



INSTRUCTIONS FOR USE

PathAssist™ Light Fiber

Read all Instructions prior to use

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

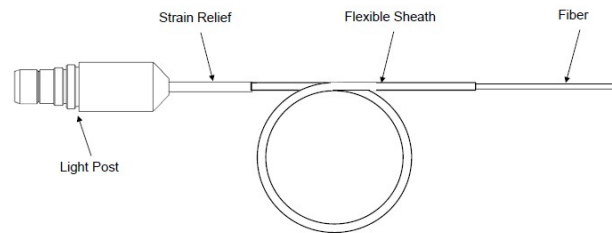
Sterility: Provided Sterile, Ethylene Oxide (EO) Sterilization

Single Use: Disposable, For Single Patient Use Only, Do Not Resterilize and/or Reuse

Storage: Store in a cool, dry place

Description

The PathAssist Light Fiber is a flexible instrument that can be connected to a light source to emit light from its distal end. It has a fiber nominal working length of 27.6cm with an outer diameter of 0.5mm (0.020"). The device consists of a flexible illumination fiber, a protective sheath and a light post, with an overall device length of 117cm.



The Light Fiber is packaged with a commercially available male tuohy borst adapter.

Indication For Use

To locate, illuminate within, and transilluminate across nasal and sinus structures in adults aged 18 and over.

Contraindications

None known

Warnings

- Do not use breached or damaged packages, since the sterility and functionality of the device may be compromised.
- Single use only. Do not re-sterilize or re-use, as it may result in compromised device performance and risk improper sterilization and cross contamination.
- Never advance or withdraw the device against unknown resistances as this can cause tissue trauma or device damage.
- Do not use the device with a Xenon light source > 300W and a light cable < 2.5mm or > 3.5mm. High energy light radiated through devices can result in high temperatures in front of the light outlet and at the connection point to the light cable, including the light post adapters. Use of a higher wattage light source may result in burns or permanent tissue damage to the user or the patient.
- Do not rest the device on the patient during surgery while it is connected to a light source, as this could result in burns to the patient.
- Allow the device to cool for a few minutes before disassembling from the light cable and light post adapter.

Precautions

- Due to the variability of sinus anatomy, review radiographic imaging (CT scan) prior to the procedure
- Do not kink the Light Fiber as this may damage the device.
- If using Light Fiber with the XprESS device, be sure to pre-load the Light Fiber into XprESS prior to shaping it into a maxillary bend configuration (i.e., approximately 135° bend) as the Light Fiber will not load when XprESS is pre-shaped in a maxillary configuration.

- Do not use the device for external transillumination of maxillary sinus by applying the device to the hard palate, as this use has not been tested.

Adverse Effects

Possible adverse effects include, but are not limited to, the following:

- Cerebrospinal fluid leak
- Damage of the orbital wall or other structures of the eye
- Tissue inflammation or trauma

Compatibility

- The device is compatible with working lumen instruments with an OD \geq 2mm (malleable suctions, sinus cannulas), and with an internal lumen diameter \geq 0.035" and a length \leq 27.5cm. Examples of devices that meet these requirements include XprESS™ Multi-Sinus Dilation Tool and Medtronic MCSK5 Suction Tube.
- The device is compatible with 2.5mm and 3.5mm light cables and standard light post adapters (ACMI, RICHARD WOLF, KARL STORZ), and a 300W Xenon light source.










Instructions for Use

1. Remove the Light Fiber and tuohy from the protective packaging.
2. Attach the tuohy to the working lumen instrument.
3. Load the distal end of the Light Fiber into the working lumen instrument aligning the distal tip of the fiber with the distal end of the instrument.
4. Secure the Light Fiber in place by tightening the tuohy.
5. Shape loaded working lumen instrument (if applicable) to desired bend configuration for targeted sinus.
6. Connect a 2.5mm or 3.5mm light cable and light post adapter (if necessary) to the light post of the Light Fiber. Connect the light cable to a 300W Xenon light source.
7. Activate the light source. Confirm that light is being transmitted through the Light Fiber.
 - The light intensity transmitted through the Light Fiber can be increased by adjusting the output of the light source or by using a smaller diameter light cable.
8. Under endoscopic visualization, place the working lumen instrument into the target location to illuminate within and transilluminate across nasal and sinus structures. Some tissue removal may be necessary to access the target location.
 - Projected illumination can be enhanced by reducing the number of competing light sources (i.e. endoscope or room light) or by advancing tip of the Light Fiber distal from the working lumen instrument.
9. After procedure, dispose of device according to appropriate environmental health safety guidelines.

Limited Warranty

Entellus Medical, Inc. warrants that reasonable care has been used in the design and manufacture of this device. Entellus Medical excludes all other warranties, whether expressed or implied, by operation of law or otherwise including, but not limited to, any implied warranties of merchantability or fitness since handling and storage as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond Entellus Medical's control, directly affect the device and the results obtained from its use. Entellus Medical shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Entellus Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Refer to *Entellus Medical, Inc. Standard Terms and Conditions*.

Graphic Symbols Contained on Device labeling

 Consult Instructions for use	 Lot Number	 Model Number	 Use By	 Reorder Number
 Sterilization with Ethylene Oxide Gas	 Manufacturer	 Do Not Reuse	 Prescription Use Only	

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RICHARD WOLF is a trademark of Richard Wolf GmbH of Knittlingen, Germany.

KARL STORZ is a trademark of Karl Storz GmbH of Tuttlingen, Germany.



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