

## **Optical Integrity Fibers**

### Reusable Fiber Instructions for Use

#### **READ ALL INSTRUCTIONS THOROUGHLY BEFORE USE.**

##### **1. Description**

The Optical Integrity Fiber is a fiber optic laser delivery system consisting of a 2 or 3 meter long silica fiber, clad in HCS, buffered with a fluorinated acrylate and with a shaped tip. As an integral part of a laser system, the Optical Integrity Laser fiber may be used for a wide variety of surgical procedures.

- The Optical Integrity Fibers are designed for use with laser systems having transmission between 532 and 1400 nm (i.e. ND:Yag, KTP or Diode laser systems) that have been cleared for medical use and accept standard SMA 905 connectors (with threaded or luer fittings).
- The Optical Integrity Fiber is a reusable product that is supplied sterile.
- This product is design to be used by physicians that are familiar with the physiological applications and have been trained in proper use and operation of surgical laser systems

##### **2. Indications**

The Optical Integrity Fibers are intended to be used for vaporization, cutting, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment including laparoscopes, hysteroscopes, arthroscopes, bronchoscopes, cystoscopes, ureteroscopes, gastroscopes, colonoscopes, or for open surgery for contact or non-contact surgery with or without hand piece for use in coagulation, incision/excision, ablation, and vaporization of soft tissue.

The Optical Integrity Fibers are indicated for use in medicine and surgery in the following specialties: Urology, Plastic Surgery, Radiology, Dermatology, Pulmonology, Gastroenterology, Gynecology, ENT, Lithotripsy, General and Vascular Surgery, Arthroscopy, Podiatry, Orthopedics, and Neurosurgery.

##### **3. Potential Complications**

Complications could include local and/or systemic infection, thermal damage to surrounding structures, local hematoma, dissection and perforation, tissue adherence, distal tip detachment, and discomfort during and/or after energy application. In the unlikely event of a detached tip, it may be visually located through an appropriate scope and removed using forceps. Irrigate the area thoroughly to remove any traces of the tip.

##### **4. Precautions**

- Use of Optical Integrity laser fibers on laser systems not recommended, may result in harm to patient or user or damage to the laser. Optical Integrity laser fibers are recommended for ND:Yag, KTP or Diode laser systems that have been cleared for medical use and accept SMA 905 connectors.
- Tissue stuck to the end of the fiber can cause burn back. This problem with laser fibers occurs because the tissue can carbonize and cause energy to be adsorbed back into the fiber creating thermal runaway wherein the fiber tip heats up very rapidly. Visible light other than the aiming beam, (sometimes seen as a flash of white light) is evidence that the fiber is burning back, and is an indication that tissue is stuck to the lasing tip. Because of this phenomenon, no laser fiber should be used if tissue is stuck to the end of the fiber. If this occurs, remove the fiber from the patient and wipe the tip with a soft tissue. If the debris cannot be removed, the fiber tip must be cleaved and the buffer stripped back for a fresh surface. (See the Stripping and Cleaving section of this instruction)

- When cleaning do not use side pressure as this may damage the tip.
- Increased laser exposure time will result in a deeper and wider zone of necrosis.
- Do not bend fiber at sharp angles.
- Care should be exercised with the glass tip to avoid severe impacts or side stresses that may fracture the tip.
- The time for treating a specific target area may be different when using the Optical Integrity laser fiber compared to using other shaped fibers. A different beam divergence and a laser spot size may alter treatment times.
- During each lasing interval, it is helpful to move the distal tip up and back 1 to 2mm to prevent the tip from sticking to tissue.
- Immediately discontinue use if breaks or fractures appear in laser fiber. These breaks or fractures may allow undirected emission of laser energy, rendering the distal tip useless and potentially causing harm to surrounding tissues.
- Always wear appropriate protective eyewear during the delivery of laser energy.
- Do not use the Optical Integrity laser fiber in the presence of flammable anesthetics or any combustible materials.

## 5. Instructions for use

1. Prior to activation of the laser, review the Laser Operator's Manual for instructions on the proper set-up and operation of the laser system.

