Integra Luxtec®
UltraLite® Plus Headlight and Sweatband

Integra Luxtec UltraLite® Plus Headlight and Sweatband
For use with high power surgical light sources
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Indications for use
This fiber optic light guide system is designed to deliver illumination from a high intensity light source to a surgical headlight for surgical site illumination, either standard or minimally invasive. While the cable light source endfittings are compatible with all light sources, brightness and spot quality vary with specific types of light sources. The UltraLite® systems perform best with Integra® xenon light sources.

Any light source used with this cable should have a maximum output of 0.25W IR at the cable port to prevent cable and/or headlight damage during use.

The Ultralite® Plus Headlight System is intended to be used by surgeons in a surgical, clinical, or medical professional environment.
Symbols

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

- Caution
- Caution: High Voltage
- Caution: HOT
- 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

FIRE HAZARD: DO NOT DRAPE OR COVER THE LIGHT SOURCE OR THE LIGHT GUIDE WHILE IT IS OPERATING. DO NOT PLACE THE LIGHT GUIDE ON A DRAPE WHILE IT IS OPERATING.

CAUTION: The metal portions of the cable at the light source get hot during operation. Allow components to cool outside of the light source for at least 5 minutes before touching.

• The user of this product should be thoroughly familiar and trained in the use and care of this product.

• 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 manufacturer’s equipment when they are use in conjunction with this product.

• Before every procedure, carefully inspect the light guide cable to ensure it has been properly maintained, cleaned and sterilized (if compatible), and that it is fully functional.

• Any light source used with this cable should have a maximum output of 0.25W IR at the cable port to prevent cable and/or headlight damage during use.

• Light sources use high intensity lamps, which produce heat as well as brilliant light. The high brightness produced by the light source and the light output of the light guide cable can cause burns when used within 10 inches.

• 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 light guide directly at the eye while in operation. The brilliant light output can cause severe eye discomfort.

• A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to patient injury, illness, or death.

• It is the user’s responsibility to study the information provided in the operations and users manual with respect to set-up, use and care of this device. Instructions should be followed with special attention given to warnings, controls and specifications. Follow the manufacturer’s instructions for other devices not recommended by this manual when used in conjunction with the headlight system.

• Before using, carefully inspect the device to ensure it has been properly maintained and cleaned and that it is fully functional. DO NOT use if inspection reveals any damage such as case damage or loose connectors.

• It is the user’s responsibility to check the specifications of any light sources attached to this headlight System to verify that it can transmit the intense light output without generating high temperatures and heat build-up in the headlight system that can cause serious burns. Integra light sources are recommended for use with the headlight systems are listed in this manual.

• Ensure that the fiber optic light guide matches the port type of the light source, to prevent damaging the optical components of the light sources and to prevent the overheating of the fiber optic light guide connectors. The high intensity light at the connecting ends of the fiber optic light guides may become hot.

• When the light source is used to power a headlight system, it is recommended that a standard 16” working distance separating the headlight and the patient is maintained. Under no circumstances should the headlight be placed closer than 10” to any tissue or object.

• Take precautions not to place and rest a hot cable, metal end fitting, or headlight on a patient, patient drape, or come into contact with unprotected skin until all components are cooled for at least 5 minutes. Failure to do so can result in burns and or tissue damage.

• A risk of injury to tissue due to exposure to intense illumination may occur. The risk of injury is reduced by using the minimum level of illumination necessary, by minimizing exposure time, and by avoiding close stationary viewing. Thermal burns of tissue can occur with improper use of the device.

• Do not use this device for Ocular Surgery or in a procedure that requiring direct illumination of the eye.

• Do not look directly at the headlight or open end of the fiber optic cable. Permanent eye damage can occur.

• Do not immerse the headlight or cable in liquids.
Assembly

Assembly of the UltraLite® Plus Headlight System
The UltraLite® Plus headlight assembly consists of a headlight with a variable spot module, a cushioned headband or sweatband, bifurcated fiber optic cable and two gown clips.

