2857-003

INSTRUCTIONS FOR USE
PathAssist™ LED 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. Do not expose to high temperatures above 50ºC (122ºF).

Indication For Use
To locate, illuminate within, and transilluminate across nasal and sinus structures.

Description
The PathAssist LED Light Fiber is a single use, disposable, flexible instrument that emits light from the distal end. The device consists of a flexible illumination fiber, a protective sheath and an integrated battery powered LED light source. When the LED Light Fiber is activated the fiber will emit red light from the distal tip for over 60 minutes. It has a fiber nominal working length of 27.6cm with an outer diameter of 0.375mm (0.015").

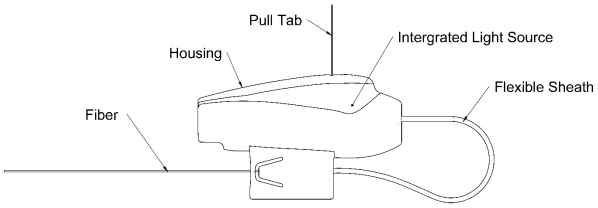

Figure 1 LED Light Fiber

The LED Light Fiber is packaged alone or may also be packaged with XprESS (LoProfile Suction Tip).

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.
- Due to the variability of sinus development in pediatric patients, review CT scan to assess each sinus's development and appropriateness for balloon dilation. Pneumatizaton may occur as early as 1-2 years of age and continues to develop throughout childhood. Do not use LED Light Fiber in a sinus that is not adequately developed.
- Never advance or withdraw the device against unknown resistances as this can cause tissue trauma or device damage.
- Do not rest the device on the patient during surgery while it is activated, as this could result in burns to the patient.
- No modification of this device is allowed.

Precautions
- Due to the variability of sinus anatomy, review radiographic imaging (CT scan) prior to the procedure.
- Do not kink the LED Light Fiber as this may damage the device.
- Be sure to pre-load the fiber into the XprESS device prior to shaping it into a maxillary bend configuration (i.e., approximately 135º bend) as the fiber will not load when XprESS is pre-shaped in a maxillary configuration.
- Wait to activate the LED Light Fiber just prior to use as once activated the fiber will emit continuous light for over 60 minutes. There is no on/off switch.
- Do not stare directly at LED Light Fiber tip, or point it directly at anyone's eyes while illumination is active.

- 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.
- Do not incinerate the device except for disposal in a controlled incinerator.

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 the XprESS Multi-Sinus Dilation System *(all suction tip sizes)*

Please refer to the XprESS Multi-Sinus Dilation System Instructions for Use for detailed information and instructions on the use of XprESS.

Instructions for Use

NOTE: *Steps 1-3 are only necessary if LED Light Fiber is packaged alone. If LED Light Fiber is packaged with XprESS device, go to STEP 4.*

1. Remove the LED Light Fiber from the protective packaging.
2. Load the fiber into the working lumen of XprESS (Figure 2).
3. Attach the LED Light Fiber housing to the barbed fitting of the XprESS device (Figure 3). Align the distal tip of the fiber with the distal end of XprESS (Figure 4).

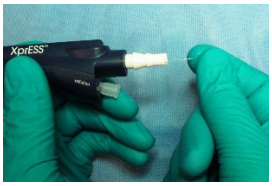

Figure 2

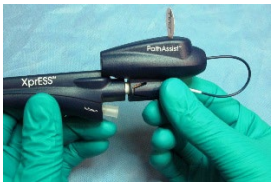

Figure 3

Figure 4

4. Shape loaded XprESS to desired bend configuration for targeted sinus.
5. Activate the LED Light Fiber by removing the pull tab. Confirm that light is being transmitted through the LED Light Fiber.
6. Under endoscopic visualization, place the loaded XprESS device into the target location to illuminate within and transilluminate across nasal and sinus structures.
   - Projected illumination can be enhanced by slightly advancing tip of the LED Light Fiber distal from the XprESS device.
7. After procedure, dispose of device according to Federal, state, and local regulations, and appropriate environmental health safety guidelines. Do not incinerate except for disposal in a controlled incinerator.

