



SUNOPTIC SURGICAL®

Headlamp System Operation and Service Manual



CE



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1. INDICATION FOR USE

Congratulations on the purchase of your new Headlamp system.

This fiber optic headlamp system is designed to deliver illumination from a high intensity light source for surgical site illumination.

This Operator Manual will help you to install the device and optimally integrate it with other components of your system. It will also instruct you how to make adjustments, how to keep it clean, and sterilize it. It will give you maintenance and service guidelines as well as recommendations for best performance results.

2. 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 this illuminator with accessories or attachments requires that the end-user follow all accessory or attachment instructions which could affect illuminator setup, usage and/or settings.



CAUTION: HOT SURFACE The module may become warm during use; if uncomfortably warm, open the iris and adjust illuminator output.



WARNING Light sources using high intensity lamps will produce heat as well as light. The high output of such systems can cause burns. 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 get hot during operation. Allow to cool outside the light source for at least five minutes before touching.



WARNING FIRE or INJURY HAZARD: Energy released by illuminators used with fiber optic light guides is retained in the cable and transmitted through a 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 injury or fire. Qualified personnel must determine a safe working distance and intensity setting for each application. The output should never be left on unattended.

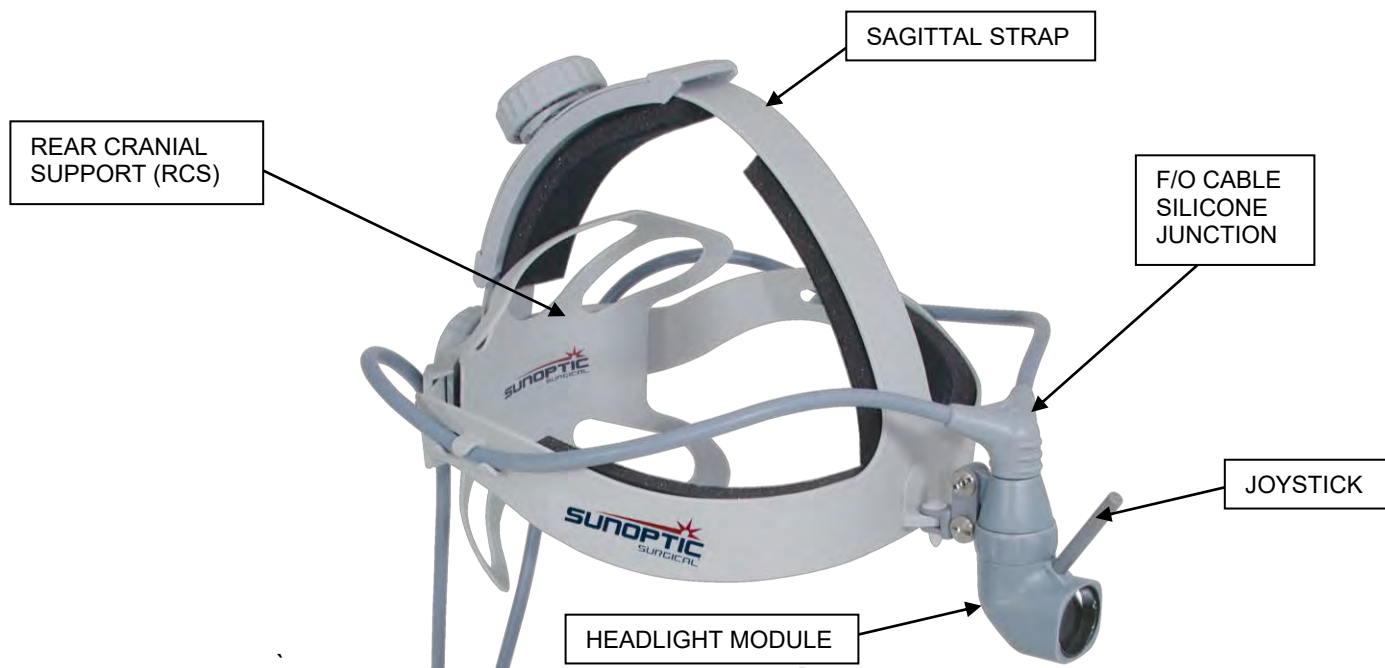


WARNING Do not expose this product to temperatures in excess of 140°C or product damage may occur.



