



Entellus Medical Functional INfundibular Endoscopic Sinus System.

INSTRUCTIONS FOR USE

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

All packaging and referenced Entellus Medical device components are LATEX FREE

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

System Description

The Entellus Medical, Inc. **F**unctional **I**nfundibular **E**ndoscopic **S**inus **S**ystem (FinESS[®]) includes the following components:

Micro-Trocar & Access Sheath

The Micro-Trocar provides a small access hole into the Maxillary Sinus through the Canine Fossa. The Micro-Trocar also delivers the Access Sheath, which is intended to maintain consistent access for procedural devices (Cannula / Endoscope & Balloon Catheter).

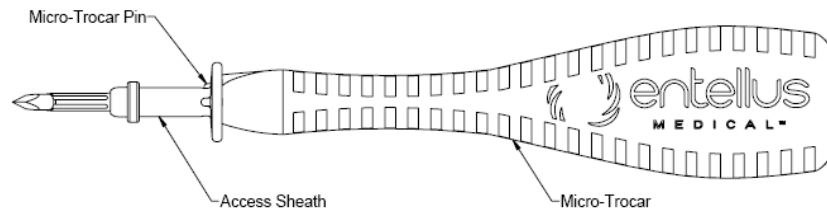


Figure 1 – Sinus Access Tools: Micro-Trocar Inserted Through Access Sheath

Cannula

The Cannula is a dual lumen instrument that allows both delivery of the Balloon Catheter and visualization with an Endoscope. The Cannula is sized to pass through the Access Sheath.

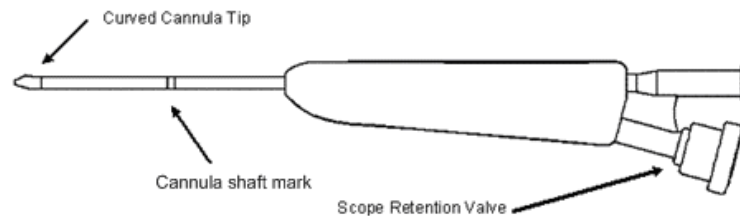


Figure 2 – Sinus Cannula

Balloon Catheter

The Balloon Catheter is designed to dilate the maxillary sinus ostium and the ethmoid infundibulum space. The balloon catheter includes a braided shaft design that allows for rotational positioning to accurately deliver the balloon into the ostium while navigating within the parasinus space.

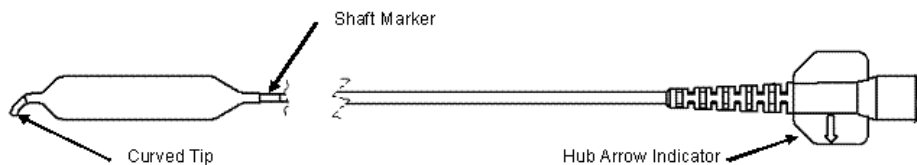


Figure 3 – Sinus Balloon Dilatation Catheter

Inflation Device

The disposable Entellus Medical, Inc. Inflation Device consists of a syringe barrel, a plunger rod assembly used to generate and control balloon inflation pressures, and a pressure limit mechanism. The pressure limit mechanism limits the amount of positive pressure the Inflation Device can generate to 12 atm \pm 1 atm (176 psi \pm 14.7 psi).

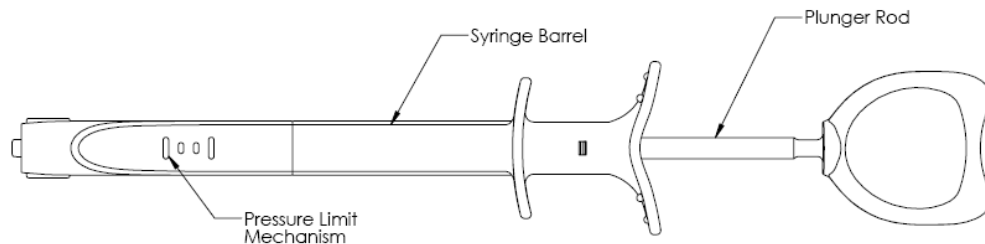


Figure 4 – Inflation Device

All components of the FinESS[®] Sinus Treatment are provided sterile.

Indication for Use

To access and treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

Contraindications

Patients with thickened polypoid mucosa excessive enough to inhibit the visualization of the maxillary ostium should not be considered candidates for the FinESS[®] Sinus Treatment.

