



INSTRUCTIONS FOR USE

ALL INSTRUCTIONS, PRECAUTIONS AND WARNINGS SHOULD BE CAREFULLY READ AND UNDERSTOOD BEFORE USE. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

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

Indication for Use

To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a transnasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

To dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older using a transnasal approach.

Description

The XprESS ENT Dilation System is intended to remodel or recreate the sinus outflow tract and dilate the Eustachian tube by transnasal balloon dilation. The XprESS device combines features of a curved suction tip and an ostium seeker with the tissue expansion effect of balloon dilation. The familiar features of this device enable a physician to track the device into the sinuses and Eustachian tubes using endoscopic visualization. Since the distal end of the device is reshapeable, one balloon can be modified to work on multiple sinuses and Eustachian tubes within the same patient.

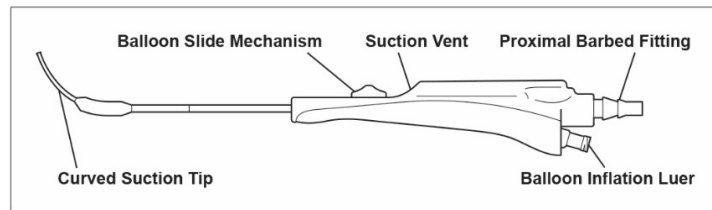


Figure 1 – XprESS ENT Dilation Device

The XprESS device curved suction tip has an atraumatic ball tip. A suction tube may be connected to the proximal barbed fitting to provide active suction by covering the suction vent. An Extension Line connected to a syringe may be connected to the proximal barbed fitting to provide irrigation. The device was designed to prevent fluid from exiting the suction vent during irrigation. The XprESS ENT Dilation System is provided sterile and for single use only.

The XprESS ENT Dilation System includes the XprESS device, Inflation Syringe, Bending Tool, and Extension Line(s). The XprESS LoProfile and Ultra ENT Dilation Systems also include the PathAssist LED Light Fiber.

XprESS is available in the following suction tip sizes and balloon sizes. All suction tips and balloon lengths are appropriate for treating all sinuses and Eustachian tubes; selection is based on physician preference. If treating only Eustachian tubes, the longer length balloons may be more efficient.

XprESS LoProfile	XprESS Ultra
LoProfile Suction Tip (1.75 mm ball tip, 0.7 mm ID, 1.2 mm OD)	Ultra Suction Tip (1.5 mm ball tip, 0.5 mm ID, 1.0 mm OD)
Balloon Diameter x Length (mm)	Balloon Diameter x Length (mm)
5 x 8	5 x 8
5 x 20	5 x 20
6 x 8	6 x 8
6 x 20	6 x 20
7 x 20	NA

The XprESS ENT Dilation System has been tested to withstand multiple inflations and device tip manipulations in a surgical case.

Contraindications

- None known

Warnings

- Never advance or withdraw the XprESS device against any resistance. Do not use excessive force or torque to advance the XprESS device or balloon/slide assembly when positioned in any paranasal or nasopharynx space. Such actions could lead to tissue trauma, bleeding, or device damage.
- Do not use breached or damaged packages, since the sterility and functionality of the device may be compromised.
- The XprESS ENT Dilation System is provided sterile and intended for single use only. Do not resterilize and/or reuse, as it may result in compromised device performance and risk improper sterilization and cross-contamination.
- Do not use the XprESS device in patients with known allergies to barium sulfate.
- Do not use XprESS to dilate Eustachian tubes in patients with a history of patulous Eustachian tubes.
- Due to the variability of anatomy, review appropriate radiographic imaging (eg, a CT scan) prior to treatment. Do not use the XprESS device to treat a hypoplastic/atelectatic maxillary sinus, atelectatic ethmoid infundibulum, or patients with evidence of internal carotid artery dehiscence.
- Due to the variability of sinus development in pediatric patients, review CT scan to assess each sinus’s development and appropriateness for balloon dilation. Pneumatization may occur as early as 1-2 years of age and continues to develop throughout childhood. Do not use XprESS in a sinus that is not adequately developed.
- Do not insert the XprESS device beyond the tubal isthmus of the Eustachian tube, as this may increase the risk of bony fracture and injury to the internal carotid artery.
- Do not advance the LED Light Fiber beyond the distal tip of XprESS when XprESS is placed in the Eustachian tube, as this may lead to tissue trauma.
- Do not exceed the maximum recommended balloon inflation pressure of 12 atm. Over-inflation of the balloon can result in serious adverse events.
- Do not use ionic or non-ionic fluoroscopic contrast solution to inflate the balloon in patients with known allergies to contrast media.