WARNING Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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



3. ASSEMBLING THE HEADLIGHT SYSTEM

Before continuing remove the protective caps.

To attach the fiber optic cable, insert the instrument end into the headlamp module until it snaps in place. A bifurcated cable fits into the cable clips on both sides and rear of the headband.

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

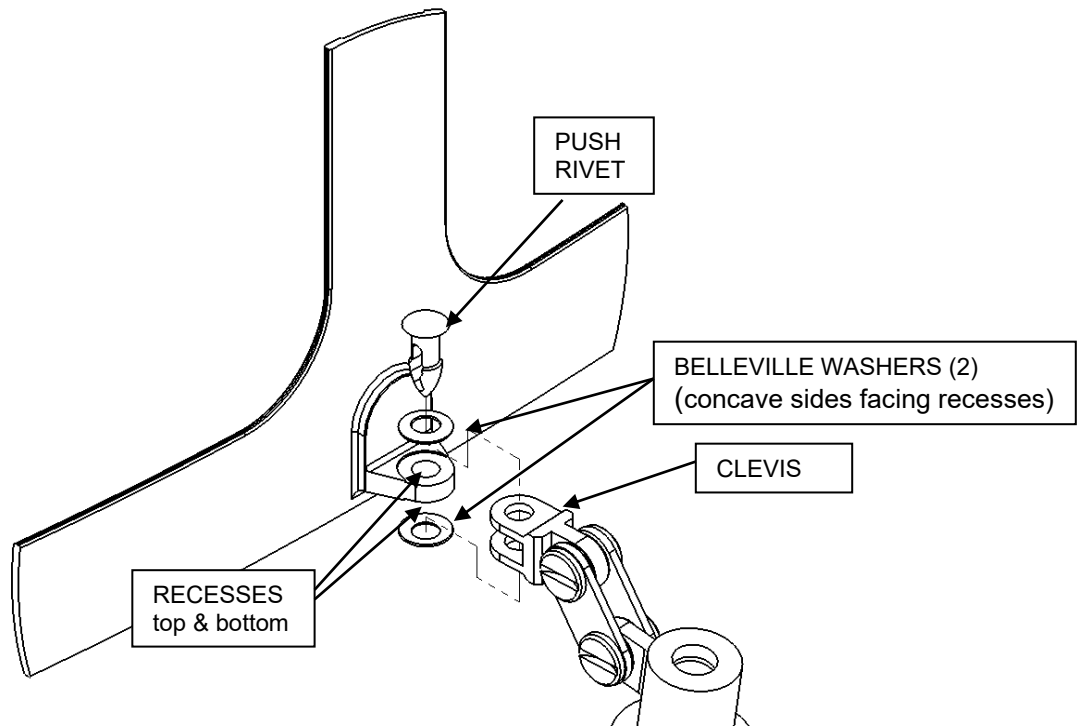
Remember, the fiber optic cable is made of glass fibers. When adjusting the cable on the headband, do not bend the cable at an angle of more than 60 degrees.

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 knob on the rear of the headband until it feels comfortable. Then adjust the top knob on the Sagittal strap for more comfort.

