



XprESS™

Multi-Sinus Dilation Tool

INSTRUCTIONS FOR USE

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

Please check annually for updates to these Instructions

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

IF YOU DESIRE A COMPLIMENTARY HARD COPY OF THESE INSTRUCTIONS, PLEASE CALL OUR CUSTOMER SERVICE DEPARTMENT AT 866-620-7615 OR FAX YOUR REQUEST TO 866-620-7616.

Description

The XprESS Multi-Sinus Dilation Tool is intended to remodel or recreate the sinus outflow tract via trans-nasal balloon dilation. The XprESS device combines features of a curved suction tip and a frontal ostium seeker with the tissue expansion effect of balloon dilation. The familiar features of this device enable a physician to track the device to the sinus ostium. Since the distal end of the device is re-shapeable, one balloon can be modified to work on multiple sinuses within the same patient.

The XprESS Multi-Sinus Dilation Tool has been tested to withstand multiple inflations and device tip manipulations (up to 25) in a surgical case wherein all 6 sinus ostia are being dilated.

The XprESS device curved suction tip has a 2 mm atraumatic ball tip with a 1 mm inside diameter. A suction tube may be connected to the proximal barbed fitting to provide active suction. An Infusion Line connected to a syringe may be connected to the proximal barbed fitting to provide irrigation.

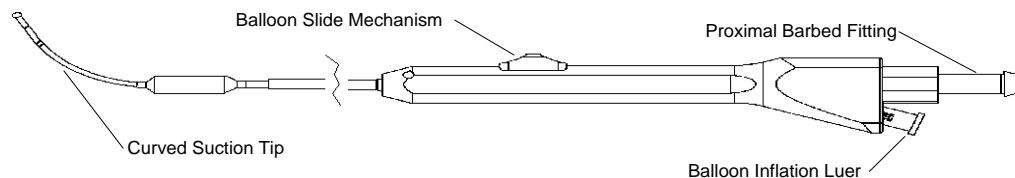


Figure 1 – XprESS Multi-Sinus Dilation Tool

The XprESS Multi-Sinus Dilation Tool is provided sterile and for single use only.

The items packaged with the Xpress Multi-Sinus Dilation Tool include the Inflation Device, Bending Tool and two Infusion Lines.

Indication for Use

To access and treat the frontal recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

Contraindications

- Do not use this XprESS device in patients who are allergic to nickel or barium sulfate.
- Do not attach the XprESS device directly to the CT Image Guidance systems. This may result in inaccurate device positioning.

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 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.
- This XprESS device is provided sterile. Do not re-sterilize because device integrity may be compromised.
- The XprESS device, inflation device and other accessories are intended for single procedure use only. Do not attempt to reuse or re-sterilize because the integrity of the XprESS devices may be compromised.
- Due to the variability of sinus anatomy, review appropriate radiographic imaging (CT scan) prior to treatment. Do not use the XprESS device to treat a hypoplastic/atelectatic maxillary sinus or atelectatic ethmoid infundibulum.
- Do not exceed the maximum recommended balloon inflation pressure of 12 atm. Over-inflation of sinus balloons 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 (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 sinus tissue which may lead to increased bleeding.
- As in any upper airway procedure or sinus surgery, do not use CPAP until the physician has confirmed that the tissue is adequately healed. CPAP usage 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 Entellus Inflation Device. Do not use other inflation devices. Use of other inflation devices 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.
- 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 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 fluoroscopy to ensure accurate placement of the balloon prior to dilation. If balloon location 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 per 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, utilizing posterior-anterior projection, or using appropriate lead shield protection. Total fluoroscopy time should be limited to 30 minutes.
- When fluoroscopy is used, minimize radiation dose to the lens of the eye and other proliferating tissues due to the potential of cataract formation or injury to the surrounding tissue.
- Do not advance or withdraw the guidewire through the suction/irrigation lumen against resistance. This could lead to device damage.
- Be aware that some guidewires may not track through the XprESS device when it is bent in the maxillary configuration.
- Use standard larger suction tubes for removal of thick secretions or other materials.
- Fully deflate the balloon and retract the balloon slide assembly before withdrawing the XprESS device from the paranasal sinus 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 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)
- Temporary or permanent facial / nasal pain
- Epistaxis
- Cavernous sinus syndrome
- Damage to the lacrimal sac affecting tearing
- Pneumocephalus
- Facial bruising and swelling
- Tissue inflammation
- Fever and infection
- Continued or worsening sinus symptoms
- Revision surgery

Supplies

The following supplies are not provided with the XprESS Multi-Sinus Dilation Tool and should be available and prepped prior to use of the device.