Warnings

- Only physicians possessing sufficient skill and expertise in similar technique (accessing maxillary sinus ostium and ethmoid infundibulum through canine fossa) should perform this procedure.
- Do not use the FinESS[®] Sinus Treatment if CT image indicates challenging anatomy such as a hypoplastic antrum or polypoid mucosa that may limit success of Canine Fossa approach.
- Do not use opened or damaged packages.
- The FinESS[®] Sinus Treatment is intended for single procedure use only. Do not attempt to reuse or re-sterilize. Device integrity may be compromised.
- Do not apply excessive penetration force when drilling the canine fossa access hole. Patient injury or device damage may occur.
- Do not exceed the maximum recommended balloon inflation pressure (12 atm). Use of the Entellus Medical Inflation Device is required to prevent over-pressurization.
- Do not advance or withdraw the Balloon when inflated. Mucosa damage or device damage may occur.
- As in any upper airway procedure or sinus surgery, do not use CPAP for approximately 7 days post-procedure with FinESS[®] Sinus Treatment. CPAP usage prior to soft tissue healing may result in facial and/or neck swelling due to subcutaneous emphysema.

Precautions

- FinESS[®] Sinus Treatment components should be stored in a cool and dry place. Never use a device that is beyond its expiration date.

- FinESS[®] Sinus Treatment components should be handled with care. Prior to use, and during the procedure, inspect the packaging and components for bends, kinks, or other damage. Discontinue the use of any component that may have been damaged.
- Pay special attention when advancing or withdrawing the Cannula or Balloon Catheter. Never advance, withdraw or torque any component that meets resistance, as this could cause kinking or breaking. If resistance is encountered, use endoscopy to help guide device manipulation. If the cause of resistance cannot be determined, withdraw all components as a system. Do not apply downward force with the Canula during removal, as this may cause damage to the cannula.
- The Balloon Catheter should only be manipulated under endoscopic observation.
- The Balloon Catheter should be positioned with its curved tip in an inferior orientation when tracking through the maxillary sinus ostium and ethmoid infundibulum to avoid tracking into the agger nasi cell.
- Patients should be advised to sneeze with an open mouth and avoid extreme inhalation and blowing through the nose for approximately 7 days post-procedure to reduce the likelihood of inflammation and/or swelling due to subcutaneous emphysema.
- It is important to review the patient's CT image prior to performing the FinESS[®] procedure in order to determine the most appropriate access location.

Adverse Effects

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

- Post-operative facial pain
- Excessive bleeding in the nose and at the canine fossa
- Complication from anesthesia
- Fracture of the anterior wall of the maxillary sinus
- Cerebrospinal fluid leak
- Loss of vision or diplopia (double vision)
- Damage to a tooth root or gingiva
- Damage to nerves potentially causing temporary (and occasionally prolonged) numbness to the cheek, lip, or teeth; mid-facial pain; and tooth pain or hypersensitivity
- Facial bruising and swelling
- Swelling of the nose and cheek
- Fever and infection
- Tissue inflammation
- Continued or worsening sinus symptoms

Supplies

The following supplies need to be available and prepped prior to use of the FinESS[®] Sinus Treatment.

Note: These supplies are not provided with the FinESS[®] Sinus Treatment.

- Entellus Flexible Endoscope ES-100 or ES-100a and compatible camera system
- Sterile Saline Solution
- 60 cc Syringe (if irrigation is to be performed)
- Needles and Syringes as required for local anesthesia injections
- Suction system
- #5 and #7 Suction Tips
- Other supplies or medication as per established laboratory protocol

System Preparation

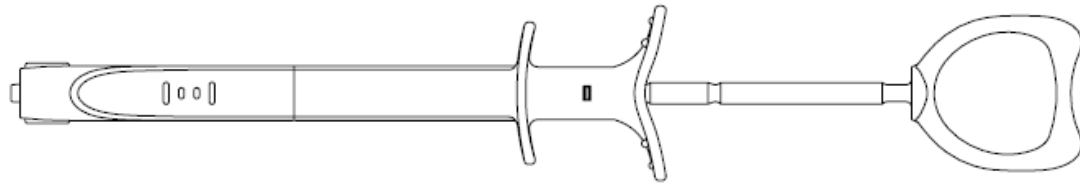
1. Prepare Imaging Sleeve and Endoscope.

- a. Verify endoscope has been disinfected per appropriate instructions. If using Entellus Flexible Endoscope ES-100, proceed to step 2.
- b. Remove the Imaging Sleeve from its sterile package.
- c. While holding the Imaging Sleeve relatively straight, insert the Endoscope into the Male Luer Adapter (see Figure 5) and slide Sleeve over Endoscope.

