Endoscopic Fiber Optic Cable

Instructions for Use and Processing Instructions

Manufacturer
Strauss Surgical
3020 NW 82nd Avenue,
Miami, FL 33122, USA
+1 305 436 0599

1. Product Description / Intended Use

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

The fiber optic cable is a device used with a light source and an endoscope in order to perform an endoscopic (minimally invasive) surgical procedure or an endoscopic (minimally invasive) medical procedure.

The Strauss Surgical fiber optic cable is designed for maximum transmission of light generated by an endoscopic light source to the endoscope.

1.1 Indications

The fiber optic cable is indicated for medical use only, where a compatible light source and a compatible endoscope is 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 up to 300 watt Xenon equivalent.

1.3 Connections

Strauss Surgical provides a large range of endoscopic fiber optic cables with specific connections for each specific light source and endoscope design. Each distinct light source and endoscope 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 endoscopic system to make sure that your cable is compatible with both the light source and the endoscope.

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 endoscope 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 This device is a non-sterile product. It is the users responsibility to clean and sterilize this device prior to the first use and after every subsequent use. Follow the cleaning, disinfection, and sterilization instructions provided in this document.

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

2.6 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 Strauss Surgical to repair or replace the device.

2.7 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.

2.8 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 105.8ºF (41ºC) 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 endoscope or fiber optic cable can cause burns to skin tissue and can cause a fire if allowed to contact flammable material such as drapes, plastics, and papers.

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

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

2.11 Replace the cable if the light transmission is compromised.

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

2.13 Use the handle / strain reliever to connect and disconnect the fiber optic cable, never pull the cable by the sheathing 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.

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

2.15 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.

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

3. Setup

Warning

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

Before setting up the system check the light source, endoscope, 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 endoscope 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 endoscope. Make sure the cable is tightly attached to the endoscope connector. Do not over tighten threaded connections.

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 and endoscope to cool.

3.2.3 Use the silicone rubber strain reliever to remove the fiber optic cable from the light source output port, *pulling gently*. Never pull the cable by the sheathing as damage may occur.

4. Processing

Warning

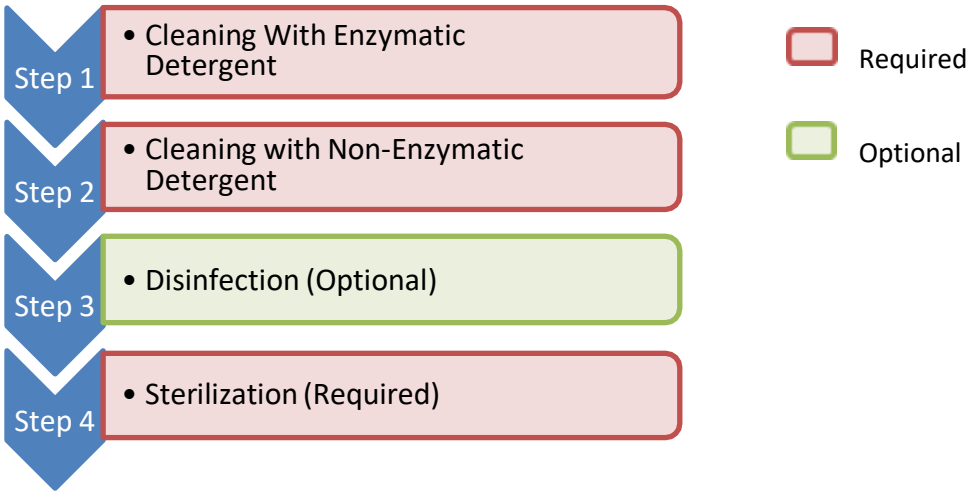
The fiber optic light cable is not intended to be processed using alkaline cleaners (pH above 10). The device will be damaged by alkaline cleaners.

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. These unapproved cleaners may also cause a tissue reaction if they come in contact with the user or patient.

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.).

4.1 It is recommended that the following processing steps are performed by the device processor.



4.2 Caution

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

4.2.2 Use only the recommended sterilization methods to process the cable. Do not use a method that is outside of the recommended parameters.

