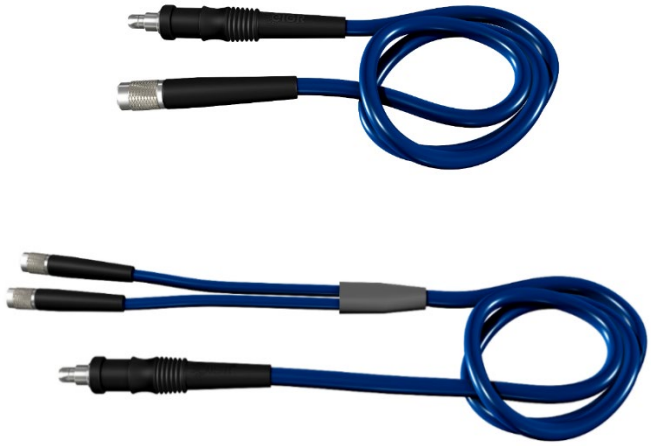
Fiber Optic Cables

REF **FC1S / FC1B / FC1SP**

Instructions for Use



Invuity, Inc.
444 De Haro Street
San Francisco, CA 94107 USA
Tel: +1-866-711-7768
www.invuity.com

EC REP Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

CE

NON STERILE

℞ Only

Consult Instructions for Use and Symbols Glossary on this website: www.invuity.com/documentlibrary

Fiber Optic Cables - Instructions for Use

Description

Invuity Fiber Optic Cables are intended for use in a wide variety of surgical procedures. The Fiber Optic Cables are non-sterile, reusable, and available with a single or bifurcated connection. It is recommended to use the Fiber Optic Cables with an LED light source, an infrared radiation-filtered 300-watt xenon or metal halide high intensity surgical light source. The Fiber Optic Cables are compatible with other Invuity devices.

Indications for Use

The Fiber Optic Cables are intended to provide surgical site illumination from a high intensity light source.

Contraindications

- Endoscopic use

For Use With

DESCRIPTION	REF
PhotonGuide, Narrow/Flat	104008
PhotonGuide, Wide/Flat	104015
PhotonGuide Adapt	PGA1
PhotonSaber F, 8 Fr, Standard, Teardrop	PSF08ST
PhotonSaber F, 8 Fr, Long, Teardrop	PSF08LT
PhotonSaber F, 12 Fr, Standard, Round	1911273
PhotonSaber F, 12 Fr, Long, Round	PSF12LR
PhotonSaber Y, Bulb Tip	ES1Y
PhotonSaber Y, Taper Tip	ES3Y
PhotonSaber Y, Metal Tip	ES4Y

Warnings and Precautions

Cleaning and Sterilization:

- See “Warnings and Precautions” in the Decontamination and Sterilization section of this Instructions for Use.

Product Use:

- Fiber Optic Cables should be handled and operated by hospital personnel familiar with and trained with their use, assembly, and disassembly. Handle all instruments with care.
- Prior to each use, inspect the Fiber Optic Cable for damage and integrity.
  - Inspect the cable for exterior damage.

    Inspect the connector ends to ensure that they are free from debris, glossy in character, wholly intact, and free of defects such as cracks, chips, loose or bent components, rough edges, or other general damage. Inspect the length of the cable for any signs of damage to the protective sheath. Discontinue use of a cable which shows this type of exterior damage.

  - Inspect the cable for internal damage to the glass fibers. Warning – Do not perform the following inspection using a light box.

    Point one end of the light cable in the direction of an ambient light such as a room light or a window and check the number of dark spots at the other end. Each of these dark spots corresponds to a broken fiber in the optical fiber bundle. When individual broken fibers become dark spots and reach a level exceeding about 20 to 25% of the light exit area, the transmission of light decreases to a clearly recognizable level and the performance of attached illumination devices will decrease. Also,

inefficient light transmission caused by broken fibers may result in heating of the cable or cable components which may cause a burn injury. Discontinue use of a cable that has this type of internal fiber damage.