- If suction through the XprESS device lumen is used during the procedure, temporarily discontinue suction (remove finger from suction vent, disconnect suction hose from device, or clamp suction hose) at the time of balloon inflation. Suction can resume subsequent to balloon deflation. Using the XprESS device in suction mode while balloon is inflated may result in barometric trauma to tissue, which may lead to increased bleeding or damage to the tympanic membrane.
- Do not irrigate within the Eustachian tube, as this may damage the tympanic membrane.
- As in any upper airway procedure or sinus surgery, do not have patient use CPAP until the physician has confirmed that the tissue is adequately healed. CPAP use prior to soft tissue healing may result in facial and/or neck swelling due to subcutaneous emphysema.
- Do not clean the XprESS device with anti-microbial agents as the compatibility of the XprESS device with these agents has not been tested.
- The XprESS device has been tested only with the Fiagon Navigation System and Stryker ENT Navigation System (compatible with XprESS LoProfile). Do not attach the XprESS device to other image guidance systems, as use with other systems may result in inaccurate device positioning. Refer to *System Operation 1.b* for instructions on how to connect XprESS to the Stryker ENT Navigation System or Fiagon system.
- The XprESS device has been tested only with the Entellus Inflation Syringe. Do not use other inflation devices with the XprESS device, as doing so may result in serious patient injury.

Precautions

- Store the XprESS device components in a cool and dry place. Never use a device that is beyond its expiration date.
- Handle the XprESS device with care. Prior to use, and during the procedure, inspect the packaging and components for bends, kinks, or other damage. Discontinue the use of the XprESS device if it may have been damaged.
- Select a balloon diameter that will result in expansion of the tissue post dilation. Do not select a balloon diameter that is larger than the bony margins of the outflow tract as this may damage the balloon.
- Pay special attention when advancing or withdrawing the balloon and slide assembly. If resistance is encountered, use endoscopy or direct visualization to help guide device out of the paranasal or nasopharynx space and then attempt to alleviate the resistance. If the cause of resistance cannot be determined, do not use the XprESS device.
- Use direct endoscope visualization with or without PathAssist LED Light Fiber or Light Fiber to ensure accurate placement of the balloon prior to dilation. If balloon location cannot be verified, image guidance or fluoroscopy can be used. If balloon location still cannot be verified, the balloon should not be inflated.
- Consider using self-limiting radiation exposure equipment when employing fluoroscopy to confirm device placement. Ensure the equipment is calibrated and maintained according to the equipment manufacturer's user manual.
- Use techniques for reducing fluoroscopic exposure when using fluoroscopy. Examples are applying pulsed beam settings, increasing target-to-panel distance, using posterior-anterior projection, and using appropriate lead shield protection. Total fluoroscopy time should be limited to 30 minutes.
- When fluoroscopy is used, especially in children, minimize radiation dose to the lens of the eye and other proliferating tissues due to the potential for cataract formation or injury to the surrounding tissue.
- Do not advance or withdraw a guidewire through the XprESS LoProfile suction/irrigation lumen against resistance. This could lead to device damage.
- Be aware that guidewires (including TGS Guidewires and Fiagon GuideWires) do not load through the XprESS LoProfile when they are bent in the recommended maxillary configuration or through the XprESS Ultra in any configuration. Other methods can be used to obtain confirmation of the treatment area, such as use of the PathAssist Light Fiber, direct visualization of the XprESS device with an aid of an endoscope, or fluoroscopic imaging of the XprESS tip.
- Use standard larger suction tubes for removal of thick secretions or other materials. XprESS LoProfile has a 0.7 mm ID comparable to that of a 4F suction tube. XprESS Ultra has a 0.5 mm ID comparable to that of a 2.5F suction tube. Both are capable of removing blood and thin mucous.
- Fully deflate the balloon and retract the balloon slide assembly before withdrawing the XprESS device from the paranasal or nasopharynx space.
- Use only liquid contrast or saline solution for inflation. Do not inflate with air.
- Consider using a new balloon if cross-contamination between sinuses or Eustachian tubes is a concern.