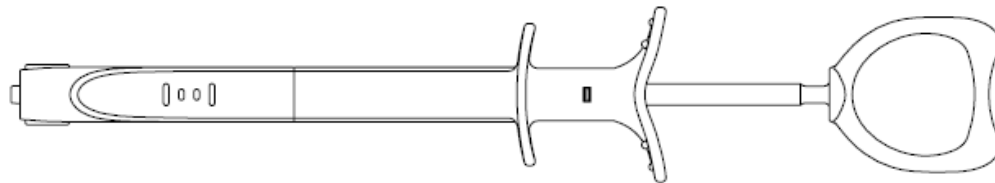
Note: The 0.5 mm Endoscope should be handled with care. Avoid stretching or kinking the Endoscope. Device damage may occur.

2. Prepare Cannula.
 - a. Insert the Endoscope into the Cannula until it is flush with the Cannula tip.
 - b. Tighten the scope retention valve (see Figure 2) to secure the scope within the Cannula. Verify the Endoscope is flush or just outside (approximately 0.5 mm) of the Cannula.
 - c. Connect Endoscope to Camera System.
 - d. While holding the Cannula with the Endoscope Retention Valve positioned down (see Figure 2), rotate the Camera relative to the eyepiece to align the image as desired.
3. Prepare Micro-Trocar.
 - a. Remove the Micro-Trocar and Access Sheath from their sterile package.
 - b. Slide the Access Sheath onto the Micro-Trocar. Rotate Access Sheath on Micro-Trocar until Micro-Trocar Pin engages with Access Sheath allowing Access Sheath to lay flush against the Micro-Trocar (see Figure 1).
- 4a. Prepare Inflation Device (to prepare the Inflation Device with provided Infusion Line, proceed to step 4b)
 - a. Remove the Inflation Device from its sterile package.
 - b. Depress the plunger rod fully into the body of the Inflation Device.
 - c. Insert the luer end of the Inflation Device into Sterile Saline Solution. Fully retract the plunger rod to the stop position (2nd Detent) as shown in Figure 6. This will fill the barrel with saline solution.
 - d. While holding the Inflation Device with the luer pointed up, advance the plunger rod into the syringe barrel up to the first detent position (shown in Figure 6) to purge air. 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 steps b – d.



Plunger Rod at Stop Position (2nd Detent)



Plunger Rod 1st Detent

Figure 6

4b. Prepare Inflation Device with Infusion Line.

- a. Remove the Inflation Device and the 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 (2nd Detent) as shown in Figure 6. This will fill the barrel with the saline solution.
- 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.
- g. With the balloon device full of saline and the plunger fully retracted (to stop position), advance the plunger to the first detent (Figure 6). 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 steps c – d.

5. Prepare Balloon Catheter

- a. Remove the Balloon Catheter from its sterile package.
- b. Connect the Balloon Catheter to the Inflation Device (or Infusion Line, if applicable).
- c. While holding the Inflation Device with the Balloon Catheter pointed down, depress the plunger rod with 2 hands, keeping the plunger rod straight, until the distal seal on the orange piston aligns with the distal mark on the inflation device.
- d. Pull back on the plunger rod to apply a vacuum to the balloon. Lock the plunger rod in position by pulling it back to the second detent.
- e. Remove the Protective Sleeve from the Balloon. Retain the Sleeve for balloon re-wrapping.

System Operation

1. Patient preparation.
 - a. Patient preparation should be consistent with standard practice.
 - b. Anesthesia should be administered appropriately to allow patient tolerance.
2. Access Maxillary Sinus
 - a. Firmly lift and retract lip to visualize gingival tissue and feel for canine fossa recess.
 - b. While retracting lip to minimize gingival tissue thickness, enter tissue with Micro-Trocar.
 - c. After accessing gingival tissue, position Micro-Trocar tip on bony surface at the intersection location described in Figure 7.

Note: *The target access location is typically on the lateral side of the canine fossa recess.*

Note: *Access location may be confirmed by gently angling the Micro-Trocar to be perpendicular to the facial plane while holding the Micro-Trocar tip on the bone at the target access location.*

- d. While holding Micro-Trocar at appropriate angle (approximately 45 degrees from the facial plane with the Micro-Trocar tip pointed at the inside corner of the eye), apply a back-and-forth rotational motion (versus a pushing motion) to gently create an access hole.

