Establishment of patency of the sinus ostia is paramount to the treatment of chronic sinusitis. Endoscopic sinus surgery has been shown to be effective in accomplishing this. Recently, catheter based balloon dilation has been introduced as an alternative method to open the sinus ostia and has demonstrated clinical success. SinuSys Corporation (Palo Alto, California, USA) has developed an osmotically driven, self-expanding dilation device to expand the maxillary sinus ostia.

The Vent-Os Sinus Dilation System enables low-pressure, gradual dilation of the maxillary sinus ostia, which is designed to maximize patient tolerability of the procedure in an office setting under local anesthesia. Unlike balloon dilation devices that use rapid, high-pressure inflation, the Vent-Os Sinus Dilation System is a small, low-pressure, self-expanding insert designed to gently and gradually open the maxillary ostia (Figure 1).

Figure 1: The Vent-Os placement cannula accesses the sinus ostium through the nasal passage, leaving the uncinate intact.
SinuSys’ proprietary dilation is comprised of osmotic elements encapsulated in the semi-permeable, expandable membrane (Figure 2). When the dilation device is placed into the target ostium, it starts to expand due to uptake of surrounding fluid (approximately 150µL). It expands gradually from an initial diameter of 3mm to a final diameter of 5mm in 60 minutes at a pressure of 2.9 atmospheres (42 psi), resulting in ostium dilation and remodeling. The device is supplied with a suture tether to allow securing of the device to the patient over dilation period.

The SinuSys Vent-Os Sinus Dilation System is provided sterile with the dilation device preloaded in the placement instrument (Figure 3). The placement instrument accesses the sinus ostium of the sinus through the nasal passageway and delivers the dilation device into the ostium. The dilation device resides in the ostium for 60 minutes, after which the dilation device is removed.

Figure 2: SinuSys’ unique osmotic self-expanding technology provides gradual, low-pressure dilation to 5mm in 60 minutes.

Figure 3: The simple design of the Vent-Os Sinus Dilation System makes the device compatible with office-based procedures performed under local anesthesia.
**PATIENT SELECTION**

The Vent-Os device is designed for the treatment of adult patients with sinusitis in whom dilation of the maxillary ostium to establish ventilation and drainage is indicated.

Prior to use of the product, individual patient anatomy and clinical condition should be carefully evaluated and confirmed to be consistent with product use, especially ensuring that there are no abnormalities that would preclude access to the ostia or diagnosis of hematological disorders.

Through nasal endoscopy and imaging studies, the physician will assess the anatomy of the nasal septum, uncinate process, and ethmoid bulla to determine accessibility for the placement of the device.

The low-pressure, gradual expansion and the simplicity of the device make it compatible with use in office-based procedures under local anesthesia. In-office placement of the Vent-Os device may be used for isolated maxillary sinus disease. In addition, treatment of recurrent acute sinusitis can also be performed to reduce or eliminate the need for recurrent medical management. In the post-operative patient, the Vent-Os system can be used to dilate and manage sinus openings to treat stenosis.

**TECHNIQUE**

The Vent-Os Dilation System should be presented and maintained sterile. Appropriate nasal endoscopy equipment should be present and in working order. Endoscopic sinus surgery instrumentation such as grasping forceps and suction should be available.

In the operating room, the use of general anesthesia or sedation will be determined by the surgeon and anesthesiologist. The application of topical and/or infiltrative anesthesia and vasoconstriction is per the surgeon’s practice.

In the office setting, a stepwise approach to maximize patient comfort and acceptance of the procedure is desirable. It is important to educate patients on the steps involved in the in-office placement of the Vent-Os device. Concerns by the physician or patient regarding the procedure and the patient’s ability to tolerate and complete the procedure should be evaluated before deciding to proceed. Although SinuSys does not recommend a specific protocol, the use of both topical and infiltrative anesthesia and vasoconstriction may be necessary as well as oral anxiolytics in specific patients. Device expansion will require 1 hour; in the office setting, the patient can be allowed to wait comfortably until the device is removed.
Placement Technique

1) Enter the nasal cavity with the device oriented vertically and the device tip superiorly.

2) Rotate the device just posterior to the uncinate, using the tip to gently lift up the uncinate.

3) Continue to rotate the device to angle the tip slightly inferiorly.

4) Exert gentle pressure to palpate the lateral wall and find the natural ostium.

5) Once found, engage the device completely with further gentle lateral pressure and release the device.

Device expansion requires 1 hour. In the operating room, the remainder of the operating procedure can be performed during this time. In the office setting, the patient can be allowed to wait comfortably until removal.

Device Removal

1) Under direct endoscopic vision, grasp the exposed proximal end of the dilation device using forceps.

2) Gently remove the dilation device. The procedural site may be examined at this time.

Follow-Up

Routine follow up should be performed by the surgeon to confirm healing and patency of the ostium.
THE OFFICE ENVIRONMENT

The simplicity of the Vent-Os device allows the procedure to integrate well into a busy office environment. The non-intimidating appearance of the device and smooth application of the dilation pressure makes pre-procedure anxiolytics rarely necessary. Similarly, this mechanism of action means that topical anesthesia alone is commonly adequate, although this certainly can be augmented by injectable local anesthetic. This streamlined approach reduces the time requirement for the physician and medical staff, as well as the patient (Table 1).

The one-handed, two step mechanism of action allows the placement of the device by the physician without assistance. This once again frees the staff to be available to maintain the flow of patient care in the office. Once the device is in place, the patient may be moved to a waiting area. After 1 hour, the patient is returned to the exam room and the device is quickly and simply removed by the physician. The patient can then be discharged and return to their normal activities.

COMPARISON OF TYPICAL DILATION PROCEDURE TIME SPANS

Maxillary Balloon Dilation (Bilateral)

<table>
<thead>
<tr>
<th>Practice Resource</th>
<th>Time (minutes)</th>
<th>Total Resource Time</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Treatment Patient Prep</td>
<td>30 Minutes</td>
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<td>Anxiolytics</td>
</tr>
<tr>
<td>Patient Procedure Chair</td>
<td>30 Minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician Assistant</td>
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<td>Physician</td>
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<tr>
<td>Recovery</td>
<td>30+ Minutes</td>
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Vent-Os™ Maxillary Dilation (Bilateral)

<table>
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<tr>
<th>Practice Resource</th>
<th>Time (minutes)</th>
<th>Total Resource Time</th>
<th>Steps</th>
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</thead>
<tbody>
<tr>
<td>Patient Procedure Chair</td>
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<td>Topical Anesthetic</td>
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<td>Physician Assistant</td>
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<tr>
<td>Physician</td>
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</tr>
<tr>
<td>Patient Waiting Room</td>
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Table 1: Because of its simplicity and patient tolerability, bilateral maxillary dilation using the Vent-Os System requires significantly fewer resources for a typical in-office procedure. For a typical Vent-Os bilateral maxillary dilation, there is essentially no patient prep and no recovery time associated with pre-op administration of anxiolytics or multiple applications of anesthetics. Actual physician operating time and overall patient procedure chair time is minimized and no physician assistant is required.
Dr. Jerome Hester co-founded SinuSys Corp. in 2010 and serves as an attending surgeon at Stanford University Hospital and Clinics and at Lucile Packard Children’s Hospital. After receiving his medical degree from The University of Texas at Houston, he completed his specialty training in Otolaryngology/Head and Neck Surgery at Stanford University. As a board certified otolaryngologist, Dr. Hester has remained active in the clinical practice of all aspects of the specialty and is an established author and lecturer on a national level.