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 approach.

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 approach.

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. The XprESS Pro ENT Dilation System also includes a Tuohy Adapter.

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.

<table>
<thead>
<tr>
<th>XprESS Pro</th>
<th>XprESS LoProfile</th>
<th>XprESS Ultra</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Suction Tip (2 mm ball tip, 1 mm ID, 1.5 mm OD)</td>
<td>LoProfile Suction Tip (1.75 mm ball tip, 0.7 mm ID, 1.2 mm OD)</td>
<td>Ultra Suction Tip (1.5 mm ball tip, 0.5 mm ID, 1.0 mm OD)</td>
</tr>
<tr>
<td>Balloon Diameter x Length (mm)</td>
<td>Balloon Diameter x Length (mm)</td>
<td>Balloon Diameter x Length (mm)</td>
</tr>
<tr>
<td>NA</td>
<td>5 x 8</td>
<td>5 x 8</td>
</tr>
<tr>
<td>NA</td>
<td>5 x 20</td>
<td>5 x 20</td>
</tr>
<tr>
<td>6 x 8</td>
<td>6 x 8</td>
<td>6 x 8</td>
</tr>
<tr>
<td>6 x 18</td>
<td>6 x 20</td>
<td>6 x 20</td>
</tr>
<tr>
<td>7 x 18</td>
<td>7 x 20</td>
<td>NA</td>
</tr>
</tbody>
</table>

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. 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 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 Pro or LoProfile suction/irrigation lumen against resistance. This could lead to device damage.
- Be aware that guidewires (including Fiagon GuideWires) do not track through the XprESS Pro or LoProfile when they are bent in the recommended 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 Pro has a 1 mm ID comparable to that of a 5F suction tube. 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. All are capable of removing blood and thin mucus.
- 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
- Damage to the lamina papyracea
- Damage of the orbital wall or other structures of the eye
- Cerebrospinal fluid leak
- Loss of vision or diplopia (double vision)
- Pain
- Bleeding
- Cavernous sinus syndrome
- Damage to the lacrimal sac affecting tearing
- Pneumocephalus
- Bruising and swelling
- Tissue inflammation
- Fever and infection
- Continued or worsening symptoms
- Revision surgery
- Tinnitus
- Damage to the Eustachian tube
- Patulous Eustachian tube
- Permanent hearing loss
- Carotid artery damage
- 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 the use of a sterile guidewire is desired (compatible with the XprESS Pro), the recommended guidewire should be sterile and ≤0.035 inches in diameter with a minimum length of 50 cm. Example of a guidewire that meets these requirements is the Entellus Medical Sinus Guidewire.
- If desired, Entellus Medical PathAssist™ LED Light Fiber, Light Fiber™, or Light Seeker

Optional Equipment
- Fiagon Navigation System and GuideWires (GuideWire and GuideWire 0.6 are compatible with XprESS Pro; 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:
1. Locate the sinus structure or Eustachian tube orifice using one of the following confirmation methods:
   - System Operation
     - Patient Preparation
   - Using Bending Tool
   - Reshaping the XprESS Device Suction Tip to Treat Multiple Spaces
     - 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.
     - Small adjustments to the above bends may be considered to accommodate different patient anatomy.

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.
       - 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.

   - 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.

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

   - 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).

   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.

   - i. Load the Fiagon GuideWire through the Tuohy Adapter and working lumen of XprESS until the tip of GuideWire aligns with the tip of XprESS.
   - ii. Secure the GuideWire in place by tightening the Tuohy Adapter.
   - iii. If using GuideWire 0.6 with XprESS Pro or LoProfile, load the GuideWire 0.6 through the working lumen of XprESS until the luer lock connector meets the proximal barbed fitting of XprESS.
v. Secure the luer lock connector on the proximal barbed fitting.
vi. Refer to Fiagon Navigation System Instructions for Use.

**Note:** Neither of the Fiagon GuideWires should be used with any XprESS device in the maxillary bend 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 required.
      **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.

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 required.
   **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.

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 required.
   **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.