

INSTRUCTIONS FOR USE

Cyclone™ Sinonasal Suction/Irrigation System

Read all Instructions prior to use

- Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.
Sterility: Provided Sterile, Ethylene Oxide (EO) Sterilization
Single Use: Disposable, For Single Patient Use Only, Do Not Resterilize and/or Reuse
Storage: Store in a cool, dry place.

Indication for Use

To provide a means to irrigate and suction within sinonasal spaces.

Description

The Cyclone Sinonasal Suction/Irrigation System is a disposable medical device that allows a user to simultaneously irrigate sinonasal cavities and suction away the effluent. The system includes the Cyclone device, a 30cc Syringe and a Bending Tool.

The Cyclone device includes an atraumatic distal tip with an irrigation spray head and a malleable hypotube that includes a flexible suction tube. Active suction is performed by connecting the suction line to a vacuum pump and covering the suction vent hole located on the slider. The included Syringe may be connected to the irrigation line to provide irrigation. Since the distal hypotube of the device is re-shapeable, one device can be modified to suction and irrigate multiple sinuses within the same patient.

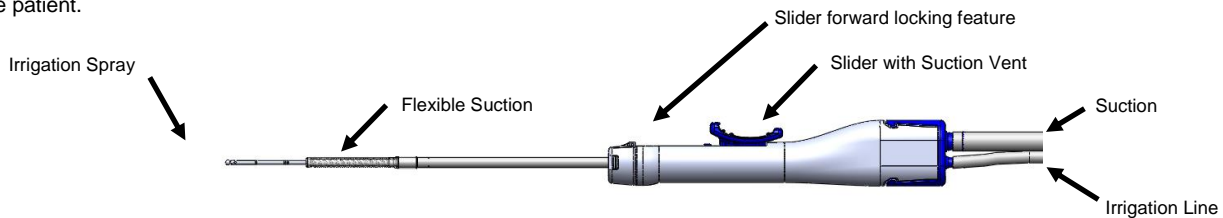


Figure 1: Cyclone Device

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 resterilize or reuse, as doing so 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 sinonasal anatomy, review radiographic imaging (e.g., a CT scan) prior to the procedure.

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, swelling, or trauma
- Damage to the lamina papyracea
- Loss of vision or diplopia (double vision)

Supplies

The following supplies are not provided with the Cyclone Sinonasal Suction/Irrigation System and should be available for the procedure:

- Appropriate endoscope and compatible camera system
- Sterile saline solution
- Standard suction tubing and suction systems/vacuum pumps

Compatibility

The device is compatible with the following equipment:

- Standard suction tubing and suction systems/vacuum pumps
- Refer to appropriate Instructions for Use and safety procedures when preparing and using compatible equipment.

Instructions for Use

1. Remove the Cyclone device from the protective packaging. Peel apart irrigation and suction line tubing as necessary.
2. If irrigation is desired, attach irrigation hub to the supplied Syringe filled with sterile saline solution (Figure 2).
3. If suction is desired, attach the suction barb to a suction system via suction tubing (Figure 3).



Figure 2: Irrigation Hub



Figure 3: Suction Barb

4. Shape the prepared Cyclone device to a desired bend configuration for the targeted sinonasal space using the Bending Tool, following the instructions provided below:

- When performing suction and irrigation of multiple sinuses, it is recommended to complete the frontal or sphenoid sinuses prior to completing the maxillary sinuses.
- **Frontal Sinuses:** When accessing the frontal ostia/recesses, a large radius curve similar to a frontal sinus seeker (Figure 4) is recommended.
- **Sphenoid Sinuses:** When accessing the sphenoid sinus ostia, a slight bend (Figure 5) is recommended.
- **Maxillary Sinuses:** When accessing the maxillary ostia/ethmoid infundibula, a bend of approximately 120 - 135° (Figure 6) is recommended to gain access to

the natural maxillary ostium.



Figure 4: Frontal Bend



Figure 5: Sphenoid Bend



Figure 6: Maxillary Bend



Figure 7: Start Maxillary Bend



Figure 8: Finish Maxillary Bend

Before shaping the maxillary bend, the device should be close to straight as shown for a sphenoid bend. With the Bending Tool in one hand, position the ball tip into the ball holder in the Bending Tool (Figure 7). Place a finger at about the 2cm mark on the suction tip and use this finger to form the maxillary bend (Figure 8). Small adjustments to the above bends may be considered to accommodate different patient anatomy.

5. Under endoscopic visualization, place the device into the target location and advance the suction tube using the slider.
6. Irrigate within the sinus spaces and suction effluent as necessary by covering the suction vent.
 - o The device may be re-shaped as described above and used in multiple sinuses if desired.
 - o The device includes a distal stop for the suction vent slider. When the slider has reached the distal stop, the irrigation spray head is unobstructed and irrigation may still be performed (Figure 9).
 - o When the suction vent slider is advanced beyond the distal stop, it engages the forward locking feature and the suction tube is locked in the fully extended position. In this position, the irrigation spray head is obstructed by the suction tube and the device acts solely as a suction instrument (Figure 10).

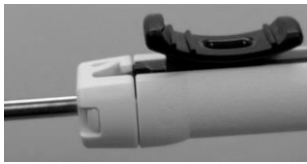


Figure 9: Slider Contacting Distal Stop



Figure 10: Forward Lock Engaged

7. After the procedure, dispose of device according to appropriate environmental health and safety guidelines.

Limited Warranty

Refer to *Entellus Medical, Inc. Standard Terms and Conditions*.

Symbols

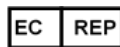
 Consult Instructions for use	 Lot Number	 Use By	 Quantity	 Reorder Number
 Sterilization with Ethylene Oxide Gas	 Manufacturer	 Do Not Reuse	 Prescription Use Only	 CE Mark

Not made with natural rubber latex.

CYCLONE is a trademark of Entellus Medical patent <http://www.entellusmedical.com/patents>



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