Fiber Optic Microscope Cable

Instructions for Use and Cleaning

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1. Product Description / Intended Use

The fiber optic light cable is composed of an optical glass fiber bundle, silicone rubber or PVC sheath, and stainless steel connectors. The fiber optic light cable is a device designed to transmit light generated by an endoscopic light source to a microscope. The proximal end of the fiber optic cable connects with a light source and the distal end connects with a microscope.

The fiber optic cable is a device used with a light source and a microscope in order to provide illumination to a specific area of the patient's body during a medical procedure.

1.1 Indications

The fiber optic cable is indicated for medical use only, where a compatible light source and a compatible microscope are used.

1.2 Compatibility

The fiber optic cable covered in this document is compatible with Xenon light sources with power ratings up to 300 watts and LED light sources with light output equivalent to a 300 watt Xenon.

1.3 Connections

Gulf Fiberoptics provides a large range of fiber optic microscope cables with specific connections for each specific light source. Each distinct light source and microscope manufacturer has their own specific design for fiber optic cable connections.

Review the product identification located at the top of the product label inside the cable case before setting up the microscope system to make sure that your cable is compatible with both the light source and the microscope.

Warning

The cable is designed to be easily connected to devices for which it was designed. Do no try to connect the cable with a device if mechanical resistance is observed.

Make sure the cable connection is compatible with the Light Source and the Microscope before use.

2. General Warnings and Cautions

2.1 Read these instructions thoroughly before using the device.

2.2 Before using this device, read the user manuals of the other devices involved in the medical procedure to ensure compatibility. Cross reference the safety and technical information described in each user manual in order to eliminate any risk to the user caused by lack of technical compatibility between components and/or incorrect use.

2.3 Federal Law of the United States of America restricts this device to use by, or on order of, a physician.

2.4 The fiber optic cable is designed to continuous use under normal conditions of use. Observe the mode of operation of the light source and the microscope before start the medical procedure.

2.5 This device is a non-sterile product. It is the responsibility of the user to clean this device prior to the first use and after every subsequent use. Follow the cleaning instructions provided in this document.

2.6 Inspect the device after unpacking it to ensure it was not damaged during shipment and storage.

2.7 Test the device before each procedure / use. If the device appears to malfunction DO NOT use the fiber optic cable and contact your distributor or Gulf Fiberoptics to repair or replace the device.

2.8 Take the device out of the service immediately in the event that there is a failure of any of the device connectors or if a puncture or other damage is found in the outer sheath.

2.9 The light source emits high energy light which is transmitted to the instrument by the fiber optic cable. The distal end of the fiber optic cable and the surfaces near the instrument connection can exceed 105.8^{o}F (41^{o}C) if the system is operating at high levels of light intensity and long periods of time. The heated areas can cause burns to the patient or user. The light output of the microscope or fiber optic cable can cause burns to skin tissue and is capable of causing a fire if allowed to contact flammable material such as drapes, plastics, and papers.

2.10 Never use the fiber optic cable in the presence of any combustible gas.

2.11 Never look into the beam of light or direct the distal end tip of the fiber optic cable or toward other people.

2.12 Replace the cable if the light transmission is compromised.

2.13 Do not modify this device in any manner. Modification of the device is strictly prohibited.

2.14 Carefully use the sheathing closest to the end tip to hold the cable while connecting and disconnecting the fiber optic cable. Make sure all retention devices are released and gently pull the sheathing nearest the end tip to disconnect. Do not abuse, puncture, pull, twist or otherwise alter the cable. Avoid stretching the cable and forming configurations involving sharp angles or kinks. Avoid contact with all sharp objects as they may damage the fiber optic faces or the protective sheath. Damage to any part of the cable is irreversible and any damage to the light fibers will compromise the light transmission.

2.15 In order to reduce the risk of skin burns wait five (5) minutes after turning off the light source to disconnect the cable.

2.16 Do not wash the cable or spray liquid onto the end tips of the fiber optic cable immediately after being used. Wait five (5) minutes for the end tips to cool before allowing any part of the cable to come in contact with any liquids.

2.17 It is recommended that a spare fiber optic cable is present at surgical site to replace the primary cable in case any issues arise.

2.18 Do not submerge the fiber optic microscope cable in any liquids. Submerging the fiber optic cable may cause permanent damage.

3. Setup

Warning

Read the User Manuals for the Light Source and Microscope before connecting the fiber optic cable to any devices.

Before setting up the system check the light source, microscope, and the fiber optic cable connections in order of make sure none of the connections are damaged or obstructed by other objects. Always make sure the cable connections are compatible with the light source and microscope connections. Using the cable with devices that have different connections than which are specified, may result in permanent damage to the cable or system.

