

INSTRUCTIONS FOR USE Entellus Medical Sinus Guidewire

Read all Instructions prior to use

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.

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

Sterility: Provided Sterile, Ethylene Oxide (EO) Sterilization, Non-Pyrogenic

Single Use: Disposable, For Single Patient Use Only, Do Not Resterilize and/or Reuse

Storage: Store in a cool, dry place

Description

Entellus Medical Sinus Guidewire is a 0.035” – compatible guidewire with a flexible angled radiopaque distal tip. It is constructed of nickel titanium alloys, stainless steel, and features a polymer coating.



Indication For Use

To provide a means to access the frontal, sphenoid and maxillary sinuses, for diagnostic and therapeutic procedures in adults aged 18 and over.

Contraindications

None known

Warnings

- Do not use breached or damaged packages, since the sterility and functionality of the device may be compromised.
- Single use only. Do not re-sterilize or re-use, as it may result in compromised device performance and risk improper sterilization and cross contamination.
- Never advance or withdraw the device against unknown resistances as this can cause tissue trauma or device damage.

Precautions

- Due to the variability of sinus anatomy, review radiographic imaging (CT scan) prior to the procedure to understand anatomy.
- If fluoroscopy is used, follow standard hospital guidelines and requirements for proper fluoroscopic use.
- Do not attempt to alter the angulation of the guidewire tip as this may result in device damage.

Adverse Effects

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

- Cerebrospinal fluid leak
- Damage of the orbital wall or other structures of the eye
- Tissue inflammation or trauma

Compatibility

The Entellus Medical Sinus Guidewire is compatible with instruments (malleable suctions, guide catheters, sinus cannulas) having OD \geq 2mm and with balloon catheters having an internal lumen with a diameter of \geq

0.035". Examples of devices that meet these requirements include Xpress™ Multi-Sinus Dilation Tool, Solo Pro™ Sinus Balloon Catheter, and Medtronic, Inc. MCSK5 Suction Tube.

Instructions for Use

1. Remove the sinus guidewire from the protective hoop.
2. Under endoscopic visualization:
 - a. Place a guide (or curved suction or sinus cannula) into the desired anatomy.
 - b. Track the sinus guidewire through the guide into the target sinus space until light resistance is felt. Do not use excessive force.









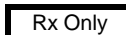



NOTE: If significant resistance is encountered while advancing or withdrawing the guidewire, change the position of the guide or rotate the angled tip of the guidewire in either direction, then advance or withdraw the guidewire in a gentle motion.

3. Confirm guidewire is located in target sinus space with endoscopic and/or fluoroscopic visualization.
4. After procedure, dispose of device according to appropriate environmental health safety guidelines.

Limited Warranty

Entellus Medical, Inc. warrants that reasonable care has been used in the design and manufacture of this device. Entellus Medical, Inc. 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, Inc.’s control, directly affect the device and the results obtained from its use. Entellus Medical, Inc. 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, Inc. 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*.

Graphic Symbols Contained on Device labeling

 Reorder Number	 Lot Number	 Model Number
 See Instructions For Use	 Keep Dry	 Do Not Reuse
 Sterilization with Ethylene Oxide Gas	 Use By	 Prescription Use Only
 Quantity	 Manufacturer	 Store in Cool Dry Place

Solo Pro is a trademark of Acclarent, Inc.
 PathAssist and Xpress are trademarks of Entellus Medical, Inc.



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