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# SinuSys™ Corp. Receives FDA Clearance for the Vent-Os® Sinus Dilation Family of Devices

PALO ALTO, Calif.--(BUSINESS WIRE)-- SinuSys Corporation, an innovative sinus health company, today announced receipt of FDA clearance for a full family of sinus dilation devices, adding two new devices that will expand the company's portfolio of low-pressure, self-expanding dilation devices to enable dilation of the frontal and sphenoid sinuses to address sinusitis symptoms. The addition of the new devices complement the previously FDA cleared Vent-Os device for maxillary sinus dilation. The FDA clearance will enable the company to bring the simplicity, patient tolerability and long-term patency shown by the maxillary system to the treatment of frontal and sphenoid sinuses. The new devices will be immediately available in the USA.

"The Vent-Os system is easy to deploy and enables physicians to bring the benefits of minimally invasive sinus dilation to their patients in an office procedure that is highly tolerable under topical or local anesthesia," said Ed Hepworth, MD, from the Denver Sinus Institute, Denver, Colorado. "By adding devices for treatment of the frontal and sphenoid sinuses, an expanded group of patients will be able to benefit from this simple, gentle sinus dilation procedure that I plan to use for both early-stage chronic sinusitis patients who have failed medical therapy and patients suffering from recurrent acute sinusitis."

In the most recent prospective, multi-center clinical study, the Vent-Os Sinus Dilation System demonstrated sustained patency rates out to three months comparable to, or better than, other available sinus dilation techniques.

Previously, in a prospective, multi-center clinical study, the Vent-Os Sinus Dilation System demonstrated the ability to maintain patent maxillary sinus ostia at 12 months in 93 percent of treated ostia.

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 sinus ostia. The Vent-Os System incorporates the Company's proprietary osmotic technology, which utilizes the body's natural mucosal fluids to expand the device before removal. In an office setting, patients are comfortably relocated to the waiting room between placement and removal of the device.

"Our proprietary low-pressure, self-expanding technology has the potential for broad application in sinus disease, and we are pleased that we can now provide ENTs and their patients with effective, long term solutions for several sinus anatomies" said SinuSys Chief Executive Officer Tom Schreck. "With FDA clearance, we are focused on immediately bringing these broader benefits to physicians in the U.S., expanding utilization of our technology, and developing innovative, new therapies to address sinus disease that affects so many millions of people worldwide."

**About Sinusitis**

Chronic sinusitis affects approximately eight percent of the adult population worldwide. 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 common surgical treatment for chronic sinusitis is Functional Endoscopic Sinus Surgery (FESS), which is conducted in a surgical suite under general anesthesia or IV sedation.

**About SinuSys Corporation**

SinuSys Corp. (www.sinusys.com) strives to improve the health of patients worldwide through the

commercialization of the Vent-Os Sinus Dilation System, the development of drug delivery product candidates, and other osmotic and rate-controlled technologies for serious ear, nose and throat conditions. The company's proprietary technologies are designed to be atraumatic, tissue-sparing and easy to use, potentially enabling clinicians to intervene at earlier stages of sinus disease.

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