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Vent-Os™ Sinus Dilation System Effectively Establishes and Maintains Patency of Maxillary Sinus Ostia at Six Months

Positive Data for Innovative Sinusitis Device Presented at the Combined Otolaryngology Spring Meetings (COSM)

PALO ALTO, Calif. – May 15, 2014 – SinuSys™ Corporation, an innovative sinus health company, today announced that the Vent-Os™ Sinus Dilation System demonstrated sustained patency of the maxillary sinus ostia at six months in its clinical study results presented at the 2014 Combined Otolaryngology Spring Meetings (COSM), taking place May 14-18 in Las Vegas. The Vent-Os System enables low-pressure, gradual dilation of the maxillary sinus ostia in a simple, two-step interventional procedure, which is intended to maximize patient tolerability 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. The Vent-Os System incorporates the Company's proprietary osmotic technology, which utilizes the body's natural mucosal fluids to expand the insert before removal. In an office setting, patients can be comfortably relocated to the waiting room between insertion and removal of the device.

The clinical study encompassed 34 chronic rhinosinusitis (CRS) patients that were treated at five sites, either as a stand-alone procedure or in conjunction with endoscopic sinus surgery. The Vent-Os device was inserted into the maxillary sinus opening at the beginning of the procedure and removed after 60 minutes. In the patient set, 57 sinus ostia were accessed and successfully dilated. There were no device-related adverse events.

At six months, 30 patients with 49 treated ostia were available for evaluation, with 92 percent of ostia (45) visibly patent and eight percent (4) unable to be visualized. All ostia were clinically functional. One patient (3.3 percent) developed sinusitis and was successfully treated medically.

Fifteen percent of patients in the study were treated in an office setting after pre-procedural injection of anesthesia. Unlike balloon dilation devices, no additional anesthesia or medication

was required for the procedure to increase patient tolerability. The remaining patients were treated in the operating room adjunctive to functional endoscopic sinus surgery (FESS). More information on the study can be found at http://sinusys.com/study/.

"These clinical results demonstrate that a self-expanding, low-pressure dilator can provide durable patency of the maxillary sinus ostia in sinusitis patients," said Peter J. Catalano, MD, FACS, Chief of Otolaryngology, St. Elizabeth's Medical Center, Boston, MA, and a clinical investigator for the study. "The simplicity and tolerability of the Vent-Os procedure make it a viable option for both early-stage chronic sinusitis patients who have failed medical therapy and patients suffering from recurrent acute sinusitis. In this latter group, restoration of maxillary ventilation and drainage can provide relief without the long-term costs and risks associated with repetitive use of antibiotics and steroids."

The six-month results are being presented as a poster during the American Rhinologic Society Spring Meeting at COSM.

The FDA has cleared the Vent-Os Sinus Dilation System in the U.S. for dilation of the maxillary sinus ostia and associated spaces in adults for diagnostic and therapeutic procedures. The Vent-Os System has also received the CE Mark, Health Canada license and Australian Therapeutic Goods Administration (TGA) Certificate, and is currently being commercialized in all of these regions.

About Sinusitis
Sinusitis affects more than 31 million people in the United States. It is more prevalent than heart disease and asthma, and has a greater impact on patients' quality of life than chronic back pain or congestive heart failure. The majority of patients with chronic sinusitis are treated with oral antibiotics and/or nasal steroids, which can increase the risk of antibiotic resistance and cause unwanted side effects such as epistaxis (nose bleeds), nasal ulcers, and nasal and oral infections. The most effective surgical treatment is Functional Endoscopic Sinus Surgery (FESS), which is conducted in a surgical suite under general anesthesia or IV sedation. The United States healthcare system currently spends more than $8 billion annually on improving the health of patients with sinus conditions.

About SinuSys Corp.
SinuSys Corp. (www.sinusys.com) develops medical device therapies to improve the health of millions of patients suffering from sinusitis worldwide. The company's proprietary self-expanding, osmotic technology is designed to be atraumatic, tissue-sparing and easy to use, potentially enabling clinicians to intervene at earlier stages of sinus disease. The company seeks to provide improved options for the 20 percent of sinusitis patients whose disease is not resolved with drug therapy.

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