Medtronic News

FDA Clears Expanded Indications for Medtronic NuVent(TM) EM Sinus Dilation System with Image Guidance

Clinical Study Conducted on Revision Subjects Support Expanded Indication for Patients with Previously Surgically Altered Tissue

DUBLIN - July 11, 2016 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) clearance of NuVent(TM), an EM sinus dilation system, for patients with scarred, granulated, or previously surgically-altered tissue - an expansion of indications. Patients coming in for revision sinus surgery (RSS) have these tissue characteristics. NuVent is the first and only balloon sinus dilation system with built-in electromagnetic (EM) surgical navigation technology that may help surgeons confirm anatomy1 and optimize placement2 during balloon sinus surgery. RSS may be needed when sinus surgery does not alleviate suffering, and can pose unique challenges due to potential scar tissue and altered anatomy from previous surgeries. Image-guided surgery may have advantages for some types of revision cases.3

"NuVent is an ingenious surgical tool that combines automatic calibration, precise electromagnetic navigation, and balloon dilation technology all in one device," said Rick Chandra, M.D., professor of otolaryngology, chief of rhinology, sinus & skull base surgery, Vanderbilt University. "It has been extraordinarily useful in accomplishing the goals of revision functional endoscopic sinus surgery, particularly to address technical challenges associated with the frontal sinus."

Surgical navigation is important because sinus anatomy can be highly variable. NuVent was designed to work with image guidance technology called the Fusion(TM) ENT Navigation System, which is a GPS-like navigation system that helps physicians target blocked sinuses4 during a minimally invasive surgery5 performed in the office. Fusion(TM) navigation technology helps physicians confirm specific anatomy, avoid critical areas,6 and optimize balloon placement to open blocked pathways.It works like GPS in a car or on a phone and displays a visual map of the sinus anatomy. This may help surgeons steer the balloon to the blocked sinuses to inflate the balloon at the precise location to reshape(dilate)the tissue and bone to clear the sinus pathway.

When performed in the doctor's office, this procedure is minimally invasive, offers faster recovery times4 and may allow eligible patients to have a lower out-of-pocket cost.7

The FDA clearance of NuVent for patients who have scarred, granulated, or previously altered tissue (revision) was based on the results of a prospective, non-randomized, non-blinded, single arm study conducted at investigational sites in the United States to assess the safety and device performance of the system.

"As the first sinus dilation system for revision surgery and the first with built-in electromagnetic tracking, NuVent is an example of transformative technology that provides meaningful benefits to patients and physicians and it has the potential to help improve patient outcomes and reduce out-of-pocket costs," said Vince Racano, vice president and general manager of Medtronic's ENT business, which is part of the Restorative Therapies Group at Medtronic. "Our innovative image-guided system used with NuVent provides surgeons with a detailed view of the sinus anatomy during the procedure and may enhance precision and allow physicians to help more patients in office."

NuVent now offers a 70° angled frontal probe, which is a familiar angle for sinus surgery, to be used with the FUSION system. Additionally, a compact version of Medtronic's FUSION(TM) system called FUSION Compact(TM) system was recently launched. This modular, portable system gives physicians the freedom to use navigation

where they need it.

For more information about the NuVent procedure, please visit http://www.sinusitissurgery.com to find new resources, including a physician finder.

About Sinusitis
Sinusitis is inflammation of the sinuses and nasal passages, which can become infected. About 31 million suffer from sinusitis and those with symptoms for 12 weeks or more are said to have chronic rhinosinusitis8. Many struggle for years before finding relief; a survey of 400 CRS sufferers, found that more than half suffering for 15 years or more.9Sinusitis causes significant physical suffering and emotional struggles, including headaches,8 facial pain8 missed work9, personal engagements9, limited physical activities9, and problems sleeping.10

It may be treated with antibiotics, decongestants and saline sprays. However, when medical management fails to relieve symptoms, sinus surgery has been proven to improve overall symptoms to reduce headaches,11 work/school time missed, frequency of doctor/nurse visits and acute infections.10

Multimedia Release
A multimedia version of this release, with downloadable graphics and backgrounders, can be found at: https://medtronicmediacap.gcs-web.com/fda-clears-expanded-indications-medtronic-nuventtm-em-sinus-dilation-system-image-guidance.

About Medtronic
Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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2 Data on File, Medtronic plc

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