



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.

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.

INSTRUCTIONS AVAILABLE AT [HTTP://WWW.FINESS-IFU.COM](http://www.finess-ifu.com). 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.

System Description

The Entellus Medical, Inc. Functional Infundibular Endoscopic Sinus System (FinESS™) includes the following components:

Micro-Trocar, Access Sheath & Access Sheath Spacer

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 (FinESS Endoscope & Balloon Catheter) and to position the FinESS Endoscope. The Access Sheath Spacer can be removed from the Access Sheath to allow the FinESS Endoscope to be re-positioned.

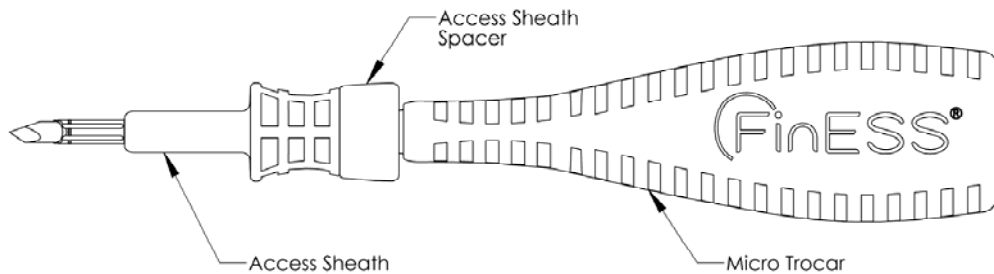


Figure 1 – Sinus Access Tools: Micro-Trocar Inserted Through Access Sheath and Access Sheath Spacer

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 paranasal space.

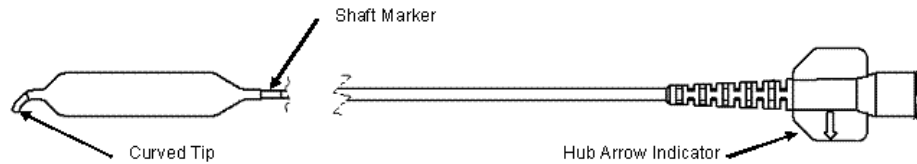


Figure 2 – Sinus Balloon Dilatation Catheter

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).

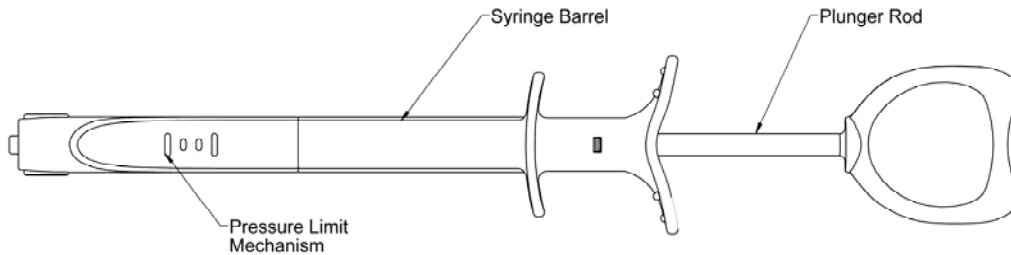


Figure 3 – Inflation Device

Infusion Line

The Infusion Line may be connected to the Inflation Device to provide extra length to maneuver the balloon if necessary.

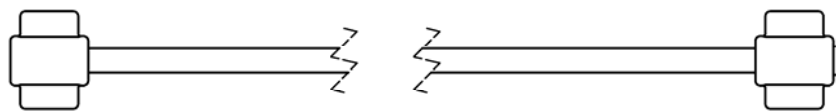


Figure 4 – Infusion Line

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 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.

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 Endoscope 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.
- The Balloon Catheter should only be manipulated under endoscopic observation.
- 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 and to appreciate unique anatomical characteristics, eg. agger nasi cell, that may impact placement of the balloon into the desired treatment location.
- Patients with dental phobias and with dentist/dental procedure anxiety are best managed in an operating environment.

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.

- FinESS Endoscope 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 the FinESS Endoscope.
 - a. Verify endoscope has been disinfected per appropriate instructions.
 - b. Connect the FinESS Endoscope to an appropriate light source and cameras specified in the FinESS Endoscope instructions for use.
 - c. While holding the FinESS Endoscope, rotate the Camera relative to the eyepiece to align the image as desired.
2. Prepare Micro-Trocar.
 - a. Remove the Micro-Trocar and Access Sheath from their sterile package.
- 3a. Prepare Inflation Device (to prepare the Inflation Device with provided Infusion Line, proceed to step 3b)
 - 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 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 one click to the position shown in Figure 7 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.



Figure 6: Plunger at Stop Position



Figure 7: Plunger at One Click

3b. 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 as shown in Figure 6.
- 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 7). 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 d – e.

4. 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. 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 on the inflation device (See Figure 8).
- 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 FinESS device, infusion line, and inflation device. Use new devices to complete the procedure.
- e. Remove the balloon protector from the Balloon. Retain the balloon protector for balloon re-wrapping.