- » Appropriate endoscopes and compatible camera system
- » ≥ 50 cc of sterile saline solution or sterile fluoroscopic contrast solution or sterile water
- » Needles and syringes as required for injections
- » 20-60 cc syringe and infusion line (if irrigation is to be performed)
- » Suction system
- » Other supplies or medication as per established laboratory protocol
- » If the use of a sterile guidewire is desired, the recommended guide wire should be made of metal, sterile, straight or curved, and 0.035 inches in diameter with a minimum length of 50 cm. Examples of guidewires that meet these requirements include the Entellus Medical Sinus Guidewire and the Acclarent Relieva Luma™ Sinus Illumination System guidewire.

Optional Equipment

- » Standard CT image guidance system and tools (Do not attach directly to XprESS device)
- » 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 Entellus Medical Inflation Device and Infusion Line.
 - a. Remove the Inflation Device and an Infusion Line from the sterile package.
 - b. Connect the Infusion Line to the Inflation Device.
 - c. Insert the luer fitting of the Infusion Line into sterile saline solution. Keep the Inflation Device luer pointed up during the prepping steps to prevent air entrapment.
 - d. Fully retract the plunger rod to the stop position as shown in Figure 2.
 - e. Advance the plunger rod fully into the syringe barrel to purge air from the system.
 - f. Repeat steps d and e until no more air is present in the system. This will fill the barrel with the saline solution.
 - g. With the inflation device full of saline and the plunger fully retracted (to stop position), advance the plunger one click (Figure 3). The Inflation device is now ready to be connected to the balloon.

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



Figure 2: Plunger at Stop Position



Figure 3: Plunger at One Click

2. Prepare XprESS Multi-Sinus Dilation Tool.
 - a. Remove the XprESS device from its sterile package.
 - b. Connect the prepped Inflation Device Infusion Line to the balloon inflation luer.
 - c. With the balloon protector in place, 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 Device (See Figure 4).
 - d. Pull back on the plunger rod to the stop position 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, discard the XprESS device, infusion line, and inflation device. Use new devices to complete the procedure.
 - e. Remove and discard the balloon protector prior to introducing the balloon into the sinus.
 - f. If suction or irrigation is planned, remove the second infusion line from its sterile package and connect to the Proximal Barbed Fitting to add a flexible connection for suction and irrigation.

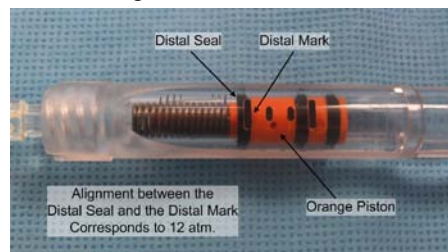


Figure 4: Alignment between Distal Seal and Distal Mark

Re-shaping the XprESS Device Suction Tip to Treat Multiple Sinuses

- » When treating multiple sinuses, it is recommended to complete balloon dilation of the frontal or sphenoid sinuses 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 5) is recommended. This is the shape/curve provided in the package.
- » **Sphenoid Sinuses:** When treating the sphenoid sinus ostia, a slight bend (Figure 6) is recommended.
- » **Maxillary Sinuses:** When treating the maxillary ostia/ethmoid infundibula, a bend of approximately 135° with a 12mm leg (Figure 7) is recommended to gain access to the natural maxillary ostium.



Figure 5: Frontal Bend



Figure 6: Sphenoid Bend

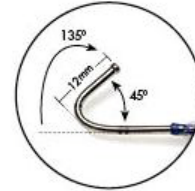


Figure 7: Maxillary Bend

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

Using Bending Tool

- » *The bending tool can be used primarily as an aid to achieve the proper maxillary bend, The tool also provides a frontal 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 8). Place a finger at about the 2 cm mark on the suction tip and use this finger to form the Maxillary Bend (Figure 9).



Figure 8: Start Maxillary Bend



Figure 9: Finish Maxillary Bend

Patient Preparation

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

Locate the Sinus Structure

1. **Direct Visualization:** Locate the treatment area or sinus structure using a standard sinus ostium seeker, suction tube (standard or XprESS) 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 sinus ostium seeker, suction tube or guidewire after locating treatment area. When treating the maxillary sinus ostia, removal of a portion of the uncinat process may be required to achieve direct visualization.
2. **CT Image Guidance:** If further confirmation of the treatment area location is desired, CT Image guidance using standard image guidance tools may be used. If CT image guidance is used, the CT scan data should be uploaded into the image guidance system prior to the start of the procedure. Use only the tools recommended by the CT image system manufacturer. **Do not attach the CT Image Guidance system to the XprESS device.**

System Operation

1. Position XprESS suction tip within the sinus structure.
 - a. Under endoscopic visualization, track the XprESS device to the same treatment area identified in the section "Locate the Sinus Structure".

