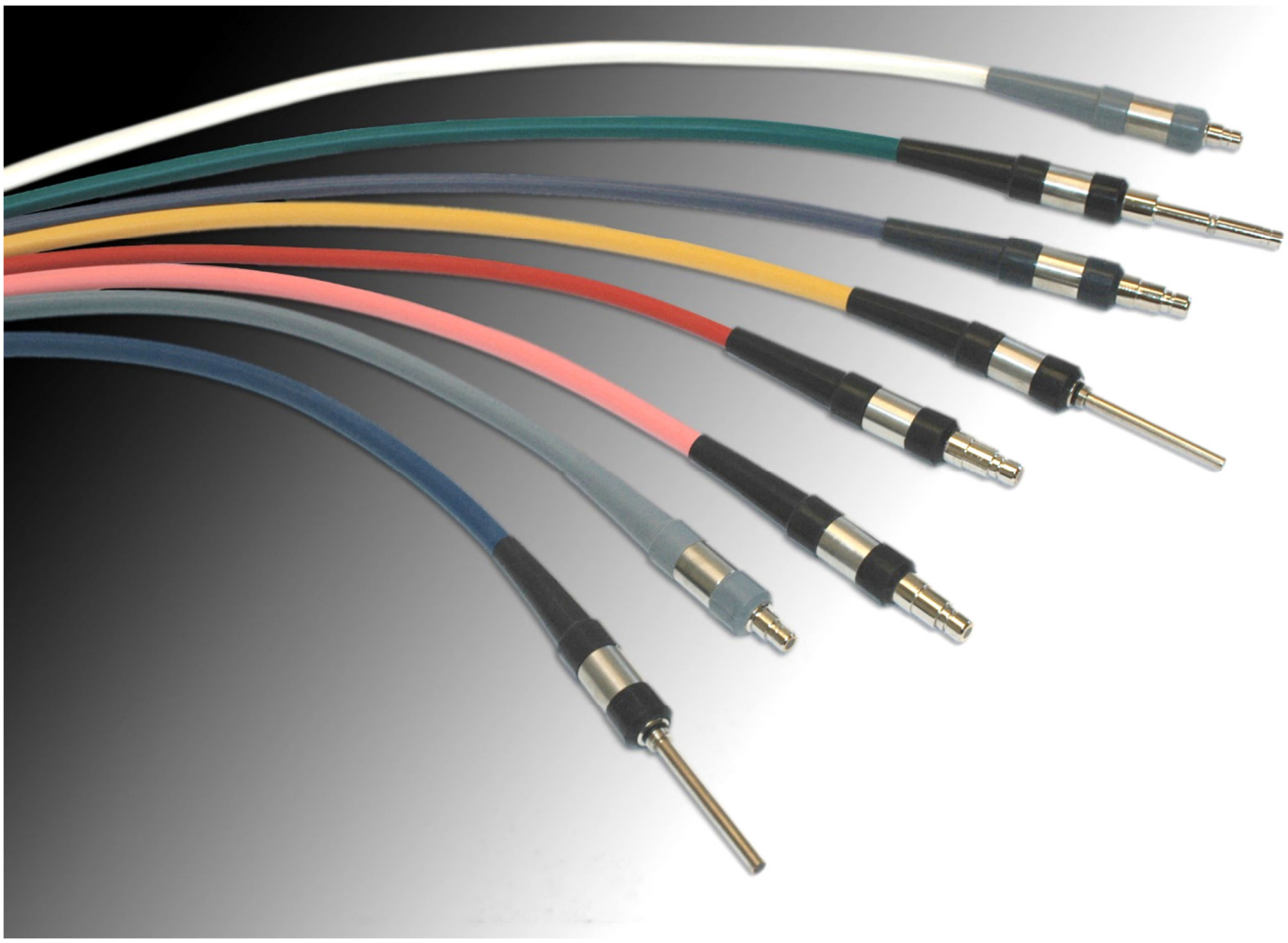
Fiberoptics Technology Inc.
Fiberoptic Cable (Medical Light Guide)



(*Photo for illustration purposes only. Packaged product may not resemble any of the included images.)