To assemble, attach the headlight module by sliding the bottom of the module clip into the module receptacle, then push the top in until it makes an audible “snap” (Figure 1). To attach the joystick, thread it into the hole in the front of the headlight module.

To attach the fiber optic cable, insert the angled end of the cable into the headlight module until it snaps into place (Figure 2). A bifurcated cable fits into the cable clips on both sides and the rear of the headband or sweatband (Figure 3).

Remove the cable from the module by grasping the body of the module in one hand and the lower-most ridges of the cable in the other hand and pulling them axially apart. Do not hold the cable by its leg(s) or strain relief.

Remember, the cable is made of glass fibers. When adjusting the cable on the headband, do not bend the cable more than 60 degrees. The cable is designed to curve gently around the shape of the headband.

All illustrations are representative and may not reflect your actual model and accessories.
Assembly continued

Next, place the headband or sweatband on your head. You can make size adjustments on the headband by turning the knob at the rear of the headband until it fits comfortably. The cross band can be adjusted for even more comfort. Push out the tab and slide the band until the fit is correct, then replace the tab. The sweatband should be pulled to a comfortable tension and closed using the velcro strip (Figure 4).

To remove the module from the headband or sweatband, a small screwdriver is needed. Insert the screwdriver into the slot at the top of the module receptacle. Lift the handle of the screwdriver and the module will slide out.

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Caution: To plug or unplug the fiber optic cable from the light source, it is recommended that the light source power be turned off. Be sure to hold the strain reliever near the end of the cable. This part of the cable is reinforced to prevent damage to the glass fibers inside, and to prevent burns.

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Adjustments

Once the headlight module and fiber optic cable are attached to the headband, the headlight assembly is ready to use.

The headlight module can be adjusted while wearing the headlight system by grasping the joystick. The joystick can be removed for autoclaving or to prevent misaligning the headlight module when working in close quarters. The iris adjustment varies the spot size from 20mm to 100mm (0.8 to 4 inches) at a 40 cm (16 inch) working distance (Figure 1a).

The headlight system comes with two gown clips to relieve the weight of the cable from the headband. The upper clip is attached to the surgical gown just below the shoulder (Figure 5). Be sure to leave enough slack in the cable to allow for freedom of head movement. If the surgeon needs to detach the cable from the light source, the lower gown clip is used to attach to the surgeon’s gown. This reduces the risk of dropping or tripping over the cable.

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CAUTION: The metal portions of the cable at the light source get hot during operation. Allow components to cool outside of the light source for at least 5 minutes before touching.

Integra manufactures its headlights to the highest quality standards. Each one is tested thoroughly before leaving the factory to ensure proper working conditions.

These instructions should help you get started with your new Integra equipment, quickly and easily. If you have any problems, please contact the Integra Service Department, 1+(914)-592-9050 (USA only), or +33 (0) 4 37 47 59 10, fax 1+(914)-592-8056, or integralife.com.
Replacement Parts for Ultralite® Plus Headlight

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AX1375BIF</td>
<td>Headband with Ultralite 2 bifurcated cable, Ultralite module and extended linkage</td>
</tr>
<tr>
<td>AX1385BIF</td>
<td>Sweatband with Ultralite 2 bifurcated cable, Ultralite module and extended linkage</td>
</tr>
<tr>
<td>AX1375BIFSL</td>
<td>Headband with Ultralite 2 bifurcated cable and Ultralite module</td>
</tr>
<tr>
<td>AX1385BIFSL</td>
<td>Sweatband with Ultralite 2 bifurcated cable and Ultralite module</td>
</tr>
<tr>
<td>AX1175SBIF</td>
<td>Headband with Ultralite 2 bifurcated cable and Ultralite module</td>
</tr>
<tr>
<td>001170BIF</td>
<td>Replacement headband for AX1175SBIF</td>
</tr>
<tr>
<td>001190</td>
<td>Module (gray)</td>
</tr>
<tr>
<td>001190EL</td>
<td>Module (gray) with extended linkage</td>
</tr>
<tr>
<td>001270BIF</td>
<td>Replacement headband for AX1375BIF or AX1375BIFSL</td>
</tr>
<tr>
<td>001290</td>
<td>Sweatband for bifurcated cable</td>
</tr>
<tr>
<td>0023009</td>
<td>Replacement cable bifurcated (add 0023009G for gray cable)</td>
</tr>
<tr>
<td>0029009</td>
<td>Ultralite 2 bifurcated cable</td>
</tr>
<tr>
<td>400282</td>
<td>Replacement kit pad for headband</td>
</tr>
<tr>
<td>400286</td>
<td>Joystick for 001190, pack of 3</td>
</tr>
</tbody>
</table>