Note: Reference marks are located 1 and 2 cm from the tip of the device.

- b. **Fluoroscopy:** If further verification of the device placement prior to dilation is desired, fluoroscopy may be used. Take two orthogonal views (AP and lateral) of the sinus. The XprESS device suction tip is stainless steel and is visible under fluoroscopy. The balloon will be proximal to the tip of the device.
- c. To further enhance visualization under fluoroscopy, insert the flexible end of the selected 0.035" guidewire through the proximal end of suction lumen (see Supplies Section for compatible guidewire). Feed the guidewire through the lumen (device is approximately 27 cm in length) until the flexible tip exits the XprESS device. If resistance in the guidewire is met, reposition the XprESS device so that the guidewire can pass freely out the distal end of the lumen. If suction was used through the suction lumen prior to guidewire advancement, clean the suction lumen by irrigating with sterile saline.

Note: The XprESS suction tip may be re-shaped to aid in device positioning.

Note: Use device as a suction tool to maintain a clear visual field during device positioning.

2. Advancing the balloon to the treatment site.

Under endoscopic visualization, fully advance the balloon slide mechanism forward to position the balloon within the sinus opening.

3. Prior to inflating balloon, discontinue the use of suction to decrease the risk of sinus barotrauma.

4. Balloon dilation of the treatment site.

- a. Slowly depress the 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 device – see Fig. 4). If these do not align, deflate the balloon and remove the XprESS device and perform a test inflation (*as described in steps 2.c and 2.d 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. Inflate the balloon for up to 20 seconds (less than or equal to 20 second), observe that the balloon is inflated endoscopically.

Note: Do not exceed 12 atm.

Note: To avoid barometric trauma to sinus tissue, do not use device in suction mode while balloon is inflated.

- c. Deflate the balloon by retracting the Inflation Device plunger rod to the stop position and retracting the XprESS balloon slide mechanism. Observe the results endoscopically.
- d. Perform additional inflations if needed until desired result is achieved. Typically 1-2 inflations are performed per sinus.

Note: To irrigate the sinus, fill a 20-60cc syringe with sterile saline or sterile water. Connect the syringe to the flexible infusion line and flush through suction/irrigation lumen as desired.

5. Remove device from treatment site.

When the sinus outflow tract has been adequately dilated, deflate the balloon (*by retracting the Inflation Device plunger rod to the stop position and retracting the XprESS balloon slide mechanism*) and remove the XprESS device from the treated sinus.

6. 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 re-establishment of ventilation and drainage of the sinus.
 7. Prepare balloon for dilation of additional sinuses (if desired).
 - a. Gently advance the plunger rod into the syringe barrel to slightly expand the balloon to remove any wrinkles using minimal pressure.
 - b. Clean the balloon prior to introduction into another sinus. This may be done by wiping the balloon with sterile wet gauze or dipping the balloon in sterile saline or sterile water.
 - c. Pull back on the plunger rod to the stop position to apply vacuum to the balloon.
 8. Repeat the same procedure to treat additional sinuses if desired.
- Note:** *The XprESS suction tip may be re-shaped to treat additional sinuses (see Figures 5-7).*
9. After completing the entire procedure, dispose of the devices and all waste products according to appropriate environmental health safety guidelines.

How Supplied

The contents of the XprESS Multi-Sinus Dilation Tool are provided sterile and are intended for single-use only.

Do not re-sterilize and/or re-use, 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.

The items packaged with the Xpress Multi-Sinus Dilation Tool include the Inflation Device, the Bending Tool and two Infusion Lines.

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*.

Symbols

| | | | |
|---|---|--|--|
|  REF Reorder Number |  LOT Lot Number |  MODEL Model Number |  Manufacturer |
|  Consult Instructions for use |  Quantity |  Do Not Reuse |  Rx Only Prescription Use Only |
|  STERILE EO Sterilization with Ethylene Oxide Gas |  Use By | | |

Does not contain natural rubber latex (raw materials contain no latex and no latex has been introduced during manufacturing).

ACCLARENT, RELIEVA, and RELIEVA LUMA are trademarks of Acclarent, Inc.
 XprESS is a trademark of Entellus Medical.



Manufactured by:
 Entellus Medical Inc.
 6705 Wedgwood Court North
 Maple Grove, MN 55311
 (763) 463-1595
 www.entellusmedical.com