



Fiberoptics Technology Inc  
1 Quasset Road  
Pomfret CT, 06258

Customer Service: 860-928-0443  
Toll Free 800-433-5248

**Printed copies are not controlled**

***This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.***



Wellkang Consulting  
 Suite B, 29 Harley Street  
 London W1G 9QR United Kingdom  
[+44\(20\)308 69438/32876300](tel:+44(20)3086943832876300)



# CONTENTS

CONTENTS .....2

INDICATION FOR USE .....3

WARNINGS / CAUTIONS .....4

INSPECTION OF UNIT PRIOR TO USE .....6

ASSEMBLING THE ILLUMINATION CABLE INTO THE HEAD LIGHT SYSTEM.....7

HANDLING .....11

CLEANING.....12

LIMITED WARRANTY .....13

***Printed copies are not controlled***

***This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.***

# INDICATION FOR USE

## **Congratulations on the purchase of your new Head Light system!**

The PureLight™ Fiber Optic Head Light system is designed to deliver illumination from a high intensity light source for surgical site illumination.

This manual will help you to install and integrate the head light with other components of your system. It will also illustrate best practice to:

- Make adjustments
- Keep your head light clean
- Provide necessary warnings for safe ownership and effective operation

This manual will also give you maintenance and service guidelines and recommendations for long lived, consistent performance.

***Printed copies are not controlled***

***This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.***

# WARNINGS / CAUTIONS



## CAUTION

Rx only. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.



## WARNING

The user of this product should be thoroughly familiar with the use and care of this product.



## WARNING

The user should carefully study this manual before making any attempt to use this product clinically.



## WARNING

Use of an illuminator with accessories or attachments requires that the end-user follow all illuminator and head light accessory or attachment instructions.



## CAUTION

**HOT SURFACE** The module may become warm during use; if uncomfortably warm, open the iris and reduce or suspend illuminator output.



## WARNING

Illuminators using high intensity sources will produce heat as well as light. The intense photonic output of such systems can cause burns and possibly start a fire if held in close proximity to a combustible source like a drape.



## WARNING

Use care to avoid pointing the light directly at anyone's eyes during operation as the brilliant light can cause severe eye discomfort.



## WARNING

**The metal end fittings of the fiber optic cable, and possibly the head light housing could become hot during operation. Allow to cool disconnected from the head light and the light source for at least five minutes before handling.**



## WARNING

**FIRE or INJURY HAZARD:** Light energy released by illuminators, used with fiber optic light guides, is transmitted through the cable and connected instrument or the cable end tip. The output of a connected headlight module or instrument,

or a bare end tip left in close proximity or contact with tissue or flammable materials presents a risk of burning, injury or fire. Qualified personnel must determine a safe working distance and intensity setting for each application. The light source and output should never be left on unattended.

 **WARNING**

The head light should never be brought closer than 12” to the patient without decreasing the light source output.

 **WARNING**

Do not force or overtighten the crown and headband adjustment knobs. Doing so could cause these adjustments to fail. Ensure the adjustment features are functional prior to every use.

 **WARNING**

While the headlight and cable should be cleaned prior to every use, following direction supplied within this manual. The headlight should NEVER be submerged. Submerging the headlight in any liquid could cause the headlight optics to fail.

 **WARNING**

The joystick mounted to the headlight optics allows the wearer to control the direction of the beam. NEVER remove the joystick for any reason; doing so could make direction adjustment unsafe if the housing gets too hot during use. Be sure to sanitize the joystick (and the entire headlight device) prior to every use.

 **WARNING**

The head light should be stored in original packaging when not in use to prevent damage to headlight components. The head light optics should always be capped when not in use to prevent entry of foreign particulates and damage to the optical lenses.

 **WARNING**

Check the condition of all comfort/perspiration liners and pads prior to every use. The pads should be clean and resist material flaking or sloughing. Replace pads/liners when necessary.

 **WARNING**

Only use OEM replacement parts/materials from the manufacturer or authorized dealer to maintain compliant functionality of this product. The use of counterfeit or substitute items voids the warranty.

# INSPECTION OF UNIT PRIOR TO USE

It is recommended that before each use of, the PureLight™ Headlamp System, the product be inspected.

