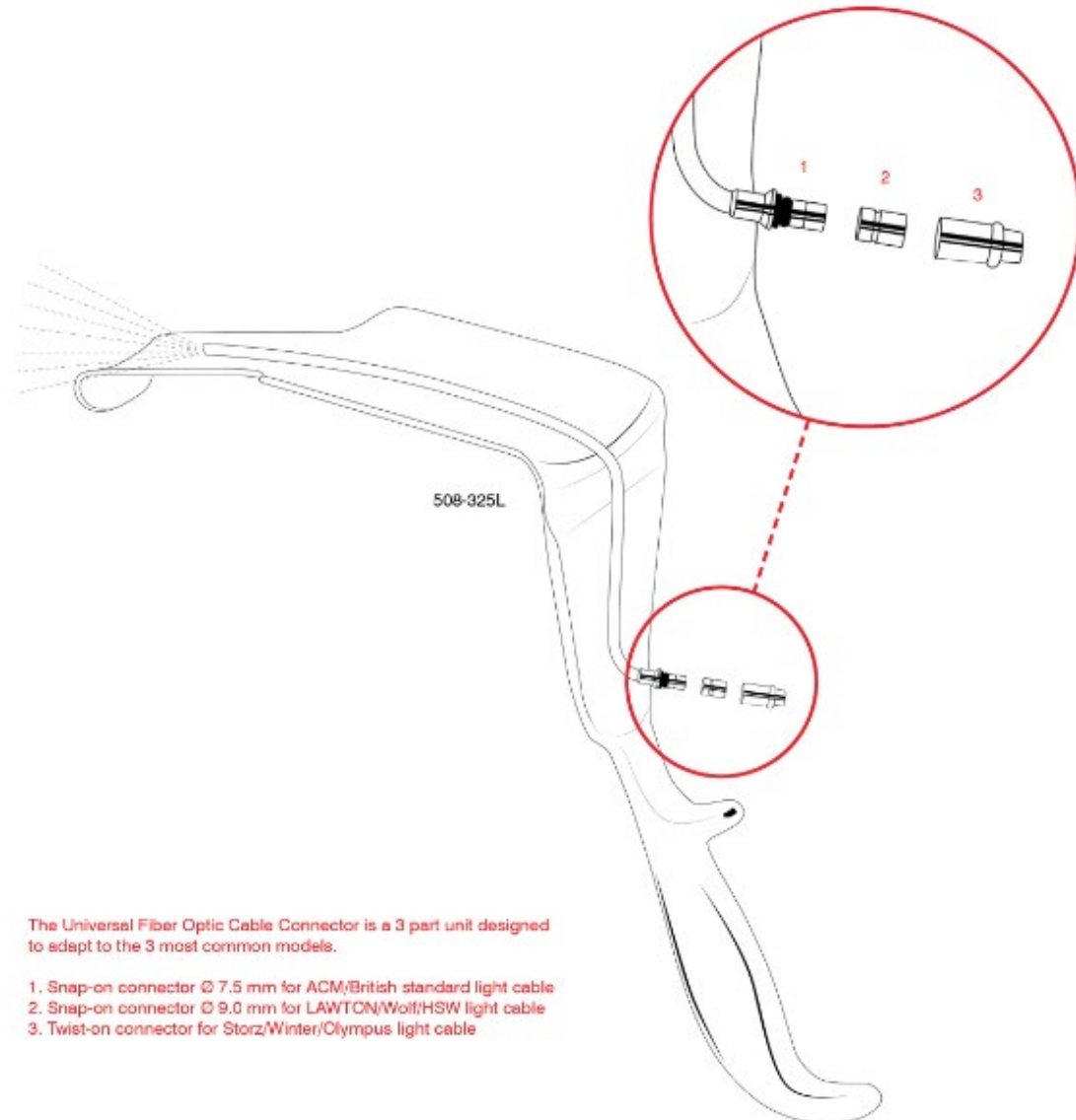


## INSTRUCTIONS FOR USE

### HANDHELD INSTRUMENTS WITH FIBER OPTIC LIGHT CARRIER





The Universal Fiber Optic Cable Connector is a 3 part unit designed to adapt to the 3 most common models.

1. Snap-on connector  $\varnothing$  7.5 mm for ACM/British standard light cable
2. Snap-on connector  $\varnothing$  9.0 mm for LAWTON/Wolf/HSW light cable
3. Twist-on connector for Storz/Winter/Olympus light cable

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

**Device Description:**

Fiber-optic handheld instruments are designed to deliver maximum light when coupled to a medical grade fiber-optic light source.

**Intended Use:**

This device is designed to illuminate a surgical site by relaying light from a fiber-optic light source onto the desired site.

**Contraindication:**

This device has no contraindication of which we have knowledge.

**Warnings and Precautions:**

- Light cables are usually provided by the manufacturer non-sterile and must be sterilized before use. See instructions from the manufacturer for proper handling, cleaning, and sterilization.
- 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 cables and handheld instruments as you would any fine optical device.
- The user of this product should be thoroughly familiar and trained in the use and care of the product.
- **FIRE HAZARD:** Never drape or cover the end of any fiber-optic cable with anything flammable.

**Adverse Events:**

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

**Recommended Care and Handling from most fiber-optic cable manufacturers:**

The optical glass fibers in the fiber-optic cable can be irreversibly damaged by careless handling. Follow the steps below to maximize the life of the cable:

- 1) Coil the fiber-optic cable in a six inch diameter or greater.
- 2) Keep cable free of foreign material.
- 3) Do not pull, stretch, or kink the cable.
- 4) Do not allow the cable to come in contact with any sharp edges or pointed objects.
- 5) Do not alter or remove end fittings.
- 6) Do not pre-vacuum high temperature autoclaves.
- 7) Allow the cable to slowly cool after autoclaving. Do not immerse in any cold liquid.

**Cleaning and Sterilization of fiber-optic light cables and fiber-optic handheld instruments:**

**Cleaning:**

Fiber-optic handheld instruments for endoscopes and microscopes are high quality optical devices. They require similar care to that which is taken for any precision optical component. After each use, the instrument 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.

We recommend following the guidelines contained in ASTM F 1518-00 “Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera.” Although written specifically for endoscopes, much of it applies to light cables and handheld instruments with fiber-optic light carriers.

**Steam sterilization (Autoclave):**

The cycle selected is dependent on equipment and hospital protocol.

**General guidelines are:**

Method	Cycle	Sterilizing Temperature	Sterilizing Time	Drying Time
Steam (wrapped)	Pre-vacuum	270 deg. F (132 deg.C)	4 minutes	20-40 minutes
Steam (wrapped)	Gravity	270 deg. F (132 deg.C)	10 minutes	20-50 minutes
Steam (wrapped)	Gravity	250 deg. F (121 deg.C)	45 minutes	20-50 minutes

**Chemical Disinfection:**

Prepare a disinfectant bath according to the disinfectant manufacturer. Place the instruments in the disinfectant bath and observe the specified soak time. Rinse the products thoroughly with fully demineralized water to remove the disinfectant without residue.

**Limited Warranty:**

Your instrument has a three (3) year warranty from the date of shipment on workmanship and all defects of material. Should your product prove to have such defects within one (1) year of shipment, we will replace or repair the product or component part at our discretion without charge.

**Warning:** If this device is/was used in a patient with or suspected of having **Creutzfeldt-Jakob Disease (CJD)**, the device **cannot be reused** and must be destroyed, due to the inability to reprocess or sterilize sufficiently to eliminate the risk of cross-contamination!