Medtronic Announces FDA Approval for the Only Full-Body MR Conditional Deep Brain Stimulation Systems

December 9, 2015 7:00 AM CT

Medtronic

Updated Labeling Allows Greater Patient Access to MRI, a Critical Diagnostic Tool

DUBLIN - December 9, 2015 - Medtronic plc (NYSE: MDT) today announced that systems within its Activa® portfolio of Deep Brain Stimulation (DBS) neurostimulators have received FDA approval for full-body Magnetic Resonance Imaging (MRI)* under specific conditions of use. Medtronic's MR Conditional DBS systems are the only approved for full-body MRI scans. This approval expands access to MRIs, making it safe for patients receiving Medtronic DBS Therapy to also receive this important diagnostic standard of care. Additionally, this approval applies to individuals receiving new Medtronic DBS systems and to an estimated 43,000 people in the U.S. already receiving Medtronic DBS Therapy as long as updated MRI guidelines are followed.*

In 2013, 33.8 million MRI scans were performed in the U.S.[1] and approximately 7 out of 10 DBS-eligible patients with movement disorders may need an MRI within 10 years of receiving their device.[2] MRI scans allow physicians to detect and/or monitor a wide range of health conditions, such as stroke, dementia, movement disorders, brain tumors, seizures, diseases of the spine, cancer, musculoskeletal issues and cardiac issues. MRIs use magnetic fields and radio waves to create detailed pictures of organs and tissues, but unlike conventional X-ray and computed tomography (CT), they do not expose patients to ionizing radiation.

"Access to full-body MRI scans has been a critical unmet need with DBS therapy, as many patients require MRI imaging but could not always safely obtain it," said Michael S. Okun, national medical director at the National Parkinson Foundation. "There will be important guidelines for centers to follow in order to apply MRI imaging in patients, however, the availability of this type of imaging is an important step that will facilitate a more optimal care experience."

Since FDA approval of MRI instructions for use in 2002, patients with Medtronic DBS could receive head scans at a low radiofrequency (RF) power limit and the DBS system had to be turned off before the MRI scan. Now with full-body scanning capability, increased MRI RF power limits allow for improved image quality, faster scan times, or larger scan coverage for better diagnostic capabilities. Additionally, when programmed to appropriate stimulation settings and certain other conditions have been met, Medtronic DBS systems allow patients to continue receiving therapy during scans.

"The use of MRI as a diagnostic tool has grown significantly, and Medtronic is proud to offer the only DBS systems that allow patients access to full-body MRIs," said Lothar Krinke, Ph.D., vice president and general manager of the Brain Modulation business, which is part of the Restorative Therapies Group at Medtronic. "Continuous innovation sets Medtronic apart, and we are allowing greater access to MRIs for those receiving DBS therapy as well as other implanted Medtronic systems such as pacemakers, ICDs and spinal cord stimulators."

To ensure our devices are safe, Medtronic performed rigorous testing, including developing proprietary test and measurement systems, in conjunction with advanced electromagnetic modeling tools. Activa DBS systems were tested and evaluated across 10 million simulated patient scans spanning over 38,000 unique implant conditions to demonstrate patient safety. In all, Medtronic has 14 years of MRI research and testing experience.

About Medtronic DBS Therapy

DBS therapy uses a surgically implanted medical device, similar to a pacemaker, to deliver mild electrical pulses to precisely targeted areas of the brain. The stimulation can be programmed and adjusted non-invasively by a trained clinician to maximize symptom control and minimize side effects. More than 130,000 patients worldwide have received Medtronic DBS Therapy.

The therapy is currently approved in many locations around the world, including the United States and Europe, for the treatment of the disabling symptoms of essential tremor, Parkinson's disease and chronic intractable primary dystonia, the latter for which approval in the United States is under a Humanitarian Device Exemption (HDE). In Europe, Canada and Australia, DBS therapy is approved for the treatment of refractory epilepsy. DBS therapy is also approved for the treatment of severe, treatment-resistant obsessive-compulsive disorder in the European Union and Australia, and in the United States under an HDE.

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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* MR Conditional. Before conducting an MRI examination on a patient with any implanted Medtronic DBS device, please refer to the *MRI guidelines for Medtronic deep brain stimulation systems* located at www.medtronic.com/mri.

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1. IMV. *Benchmark Report: MR2013*. Des Plaines, IL; IMV Medical Information Division, Inc.; 2013:7.
2. Falowski S, Safriel Y, Ryan M, Hargens L. The need for magnetic resonance (MR) imaging in the United States (US) deep brain stimulation (DBS) population. Presented at: 18th Annual North American Neuromodulation Society Conference; December 11-14, 2014; Las Vegas, NV.

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