Fiber Optic Cables

Made in USA

Sunoptic Technologies®
6018 Bowdendale Avenue
Jacksonville, FL 32216, USA
(904) 737 7611

Arthrex, Inc.
1370 Creekside Blvd.
Naples, FL 34108, USA
(800) 934-4404

Arthrex GmbH
Erwin-Hielscher-Strasse 9
81249 München, Germany
+49 89 909005-0

Arthrex Distribution Hub EMEA B.V.
Ampèrestraat 9
5928 PE
Venlo, Netherlands
+31 88 712-9800

EC REP
AJW Technology Consulting GmbH
Breite Straße 3
40213 Düsseldorf, Germany
+49 211 54059 6030

Device Symbols Used:

Manufacturer

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

Distributor

Non sterile

Importer

See Instructions for Use

Authorized Representative in the European Community

Caution:
Instructions for preventing personal injury

Medical Device

INSTRUCTIONS FOR USE

1. About this document

Arthrex fiber-optic cables are designed to deliver maximum light when coupled to a medical grade fiber-optic light source. Arthrex fiber-optic cables can be used with quartz halogen, metal halide, LED, or xenon light sources. They are compatible with virtually all endoscopes, medical instruments, and microscopes.
Arthrex fiber-optic cables are reusable devices that are provided non-sterile, but must be sterilized before their initial use and after each use. This document describes the correct handling and recommended methods for their processing.
Users of these fiber-optic cables are encouraged to contact their Arthrex representatives if, in their professional judgment, they require more comprehensive information on its use and care. The current version of this document can be found on the internet at http://www.arthrex.com. You can also request this document from Arthrex.

2. Intended Use

Arthrex fiber-optic cables are designed to illuminate a surgical site by relaying light from a fiber-optic light source onto the desired site. Arthrex fiber-optic cables are medical grade, high transmittance, peak efficiency.

3. Contraindications

These fiber-optic cables have no contraindications of which we have knowledge.

4.  Warnings and Precautions

- Users of these fiber-optic cables should be thoroughly familiar and trained in the use and care of the product. Users are encouraged to contact their Arthrex representatives if, in their professional judgment, they require more comprehensive information. The Arthrex website (www.arthrex.com) also provides detailed information.
- Arthrex fiber-optic cables are provided non-sterile and must be sterilized before each use and after each use. See instructions for cleaning and sterilization.
- Read, observe and store these instructions and any other applicable instructions.
- After receipt of the fiber-optic cable, and prior to each use, always inspect for any evidence of damage. Pay particular attention to optical surfaces, looking for scratches or dings.
- Use fiber optic cable only as intended.
- Use caution to treat Arthrex fiber-optic cables as you would any fine optical device.
- Do not look into the end of the fiber optic cable while it is connected to a light source and the light source is ON. Eye injury or blindness will result.
- WARNING: Risk of burns! The optical fibers emit high-energy light at the distal end of the fiber-optic cable. This can cause the temperature of the body tissue to rise to 106 °F (41°C).

- Avoid direct contact of the distal end with body tissue or flammable materials, such as drapes, as it can cause burns and fires.
- Reduce the light intensity of the light source when working near body tissue or flammable materials.
- Bring the fiber optic cable to the decontamination area as soon as possible after use. Observe valid protective measures to prevent contaminating the environment.

5. Cleaning and Disinfection

5.1 Inspection and Preparation for Cleaning, Disinfection and Sterilization

- Arthrex fiber-optic cables are delicate medical instruments and must be used and handled with care. It is recommended that fiber-optic cables are reprocessed as soon as is reasonably practical following use. Observe valid protective measures to prevent contaminating the environment. When properly performed, cleaning, disinfection and/or sterilization do not compromise the use and mechanical performance of these fiber-optic cables.
- These fiber-optic cables are 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 use on each patient.
- Fiber-optic cables for endoscopes, microscopes, and surgical instruments are high quality optical devices. Arthrex recommends the following Steam Sterilization (Autoclave) guidelines.