Care and Maintenance

All Headlight Systems:
To ensure long life for the headband, cable, and modules, they should be stored in the duffel bag or case provided. 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 which 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 include endoscopic use)

- Do not use your fiber optic cable with any alterations to it’s 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 silicone tube will render the cable unsafe. It should be taken out of service immediately.

Cleaning Modules:
The headlight module may be wiped down with alcohol. The lens should be cleaned only with lens tissue available at any camera store. Follow the package directions.

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

Cleaning Joystick (only):
The joystick can be removed from the module for autoclaving.

Cleaning Sweatband:
The sweatband may be cleaned using standard wash cycles in warm water and mild detergent. Air dry.

Cleaning Headband:
The headband may be cleaned by an alcohol wipedown or washed with lukewarm water and mild detergent. Rinse thoroughly with water.

Cleaning Cable:
Wipe the fiber optic cable sheathing with a water dampened paper towel, cloth, or gauze before using 70 % Alcohol as the disinfectant.

Disinfecting Cable:
Soaking the UltraLite 2 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 lensing.

Sterilizing Cable:
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.

WARNING: Do not autoclave the headband, cables, sweatband or headlight modules.
Troubleshooting
For additional technical assistance, please contact the Integra Service Department, 1+(914)-592-9050 (USA only), or +33 (0) 4 37 47 59 10, fax 1+(914)-592-8056, or integralife.com.

Integra Headlight Warranty
Integra warrants that the equipment manufactured by Integra 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. Integra’s sole and exclusive liability under warranty shall be, at Integra’s option, either to repair or replace any component 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 paid by Integra and,
3. Upon inspection, Integra finds the equipment to be defective.

Integra Cable Warranty
Integra warrants that the cables 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. Integra’s sole and exclusive liability under this warranty shall be, at Integra’s option, either to repair or replace any components of the cable which fails during the warranty period due to workmanship or material F.O.B. factory if:

1. Customer promptly reports such a defect to Integra in writing,
2. If requested by Integra, customer returns equipment to Integra with shipping charges prepaid and,
3. Upon inspection, Integra finds the cable to be defective.

This warranty is contingent upon normal and proper use of the equipment. It does not cover equipment modified without the written approval of Integra, subjected to unusual physical or electrical stress, or damaged during shipment. This warranty is nontransferable unless authorized in writing by Integra. Integra reserves the right to make design changes on its products without liability to incorporate said change in Integra products previously designed or sold.

Upon receipt of the product, it should be carefully inspected. If any defect is discovered, notification must immediately be given to the manufacturer.

This warranty is contingent upon normal and proper use of the cable and does not cover:

• Fiber Breakage,
• Soaking of cable lens in sterilizing disinfectant, or autoclaving,
• A cable which has been modified without the written approval of Integra,
• A cable that has been subjected to unusual physical stress, or
• A cable that was damaged during shipment.

All of the above warranties are non-transferable unless authorized in writing by Integra. If Integra is unable to remedy any defect in the cable as required by the foregoing warranties, LUXTEC’s liability shall in no 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 OR MERCHANTABILITY AND FITNESS 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.

Repair and Return
Any device must be clean when returned to Integra. Integra reserves the right to return unrepaird any equipment that is contaminated with blood or other organic material.

To obtain service under warranty or return product for repair, the customer should contact the local Integra distributor or call Integra Customer Service at 1+(914)-592-9050 (USA only), or +33 (0) 4 37 47 59 10, fax 1+(914)-592-8056, or integralife.com.