Adverse Effects

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

- | | | |
|---|--|---------------------------------|
| • Complication from anesthesia | • Cavernous sinus syndrome | • Revision surgery |
| • Damage to the lamina papyracea | • Damage to the lacrimal sac affecting tearing | • Tinnitus |
| • Damage of the orbital wall or other structures of the eye | • Pneumocephalus | • Damage to the Eustachian tube |
| • Cerebrospinal fluid leak | • Bruising and swelling | • Patulous Eustachian tube |
| • Loss of vision or diplopia (double vision) | • Tissue inflammation | • Permanent hearing loss |
| • Pain | • Fever and infection | • Carotid artery damage |
| • Bleeding | • Continued or worsening symptoms | • Tympanic membrane damage |

Supplies

The following supplies are not provided with the XprESS ENT Dilation System and should be available and prepped prior to use of the device.

- Appropriate endoscopes and compatible camera system
- ≥50 mL of sterile saline solution, sterile fluoroscopic contrast solution, or sterile water
- Needles and syringes as required for injections
- 20-30 mL syringe and Extension Line (if irrigation is to be performed)
- Suction system
- Other supplies or medication as established by laboratory protocol
- If desired, Entellus Medical PathAssist™ LED Light Fiber, Light Fiber™, or Light Seeker

Optional Equipment

The following equipment is not provided with the XprESS ENT Dilation System and may not be available in all markets.

- Stryker ENT Navigation System and TGS Guidewire (compatible with XprESS LoProfile)
- Fiagon Navigation System and GuideWires (GuideWire 0.6 is compatible with XprESS LoProfile)
- Fluoroscopy may be used in conjunction with the endoscope if desired.
- Refer to appropriate Instructions for Use and safety procedures when preparing and using equipment.

Instructions for Use

System Preparation

1. Prepare the Inflation Syringe and Extension Line

- a. Remove the Inflation Syringe and Extension Line from its sterile package.

Note the 3 referenced Inflation Syringe plunger positions:

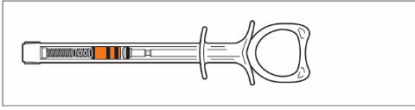


Figure 2 - Plunger all the way in

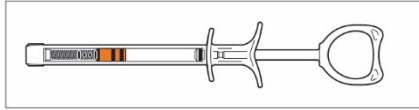


Figure 3 - First Click position

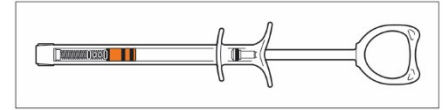
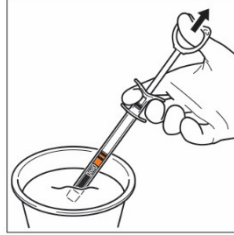


Figure 4 - Second Click position (all the way out)

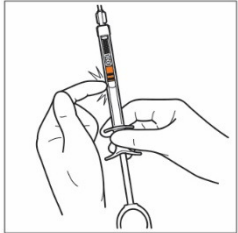


- b. Begin with the Inflation Syringe plunger **all the way in** (Figure 2).

