



**SinuSys Receives CE Mark for AerOs™ Sinus Dilation System,
Completes FDA 510(k) Submission**

*Novel Interventional Device Designed to Gently and Simply Resolve
Painful Chronic Sinusitis Now Available in Europe*

PALO ALTO, Calif. – September 6, 2012 – [SinuSys Corporation](#), an innovative sinus health company, today announced that the Company has received CE Mark for its [AerOs™ Sinus Dilation System](#), designed to gently open the sinus ostia, thereby restoring natural sinus drainage and ventilation using a simple, two-step interventional approach. The Company has shipped devices to the United Kingdom in the first phase of its European commercialization strategy, while it completes its initial clinical study in Canada and awaits a response to its FDA 510(k) submission.

Unlike balloon dilation devices that use rapid, high-pressure inflation, the AerOs Sinus Dilation System is a low pressure, self-expanding insert designed to gently and gradually open the maxillary ostia (openings that connect a sinus to the nasal cavity.) The AerOs device incorporates the Company's proprietary osmotic technology, which utilizes the body's natural fluids to expand the insert. After the ostia are opened, the insert is removed. The low-pressure, gradual expansion and simplicity of the device are designed to make it compatible for use in office-based procedures under local anesthesia.

"In our current clinical study of patients treated in the operating room, the AerOs System is demonstrating the attributes that may make it a tool of choice to treat chronic sinusitis in an office setting. The device is simple to use and its low-pressure expansion should be well-tolerated by patients under local anesthesia," said Dr. Amin Javer, Director of the University of British Columbia Sinus Centre. "Ultimately, this may allow us to treat sinus disease earlier in its progression to help a broader range of patients."

"Our CE Mark demonstrates the significant momentum we are generating leading toward a global presence," said SinuSys Chief Executive Officer [Thomas Schreck](#). "We are enthusiastic about commercialization of the AerOs System for otolaryngologists and their sinusitis patients in Europe. At the same time, we plan to expand application of our technology into other devices that can address the multi-factorial nature of sinus disease, including devices for the frontal and sphenoid sinuses."

About Sinusitis

Chronic 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 U.S. healthcare system currently spends more than \$8

billion annually on improving the health of patients with sinus conditions. However, approximately 20 percent of sinusitis patients do not experience adequate relief from current pharmaceutical treatments, which can have unpleasant side effects even when effective. For these patients, the most effective treatments to-date have been Functional Endoscopic Sinus Surgery (FESS) and high-pressure balloon dilation, which can cause significant patient discomfort and are conducted in a surgical suite under general anesthesia or IV sedation.

About SinuSys Corp.

SinuSys Corp. (www.sinusys.com) develops medical device therapies to improve the health of millions of patients suffering from chronic 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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