**! Caution: Do not exceed the maximum wattage or minimum fiber size ratings for fibers on the laser. See table in item 9 below**

2. Remove the fiber from the sterile pouch using aseptic technique.

**! Caution: Do not use if the pouch has been opened or if there is visual damage to the pouch.**

3. Make sure the laser is "OFF" or on "STANDBY" mode before inserting the fiber into the laser aperture port. Attach the SMA 905 connector to the laser and finger tighten until a secure connection is achieved.
4. Handle the fiber with care as damage may occur if struck or bent sharply. If the fiber delivery system is damaged during use, it should not be repaired.
5. Activate the laser aiming beam and carefully inspect the full length of the fiber for breaks. These will appear as bright red spots along the length of the fiber. When the tip is held about 3mm from a light colored surface, the laser aiming beam should be visible.
6. Perform Calibration of the laser (Calibration of the fiber is not required) – See Laser Operator's Manual. Note: there are no known reciprocal interferences posed by the laser fiber.
7. If no breaks are visible, the fiber is ready for use.
8. Begin treatment: With the laser in "STANDBY" mode, hold the probe about 5cm from the distal tip. If using an endoscopic delivery system, insert the probe until the tip extends approximately 1cm from the distal end of the endoscope. Adjust the laser power to the level appropriate for the intended use.
9. Set the laser system to the desired power output up to a maximum as follows.

Fiber Core Size	Type of Laser Equipment		Minimum Bend Diameter
	Air cooled	Water or Assisted cooling	
400 and 600 microns	25 Watts	100 Watts	30mm

## 6. Inspection of proximal (connector) end of the fiber

1. With a magnifying eyepiece, microscope or endoscope with operating room video system (minimum magnification 15x), inspect the fiber face at the proximal end of the fiber (at the SMA connector). While inspecting the fiber, slightly change the angle of the fiber face to view a variety of angles at which light strikes the fiber.
2. The fiber face should be free of any defects such as chips, cracks, scratches, pits, blemishes or debris. Using the fiber with defects may damage the laser system.

! Caution: *If defects exist, do not use the fiber.*

3. With a magnifying eyepiece, microscope or endoscope with operating room video systems (minimum magnification 15x), inspect the fiber face at the distal end of the fiber. While inspecting the fiber, slightly change the angle of the fiber face to view a variety of angles at which light strikes the fiber.
4. Degradation of the fiber face at the distal tip is normal and will occur with use. If pitting, cracks, chips or debris are observed, the fiber should be stripped and cleaved. See instructions that follow.

## 7. Strip and Cleave the Distal Tip of the Fiber

The following tools are recommended for stripping/cleaving the Optical Integrity Scope Safe™ Fiber. The Supplier is Micro Electronics, Inc., Seekonk, MA 02771

	400mm fiber	600mm fiber
Stripping tool	MS1-27S-31FS	MS1-27S-46FS
Cleaving tool	200/600-C	200/600-C

Note: Verify that the stripping tool corresponds with the fiber size. Read the instructions provided with the stripping tool.

### Stripping and Cleaving 400 and 600 mm core fibers

#### 1. Stripping the buffer

Hold the tool in one hand, the fiber in the other. With handles fully expanded insert the fiber in the guide until the fiber end aligns approximately with the tool's 2.5cm (1 inch) rule marking. Squeeze the handles and maintain the closed position while simultaneously withdrawing the fiber from the tool. If the fiber cannot be inserted into the fiber guide, use the scissors to cut approximately 1.2cm (1/2 inch) of the fiber off the distal tip.

## 2. Cleaving the fiber

With the cleaving tool, gently score the exposed fiber with a straight line perpendicular to the fiber one time approximately 20mm from the distal tip. Do not attempt to cut the fiber with the cleaving tool. Hold the buffered fiber in one hand and the stripped portion between the thumb and index finger of the other hand. Pull the stripped portion away from the buffered section to remove the cleaved tip from the fiber. Do not bend the distal tip while cleaving or break the fiber with a sideways motion. This will result in a poor cleave. Inspect the quality of the cleave as instructed above.