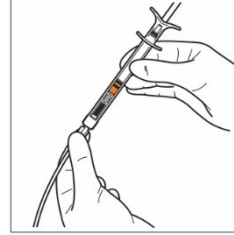
- c. Then submerge tip in sterile saline solution.



- f. Point the syringe tip **towards the ceiling**. Tap the Inflation Syringe until a large bubble is visible beneath the orange piston.

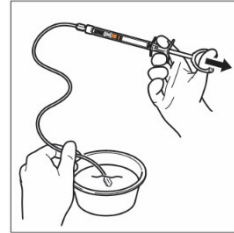


- d. Fill Inflation Syringe by slowly drawing plunger back to **second click position** (all the way out) (Figure 4).

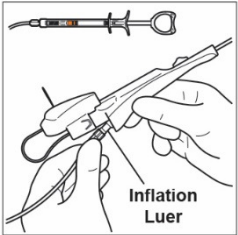


- e. Attach an Extension Line to the filled Inflation Syringe.

- g. While still pointing the syringe tip **towards the ceiling**, push the plunger **all the way in** (Figure 2), to purge all air and fluid from the syringe.



- h. Submerge the free end of the Extension Line in sterile saline solution. **Slowly** draw plunger back to the **first click position** (Figure 3) to fill the syringe.



2. Prepare XprESS ENT Dilation System.

- a. Remove the XprESS device from its sterile package.
- b. Remove and discard the balloon protector.
- c. Connect the free end of the prepped Extension Line to the XprESS balloon inflation luer.

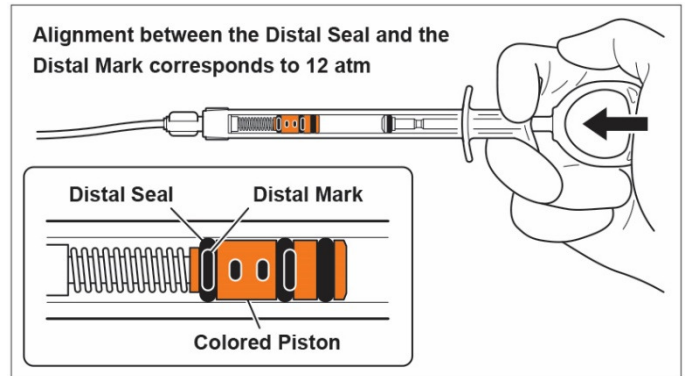
Note: Inspect the syringe barrel to ensure there is minimal air in the system. If excessive air remains in the system, repeat the prepping process.

- d. Perform a test inflation of the system by depressing the plunger rod until the distal black seal on the orange piston is aligned with the distal black mark of the Inflation Syringe (See Figure 5). If the seal and black mark do not align, disconnect the Inflation Syringe and Extension Line and repeat the prepping process.

- e. Pull the plunger rod back to the 2nd click to apply a vacuum to the balloon. Ensure there is no air introduced into the system during deflation of the balloon. If a leak is detected and the source cannot be identified and corrected, do not use the XprESS device, Extension Line, and Inflation Syringe. Use new devices to complete the procedure.

- f. If suction or irrigation is planned, connect the Extension Line to the proximal barbed fitting to add a flexible connector for suction or irrigation.

Figure 5: Alignment between Distal Seal and Distal Mark



Reshaping the XprESS Device Suction Tip to Treat Multiple Spaces

- When treating multiple spaces, it is recommended to complete balloon dilation of the frontal or sphenoid sinuses or Eustachian tubes prior to treatment of the maxillary sinuses.
- **Frontal Sinuses:** When treating the frontal recesses, a large radius curve similar to a frontal sinus seeker (Figure 6) is recommended. This is the shape/curve provided in the package.
- **Sphenoid Sinuses:** When treating the sphenoid sinus ostia, a slight bend (Figure 7) is recommended.
- **Eustachian Tubes:** When treating the Eustachian tubes, a bend of approximately 45° at the 2 cm mark (Figure 8) is recommended.
- **Maxillary Sinuses:** When treating the maxillary ostia/ethmoid infundibula, a bend of approximately 120 - 135° (Figure 9) is recommended to gain access to the natural maxillary ostium. Use the included Bending Tool to achieve this geometry.