Note: *Do not apply excessive penetration force when making access hole.*

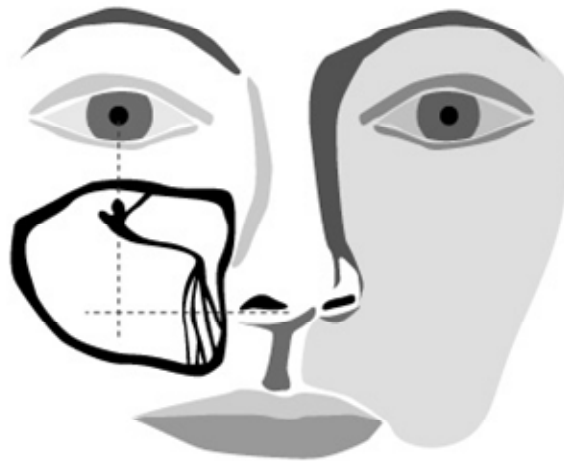


Figure 7 –Target Access Site Location

- e. After sinus access is achieved, continue rotating Micro-Trocar with back-and-forth motion while gently angling the Micro-Trocar tip toward the Maxillary Sinus Ostium (corner of the eye). The gentle side-cutting motion provides a range of motion for the Cannula to visualize the Sinus Ostium.

Note: *The Micro-Trocar must be rotated with a back-and-forth motion prior to angling the Micro-Trocar.*

Note: *The Micro-Trocar Pin must be engaged with the Access Sheath to allow side-cutting. If Pin pulls out of Access Sheath, re-insert and continue Micro-Trocar rotations.*

- f. While holding Access Sheath in access site with one hand, slide the Micro-Trocar out of the Access Sheath with the other hand by using thumb to push the Access Sheath off of the Micro-Trocar. Do not apply downward force with the Micro-Trocar during removal.

Note: *If Access Sheath slips out of access site (even if it is just removed from the hole in the bone) at any time, re-load Access Sheath onto Micro-Trocar and use Micro-Trocar to locate original hole, or to re-access in a secondary location. Do not attempt to re-access the hole with the Access Sheath only. Access Sheath damage may occur.*

g. Use a standard #5 suction tip to aspirate fluid from the access sheath as required.

3. Insert Cannula into Access Sheath under endoscopic visualization.

Note: *The Cannula should be inserted up to the Cannula Shaft Mark (see Figure 2) to ensure the Cannula passes completely through the Access Sheath. Failure to accurately position the Cannula Shaft Mark may result in balloon damage.*

Note: *At any time during the procedure, the Cannula may be removed from the Access Sheath to clean the Endoscope by gently pulling the Cannula tip / Endoscope tip across a surgical wipe soaked in an appropriate cleaning medium. Do not apply downward force with the Cannula during removal.*

4. Visualize presence of air / fluid level within sinus.

a. If fluid level impedes endoscopic visualization, aspiration and/or irrigation may be required.

b. Remove Cannula from Access Sheath to complete aspiration and/or irrigation.

c. Insert Cannula into Access Sheath. Verify acceptable fluid level. Excess residual saline in the sinus should be gently aspirated through a standard #5 suction device.

5. Visualize the maxillary sinus ostium.

a. While holding the Access Sheath in the access site, gently manipulate the Cannula to visualize the maxillary sinus ostium.

b. While visualizing the ostium, topical anesthetic may be sprayed through the Cannula for additional topical anesthesia as required.

Note: *Use suction to remove residual anesthetic from Cannula using a standard #5 tip as required.*

6. Introduce the Balloon Catheter through the Cannula.

Note: *The Balloon Catheter should be tracked through the Cannula while under vacuum from the Inflation Device.*

7. Advance the Balloon across the ostium under endoscopic visualization.

a. When the Balloon Catheter tip is positioned just outside of the ostium, advance the balloon into the sinus ostium with the curved catheter tip pointed posterior / inferior.

Note: *The arrow on the Balloon Catheter hub indicates the direction of the tip curve.*

b. Using the Shaft Marker (see Figure 3) as a visual reference for the proximal balloon end, position the Balloon within the ostium / infundibulum.

Note: *The Balloon Catheter may be rotationally steered to allow full insertion of the balloon into the ostium and infundibulum.*

8. Inflate Balloon.

a. Slowly depress the plunger rod with 2 hands, keeping the plunger rod straight, to inflate the balloon. The pressure should be increased slowly (5 – 7 seconds) until the distal seal on the orange piston reaches the distal mark on the inflation device.

Note: *Do not use air or any gaseous medium to inflate the balloon.*

b. Inflate sinus balloon until desired result is achieved. Endoscopically observe balloon dilation.

Note: *Do not exceed the maximum pressure of 12 atm.*

- c. After balloon dilation is complete, deflate the sinus balloon by gently pulling back on the plunger rod. Confirm the balloon deflation endoscopically.
- d. Lock the plunger rod in place by pulling it back to the second detent position. A stop will prevent the plunger rod from being removed from the inflation device.
- e. Verify the Cannula is inserted into the Access Sheath up to the Shaft Mark to ensure the Cannula tip is inserted beyond the Access Sheath.
- f. Withdraw balloon from Cannula under endoscopic visualization.