Usage, Maintenance and Sterilization Instructions

Contents

Indications for Use

The Fiberoptics Technology light guide is designed to provide illumination to a surgical site by efficiently transferring light from a fiber optic light source to an appropriate surgical instrument, endoscope (all types) or surgical headlight.

The light guide may be used with compatible halogen, metal halide, xenon and LED light sources.

⚠ **WARNING:** 300 watt or greater xenon light source should have at least 90% IR filtering to prevent damage to light guides.

⚠ **WARNING:** Make sure the fiber optic active diameter matches the fiber optic size of the scope instrument to ensure maximum light transmission and minimize end fitting temperature (Figure 1). Use the instrument manufacturer's recommendations for light guide sizing to minimize scope or headlight fitting temperature. For headlights, make sure the port ID matches the Light guide OD configuration (Figure 2).

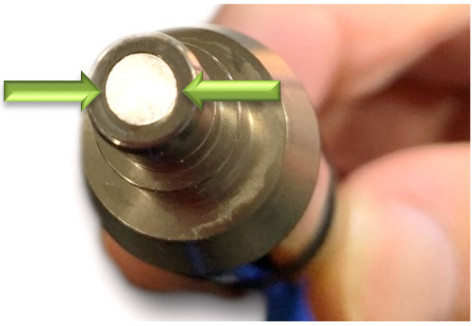


Figure 1 - Fiber optic active diameter – diameter of the fiber bundle (between the arrows) should match the active diameter of the mating scope post.

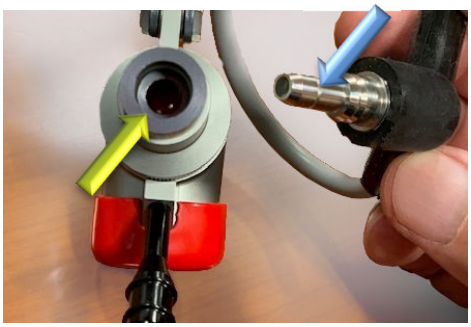


Figure 2- For headlights, make sure the light guide post (On the right), securely mates with the instrument port (on the left). Some headlight instruments use a light guide with a lens (Figure 10). Consult your headlight manual to assure proper cable configuration.

NON STERILE **WARNING:** The light guide is provided non-sterile and must be sterilized before use. See cleaning and sterilization instructions elsewhere in this manual.

Instructions for Use

1. Verify end fitting port connections match light guide end fitting configuration. **DO not force** the connection at either end (Figure 3).
2. Attach light guide to light source and instrument per each manufacturer's instructions.
   Note: Verify all connections to light source and instruments are secure before use.

WARNING: Light emitted from light guide contains significant energy. The temperature of the end fittings is affected by the light source and instrument. End fitting surfaces may exceed 50°C during or immediately following operation.

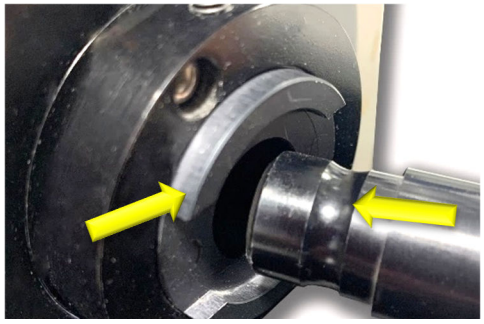


Figure 3 – The Light guide end fitting (on the right) and the light source port should mate with little effort – DO NOT force the connection or use the system if the connection is loose or not fully connected.

WARNING: When connected to an operating light source, unintended light exposure from a light guide may result in burns or cause fire (figure 4).

