



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 & 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.

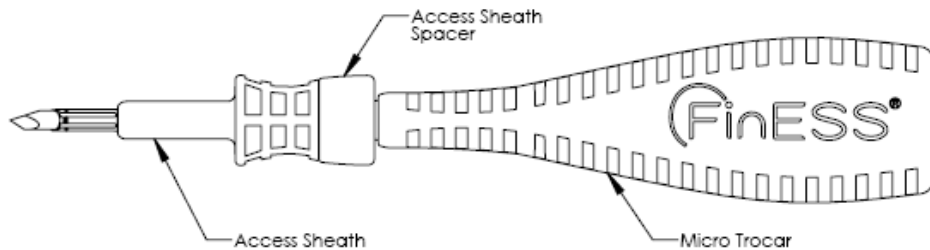


Figure 1 – Sinus Access Tools: Micro-Trocar Inserted Through Access Sheath and Access Sheath Spacer

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.

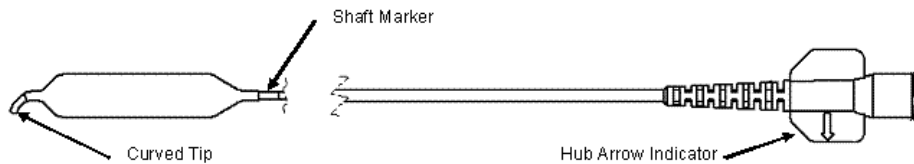


Figure 2 – Sinus Balloon Dilatation Catheter

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).

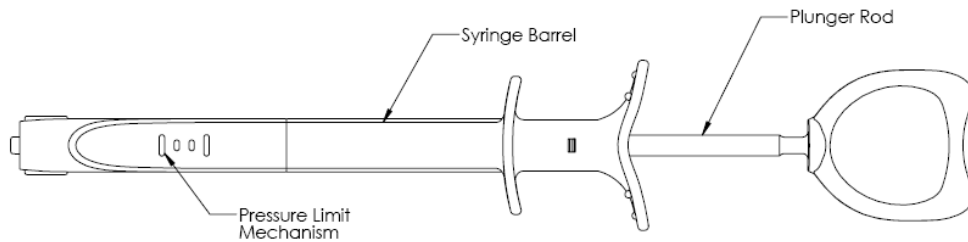


Figure 3 – Inflation Device

Infusion Line

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

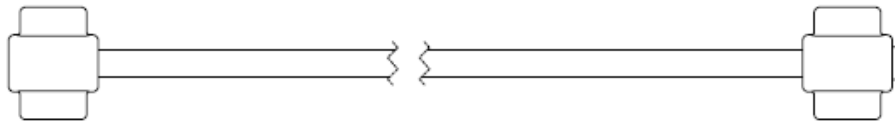


Figure 4 –Infusion Line

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.

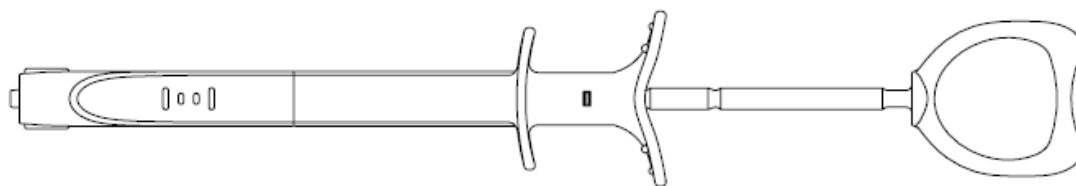
Note: These supplies are not provided with the FinESS Sinus Treatment.

- 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

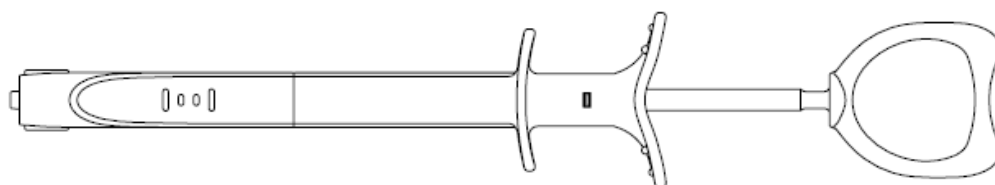
System Preparation

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 (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 one click to the 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

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 (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 inflation 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 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. 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 the stop (2nd detent) position to apply a vacuum to the balloon.
- e. Remove the balloon protector from the Balloon. Retain the balloon protector 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. 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 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.

- 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 with 2 hands, keeping the plunger rod straight, to inflate the balloon. The pressure should be increased slowly (3 – 5 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 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 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	

This product is protected by US Patent No. 7,520,876. Other US Patents Pending.

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