Note: Rotating the Catheter as the Balloon begins to engage the Cannula will assist in balloon withdrawal.

9. Endoscopically observe balloon dilation result.

- a. If the maxillary sinus ostium has been adequately dilated, remove Cannula and Access Sheath from access site. Do not apply downward force with the Cannula during removal, as this may cause damage to the cannula.

Note: Adequate dilation can be visually confirmed by observing the balloon during inflation, visually verifying balloon positioning during inflation, and ensuring that the recommended inflation pressure is achieved.

- b. If additional balloon dilation is required, prepare Balloon Catheter per step 10 and repeat steps for Balloon inflation.

10. Prepare Balloon Catheter for additional dilations (if required).

- a. Gently advance the plunger rod into the syringe barrel to expand the balloon using minimal pressure.
- b. Rinse balloon with sterile saline or water.
- c. Wipe balloon dry using gauze pad.
- d. Point the distal tip of the balloon catheter down. Gently pull back on the plunger rod to apply vacuum to the balloon. Lock the plunger rod by pulling it back to the second detent position.
- e. Re-wrap the tri-folded balloon by gently folding the wings around the catheter shaft in a clockwise direction.
- f. Slide the Protective Sleeve on the re-wrapped balloon to restore original balloon profile.
- g. Before additional balloon dilatation, remove the Protective Sleeve from the Balloon. Retain the Sleeve for Balloon re-wrapping.

11. Repeat procedure for contralateral maxillary sinus if needed.

Note: The scope image may need to be re-aligned prior to viewing second side. While holding the Cannula with the Endoscope Retention Valve positioned down (see Figure 2), rotate the Camera relative to the eye piece to align the image as desired.

12. After completing the entire procedure, withdraw all system components and discard.

Limited Warranty

Entellus Medical, Inc. warrants that reasonable care has been used in the design and manufacture of the FinESS[®] Sinus Treatment system. This limited warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied, written or oral, by operation of law or otherwise including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose, or warranties arising from a course of dealing or usage or trade. Handling, storage, cleaning and sterilization of the FinESS[®] Sinus Treatment system, as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond Entellus Medical, Inc.'s control, directly affect the FinESS[®] Sinus Treatment system and the results obtained from its use. This limited warranty does not extend to any abuse or misuse of the FinESS[®] Sinus Treatment system (including, without limitation, off-label use), accident to or neglect of the FinESS[®] Sinus Treatment system, failure to follow any instructions or specifications provided with the FinESS[®] Sinus Treatment system (including, without limitation, any re-use, re-processing or re-sterilization of the FinESS[®] Sinus Treatment system not in accordance with such instructions or specifications), in each case whether caused or carried out by Customer or by any third party.

Entellus Medical's obligation under this limited warranty is limited, at Entellus Medical, Inc.'s option, to the repair or replacement of the FinESS[®] Sinus Treatment system for a period of twelve (12) months from the date of purchase (the "Warranty Period") using commercially reasonable efforts within a reasonable period of time. Entellus Medical, Inc. shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from use of the FinESS[®] Sinus Treatment system. Repair or replacement of the FinESS[®] Sinus Treatment system shall not extend the term of any applicable warranty and the original term of such warranty shall remain in effect. Repairs, modifications or alterations of the FinESS[®] Sinus Treatment system performed by any person or entity other than Entellus Medical, Inc. or approved by Entellus Medical, Inc. in writing shall nullify and otherwise void all applicable warranties hereunder.











Entellus Medical, Inc. shall be obligated to honor the express limited warranties contained herein only upon receipt of full payment for the FinESS[®] Sinus Treatment system or otherwise in accordance with the payment terms agreed to by Entellus Medical, Inc. and Customer.

Entellus Medical, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with the FinESS[®] Sinus Treatment system.

Limitation of Liability

In no event will either Entellus Medical, Inc. or Customer be liable to the other or to any third party for loss of profit, goodwill or other indirect, incidental, special or consequential or other similar damages arising out of these Terms and Conditions or any Related Purchase Document. The limitation of liability described in this section is in addition to any limitation provided for by the Limited Warranty provisions.

Symbols

 REF Reorder Number	 LOT Lot Number	 MODEL Model Number
 See Instructions For Use	 SN Serial Number	 Do Not Reuse
 STERILE EO Sterilization with Ethylene Oxide Gas	 Use Before	Rx Only Prescription Use Only
 Quantity	 Manufacturer	

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