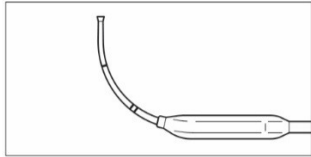


Figure 6: Frontal Bend

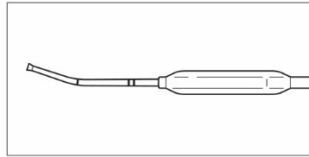


Figure 7: Sphenoid Bend

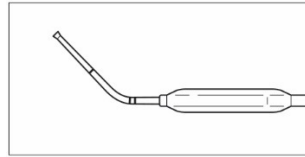


Figure 8: Eustachian Tube Bend

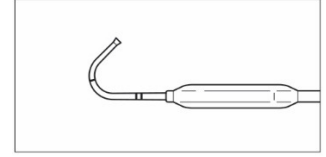


Figure 9: Maxillary Bend

- Small adjustments to the above bends may be considered to accommodate different patient anatomy.

Using Bending Tool

- The Bending Tool should be used to achieve the proper maxillary bend. The tool also provides a frontal and sphenoid bend configuration if needed.
- **Maxillary Bending with Bending Tool:** Before shaping the maxillary bend, the device should be close to straight as shown for a Sphenoid Bend. With the Bending Tool in one hand, position the ball tip into the ball holder in the bending tool (Figure 10). Place a finger at about the 2 cm mark on the suction tip and use this finger to form the Maxillary Bend (Figure 11).

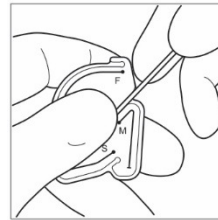


Figure 10 – Start Maxillary Bend

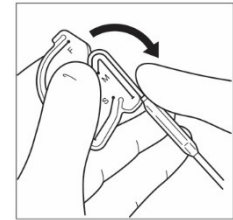


Figure 11 – Finish Maxillary Bend

Patient Preparation

1. Patient preparation should be consistent with standard practice.
2. Anesthesia should be administered appropriately to allow patient tolerance.