5.2 Manual cleaning

- 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.
- Scrub fiber-optic cable with a soft brush and 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.

5.3 Automated cleaning (full cycles)

- The devices shall be run through a hospital grade washer full cycle. The minimum parameters for the full cycle are as follows.

Motor Speed High [USA Parameters]			
Phase	**Recirculation Time [Minutes]**	**Temperature**	**Detergent Type and concentration**
Pre-Wash 1	02:00	Cold Tap Water	NA
Enzyme Wash	03:00	Hot Tap Water	Enzol®, 1oz/gal (Neutral pH 7.8-8.8)
Rinse 1	00:15	Hot Tap Water 60° C	NA
Drying	06:00	90° C	NA

Motor Speed High [European Parameters]			
Phase	**Recirculation Time [Minutes]**	**Temperature**	**Detergent Type and concentration**
Pre-Wash 1	02:00	Cold Tap Water	NA
Enzyme Wash	03:00	Hot Tap Water	Neodisher® Mediclean Forte ¼ oz / gal (pH 10.5-11)
Rinse 1	00:15	Hot Tap Water 60° C	NA
Drying	06:00	90° C	NA

6. Sterilization

6.1 Steam Sterilization

- The cycle selected is dependent on equipment and hospital protocol. General guidelines are:

STERILIZATION PARAMETERS			
Method	**Cycle**	**Minimum Exposure Temperature**	**Exposure Time**
Steam (Wrapped)	**Pre-vacuum**	132° C (270° F)	4 Minutes
Steam (Wrapped)	**Gravity**	132° C (270° F)	15 Minutes
Steam (Un-Wrapped)	**Gravity**	132° C (270° F)	10 Minutes

6.2 Steris® VPro®

- The cycle selected is based on equipment and hospital protocol. General guidelines are:

V-PRO Sterilizer / Sterilization Cycle	Sterilant Exposure (min)	Pre-injection pressure (Torr)	Cycle Time (min)
V-PRO 1 Standard Cycle V-PRO 1 Plus Lumen Cycle V-PRO maX Lumen Cycle	32	0.4	55
V-PRO 60 Lumen Cycle	35.6-.9.2		60
V-PRO 1 Plus Non Lumen Cycle V-PRO maX Non Lumen Cycle	12	1.0	28
V-PRO 60 Non Lumen Cycle	11.4-12.6		
V-PRO maX Flexible Cycle	12	0.4	35
V-PRO 60 Flexible Cycle	13-15.2		38

6.3 Chemical Disinfection

- It is recommended that the guidelines below, published by Advanced Sterilization, a Johnson & Johnson company, be followed.

CHEMICAL DISINFECTION PARAMETERS	
Product	**High Level Disinfection Sterilization**
Cidex Activated Dialdehyde Solution	45 minutes @ 25° C (77° F)
Cidex Plus 28 Day Solution	20 minutes @ 25° C (77° F)

6.4 Sterrad®

- The following equipment and cycles may be used:

Sterrad Sterilizer	Cycle(s)
100S	Short, Long
NX	Standard, Advanced
100NX	Standard

6.5 ⚠ 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.

7. Limited Warranty

- Your fiber-optic cable has a one (1) year warranty from the date of shipment on workmanship and all defects of material except for broken fiber. Should your product prove to have such defects within one (1) year of shipment, Arthrex will repair or replace the product or component part without charge.
- Should your fiber-optic cable need servicing under this warranty, please contact your distributor or your customer support specialist for return authorization documentation. You should carefully pack the product in a sturdy carton, including a note describing the defects, your name, your company name, telephone number and a return address. Warranty does not cover equipment subject to misuse, accidental damage, and normal wear and tear. This warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

8. Post Warranty Repair

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

9. Storage

Fiber-optic cables should be stored in a clean, dry environment.

10. Disposal

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