Specifications

Item	Specification
Weight	< 40 grams
Nominal working length of fiber	27.6cm
Fiber outer diameter	0.375mm (0.015”).
Light source (red LED)	625nm wavelength
Activation time	Over 60 minutes
Battery type	Lithium manganese dioxide, CR2, 3Volts
Power source	Internally powered
Maximum LED output power for treatment	1 W
Mode of operation	Continuous
Safe operating ambient temperature range	15 - 33ºC (59 - 91ºF)
Safe storage and transport temperature range	-10 - 50ºC (14 - 122ºF)
Safe operating, storage, & transport relative humidity range	0 – 95% RH
Complies with medical safety standards:	IEC 60601-1:2005/AMD 1:2012; CAN/CSA-C22.2 No. 60601-1:2014

Complies with medical EMC standard:	IEC 60601-1-2:2014; Type BF applied part

Electromagnetic Compatibility (EMC)

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section. Portable and Mobile RF communications equipment can affect Medical Electrical Equipment.

Guidance and Manufacturer's Declaration - Emissions		
The LED Light Fiber is intended for use in the electromagnetic environments specified below. The customer or the user of the LED Light Fiber should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The LED Light Fiber uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electrical equipment.
RF Emissions CISPR 11	Class B	The LED Light Fiber is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	N/A	
Flicker IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration – Immunity			
The LED Light Fiber is intended for use in the electromagnetic environments specified below. The customer or the user of the LED Light Fiber should assure that it is used in such an environment.			
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
ESD EN/IEC 61000-4-2	±6kV Contact, ±8kV Air	±6kV Contact, ±8kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the RH should be at least 30%.
EFT EN/IEC 61000-4-4	±2kV Mains, ±1kV I/Os	N/A *(LED Light Fiber is powered by internal battery)*	N/A
Surge EN/IEC 61000-4-5	±1kV Differential, ±2kV Common		
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds		
Power Frequency 50/60Hz, Magnetic Field EN/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity			
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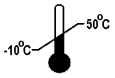
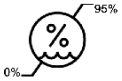
Immunity Test	**EN/IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF EN/IEC 61000-4-6	3Vrms, 150kHz to 80MHz	N/A *(LED Light Fiber is powered by internal battery)*	Portable and mobile RF communications equipment should be used no closer to the LED Light Fiber than the distances calculated or listed below. **Recommended Separation Distance** $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5MHz Where *P* is the maximum output power rating of the transmitter in watts and *d* is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level (E1). Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF EN/IEC 61000-4-3	3Vms, 80MHz to 2.5GHz	3V/m (E1)	

Recommended Separation Distances between portable and mobile RF communications equipment and the LED Light Fiber			
The LED Light Fiber is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the LED Light Fiber can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment (transmitters) and the LED Light Fiber as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power of Transmitter (Watts)	**Separation distance according to frequency of transmitter (m)**		
	150kHz to 80MHz $d = (1.2)(\sqrt{P})$	**80MHz to 800MHz** $d = (1.2)(\sqrt{P})$	**800MHz to 2.5GHz** $d = (2.3)(\sqrt{P})$
0.01	N/A *(LED Light Fiber is powered by an internal battery)* Conducted RF Immunity testing does not apply, resulting in no separation data from 150kHz to 80MHz.	0.12	0.23
0.1		0.38	0.73
1		1.2	2.3
10		3.8	7.3
100		12	23

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	 Quantity	 Authorized Representative in the European Community
 Sterilization with Ethylene Oxide Gas	 Manufacturer	 Do Not Reuse	 Prescription Use Only	 Temperature Limit
 Type BF applied part	 Reorder Number	 Use By	 2797 CE Mark	 Humidity Limitation

Not made with natural rubber latex.

PathAssist, Light Fiber and XprESS are trademarks of Entellus Medical.

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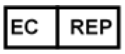

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