EUSTACHIAN TUBE DILATION TECHNIQUE GUIDELINES
A physician using XprESS products for Eustachian tube dilation must either (i) have experience with a Eustachian tube balloon dilation device or (ii) undergone cadaver training on the use of a balloon dilation device for Eustachian tube dilation. If a physician who intends to use XprESS for Eustachian tube dilation does not meet at least one of these criteria, please contact your Entellus Medical representative to arrange training.
Eustachian tubes: When treating the Eustachian tubes, a bend of approximately 45° at the 2cm mark is recommended

- Straighten the hypotube of the XprESS and then using your fingers make a 45 degree bend beginning at the 2cm depth mark
- Remove LED Light Fiber prior to accessing the Eustachian tubes
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.

Any size XprESS may be used; selection is based on physician preference.

**Eustachian Tube Treatment Technique**
Eustachian Tube Treatment Technique

- Position XprESS within the cartilaginous portion of the Eustachian tube so that the 2cm mark is just visible
  
  **Tip:** Positioning may be easier with a tip down approach
  
  **Tip:** When anatomy is restrictive to having both XprESS and the scope in the same side, it may be easier to place the scope in the contralateral side

- Never advance the XprESS device against resistance. This may lead to tissue trauma or device damage

**CARTILAGINOUS PORTION OF EUSTACHIAN TUBE**
• When bent at an angle of approximately 45 degrees at the 2cm mark the device can only be inserted 20mm into the Eustachian tube.

• It is well established that the cartilaginous portion of the Eustachian tube is 24mm in length\(^1\).

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Eustachian Tube Treatment Technique

• Fully advance the balloon slide mechanism forward to position the balloon within the Eustachian tube

• If suction is being used 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
Eustachian Tube Treatment Technique

- 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)

ALIGNMENT BETWEEN THE DISTAL SEAL AND THE DISTAL MARK CORRESPONDS TO 12ATM
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

**Tip:** A two handed inflation technique may be used to ease pressure on hands during the 2 minute inflation time.
Eustachian Tube Treatment Technique

- When using the 8mm length balloon, multiple inflations may be needed in order to achieve the desired result. Partially retract the balloon slide mechanism between inflations using the 5mm handle reference marks to ensure full length treatment.
Remove Device From Treatment Site

- When the Eustachian tube has been adequately dilated, deflate the balloon by retracting the Inflation Syringe plunger rod to the second click position
- Retract the XprESS balloon slide mechanism
- Observe the results endoscopically
- Remove the XprESS device from the treatment site
**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.

Please see Instructions for Use (IFU) for a complete listing of warnings, precautions, and adverse events.

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

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