Medtronic Introduces the First and Only Neurostimulation Systems with CE Mark Approval for Full-Body MRI Scans

The Associated Press

TOLOCHENAZ AND MINNEAPOLIS - January 30, 2013 - Medtronic, Inc. (NYSE: MDT) today introduced in Europe the first and only implantable neurostimulation systems indicated for use in the treatment of chronic back and/or leg pain that are designed for full-body Magnetic Resonance Imaging (MRI) scans under specific conditions.

The first new system implants have been performed by Dr. JP Van Buyten and Dr. Iris Smet in Belgium; Dr. Rasche and Professor Tronnier in Germany; Dr. J. De Andres in Spain; Dr . K. Gatzinsky in Sweden, and Professor Buchser in Switzerland.

Medtronic neurostimulation systems for the treatment of chronic pain recently received Conformité Européenne (CE) Mark approval for compatibility with full-body MRI scans. Neurostimulation systems enhanced with this technology and using VectrisTM SureScan® MRI leads include: RestoreSensor® SureScan® MRI, PrimeAdvanced® SureScan MRI, RestoreAdvanced® SureScan MRI, and RestoreUltra® SureScan MRI. Medtronic SureScan neurostimulation systems for the treatment of chronic pain are not approved by the U.S. Food and Drug Administration for use in the United States.

"Neurostimulation therapy has become a mainstay of chronic pain management, and the introduction of full-body, MRI-compatible spinal cord stimulation systems is an important advancement that will help ensure neurostimulation patients have access to the diagnostic tools needed to quickly identify potentially critical health conditions," said Dr. JP Van Buyten from the AZ Niklaas Hospital in Belgium.

MRI scans allow physicians to make a wide range of health diagnoses by viewing highly detailed images of internal organs, blood vessels, muscle, joints, tumors, areas of infection and more. MRI utilizes strong magnetic fields and radio frequency pulses to create images of structures inside the body.

As advancements in technology have increased MRI accuracy, effectiveness and patient comfort, MRI use has increased dramatically in recent years. It is estimated that 60 million MRI procedures are performed worldwide each year.1 In Western Europe alone, 29 million scans were performed in 2010, with the number of scans doubling every five years.2

Medtronic SureScan neurostimulation systems address a significant medical need for full-body MRI compatibility by enabling patients who are receiving Medtronic neurostimulation therapy for chronic back and/or leg pain (also called spinal cord

stimulation, or SCS) to have access to the benefits of full-body MRI. Until now, SCS patients were denied full-body MRI scans because of fears of the system being affected by the large magnets involved in MRI.

"Delivering systems that are compatible with a full-body MRI scan means that spinal cord stimulation patients will not have to compromise when it comes to their healthcare, and they can feel secure knowing that MRI is a diagnostic option," said Julie Foster, general manager and vice president, Pain Stimulation and Targeted Drug Delivery in the Neuromodulation business of Medtronic, Inc. "Medtronic's development of these systems is another example of our commitment to advancing increasingly innovative and cost effective solutions that make it easier for clinicians to safely, effectively and efficiently diagnose and treat the patients they serve."

Medtronic SureScan neurostimulation systems include enhancements to existing devices as well as specially designed leads to reduce or eliminate the hazards produced by the MRI environment. The devices also include a proprietary SureScan programming feature, which sets the device into an appropriate mode for the MRI environment.

These systems are the latest additions to a growing number of Medtronic devices which are safe for MRI access to any region of the body when used according to specified MR Conditions for Use, including the Medtronic SynchroMed® II programmable drug infusion system and the Advisa DR MRI(TM) SureScan® pacing system available outside the U.S. In the U.S , such devices include the Medtronic SynchroMed® II programmable drug infusion system and the Revo MRI® SureScan® pacing system which are safe for MRI access to any region of the body when positioning guidelines are followed.

About Medtronic Neurostimulation Therapy for Chronic PainMedtronic 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. Instead of pain, patients feel a tingling sensation from the neurostimulation in areas where they had previously experienced pain.

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.

- end -

1Sutton 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.

2World Bank population data http://data.worldbank.org/indicator/SP.POP.TOTL and OECD health data http://www.oecd.org/health/healthpoliciesanddata/OECDHealthData2012FrequentlyRequestedData_Updated.xls PDF summary: http://www.oecd.org/health/healthpoliciesanddata/49105858.pdf. Both accessed: October 26, 2012.

Contacts: Jon Pike Media Relations +44 1923205128

Donna Marquard Public Relations +1-763-526-6248 Jeff Warren Investor Relations +1-763-505-2696

This announcement is distributed by Thomson Reuters on behalf of Thomson Reuters clients. The owner of this announcement warrants that: (i) the releases contained herein are protected by copyright and other applicable laws; and (ii) they are solely responsible for the content, accuracy and originality of the information contained therein. Source: Medtronic, Inc. via Thomson Reuters ONE

HUG#1673992

Source URL (retrieved on *07/29/2014 - 4:54am*):
http://www.mdtmag.com/news/2013/01/medtronic-introduces-first-and-only-neurostimulation-systems-ce-mark-approval-full-body-mri-scans