Medtronic News

Medtronic Introduces the First and Only Neurostimulation Systems for Chronic Pain Designed for Full-Body MRI Safety*

Thomson Reuters ONE via COMTEX) --Innovative Design Enhancements Provide Patients Unprecedented Access to Diagnostic Care

MINNEAPOLIS - August 6, 2013 - With the first U.S. implants of its new RestoreSensor® SureScan® MRI neurostimulation systems, Medtronic, Inc. (NYSE: MDT) is introducing the first and only implantable neurostimulation (also known as spinal cord stimulation, or SCS) systems for use in the treatment of chronic, intractable back and/or limb pain that are approved by the U.S. Food and Drug Administration (FDA) for conditionally safe* full-body Magnetic Resonance Imaging (MRI) under specific conditions.

MRI scans have become a diagnostic standard of care, allowing physicians to detect a wide range of health conditions by viewing highly detailed images of internal organs, blood vessels, muscle, joints, tumors, areas of infection and other areas of the body by using strong magnetic fields and radio frequency pulses to create images of structures inside the body. As advancements in technology have increased accuracy, effectiveness and patient comfort, MRI use has grown dramatically in recent years. Worldwide, it is estimated that 60 million MRI procedures are performed each year.1 In the United States, the number of scans has nearly doubled in the past decade, with 32 million scans - more than one MRI per second -- performed in 2011.2

Until now, SCS patients referred for a body MRI were denied a scan due to concerns about the system being affected by the large magnetic fields and radio frequency (RF) energy involved in MRI. Medtronic's neurostimulation systems with SureScan MRI technology and Vectris® SureScan® MRI percutaneous leads are specially designed with enhancements to reduce or eliminate the hazards produced by the MRI environment. The systems also include a proprietary SureScan feature, which sets the neurostimulator into an appropriate mode for the MRI environment, enabling the radiology departments to easily and conveniently confirm a patient's implantable system is safe for MRI scanning.

Among the first physicians to implant these new systems are neurosurgeon Ali Rezai, M.D., professor and director of the Center for Neuromodulation and Functional Neurosurgery at The Ohio State University Wexner Medical Center in Columbus, Ohio, and president of both the North American Neuromodulation Society and Congress of Neurological Surgeons; David L. Caraway, M.D., Ph.D., medical director for St. Mary's Pain Relief Center in Huntington, W.Va., and a member of the board of directors for the North American Neuromodulation Society and executive vice president, American Society of Interventional Pain Physicians; and Mehul J. Desai, M.D., M.P.H., director, spine, pain medicine and research at Metro Orthopedics and Sports Therapy (MOST) in Silver Spring, Md.

"The ability to safely perform MRI scans after a spinal cord stimulator implant (SCS) is an important advance and a major benefit for our patients," said Dr. Rezai. "In today's medical practice, MRI examinations are necessary and routinely performed for diagnosis and clinical care. It is very likely that a patient with chronic pain, spinal disease, neurological and orthopedic disorders will require an MRI scan. However, until now, this was not feasible with SCS implants. I am happy that we will now be able to offer MRI scans for our patients."

The RestoreSensor SureScan MRI neurostimulation system is one of a portfolio of new Medtronic neurostimulation systems enhanced with this technology and using Vectris® SureScan® MRI leads, which

include: PrimeAdvanced® SureScan MRI, RestoreAdvanced® SureScan MRI, and RestoreUltra® SureScan MRI. The systems received FDA approval in March 2013 and Conformite Europeenne (CE) Mark approval in January 2013.

"The approval of Medtronic's SureScan neurostimulation systems means patients finding relief from their chronic pain with neurostimulation therapy can feel confident knowing they have access to an important diagnostic tool without compromising their healthcare," said Julie Foster, general manager and vice president, Pain Stimulation and Targeted Drug Delivery in the Neuromodulation business of Medtronic, Inc. "This latest innovation is yet another example of our ongoing commitment to provide clinicians with safe, effective solutions to meet the needs of their patients."

Medtronic SureScan neurostimulation systems with Vectris SureScan percutaneous MRI leads for chronic pain are the latest additions to a growing number of existing Medtronic devices that are designed for MRI access. These include the Medtronic SynchroMed® II programmable drug infusion system and Medtronic SureScan® pacing systems, which are available worldwide.

Multimedia Release

A multimedia version of this release, with links to graphics, animation and additional background information can be found at: http://bit.ly/16WTXwu

About Medtronic Neurostimulation Therapy for Chronic Pain

Medtronic neurostimulation therapy for chronic pain uses a medical device placed under a patient's skin to deliver mild electrical impulses to the spinal cord, which act to block pain signals from going to the brain. Since Medtronic developed the therapy in partnership with physicians in the 1980s, Medtronic neurostimulation therapy has helped nearly 200,000 people worldwide manage their chronic pain and enhance their lives. In 2011, the FDA approved Medtronic's AdaptiveStim® with RestoreSensor®, the first neurostimulator to incorporate motion sensor technology to help treat chronic pain. The innovative system uses a proprietary sensor and algorithm to automatically detect and respond to changes in the patient's body position, resulting in effective pain relief and convenience. More information about Medtronic's SureScan MRI Technology for spinal cord stimulation can be found at: www.mrisurescan.com.

Medtronic's Leadership in Neuromodulation

Medtronic developed and leads the field of neuromodulation, the targeted and regulated delivery of electrical pulses and pharmaceuticals to specific sites in the nervous system. The company's Neuromodulation business includes implantable neurostimulation and targeted drug delivery systems for the management of chronic pain, common movement disorders, spasticity and urologic and gastrointestinal disorders.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, Minnesota, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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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* Under specific conditions. Refer to approved labeling.

References:

1 Sutton R, Kanal E, Wilkoff BL, Bello D, et al. Safety of magnetic resonance imaging of patients with a new Medtronic EnRhythm MRI SureScan pacing system: clinical study design. Trials 2008, 9:68.

2 IMV Benchmark Report 2012. IMV Medical Information Division. Des Plaines, Illinois. Page 1.

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Source: Medtronic, Inc. via Thomson Reuters ONE

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