- Discard damaged cable according to hospital procedures and in accordance with local, state and federal laws and regulations related to clinical waste.

- Never use the Fiber Optic Cables without an Invuity device. Use the Single Fiber Optic Cable when one Invuity device is needed. Use the Bifurcated Fiber Optic Cable when two Invuity devices are needed.
- Do not use with a xenon light source greater than 300 watts. Using Invuity Cables with a xenon light source with output greater than 300 watts or without an infrared (IR) filter may cause thermal injury to the patient or user or may cause damage to equipment.
- Refer to the Instructions for Use for the PhotonGuide, PhotonGuide Adapt, PhotonSaber Y, PhotonSaber F, and Invuity Retractors for additional information.

Safety:

- Use of instruments for any purpose or in any manner other than described in this Instructions for Use may cause instrument damage or failure, which could result in patient or user injury.
- When attached to the surgical light source, the Bifurcated Fiber Optic Cable requires two Invuity devices to be used simultaneously.
- Never leave one branch (or both branches) of the Single or Bifurcated Fiber Optic Cable un-used. The output of the Fiber Optic Cable is extremely intense and may cause burns, ignite drapes/gowns, or temporarily blind vision.

Directions for Use

The following directions serve as general procedures for the Invuity Fiber Optic Cables.

1. Identify the Invuity device(s) that will be used with the Fiber Optic Cable.

   Note: Use the Single Fiber Optic Cable when one Invuity device is needed. Use the Bifurcated Fiber Optic Cable when two Invuity devices are needed.
2. Inspect the Fiber Optic Cable for cleanliness and damage prior to assembling. Do not use if the product is damaged.
3. Verify the surgical light source is 300 watts or less and is equipped with an infrared (IR) blocking filter or is a LED light source
4. Attach the Invuity Fiber Optic Cable to the Invuity device(s).

   Note: When attached to the surgical light source, the Bifurcated Fiber Optic Cable requires two Invuity devices to be used simultaneously. Never leave one branch (or both branches) of the Single or Bifurcated Fiber Optic Cable un-used. The output of the Fiber Optic Cable is extremely intense and may cause burns, ignite drapes/gowns, or temporarily blind vision.
5. Connect the Invuity Fiber Optic Cable to the ACMI port on the surgical light source.
6. Reduce the intensity setting of the light source to the minimum level before turning on the power. Then, turn the surgical light source on.
7. Increase the intensity setting of the light source to approximately 50% and assess the illumination transmitted by the Invuity device(s). Avoid increasing the intensity setting of the light source beyond the level of illumination required to perform the procedure.
8. After the procedure has been completed, turn the surgical light source off and disassemble the Invuity Fiber Optic Cable from the Invuity device(s).

9. Carefully disconnect the Fiber Optic Cable from the surgical light source.

Note: If further instructions are required for use of the Invuity devices, refer to their respective Instructions for Use.

Preparation for Cleaning

Equipment and Materials

WARNING: Use only Invuity-approved equipment unless otherwise specified. DO NOT modify any system component or accessory.

The following equipment is required to process devices per the instructions in this manual:

- Warm water (See the Water Quality section)
- Prepared, specially formulated cleaning agents (See the Cleaning Agents section)
- Absorbent wipes
- Soft, nonlinting cloth
- Syringe
- Non-abrasive, soft, flexible, synthetic bristle brushes
- Washer-disinfector (complies with ISO 15883 series)
- Cleaning agents as required by the washer-disinfector manufacturer
- Instrument air[1] < 140 kPa [< 20 psi]
- Oven

[1]Instrument air is medical gas that falls under the general requirements for medical gases as defined by the National Fire Protection Association (NFPA) Health Care Facilities Code, is not respired, is compliant with the American National Standards Institute (ANSI) / International Society of Automation (ISA) Quality Standard for Instrument Air, and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40 °C [-40 °F].