System Operation

1. Locate the sinus structure or Eustachian tube orifice using one of the following confirmation methods:
 - a. **Direct Visualization with or without Light Confirmation:** Locate the treatment area using XprESS with or without LED Light Fiber, Light Fiber, Light Seeker, a standard sinus ostium seeker, and/or guidewire with the aid of an endoscope. Observe the location of the treatment area relative to the anatomical landmarks through the endoscope. Remove the Light Seeker, sinus ostium seeker, or guidewire after locating treatment area.
Note: If using the PathAssist LED Light Fiber or Light Fiber, refer to the Instructions for Use (IFU) for complete instructions.
 - b. **CT Image Guidance:** If further confirmation of the treatment area location is desired, CT image guidance using the Stryker ENT Navigation System and TGS Guidewire, or Fiagon Navigation System and GuideWire 0.6 may be used.
 - i. **If using TGS Guidewire or GuideWire 0.6 with XprESS LoProfile,** load the guidewire through the working lumen of XprESS until the luer lock connector meets the proximal barbed fitting of XprESS.
 - ii. Secure the luer lock connector on the proximal barbed fitting.
 - iii. Refer to Stryker ENT Navigation System or Fiagon Navigation System Instructions for Use.
Note: The TGS Guidewire and Fiagon GuideWire 0.6 must be loaded through the working lumen of the XprESS LoProfile device before placing into the maxillary bend configuration. Guidewires do not load through the XprESS Ultra in any configuration.
Note: Do not attach the XprESS device to other image guidance systems.
 - c. **Fluoroscopy:** If further confirmation of the treatment area is desired, fluoroscopy may be used. Take two orthogonal views (AP and lateral). The XprESS device suction tip is stainless steel and is visible under fluoroscopy. The balloon will be proximal to the tip of the device.
2. Under endoscopic visualization, track the XprESS device to the same treatment area identified above.
 - a. Position XprESS suction tip within the sinus ostia or within the cartilaginous portion of the Eustachian tube.
Notes: Reference marks are located 1 and 2 cm from the tip of the device.
The XprESS suction tip may be reshaped to aid in device positioning.
Use device as a suction tool to maintain a clear visual field during device positioning. Cover suction vent with finger to allow suction.
3. Advance the balloon by fully advancing the balloon slide mechanism forward to position the balloon within the sinus opening or Eustachian tube.
4. Prior to inflating balloon, discontinue the use of suction (remove finger from suction vent, disconnect suction hose from device, or clamp suction hose) to decrease the risk of barotrauma.
5. Balloon dilation of the treatment site:
 - a. Slowly depress the Inflation Syringe plunger rod to inflate the balloon. The pressure should be increased slowly (3-5 seconds) until the orange piston bottoms out (distal black seal of the piston reaches the distal black mark on the Inflation Syringe – see Figure 5). If these do not align, deflate the balloon and remove the XprESS device and perform a test inflation (as described in steps 2.d and 2.e of the System Preparation section). Alignment of the distal mark and distal seal will ensure that 12 atm of pressure is reached.
Note: Do not use air or any gaseous medium to inflate the balloon.

- b. Inflate the balloon until the desired result is achieved or until it reaches 12 atm.

Sinus Dilation: Inflate the balloon for up to 20 seconds (less than or equal to 20 seconds); observe that the balloon is inflated endoscopically.

Eustachian Tube Dilation: Inflate the balloon for approximately 2 minutes by holding in the plunger rod; observe that the balloon is inflated endoscopically.

Note: Do not exceed 12 atm.

Warning: To avoid barometric trauma to tissue, do not use device in suction mode (remove finger from suction vent, disconnect suction hose from device, or clamp suction hose) while balloon is inflated.

- c. When using the 8 mm length balloon, multiple inflations may be needed in order to achieve the desired result. Partially retract the balloon slide mechanism between inflations using the 5 mm handle reference marks to ensure full length treatment. See Figure 12.

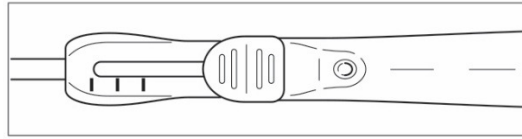


Figure 12: Handle Marks for 8mm Length Balloon

- d. Deflate the balloon by retracting the Inflation Syringe plunger rod to the second click position and retracting the XprESS balloon slide mechanism. Observe the results endoscopically.

- e. Perform additional inflations if needed until desired result is achieved.

Note: To irrigate the sinus, fill a 20-30 mL syringe with sterile saline. Connect the syringe to a flexible Extension Line and purge air. Connect Extension Line to proximal barbed fitting and flush through suction/irrigation lumen as desired. The suction vent does not need to be covered during irrigation.

6. Remove device from treatment site: When the sinus outflow tract or Eustachian tube has been adequately dilated, deflate the balloon (*by retracting the Inflation Syringe plunger rod to the stop position*), retract the XprESS balloon slide mechanism, and remove the XprESS device from the treatment site.
7. If necessary, clean up the ostium site by cutting or removing flaps of tissue, fragments of exposed bone, or any other bone and mucosa that may obstruct or otherwise prevent ventilation and drainage of the sinus.
8. Repeat the same procedure to treat additional spaces if desired.
9. After completing the entire procedure, dispose of the devices and all waste products according to appropriate environmental health safety guidelines.