NEVER operate the light source and light guide unless an instrument is attached. Do not allow the instrument end to directly contact tissue or other heat sensitive materials. Do not place the exposed instrument end on or near drapes, gowns or other textiles. Do not contact patient directly. Do not use for transillumination.

Allow light source end fitting to cool, and avoid touching the metal part after use if possible. Handle the light source end by firmly grasping the handle only (figure 6).

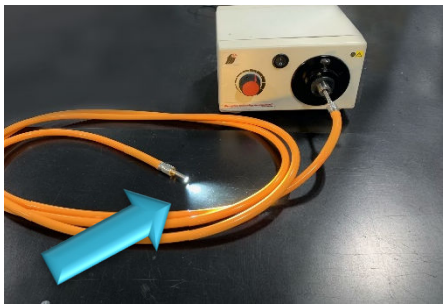


Figure 4 - Energy from detached light guide is strong enough to cause burns and start fires. Always use the lightguide attached to a device.

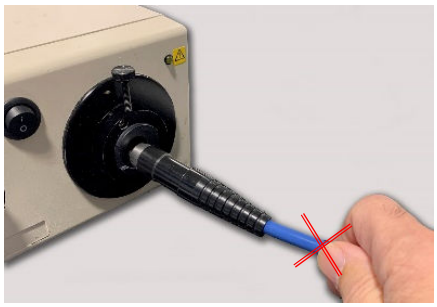


Figure 5 – NEVER remove the light guide by pulling on the cord!

Figure 6 - Always grasp the light guide end fitting by the handle to remove the lightguide from the light source and instrument.

NEVER pull on the light guide by grasping the soft flexible jacket (Figure 5). Firmly grasp the hard "rubber" end fitting handle and carefully pull with minimum force required to disengage the light guide (Figure 6). Pulling on the jacket will cause separation of fitting and jacket (Figure 9).

CAUTION: The fiber optic cable is a precision optical instrument. Do not cut, stretch, kink, puncture or otherwise damage or alter the cable. Any of the preceding abuses will reduce light transmission and/or effect user and patient safety. Discard or repair if damage.

CAUTION: Do not drop the end fittings or allow them to strike any hard surface. Doing so could cause the glass fiber.

Preventative Maintenance/Quality Checks

This medical light guide has been engineered with quality materials and designed for long life. With proper care, the light guide should perform for 200 autoclave cycles, assuming the user follows all recommended procedures.

In addition, the following should be checked before and after every use.

1. Inspect the cable length for cuts tears, kinks, perforations, or crushed sections. Remove from service if any observed defects are found (Figures 7 & 9 examples).
2. Check the ends of the light guides for cracks in the polished fiber face(s) (Figure 8). Cracks caused by dropping the cable or cracks formed from excessive heat (improper installation) will allow moisture to enter the light guide housing. Moisture will erode the performance of the light guide and contribute to premature failure.

3. To maximize performance, clean ends of both fiber faces with an alcohol swab before every use.
4. Avoid storing the cables in a tight coil. (Coil diameter greater than 12" is recommended.)
5. Do not allow light guides to submerge in any liquid.
6. Check to ensure the connection integrity of the metal fitting and silicone jacket at each end; they should not separate (Figure 9).
7. Some light guides include a lens. Check to make sure the lens is intact with no cloudy appearance (Figure 10).

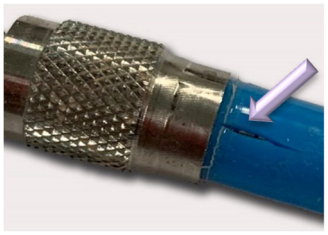


Figure 7 - This sheathing has a tear, it should be removed from service.

Figure 8 –The Glass portion of the end tip should be inspected for cracks that could occur from mishandling or excessive heat. If you see a crack, remove the light guide from service.