4.2.3 The fiber optic cable is a precision optical device, always handle the device with care.

4.2.4 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.

4.2.5 Do not place the cable in a Tyvek® pouch for Steam or STERRAD® systems as the pouch may melt to the fiber optic cable and cause permanent damage to the device

4.2.6 Do not use any sterilization method that is not specifically validated and listed on in these instructions.

4.2.7 Failure to follow these instructions may void the warranty.

4.3 Equipment and Materials

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

4.3.2 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.

4.4 Inspection and Preparation for Cleaning, Disinfection and Sterilization.

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

4.4.2 This fiber optic cable may be used with patients who may harbor both recognized and unrecognized infections. To prevent the spread of infection, all fiber optic cables must be thoroughly cleaned, disinfected, and sterilized after each use.

4.4.3 Fiber optic cables for endoscopes are high quality optical devices. Strauss Surgical has validated this device for several different types of sterilization. The validated methods and applicable parameters are listed below in Section 4.8.

4.4.4 If there is liquid inside the cable sheathing do not re-process 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.

4.5 Manual Cleaning

4.5.1 Fiber optic cables require similar care to that taken for any precision optical component. After each use, and prior to disinfection or sterilization, the fiber optic cable should be washed and cleaned of all debris.

4.5.2 Scrub the fiber optic cable with a soft brush using a neutral pH enzymatic cleaner or mild detergent until all visible contamination has been removed, paying particular attention to any crevices or seams. Always avoid any harsh materials or detergents that can scratch or in any way damage the optical surfaces on each end of the fiber optic cable.

Warning

To avoid health risks from aerosol contamination, brush the device only when it is submerged in liquid.

4.6 Automated cleaning

4.6.1 The device is approved for automated cleaning in hospital grade washer using the full cycle.

4.6.2 Use the parameters recommended by the washer manufacturer and detergent manufacturer for this type of device.

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.

4.7 Chemical Disinfection

4.7.1 Chemical disinfection is recommended for use on this device for each processing

4.7.2 Only use chemical disinfectants that are approved for use on this type of device. Follow the parameters suggested by the manufacturer of the disinfectant for this type of device.

4.8 Sterilization

4.8.1 For best sterilization performance and longest device life it is best to sterilize the cable separately. Other items in the sterilization tray may result in incomplete sterilization or damage to the fiber optic cable.

4.8.2 Place the fiber optic cable in a tray approved for use with this type of device.

4.8.3 Do not place the cable in a Tyvek® pouch for Steam or STERRAD® systems as the pouch may melt to the fiber optic cable and cause permanent damage to the device.

4.8.4 After sterilization allow the cable to cool slowly to room temperature. Do not immerse or rinse with cold liquid as fiber breakage will occur and cause permanent damage to the device.

4.8.5 Steam Sterilization

The fiber optic cable is validated for steam sterilization using the following parameters:

Steam Sterilization Parameters				
Method	**Cycle**	**Exposure Temperature**	**Exposure Time**	**Dry Time**
Steam	Pre-vacuum	134° C (273° F)	3 Minutes	20 Minutes

4.8.6 Other Validated Sterilization Methods

The fiber optic cable has also been validated for sterilization in the following sterilization systems. Always follow the recommended settings of the sterilization system manufacturer for this type of device.

- STERRAD® Systems – 100NX, 100S, 50, 200

- STERIS System 1®
- STERIS V-PRO® Low Temperature Sterilization Systems – 1, Plus, maX, 60
- STERIZONE® VP4 Sterilizer Cycle 1

Special Precaution

Transmissible Spongiform Encephalopathy Agents

It is outside the scope of this document to describe in detail the precautions that should be taken for Transmissible Spongiform Encephalopathy Agents.

The agents for transmission of Creutzfeldt-Jakob disease (CJD) are believed to be resistant to normal processes of disinfection and sterilization and therefore the normal processing methods of decontamination and sterilization as described above may not be appropriate where CJD transmission is a risk.

In general, the tissues that come into contact with equipment are those of low TSE infectivity. However, particular precautions should be taken when handling equipment that has been used on known, suspected, or at-risk patients.

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, Strauss Surgical 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.