How Supplied

The XprESS ENT Dilation System is provided sterile and is intended for single-use only. Do not resterilize and/or reuse, as it may result in compromised device performance and risk improper sterilization and cross-contamination. Do not use breached or damaged packages, since the sterility and functionality of the device may be compromised.

Limited Warranty

Refer to Entellus Medical, Inc. Standard Terms and Conditions.

Symbols

 Consult Instructions for use	 Lot Number	 Model Number	 Quantity	 Authorized Representative in the European Community
 Sterilized using Ethylene Oxide	 Manufacturer	 Do Not Reuse	 Prescription Use Only	 Temperature Limit
 Type BF Applied Part	 Catalog Number	 Use by Date	 CE Mark	 Humidity Limitation

Not made with natural rubber latex.

XPRESS, PATHASSIST and LIGHT FIBER are trademarks of Entellus Medical.

patent <http://www.ent.stryker.com/patents>



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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 50°C (122°F).

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”).

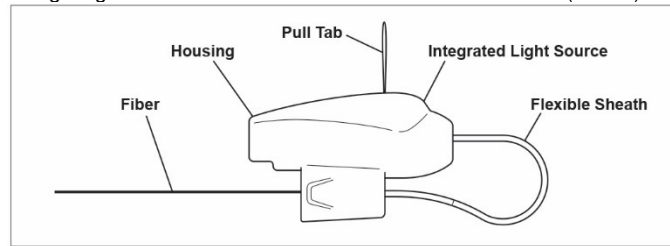


Figure 1 LED Light Fiber

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

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. Pneumatization 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 135° 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)

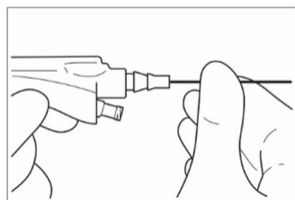


Figure 2

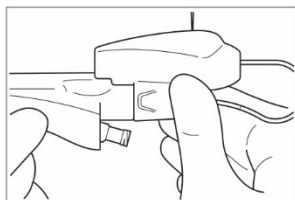


Figure 3

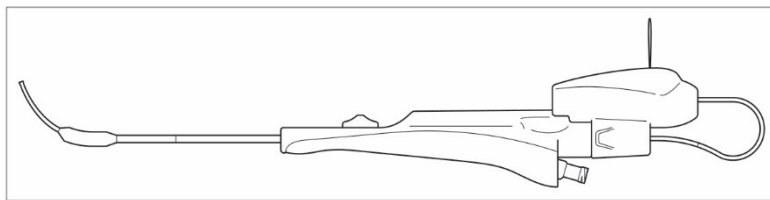


Figure 4

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 - 33°C (59 - 91°F)
Safe storage and transport temperature range	-10 - 50°C (14 - 122°F)
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.



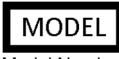





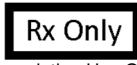






Guidance and Manufacturer's Declaration – Immunity			
The LED Light Fiber is intended for use in the electromagnetic environments specified below. The customer or the user of the LED Light Fiber should assure that it is used in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF EN/IEC 61000-4-6	3Vrms, 150kHz to 80MHz	N/A <i>(LED Light Fiber is powered by internal battery)</i>	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	3Vrms, 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 <i>(LED Light Fiber is powered by an internal battery)</i>	0.12	0.23
0.1		0.38	0.73
1	Conducted RF Immunity testing does not apply, resulting in no separation data from 150kHz to 80MHz.	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
 Sterilized using Ethylene Oxide	 Manufacturer	 Do Not Reuse	 Prescription Use Only	 Temperature Limit
 Type BF Applied Part	 Catalog Number	 Use by Date	 2797 CE Mark	 Humidity Limitation

Not made with natural rubber latex.

PathAssist, Light Fiber and XprESS are trademarks of Entellus Medical.
patent <http://www.ent.stryker.com/patents>


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