Figure 9 - The sheathing has been pulled away from the end tip, most likely caused by improper handling. Remove this light guide from service

Figure 10 - Medical headlight cable with a lens. Check to make sure the lens is secure, clear, with no cracks.

Cleaning

The Fiberoptics Technology, Inc (FTI) light guide may be cleaned using alcohol, a mild soap or non-oil cleaner with a pH range of 5 to 9 .

⚠ **CAUTION:** DO NOT use synthetic detergents or oil-based soaps. The petroleum components of these soaps may be absorbed by the silicone rubber components and may leach out during use to cause a tissue reaction.

⚠ **CAUTION:** Do not use abrasives to remove debris.

⚠ **CAUTION:** Avoid scratching glass fibers at ends of light guide (Figure 8). Damage to fibers may reduce light transmission.

1. Clean thoroughly using a soft-bristled brush and lukewarm water-soap solution to remove any possible contamination.
2. Rinse thoroughly in lukewarm water.
3. Rinse thoroughly in distilled water.
4. Allow to air dry or re-sterilize, per facility policy.

Autoclaving and Steam Sterilization

⚠ **CAUTION: DO NOT use a HIVAC sterilizer unless necessary.** It may cause the silicone tubing to expand excessively.

⚠ **CAUTION:** Remove the fiber optic cable from the sterilizer and allow to cool slowly to room temperature**.**

⚠ **CAUTION: DO NOT immerse or rinse HOT fiber optic cables in cold water or liquid.** This may cause glass breakage which may reduce light transmission.

GRAVITY DISPLACEMENT STEAM STERILIZATION:

- Gravity displacement sterilizer, 121°C
- Cable wrapped in an instrument tray or fully perforated sterilization box.
- 30minute exposure time
- 20minute dry time

PRE-VAC "FLASH" STEAM STERILIZATION (CAUTION: FOR URGENT USE ONLY)

- Pre-vacuum sterilizer
- Cable unwrapped in an instrument tray or fully perforated sterilization box.
- 3 preconditioning pulses
- Minimum temperature: 132°C
- 4 minute exposure time

Note: tubing may appear collapsed.

STERRAD®

- Use the manufacturer's instruction for operation.
- Do not sterilize in sterilization pouches. Doing so may result in damage to device.

ETHYLENE OXIDE (EtO)

- Wrapped
- 100% EtO (725-750mg/l)
- 1 hour 45 min exposure at 54°C
- 12 hour aeration at 54°C

Limited Warranty and Repair

This fiber optic cable is warrantied to be free from defects of material and workmanship to the original purchaser for a period of 12 months from the date of purchase. This warranty is limited to the repair or replacement of the fiber optic cable. All inquiries / requests for warranty repair or replacement must be made to:

Fiberoptics Technology, Inc.
1 Quassett Road
Pomfret, CT 06258 USA

Phone (800) 928-5248
Facsimile (860) 928-7664
www.fiberopticstech.com

All returns for repair or replacement must be pre-approved. Contact our Sales Administrator through the above listed phone number or make a request through our website (above) to obtain a Return Material Authorization (RMA.) FTI will not accept responsibility for items returned without an RMA.

The warranty does not cover damage resulting from misuse, mishandling, or use or processing outside of recommendations in this user instruction. No other warrantees are expressed or implied.

REGULATORY (SYMBOLS AND INFORMATION)

	Manufactured By: Fiberoptics Technology Inc. 1 Quassett Rd. Pomfret, CT 06258 USA
	EU Declaration of Conformity Provided by Manufacturer's Authorized EC Representative (see below)
	Wellkang Ltd. 1 Beraghmore Road Derry, Northern Ireland BT48 8SE Northern Ireland, United Kingdom
	Consult these Instructions prior to use
	Consult Accompanying Document(s)
	Do not use if outer packaging is damaged
	Non-sterile as originally manufactured / shipped
	Rx Only; This device should only be sold to, or by the order of, a licensed healthcare practitioner
	Device will be Lot or Serial Number controlled