## 8. Inspecting the quality of the cleaved fiber (distal end)

1. Using a magnifying eyepiece, microscope or endoscope with operating room video system (minimum magnification 15x), inspect the fiber face at the distal end of the fiber to verify a smooth, clean cleave.
2. Connect the fiber to the laser and turn on the laser aiming beam.
3. Hold the fiber tip approximately one inch from a white surface to examine the pattern of the aiming beam.
4. A well-defined circular pattern indicates a good cleave. A slightly oval or distended pattern that remains well defined is an acceptable cleave. A poorly defined pattern with one or more “rays” extending from the central core of the pattern indicates an unacceptable cleave.
5. Unacceptable cleaves can result from too much pressure when scoring the fiber core, sideways motion when separating stripped from buffered sections or scoring the tip at an angle other than perpendicular (90 degrees) to the fiber.
6. If the cleave is unacceptable, repeat the initial cleaving procedure.

## 9. Instructions for Reuse

**Before reuse, the Optical Integrity surgical laser fiber must be cleaned, inspected and if necessary, stripped and cleaved. Fiber re-sterilization must also be completed.**

### 1. Cleaning

- Immerse the fiber for five minutes in an enzymatic detergent suitable for cleaning surgical instruments.
- Use a soft gauze pad soaked in enzymatic surgical detergent to wipe the fiber. Remove all residue and debris.
- Thoroughly rinse the fiber in warm tap water to remove residue and solution.
- Dry the fiber with a soft gauze cloth.

### 2. Inspection

- With a magnifying eyepiece, microscope or endoscope with operating room video system (minimum magnification 15x), inspect the fiber face at the proximal end of the fiber (at the SMA connector). While inspecting the fiber, slightly change the angle of the fiber face to view a variety of angles at which light strikes the fiber.
- The fiber face should be free of any defects such as chips, cracks, scratches, pits, blemishes or debris. Using the fiber with defects may damage the laser system. If defects exist, do not reuse the fiber.
- With a magnifying eyepiece, microscope or endoscope with operating room video systems (minimum magnification 15x), inspect the fiber face at the distal end of the fiber. While inspecting the fiber, slightly change the angle of the fiber face to view a variety of angles at which light strikes the fiber.
- Degradation of the fiber face at the distal tip is normal and will occur with use. If pitting, cracks, chips or debris are observed, the fiber should be stripped and cleaved.

### 3. Sterilization

Note: The fiber must be cleaned prior to sterilization. Optical fibers are extremely fragile and should be handled with care. The individual user must verify sterility.

The fiber may be sterilized by ethylene oxide or steam sterilization. The parameters shown below are offered as a reference.

#### ETO Sterilization

1. Place the loosely coiled fiber in an EtO sterilization pouch and seal the pouch.
2. Sterilize in an EtO chamber with the following conditions:

Preconditioning Parameters: Sterilization Parameters

Temperature	55°C ± 2°C	EtO Concentration	725 ± 25 mg/ml
Relative Humidity	70 ± 5%	Relative Humidity	70 ± 5%
Steam Partial Pressure	2.28 psia	Exp. Time	1 hour
Preconditioning Set Point	1.60 psia	Temp.	130° F (55° C)
Preconditioning Time	60 min	Aeration	12 hours

#### Steam Sterilization

3. Place the loosely coiled fiber in a steam sterilization pouch and seal the pouch.
  4. Sterilize in a steam sterilization chamber with the conditions:
- Gravity Displacement Sterilizer

- Temperature 270° F (132° C)
- 15 minute exposure
- 15 minute drying cycle

**10. How the fiber is Supplied and Stored**

- The Optical Integrity Fiber is supplied as EtO sterilized disposable product. Sterility is guaranteed only if the package is not opened, damaged or broken.
- Each package contains 1 in a dispensing coil and 1 instruction for use booklet.
- Store in a dry, cool place.

**Optical Integrity's European Representative is:**

**0413 European Device Solutions, Inc.**

email: [TOMUK@aol.com](mailto:TOMUK@aol.com)

**This symbol means, Caution ! The information provided is important and can affect the safety or efficacy of the product.**

**This symbol means that the information provided is instructional for the safe and effective use of the product.**