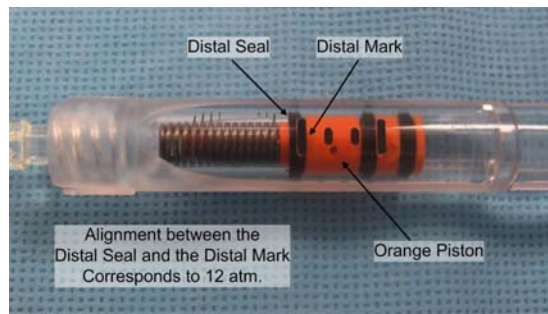


Figure 8

System Operation

1. Patient preparation.
 - a. Patient preparation should be consistent with standard practice.
 - b. Anesthesia should be administered appropriately to allow patient tolerance. Use of both topical and local anesthesia is recommended in awake outpatients for this procedure.
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 9.

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.*

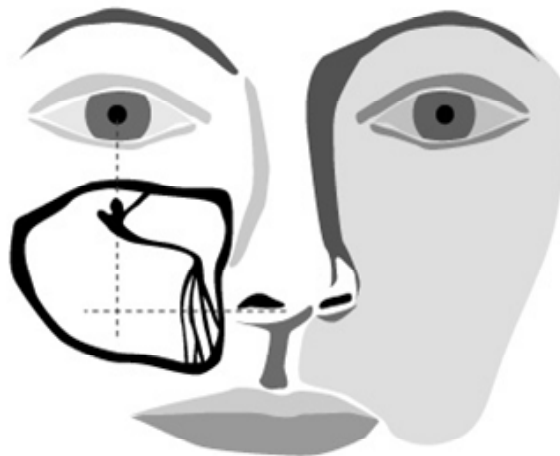


Figure 9 –Target Access Site Location

- 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 FinESS Endoscope 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 must be engaged with the Access Sheath to allow side-cutting. If Micro-Trocar 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. While holding the FinESS Endoscope in an upright position insert the FinESS Endoscope into Access Sheath under endoscopic visualization.

Note: *The FinESS Endoscope should be inserted into the Access Sheath until the Endoscope is seated against the Access Sheath Spacer (see Figure 1). Failure to accurately position the Endoscope may result in balloon damage.*

Note: *The Access Sheath Spacer may be removed from the Access Sheath to allow additional Endoscope insertion depth if necessary. The FinESS Endoscope should be inserted until the Endoscope is seated against the Access Sheath (see Figure 1). Failure to accurately position the Endoscope may result in balloon damage.*

Note: *At any time during the procedure, the Endoscope may be removed from the Access Sheath to clean the Endoscope by gently wiping the Endoscope tip across an alcohol prep pad or anti-fog cleaning pad.*

4. Visualize presence of air / fluid level within sinus.
 - a. If fluid level impedes endoscopic visualization, aspiration and/or irrigation may be required.
 - b. To irrigate, fill a 60 cc syringe with Sterile Saline Solution and purge air. Connect the syringe to the FinESS Endoscope balloon port and flush with saline.
 - c. 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 Endoscope to visualize the maxillary sinus ostium.
- b. While visualizing the ostium, topical anesthetic may be sprayed through the Endoscope for additional topical anesthesia as required.

Note: *Use suction to remove residual anesthetic from Endoscope using either a standard #5 tip or connecting the suction to directly to the balloon port of the Endoscope.*

6. Introduce the Balloon Catheter through the FinESS Endoscope.

Note: *The Balloon Catheter should be tracked through the FinESS Endoscope 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 to inflate the balloon. The pressure should be increased slowly (3 – 5 seconds) until the distal black seal on the orange piston reaches the distal black mark on the inflation device (See Figure 8). If these do not align, deflate the balloon and remove the balloon catheter and perform a test inflation (*as described in steps 4.c and 4.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 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 stop position. The stop will prevent the plunger rod from being removed from the inflation device.

- e. Verify the FinESS Endoscope is seated against the Access Sheath Spacer or Access Sheath to ensure the Endoscope tip is inserted beyond the Access Sheath.

- f. Withdraw balloon from Endoscope under endoscopic visualization.

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

9. Endoscopically observe balloon dilation result.

- a. If the maxillary sinus ostium has been adequately dilated, remove Endoscope and Access Sheath from access site.

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 stop position.

- e. Re-wrap the tri-folded balloon by gently folding the wings around the catheter shaft in a clockwise direction.











11. Repeat procedure for contralateral maxillary sinus if needed.

12. After completing the entire procedure, withdraw all system components. Discard FinESS Sinus Treatment System components and all waste products according to appropriate environmental health safety guidelines. Set the FinESS Endoscope aside for reprocessing.

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
 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	

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

©2009 Entellus Medical. All rights reserved. FinESS is a registered trademark of Entellus Medical.



Entellus Medical Inc.
 6705 Wedgwood Court North
 Maple Grove, MN 55311
 866-620-7615 (f)866-620-7616
www.entellusmedical.com