# CLEANING & STERILIZATION PARAMETERS

## 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 requests for warranty repair or replacement must be made to:

Ambler Surgical
730 Springdale Drive
Exton, PA 19341 USA

All returns for repair or replacement must be pre-approved. Contact address above to obtain a Return of Material Authorizatio (RMA.) Ambler Surgical 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.

## Fiberoptic Cable (Light Guide)

### Intended Use

Ambler Surgical 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, laparoscope or surgical headlight.

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

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

NOTE: Careful matching of fiber optic cable bundle size to instrument will ensure maximum light transmission and minimize end fitting temperature. Use the instrument manufacturer's recommendations for light guide sizing to minimize scope fitting temperature.

NOTE: The light guide is provided non-sterile and must be sterilized before use. See cleaning and sterilization instructions

### INSTRUCTIONS FOR USE

1. Verify mating connections are compatible with light guide.
2. Attach light guide to light source and instrument per each manufacturer's instructions.

Note: Verify all connections to light source and instruments are firm before use.

WARNING: Light emitted from this light guide contains significant energy. When connected to operating light source, unintended contact with the light from a light guide not attached to a device may result in burns. Do not allow distal end to directly contact tissue or other heat sensitive materials. Do not place on or near drapes, gowns or other textiles. Do not contact patient directly. Do not use for transillumination.

The temperature of the end fittings is affected by the light source and scope. These surfaces may exceed 50°C during operation.

Allow light source end fitting to cool, or avoid contact after use.

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

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## Cleaning

Ambler Surgical light guide may be cleaned using a mild soap or non-oil cleaner.

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: Avoid scratching glass fibers at ends of light guide. Damage to fibers may reduce light transmission.

NOTE: Use a mild cleaning solution with a pH range of 5 to 9.

1. Clean thoroughly using a soft-bristled brush in a 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.

## Sterilization

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

PRE-VAC “FLASH” STEAM STERILIZATION

CAUTION: FOR URGENT USE ONLY
o Pre-vacuum sterilizer
o Cable unwrapped in an instrument tray or fully perforated sterilization box.
o 3 preconditioning pulses
o Minimum temperature: 132°C
o 4 minute exposure time
Note: tubing may appear collapsed

STERRAD®
o Use the manufacturer’s instruction for operation.
o Do not sterilize in sterilization pouches. Doing so may result in damage to device.

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