any of the optical surfaces.

Follow the manufacturer's instructions to prepare the CIDEX PLUS® Sterilant to the manufacturer's recommended effective concentration. Use the CIDEX PLUS® solution test strip to verify effectiveness of the sterilant.

Submerge Cable in CIDEX PLUS

Allow thorough soak for 10 hours at 68 -77 °F (20- 25 °C)

Dry per manufacturer's recommendations.

Sterilization (UltraLite® headlight cables*):

The UltraLite® fiber optic cable has not been specifically designed to withstand sterilization. There is a lens assembly at the light source end, which is not sealed, and could allow moisture to penetrate behind the lensing.

Meticulous care should be taken to avoid cable contact with sharp or pointed objects.

Ensure your autoclave is operating correctly for effective sterilization. Consult your autoclave manual for specific instructions, conditions and exposure periods.

The pressure differential, which occurs during steam autoclaving, may cause small bubbles in the tubing. These bubbles will not affect the fiber optic cable and will dissipate in time.

Following sterilization of your fiber optic cable, allow it to cool very slowly to room temperature. **DO NOT** immerse or rinse in a cold liquid, as this will cause fiber breakage and extensive light transmitting losses.

REPAIR AND RETURN INFORMATION

Indications for replacement:

1. When a fiber optic cable shows 30% loss of light transmission of its fibers, the cable needs to be replaced. This can be determined while holding both ends of the cable: point one cable end toward a light while looking at the other end. **DO NOT PERFORM THIS CHECK WHILE THE FIBER OPTIC CABLE IS ATTACHED TO AN OPERATING LIGHT SOURCE.** The brilliant light output can cause severe eye discomfort.
2. When there is separation of the cable components that can be seen with a visual inspection, such as strain relief and sheath or endfittings.
3. When a cable has been excessively stretched or cut.

Contact your local LUXTEC representative to order replacement cables or call Luxtec customer Service Department at 1-800-325-8966 (USA & Canada) or at +1-508-835-9700.

ATTENTION: OPERATING ROOM PERSONNEL

We require that you clean and sterilize (if compatible) all equipment before returning for repair. If equipment is received in an unsanitary condition, an additional cleaning fee will be charged, including those pieces repaired under our warranty. Please note on shipping packaging if contents have not, or cannot be sterilized.

LIMITED EXPRESS WARRANTY

LUXTEC warrants that the fiber optic cable furnished hereunder shall be free from defects in material and workmanship under normal use and service for a period of eighteen (18) months from the date of shipment from LUXTEC, excluding fiber breakage. LUXTEC Premium UltraLite® headlight cables feature a lifetime warranty against browning.

LUXTEC's sole and exclusive liability under this warranty shall be, at LUXTEC's option, either to repair or replace any component of the cable which fails during the warranty period due to any defect in workmanship or material F.O.B. factory if:

- (1) customer promptly reports such defect to LUXTEC in writing,
- (2) if requested by LUXTEC, customer returns equipment to LUXTEC with shipping charges pre-paid and
- (3) upon inspection, LUXTEC finds the cable to be defective.

This warranty is contingent upon normal and proper use of the cable and does not cover fiber breakage or a cable which has been modified without written approval of LUXTEC, subjected to unusual physical stress, or damaged during shipment. This warranty is nontransferable unless authorized in writing by LUXTEC.

If LUXTEC is unable to remedy any defect in the cable as required by the foregoing warranties, LUXTEC's liability shall not in any event exceed the purchase price received hereunder by LUXTEC for the equipment.

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* UltraLite® and Sweatband headlight cables can be identified by the curved lens at the light source end.



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THE INSTRUMENT PEOPLE

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