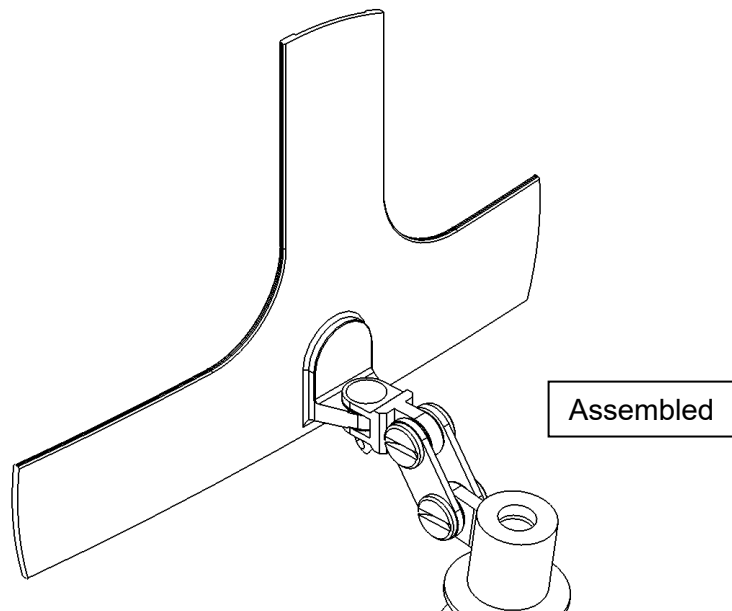
Once the headlamp module and cable are connected, the unit is ready for use. The headlight is provided with two prepackaged joysticks. The joystick is to be threaded onto the headlight module as shown in fig.1 and used to align and position the module.

The system comes with gown clips to relieve the weight of the cable from the headband. One gown clip is attached below the shoulder; the other is used to connect the cable to the surgeon's gown. This eliminates the risk of tripping or dropping the illuminator end.

When replacing Headlight Module:



Position Belleville washers in recess of mounting ear. Engage clevis of headlight into place. Align parts and push plastic rivet into place.



CAUTION: The metal portion of the fiber optic cable at the Lightsource gets hot during operation. Allow cooling for a minimum of five minutes outside the illuminator before touching.

4. MAINTENANCE

Storing the headlamp system in a safe place will prolong the life of the unit.
Fiber optic cables are an optical instrument.

The following guidelines will help in sustaining the headlamp systems useful life:

- 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.
- Keep the optical faces of the cable from touching hard surfaces, which may cause scratches on the surface. Scratches on the surface will diminish the light output.
- When cuts or punctures are visible in the silicone tubing the cable is no longer safe to use, it should be taken out of service immediately.

5. CLEANING

The headlamp module can be wiped down with alcohol. The lens should be cleaned only with lens tissue, available in any camera store, follow the directions on the package.

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

The sweatband and soft “sport” headband may be cleaned using a standard wash cycle in warm water and detergent.

The headband can be cleaned with a alcohol wipe down or washed with a lukewarm solution of water and mild detergent. Rinse thoroughly.

Do not steam autoclave lensed fiberoptic cables. Steam will enter the cable 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 the cables performance and can cause a damaging hot spot.

WARNING: Do not autoclave the Headband, Lensed Cables or Sweatband.

6. REPLACEMENT PARTS

Item	Part number
Fiber Optic cable, Bifurcated with lens	SU-0080
Fiber Optic cable, Straight with lens	SL-0060
Duffel Bag	SL-0025
Garment Clips (Quantity 10)	SL-0016
Joy Sticks (Quantity 10)	SL-0013
Titan/Solar Plus Sport Band (Quantity 2)	SPORT2
Titan/Solar Plus headband	SL-0200
Comfort Liner, Set	SL-0040


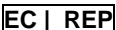












7. LIMITED WARRANTY

Your fiberoptic product(s) carry a 3-year warranty from the date of shipment on workmanship and all defects of material, excluding replaceable sweatbands, headband, fiberoptic cable and lamps. Should your product prove to have such defects within three years of the shipment, **Sunoptic Technologies®** will repair or replace the product or component part without charge. Should your fiberoptic product(s) need servicing under this warranty, please contact **Sunoptic Technologies®** for return authorization documentation. You should carefully pack unit in a sturdy carton and ship it to the factory. Please include a note describing the defects, your name, telephone number and a return address. Warranty does not cover equipment subject to misuse, accidental damage, normal wear and tear or if transferred to a new owner without authorization from **Sunoptic Technologies®**. 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 inspected and an estimate of repair charges will be submitted to you for approval. Payment must be received before repairs are completed.

- Telephone: toll free 877-677-2832
- FAX number: 904 733-4832
- Customer Service: 904 737-7611

8. 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
	Medical device
	Non-Sterile
	Storage / Shipping Temperature
	Storage / Shipping Humidity
	Barometric Pressure
	Unique Device Identifier
	Keep Dry