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Description of Product Family

- FTI Medical Light Guides accommodate all major medical end fittings, a wide variety of silicone sheathing colors and lengths, and varying active area glass bundle sizes. All custom variations specified by a customer can be accommodated in the design. The selection of sizes, colors, lengths and medical device compatibility is nearly endless.
- Used to convey light from light source as a Light Carrier (FDA Class I) to Endoscopes, Arthroscopes, Lighted Instruments, Microscopes and other devices.
- FTI Medical Light Guides are compatible with common cleaning, sterilization and processing methods.

Intended Device Use, Functions, Where Used with What and By Whom

- FTI Medical Light Guides are intended to effectively conduct light from a light source to a lighted instrument, such as an endoscope, surgical headlight or a number of other medical devices.
- FTI Medical Light Guides are **not** intended as diagnostic or treatment equipment
- The product is typically used in a private doctor or dentist office, clinic, surgical center, hospital operating room, mobile hospital, emergency medical care center, and a host of other arenas.
- FTI Medical Light Guides are most always used with dedicated fiber optic light sources and dedicated lighted instruments as mentioned above.
- This product is used, in a professional manner, by trained and certified health care professionals to support diagnostic or treatment procedures.

Components, Specifications, Packaging and Literature (and RoHS Information)

- Nickel Plate aluminum or stainless steel end fittings to accommodate all major medical instruments
- Silicone flexible sheathing USP Class VI Medical Grade
- Borosilicate or silica optical fiber
- Active bundle diameter – varies upon customer requirement
- Wavelength output – 400nm-700nm
- Numerical Aperture - .25 to .66



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- Length – varies upon customer requirement
- Packaging typically includes individual plastic bag, but can also vary upon customer request including but not limited to foam lined box, custom printed box, and heat-sealed plastic.
- Literature exists as an FTI [User's Manual](#) in English, German, French, Spanish and Italian. Special customer required spec sheets and user manuals may be used in place of the FTI [User's Manual](#).
- RoHS Compliant per exemptions 13a and 29 of RoHS Directive 2011/65/EU

The Manufacturing Process

- Manufacturing of new Medical Light Guides begins with the drawing of the raw fiber as outlined in [QSP-071](#). The assembly of light guides, as outlined in [QSP-028](#), follows. Potting, [QSP-015](#) or [QSP-016](#), and grinding and polishing, [QSP-017](#), are then conducted. The finished product is then cleaned per [QSP-067](#), and then ready for packaging per customer requirements.
- Manufacturing/Repair of used light guides begins with the repair evaluation, as outlined in [QSP-019](#). Repair of the evaluated light guide is then assembled per [QSP-020](#), potted per [QSP-015](#) or [QSP-016](#), and ground and polished per [QSP-022](#). The finished product is then cleaned per [QSP-067](#), and then ready for packaging per customer requirements.

Process Validation Methods

- Fiber drawing validations are conducted using the following:
 - [QSP-011 – Calibration System Procedure](#)
 - [QSP-036 – Training and Developmental Needs Procedure](#)
 - [QSF-040 – Vertical Feed Rate Chart](#)
 - [QSF-042 Fiber Lot Number Record](#)
 - [QSF-067 – Fiber Drum Calibration Form](#)
 - [QSF-068 – Fiber Drum Screw Feed Rate Measure Form](#)
 - [QSF-081 – Fiber Conformance History Log](#)
 - [QSF-084 – Fiber Drum Maintenance Log](#)
 - Any other relevant work instructions
- Assembly, Potting, Grinding and Polishing, and Cleaning validations are conducted using the following:
 - [QSP-009 – Non-Conforming Material Procedure](#)
 - [QSP-011 – Calibration System Procedure](#)
 - [QSP-025 – In Process Inspection Procedure](#)
 - [QSP-026 – Final Inspection Procedure](#)



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- [QSP-027 – Contract Review Procedure](#)
- [QSP-036 – Training and Developmental Needs Procedure](#)
- [QSF-063 – Instrument Calibration Form](#)
- [QSF-092 – Packaging Specification Sheet](#)
- QSF-105 – Job Traveler
- All relevant engineered prints and work instructions
- Repair Assembly, Potting, Grinding and Polishing, and Cleaning validations are conducted using the following:
 - [QSP-011 – Calibration System Procedure](#)
 - [QSP-023 – Medical Repair QA Procedure](#)
 - [QSP-025 – In Process Inspection Procedure](#)
 - [QSP-036 – Training and Developmental Needs Procedure](#)
 - [QSF-063 – Instrument Calibration Form](#)
 - [QSF-092 – Packaging Specification Sheet](#)
 - All relevant engineered prints and work instructions

Accessories

- Nickel Plated aluminum or stainless steel clips, or inserts for adaptation to other medical instruments