After removing the headlamp carefully from its original packaging, review the following and adhere to suggested actions:

## Inspect For:

Damage to the frame/headband	Contact FTI Service for Repair
Damage to the linkage	Contact FTI Service for Repair
Damage to the optical housing	Contact FTI Service for Repair
Damage to the lens	Contact FTI Service for Repair
Damage to headlamp padding	Replace; Contact FTI Service to Order
Illumination cable tears	Contact FTI Service for Repair
Broken fiber in the illumination cable	Contact FTI Service for Repair
Damage to illumination cable's fiber surfaces	Contact FTI Service for Repair

## Ensure:

Cleanliness of the headlamp	Reference CLEANING on page 12
Cleanliness of the illumination cable's fiber surface	Reference CLEANING on page 12
Cleanliness of optical housings adapter port	Reference CLEANING on page 12
Crown and cranial adjustment knob mobility	Contact FTI Service for Repair
Linkage mobility	Contact FTI Service for Repair
Headlamp Iris freely opens and closes	Contact FTI Service for Repair

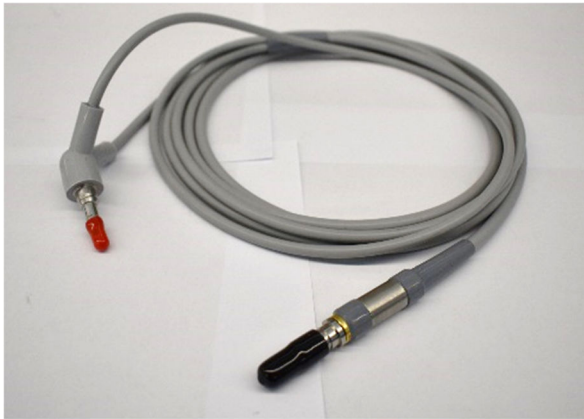
***Printed copies are not controlled***

***This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.***

# ASSEMBLING THE ILLUMINATION CABLE INTO THE HEAD LIGHT SYSTEM

**A bifurcated lightguide is recommended for maximum comfort when using the Pure Light™ Head Light system**

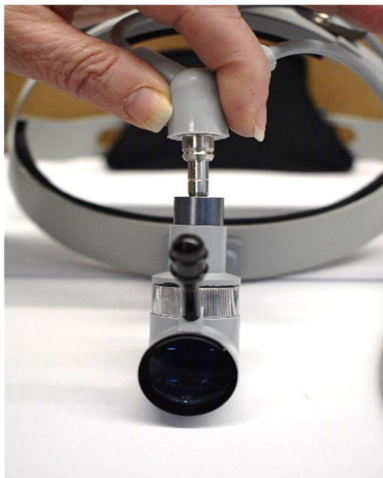
*Remove the rubberized protective caps from the light guide if they are present. Only use a bifurcated cable type designed for this head light. If you are unsure of the specific type, contact your supplier. FTI's standard cable type is FTIMG16500. [See Figure-1]*



[Figure-1]

To attach the fiber optic cable, insert the instrument end into the Head Light module until the clip engages. When properly seated there should be intimate contact with the silicone junction and the Head Light module band. See Figure-2 for reference.

[Figure-2]