3.1 Assembly

3.1.1 If the light source has multiple connection types set the light source to the correct connection type for the cable.

3.1.2 Insert the cable proximal tip into the light source light output port. Make sure the cable is tightly attached to the light output port.

3.1.3 Connect the distal tip to the microscope. Make sure the cable is tightly attached to the microscope connector.

3.1.4 Turn the light source on.

3.1.5 Adjust the light source intensity from 0% to 100% to make sure the intensity adjustment is functioning properly

3.2 Disassembly

3.2.1 Turn off the light source or set on the light source standby mode.

3.2.2 Wait five (5) minutes for the fiber optic cable to cool.

3.2.3 Use the sheathing nearest the end tip to remove the fiber optic cable from the light source output port, *pulling gently*. Make sure all retention devices are released and only pull gently. Excessive pulling may damage the fiber optic cable.

4. Processing

Warning

The fiber optic microscope cable is not intended to be sterilized or submerged into liquids. Do not use synthetic detergents, oil-based soaps or any other cleaner not designed and certified for medical use. The interaction of these products with the fiber optic cable can cause a chemical reaction modifying the original structure of the cable materials.

4.1 Caution

4.1.1 Never use any metal / abrasive brushes or pads to clean the fiber optic cable.

4.1.2 The fiber optic cable is a precision optical device; always handle the device with care.

4.1.3 Do not allow the end tips of the fiber optic cable to come in contact with any other items or surfaces as it may damage the end tips or the fiber optic face.

4.1.4 Failure to follow these instructions may void the warranty.

Caution

Fiber optic cables are not intended to be cleaned using alkaline cleaners (pH above 10). They will be damaged by alkaline cleaners and must be cleaned with enzymatic cleaners per the instructions.

The processor is responsible for the device preparation process. It is highly recommended that the processor observe any applicable standards or local standards before conducting any medical device reprocessing.

It is the responsibility of the processor to ensure the cables are processed properly (using validated methods, correct equipment, proper materials, trained personnel, etc.).

4.2 Equipment and Materials

4.2.1 The processor is responsible for selecting the correct methods to process the cable.

4.2.2 The processor is responsible for observing the local standards that regulate medical device processing for re-use and application of the practices that cover the standard requirements.

4.3 Inspection and Preparation for Cleaning.

4.3.1 Fiber optic cables are delicate medical devices and must be used and handled with care. If cleaning is required it is recommended that fiber optic cables are cleaned as soon as reasonably possible following use. Observe valid protective measures to prevent contamination of the surrounding environment. When properly performed, cleaning will not compromise the mechanical integrity or performance of the fiber optic cable.

4.3.2 If there is liquid inside the cable sheathing do not use the cable. In the event that liquid is discovered in the cable classify the cable as a defective device and replace it immediately. After classifying the cable as a defective device follow the organizational methods to discard the cable.

4.4 **Cleaning**

4.4.1 Fiber optic cables require similar care to that taken for any precision optical component.

4.4.2 A moist cloth or soft bristled brush moistened with a neutral pH enzymatic cleaner or mild soap and water is recommended to remove visible debris. Wipe or brush as necessary to remove the debris. Do not use detergents or oil based soap, the chemicals can damage the cable. Rinse thoroughly in warm tap water, followed by a distilled water rinse.

Warning

The microscope cable is not intended to be sterilized by any kind of sterilization method.

5. Limited Warranty

5.1 The fiber optic cable has a one (1) year warranty from the date of shipment against defects in materials and workmanship, except for broken fiber. Should the product prove to have such defects within one (1) year of shipment, Gulf Fiberoptics will repair or replace at the product or component part at their discretion without charge.

5.2 Should the fiber optic cable need servicing under this warranty, please contact your distributor or your customer support specialist for return authorization documentation. Warranty does not cover equipment subject to misuse, accidental damage, and normal wear and tear.

6. Post Warranty Repair

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

7. Storage

Fiber optic cables should be stored in a clean, dry, temperature controlled environment. Always store the cable inside the original packing container with the label when not in use. Do not discard the label that is supplied in the cable case with the cable. Do not stack cables in their original packaging more than 20 units tall. Do not stack other products on the cable container.

8. Product Shelf Life

The fiber optic cable is not susceptible to degradation caused by aging when stored in the recommended conditions. Beyond five (5) years from the date of manufacture of the cable (marked on the cable case label) it is recommended that an inspection is performed on the device, following institutional procedures, in order to mitigate any risk of damage caused during the storing time.

9. Disposal

Observe local specific regulations and laws for the disposal of medical products.