Location of Design Responsibility and Manufacturing Facilities

- Design
 - Fiberoptics Technology Inc
1 Quassett Rd.
Pomfret, CT 06258
- Manufacturing Facilities
 - Fiberoptics Technology Inc
1 Quassett Rd.
Pomfret, CT 06258
 - Fiberoptics Technology Inc
4000 Domestic Ave.
Naples, FL 34164



Classification of the Device and Rationale

- Class I FDA Medical Device Listings [EQH](#) and [LXH](#)
- FDA 21 CFR Regulation:

§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

(a) *Identification.* An ear, nose, and throat fiberoptic light source and carrier is an AC-powered device that generates and transmits light through glass or plastic fibers and that is intended to provide illumination at the tip of an ear, nose, or throat endoscope. Endoscopic devices which utilize fiberoptic light sources and carriers include the bronchoscope, esophagoscope, laryngoscope, mediastinoscope, laryngeal-bronchial telescope, and nasopharyngoscope.

b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §874.9.
[51 FR 40389, Nov. 6, 1986, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 876.1500 Endoscope and accessories.

(a) *Identification.* An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anosopes, binocular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethrosopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, *fiberoptic illuminators for endoscopes*, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethrosopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

(b) *Classification.* (1) Class II (performance standards).

Route of Compliance

- Annual FDA Device Listing Registration – Registration Number 1222275

Shelf-Life, Operational-Life, and Environmental Limitations

- Shelf Life – 10+ Years
- Operational Life – Approximately 200 autoclave or sterilization cycles
- Extreme Heat – should not exceed exposure of more than 600 degrees Fahrenheit



Record Retention

- All Device History Files, Competent Authority and Notifying Body Records are retained at the following location:
 - Fiberoptics Technology Inc
Quality Assurance Department
1 Quassett Rd.
Pomfret, CT 06258

Medical Device Reporting Procedure

- [QSP-065 Advisory Notices and Reporting Procedure](#)

Other Design Input Specifications

- Target Market – Worldwide general purpose medical fiber optic lighting
- Efficiency – Transmit no less than 50% of accepted incident light to distal end of a 10 foot long medical light guide
- Provide minimum discoloration of light over ten feet
- Material – Must resist corrosion or discoloration, and withstand exposure to steam
- Safety – Material must not exceed 50 degrees Celsius during use at any user accessible surface.
- Weight – Varies upon design
- Labeling – As requested by customer
- Sterilization
 - Shipped non-sterile
 - Compatible with sterilization by steam autoclave and Ethylene Oxide
 - Compatible with disinfection by Steris 20 and Cidex (Glutaraldehyde)



References to Standards Adhered to

- Class I FDA Medical Devices 21 CFR 874.4350 and 876.1500 (referenced earlier)
- [ISO 13485:2003](#)
- [ISO 9001:2008](#)
- [93/42/EEC Medical Device Directive 2007 to enable CE marking](#)

Testing Results and Clinical Evaluations

- [Nelson Laboratories – Steam Sterilization Test Final Report February 8, 2011](#)
- [Microtest – Standard ETO Sterilization Test Report October 14, 2011](#)
- Other FTI Tests
 - Efficiency – Transmit no less than 50% of Accepted Incident light to distal end of 10 foot light guide
 - Results – Transmitted light measured at 58%
 - Provide minimum discoloration of light over ten feet
 - Results – Light became a bit more yellow when compared directly to input light. However, color appeared white when viewed separately.
 - Bundle diameter 0.5mm to 6.5mm
 - Test bundle was 4.8mm. Various bundle diameters available
 - Optical Output Numeric Aperture - .44, .55 and .64
 - Results – Test bundle was .64. Other NA glass optional
 - Flexible Materials must have USP Class VI or higher tissue compatibility
 - Results – All flexible components are made of USP Class VI material
 - Operate in 50 to 105°F (10 to 40.5°C)
 - Results – Light guide functioned normal at the temperature extremes
 - Operate in 30-80 % humidity (non-condensing)
 - Results – Light guide functioned normally at the humidity extremes
 - Must not present handling hazards.
 - Results – Handling and inspection of light guide show no sharp edges which could injure user or damage or degrade any surface or material to which light guide may come into contact.
 - Must not exceed 50°C during use at any user accessible surface
 - Results – No user accessible surface or component exceeded 50°C during testing or handling. (Note: During use, non-exposed areas will exceed 50°C. Warnings noted in IFU regarding post-usage handling.)



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Risk Analysis

- [FTI Medical Light Guide Risk Analysis Report](#)

Labeling

- [Label with CE Mark](#)

Marketing Material

- [Medical Cable Brochure](#)
- [Medical Cable Repair Brochure](#)
- [Medical Light Guide Sell Sheet](#)