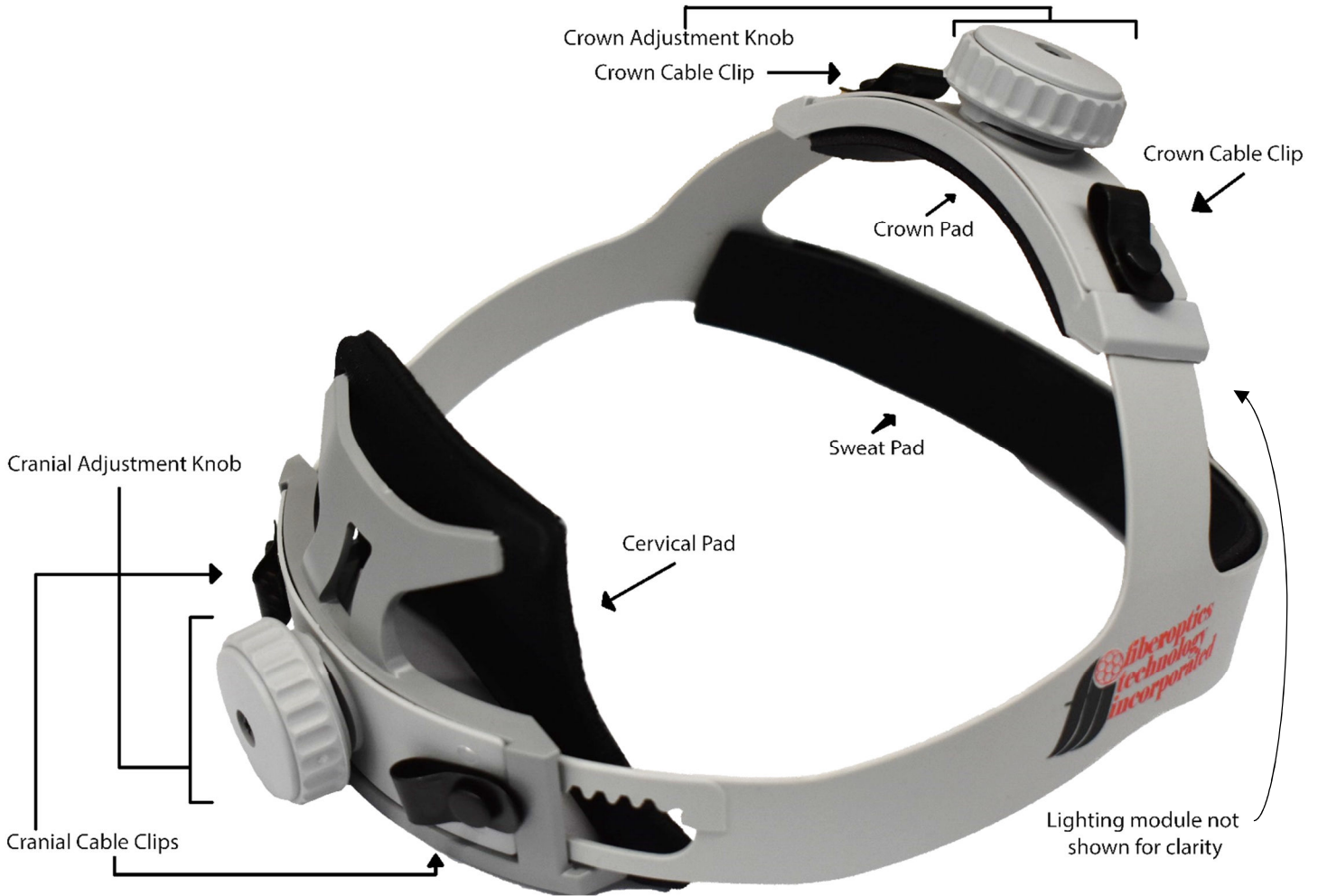


***Printed copies are not controlled***

***This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.***

Route each leg of the bifurcated cable into a cable clip on each side and at the rear of the headband. There are 4 clips on the headlight assembly, see figure-3.

[Figure-3]



[Viewed from rear of the headlight]

***Printed copies are not controlled***

***This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.***



**NOTE:** The fiber optic cable is made of glass fibers. When adjusting the cable on the headband, do not bend the cable at an angle of more than 60 degrees.

**NOTE:** Always remove the cable from the headlight by pulling from the cable junction or end-tip band.

To remove the cable from the head light module, grasp the headlight module in one hand and the silicone junction of the cable in the other and pull apart. Do not pull the cable by its legs.

**RIGHT**

[Figure-4]

**WRONG**



The optical housing of the module in one hand and the silicone junction in the other hand prior to pulling the two apart.



NEVER pull on the cable by the silicone legs to remove the headlight or detach from the illuminator.

Silicone junction

***Printed copies are not controlled***

***This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.***

Once the cable is connected to the headlight, the joystick should be threaded onto the headlight module and used to align and position the module. See figure-5 for reference.

**NOTE:** The disposable joystick is not prepackaged sterile. It should be wiped down with alcohol prior to use.

[Figure-5]



Next, place the headband on your head with the Rear Cranial Support sitting comfortably on the back of your head; you can make size adjustments by turning the cranial adjustment knob on the rear of the headband until it feels comfortable. Then adjust the top crown adjustment knob on the Coronal strap for more comfort.

The system comes with gown clips to relieve the weight of the cable from the headband. How many gown clips and gown clip usage are subject to change depending on personal preference. One gown clip can be attached below the shoulder; along with another clip connected to the surgeon's gown near



***Printed copies are not controlled***

***This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.***

the lower back. This eliminates the risk of tripping or dropping the illuminator end. Illustration shown in figure-6.

Insert the light guide into the illuminator and turn on the illuminator.

With continued illumination, the headlight module will become warm. Fiberoptics Technology has integrated an advanced heat management design to mitigate extreme temperatures during extended use. See temperature data on figure-7 under troubleshooting.