Cleaning and Sterilization

Warnings/Precautions	• The Fiber Optic Cables are provided non-sterile and must be thoroughly cleaned and sterilized prior to use. • The Fiber Optic Cables are delicate medical devices and must be handled with care during cleaning and sterilization. If the devices are not handled appropriately, surface abrasions may occur. • When decontaminating Fiber Optic Cables, use a neutral detergent to prevent stains. Do not use cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry sterilize as damage to the instrument finish may occur. • Do not use Sterrad® or other sterilization processes that contain chlorine (bleach) or enzymatic solutions. • It is recommended to use the appropriate Invuity Sterilization Trays to help protect the Fiber Optic Cables from damage during transport, decontamination, sterilization, and storage. • Do not process instruments of different metals during sterilization, oxidation due to electrolytic effects may occur. • When coiling the Fiber Optic Cables for sterilization, do not coil cables tighter than a 6 inch [15.24 cm] diameter.
Cleaning	1. After each use, gently remove debris using a soft brush and mild neutral pH detergent. Higher pH detergents have not been tested and cannot be recommended. 2. Do not submerge or soak the Fiber Optic Cables for any period of time. 3. Use special care to avoid scratching or damaging the optical surfaces on the ends of the Fiber Optic Cables. **Note: Do not use a stiff bristle brush or metal type brush to clean the instruments. Avoid contact with other metal instruments or object which may dent, ding, scrape or otherwise damage the optical surface of the Fiber Optic Cable.** 4. Rinse the Fiber Optic Cable to remove residual debris and cleaning agents.

<table>
<tr><td>Water Quality</td><td>WARNINGS:
Use appropriate water quality for each stage of the cleaning process. Mineral residues from hard water can stain the equipment and/or prevent effective cleaning and decontamination.
Use utility water for flushing, washing, and rinsing the equipment. Utility water is water that comes from the tap.
Use potable water for diluting cleaning agents. Potable water is water that is treated and delivered in a matter so that it meets United Sates (US) Environmental Protection Agency (EPA) or local guidelines as suitable for drinking.
Use critical water for final rinsing of the equipment prior to sterilization. Critical water is water that is extensively treated usually by a multistep treatment process that could include a carbon bed, softening, deionization, and reverse osmosis or distillation to ensure that the microorganisms and the inorganic and organic material are removed from the water. A final submicron filtration could also be part of the treatment process.
CAUTIONS:
Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per Association for the Advancement of Medical Instrumentation (AAMI) TIR 34.
Warm water with an optimum temperature range of 27 to 44°C [80 to 110°F] is recommended for manual cleaning. The water should not exceed 60°C [140°F] and should be warm to the touch.</td></tr>
<tr><td>Disinfection (Optional)</td><td>Disinfection processes do not ensure the margin of safety associated with sterilization processes. Therefore, disinfection is optional.</td></tr>
<tr><td>Packaging</td><td>Fiber Optic Cables may be loaded into dedicated instrument trays or general purpose sterilization trays.</td></tr>
<tr><td>Sterilization</td><td>Fiber Optic Cables should be sterilized using steam sterilization by either gravity displacement or pre-vacuum. The following sterilization parameters have been validated for instruments in a tray, wrapped or unwrapped.

Note: Invuity endorses the following sterilization parameters per AAMI recommendations for wrapped instruments and container with combined weight of less than 25 lbs. [11.3 kg].
<table><tr><td colspan="3">Steam Sterilization Parameters</td></tr><tr><td>Description</td><td>Gravity Displacement</td><td>Pre-Vacuum</td></tr><tr><td>Temperature</td><td>132°C[2]
(270°F)</td><td>132-138°C
(270-280°F)</td></tr><tr><td>Cycle Time</td><td>15 minutes[1]</td><td>3-8 minutes[1]</td></tr><tr><td>Dry Time</td><td>45 minutes</td><td>30 minutes</td></tr></table>[1] Maximum exposure time may be extended to 18 minutes.
[2] Maximum sterilization temperature may be extended to 137°C.
Note: Do not use Sterrad® or other sterilization processes that contain chlorine (bleach) or enzymatic solutions.

