Integra® Luxtec®
Fiber Optic Headlight Cables

Integra Luxtec Fiber Optic Headlight Cables
for use with high power surgical light sources
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Indications for use

This fiber optic headlight cable is designed to deliver illumination from a high intensity light source to a surgical headlight 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. This device is intended to be used by professional users.

Fiber optic headlight cables should never be used in ocular surgery or in a surgical procedure requiring direct illumination of the eye.

See instructions for use for light source being used to ensure compatibility.

This device is CE marked in accordance with the Medical Devices Directive 93/42/EEC.
Symbols

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

- Attention: Consult Accompanying Documents
- Caution: High Voltage
- High Temperature
- Refer to Instruction Manual
- Equipotentiality
- Protective Earth
- Humidity Limitation
- Temperature Limitation
- Atmospheric Pressure Limitation
- Keep dry
- Part Number
- Batch Code
- Serial Number
- Authorized Representative in the European Community
- Manufacturer
- Date of Manufacture
- This device meets CE requirements
- Certified by CSA
- Consult Instructions for Use
- Fuse
- Alternating Current
- Type CF Equipment
- Type BF Equipment
- Do Not Dispose
- On / Off
- Stand-by
- System Status Display
- System
- Push
- Hours
- Intensity
- Motor
- Fan
- Over Temperature
- Lamp
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.

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.

• 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 cleaned and maintained.

• Care should be taken to follow the maintenance and cleaning instructions.

• Excessive bending of the cable should be avoided.

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 a 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 unprotected 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 headlight 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 that are provided to keep the headlight cable secured to the surgeon’s gown for greater comfort and maneuverability.

• Do not use your fiber optic cable with any alterations to its original design or fabrication.

• Keep the optical faces from contacting the floor or other hard surfaces. The resulting scratches will diminish light output.

• 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 (UltraLite® headlight cables*):
Wipe the fiber optic cable sheathing with a water dampened paper towel, cloth, or gauze before using 70% Alcohol as the disinfectant.

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 (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 lens.

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

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

Indications for replacement:
1. When a fiber optic headlight cable shows 30% loss of light transmission of its fibers, the cable should 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 Integra representative to order replacement cables or call Integra customer Service Department at 1-800-431-1123 (USA & Canada) or at +1-914-789-7094.

ATTENTION: OPERATING ROOM PERSONNEL
We require that you clean 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

Integra warrants that the fiber optic headlight 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 Integra, excluding fiber breakage. Integra Premium UltraLite® headlight cables feature a lifetime warranty against browning.

Integra’s sole and exclusive liability under this warranty shall be, at Integra’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 Integra in writing,

(2) if requested by Integra, customer returns equipment to Integra with shipping charges pre-paid and

(3) upon inspection, Integra 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 Integra, subjected to unusual physical stress, or damaged during shipment. This warranty is nontransferable unless authorized in writing by Integra.

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

THE WARRANTIES SET FORTH HEREIN ARE IN LIEU OF ANY OTHER REPRESENTATIONS OR WARRANTIES. INTEGRA DISCLAIMS AND CUSTOMER WAIVES ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, ALL IMPLIED WARRANTIES OF MERCHANTABILITY FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL INTEGRA BE LIABLE TO ANY PARTY FOR INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER RELATED TO THIS OR ANY OTHER CLAIM, REGARDLESS OF ANY KNOWLEDGE OF INTEGRA OF SUCH POTENTIAL DAMAGES.

Disposal of the product, packaging material and accessories;

For disposal, observe the relevant regulations and laws valid in your country. For further information, please contact Integra.