**CAUTION: The metal portion of the fiber optic cable at the light source gets warm during operation. Allow cooling for a minimum of five minutes before touching.**

## HANDLING

Fiber optic cables are optical instruments and *[Figure-6]* fully.

The following guidelines will help maximize the Head Light system's useful life:

1. Store the PureLight™ Head Light system in proprietary original packaging and cap the optical lens when not in use.
2. Forming the cable in sharp angles and kinks should be avoided whenever possible. The internal fibers are made of glass, which will break under these conditions.
3. Keep the optical faces of the cable from touching hard objects, which may cause scratches on the fiber surface. Scratches on the fiber surface will diminish light output.
4. When cuts or punctures are visible in the silicone tubing, the cable is no longer safe to use. Damaged cables should be taken out of service immediately.

# CLEANING

The Head Light module can be wiped down with alcohol.

The lens should be cleaned only with lint free cloth.

Any existing debris inside the light housing module's adapter port should be cleaned out using a Q-Tip and alcohol.

The Illumination cable's fiber surface should be cleaned using a Q-Tip or lint free cloth and alcohol.

Follow all applicable bloodborne pathogen procedures as required by OSHA and/or your hospital when cleaning/ disinfecting your headlight.

The absorbent headlight system pads may be cleaned using a standard wash cycle in warm water and mild detergent.

The PureLight™ system, including frame and headband pads, can be cleaned by hand using an alcohol wipe or washed with a lukewarm solution of water and mild detergent. Rinse thoroughly.

**WARNING:** Do not steam autoclave or submerge lensed fiberoptic cables or headlights. Steam will enter the cable/headlight housing and moisture will condense between the lens and the cable when it cools. When heated again in use, the water will evaporate, leaving water spots that can degrade performance and cause a damaging hot spot. Consult with your sales representative to determine whether your light guide contains a lens.

## REPLACEMENT PARTS

Item	Part number
Fiber Optic cable, Bifurcated.....	FTIMG16500
Gown Clips (Quantity 4).....	M158159
Joy Sticks (Quantity 2).....	M158167
PureLight™ Breathe-o-Prene Liner, 3pc Set.....	M161379

## LIMITED WARRANTY

Your PureLight™ Head light carries a 2-year warranty from the date of shipment on workmanship and all defects of material, excluding replaceable padding, clips, fiberoptic cables and lamps. Should your product prove to have a defect within two years of shipment, **Fiberoptics Technology** will repair or replace the product or component part without charge. Should your fiber optic product(s) need servicing under this warranty, please contact **Fiberoptics Technology** for return authorization documentation.

You should carefully pack unit in its original packaging, or a sturdy carton and ship it to the factory. Please include a note describing the defects, your name, telephone number and a return address, along with the return authorization code clearly marked. Warranty is limited to defects in material and workmanship. Warranty does not cover equipment subject to misuse, accidental damage, or normal wear and tear. Warranty cannot be transferred to a new owner without authorization from Fiberoptics Technology. This warranty gives you specific legal rights and you may also have other rights that vary from state to state.

**POST WARRANTY REPAIRS:** You may return your product(s) for repair, shipping prepaid to the factory. Your product will be evaluated, and an estimate of repair charges will be submitted to you for approval. Payment must be received before repairs are completed.

### Telephone:

**Toll free Sales** ..... 800-433-5248

**Sales Outside US** ..... 001-860-928-0443

**Service**..... 860-928-1236

***Printed copies are not controlled***

*This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.*

To Request an RMA ..... 800-433-5248

**FAX number:**








Sales ..... 860-928-7664

Toll Free Service ..... 888-928-4362

Outside US ..... 001-860-928-7664

Email ..... service@fiberoptix.com

**CHART OF MEDICAL DEVICE SYMBOLS USED**

	Manufacturer
	Symbol for "Authorized Representative in the European Community."
	Caution, consult accompanying documents
	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)
	Consult Instructions for Use
	CE mark
	Caution: Hot Surface

***Printed copies are not controlled***

***This document and all information contained herein is protected as confidential, proprietary, and trade secret, and solely the property of Fiberoptics Technology Inc. Use of this document is strictly controlled by written agreement. Anyone receiving this document without explicit written authorization from Fiberoptics Technology, Inc. shall not use this document for any purpose and shall immediately contact Fiberoptics Technology Inc.'s Compliance Officer at 860-928-0443.***