The final responsibility for verification of sterilization techniques lies directly with the hospital. To ensure the efficacy of hospital processing, all cycles and methods should be verified for different sterilization chambers, wrapping methods, and/or various loading configurations.
International sterilization parameters are per the following standards:
Australia/New Zealand per AS/NZS 4187
Netherlands per Field Standard for Loaner Instruments, Rev 03.02, April 2008
Europe and the United Kingdom per EN ISO 17664
Canada per CSA ISO 17664</td></tr>
<tr><td>Storage</td><td>Store Fiber Optic Cables in a clean, dry area.</td></tr>
</table>

Warranty

INVUITY warrants, for the earlier of (i) the expiration date, if applicable, or (ii) one (1) year from the date of purchase, that this medical device is free from defects in both material and workmanship when used normally for its intended purposes. Suitability of the medical device for any surgical procedure shall be determined by the user alone (in light of relevant instructions for use) and not by INVUITY, and such user shall be responsible for understanding how to use the device for its intended purpose. In the event that purchaser believes that any INVUITY medical device is defective, purchaser will promptly notify INVUITY. Any INVUITY brand named instrument delivered from INVUITY proving to be defective will, as purchaser's sole and exclusive remedy, be replaced at no charge or the amount paid refunded, at INVUITY's discretion, so long as the defect is discovered and reported to INVUITY within the earlier of thirty (30) days of discovery or one (1) year of purchase, and INVUITY determines that the product is defective and is covered by the warranty. Notwithstanding, INVUITY shall not be responsible for normal wear and tear, including minor cosmetic damage compromise or defect caused by re-sterilization. INVUITY does not repair, sharpen, recoat or otherwise refurbish any used product. The foregoing limited warranty and limited obligation of replacement is void and of no effect in the event that there is any modification made to the medical device or the medical device is used for any purpose other than its intended purpose.

LIMITATION OF LIABILITY. INVUITY DOES NOT ACCEPT LIABILITY TO CUSTOMER OR ANY THIRD PARTY BEYOND THE REMEDIES EXPRESSLY SET FORTH HEREIN, INCLUDING ANY LIABILITY FOR PRODUCTS NOT BEING AVAILABLE FOR USE. IN NO EVENT SHALL INVUITY BE LIABLE FOR LOST PROFITS, LOSS OF BUSINESS, LOSS OF USE, COSTS OF PROCUREMENT OF SUBSTITUTE GOODS, OR ANY OTHER CONSEQUENTIAL, EXEMPLARY, INCIDENTAL, SPECIAL, INDIRECT OR PUNITIVE DAMAGES, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR FOR ANY CLAIM BY ANY THIRD PARTY, EXCEPT AS EXPRESSLY PROVIDED HEREIN.

Customer must obtain a Return Material Authorization to return product to Invuity. Returned product must be thoroughly cleaned and sterilized.

CUSTOMER ACKNOWLEDGES UNDERSTANDING THAT NO OTHER REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT AS TO ITS MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER, EVEN WHEN APPLIED OR UTILIZED IN ACCORDANCE WITH ITS INSTRUCTIONS, ARE MADE OR GIVEN BY INVUITY. AND INVUITY EXPRESSLY DISCLAIMS ALL SUCH REPRESENTATIONS AND WARRANTIES.

Rev	CO #	Description	Approved Date	Effective Date	Originator
A	19-0116	Initial Release	05/01/2019	05/13/2019	J. Wentz

PRINTING INSTRUCTIONS

Print in house or at an approved supplier and route to receiving.

Do not print Revision History or Printing Instructions page (page 7 & 8).

Print in black ink on white paper.

Fold in booklet and staple fold (folded size is 4.25 in x 5.5).