



CoreLink[®]

FIBEROPTIC CABLES INSTRUCTIONS FOR USE

Manufactured for:
CoreLink, LLC
2072 Fenton Logistics Park
Fenton, MO 63026

Phone: 1-888-349-7808

Manufactured By:
Sunoptic Technologies
6018 Bowdendale Avenue
Jacksonville, FL 32216

PLEASE READ BEFORE USE

Failure to follow these instructions could render the device unusable and void any warranty.

Device Description

CoreLink fiberoptic cables are designed to deliver maximum light when coupled to a medical grade fiberoptic light source. **CoreLink** fiberoptic cables can be used with quartz halogen, metal halide, or xenon light sources. They are compatible with virtually all endoscopes, medical instruments, and microscopes.

Intended Use

This device is designed to illuminate a surgical site by relaying light from a fiberoptic light source onto the desired site. **CoreLink** cables are medical grade, high transmittance, peak efficiency.

NOTE: The style of cable suitable for a given lightsource can be determined from the table below.

	Standard Cable	Clad Rod Cable	Lensed Cable	Fused Cable
Cuda / Sunoptic 250W Halogen	X			
Other 250W Halogen		X		
Focused Ceramic Xenon		X		X
Other Xenon ≤ 300W	X		X	
Xenon >300W				X
Metal Halide ≤ 75W	X			
LED 4000				X

- For use with Xenon lightsources, be sure lightsource is filtering at least 90% of infrared radiation (IR) to prevent high heat.
- The following adaptors can be used with the CoreLink fiberoptic cables.

6230-007	UNIVERSAL ADAPTOR - ACMI
6230-006	UNIVERSAL ADAPTOR - OLYMPUS
6230-004	UNIVERSAL ADAPTOR - STORZ
6230-005	UNIVERSAL ADAPTOR - WOLF

Contraindications

This device has no contraindications of which we have knowledge.

Warnings and Precautions 

- **CoreLink** light cables are provided non-sterile and must be sterilized before use. See instructions for cleaning and sterilization.
- Prior to use, instruments must be inspected for signs of wear, damage, and proper function. If an instrument is suspected to be damaged, please contact CoreLink for a replacement.
- There are no intended patient contact materials. If contact occurs, the materials it will come in contact with are stainless steel, silicone, or epoxy.

- Always inspect cables for any evidence of damage prior to use. Pay particular attention to optical surfaces looking for scratches or dings.
- Use caution to treat **CoreLink** cables as you would any fine optical device.
- The user of this product should be thoroughly familiar and trained in use and care of the product.
- Match the cable size to the endoscope. Using a larger cable (fiber bundle size) than the endoscope requires will result in overheating the endoscope's proximal end.
- Light loss and warmer than normal instrument temperatures may be encountered if using a light source fiber optic cable with a larger aperture or bundle diameter than the instruments receiving aperture or bundle diameter.
- **FIRE or INJURY HAZARD:** Energy released by illuminators used with fiber optic light guides is retained in the cable and transmitted to a connected instrument through the cable end tip. The output of a connected instrument or 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.

Adverse Events

We have no knowledge of any adverse events with this product.

Cleaning of headband, headlight and headlight cable.

Exterior surface of headband and module can be wiped clean with 70% Isopropyl alcohol or mild soap. Headlight cable is not to be steam autoclaved. Autoclaving will cause damage to the non-sealed Proximal end of the cable which has a lens on it. The headlight cable can be wiped in same process as the headband and module.

Cleaning and Sterilization of Fiberoptic Light Guides

Cleaning

Fiberoptic light guides for endoscopes, microscopes, and surgical instruments are high quality optical devices. They require similar care to that taken for any precision optical component. After each use, the light guide should be washed and cleaned of all debris. A soft brush and mild detergent should be used to clean the device. Pay particular attention to any crevices or seams. Avoid any harsh materials or detergents that can scratch or in any way damage the optical surfaces on each end of the light guide. **CoreLink** recommends the following Steam Sterilization (Autoclave) guidelines:

Automated cleaning (full cycles)

The device shall be run through a hospital grade full cycle. The minimum parameters for the full cycle are as follows:

Motor Speed High [USA Parameters]			
Phase	Recirculation Time [Minutes]	Temperature	Detergent Type and Concentration
Pre-Wash 1	02:00	Cold Tap Water	NA
Enzyme Wash	03:00	Hot Tap Water	Enzol®, 1 oz/gal (Neutral pH 7.8-8.8)
Rinse 1	00:15	Hot Tap Water 60°C	NA
Drying	06:00	90°C	NA

Steam Sterilization (Autoclave)

The cycle selected is dependent on equipment and hospital protocol. General guidelines are:

METHOD	CYCLE	MINIMUM TEMPERATURE	EXPOSURE TIME
Steam (wrapped)	Prevacuum	270 deg. F (132 deg. C)	4 minutes
Steam (wrapped)	Gravity	270 deg. F (132 deg. C)	10 minutes
Steam (wrapped)	Gravity	250 deg. F (121 deg. C)	45 minutes

The above sterilization parameters have been validated and are effective. Materials used in construction will withstand temperatures of 134C up to the times listed with no know adverse impact.

Chemical Disinfection

It is recommended that the guidelines below published by Advanced Sterilization, a Johnson & Johnson company be followed.

Product	High Level Disinfection Sterilization	Sterilization
Cidex Activated Dialdehyde Solution	45 minutes @ 25 degrees C 77 degrees F	10 Hours
Cidex Plus 28 Day Solution	20 minutes @ 25 degrees C 77 degrees F	NA

Steris Sterilization

Follow Steris Corporation Guidelines

Sterrad Sterilization

Follow Sterrad (a J&J Company) Guidelines

Limited Warranty









Your fiberoptic cable has a one (1) year warranty from the date of shipment on workmanship and all defects of material except for broken fiber. Should your product prove to have such defects within one (1) year of shipment, **CoreLink** will repair or replace the product or component part without charge.

Should your fiberoptic cable need servicing under this warranty, please contact your distributor or your customer support specialist for return authorization documentation. You should carefully pack the product in a sturdy carton, including a note describing the defects, your name, your company name, telephone number and a return address. Warranty does not cover equipment subject to misuse, accidental damage, and normal wear and tear. This warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

Post warranty repairs

Please contact your distributor or your customer support specialist for return authorization documentation.

Chart of medical device symbols used

	Caution, consult accompanying documents
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Keep product dry
	Batch code / lot number
	Consult Instructions for Use
	Nonsterile
	Catalog, reorder or reference number
	Do not use if package is damaged