

## Medtronic Announces European Approval of the First and Only Full-Body MR Conditional Deep Brain Stimulation Systems

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### *Updated Labelling Allows Greater Patient Access to MRI*

**DUBLIN - April 22, 2015** - Medtronic plc (NYSE: MDT) today announced that systems within its Activa® portfolio of Deep Brain Stimulation (DBS) Therapy neurostimulators have received European regulatory approval for MR Conditional full-body Magnetic Resonance Imaging (MRI).<sup>[\*]</sup> The expanded approval for full-body MRI scans applies to all patients receiving a new system and to an estimated 13,000 people in Europe already receiving Medtronic DBS Therapy.\* Medtronic DBS systems have previously been approved for MRI scans of the head only, under limited conditions. Medtronic DBS systems are not approved in the United States for full-body scans.

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 tumors, internal organs, blood vessels, muscles, joints and other areas of the body by using strong magnetic fields and radio frequency pulses to create images of structures inside the body. Worldwide, it is estimated that approximately 60 million MRI procedures are performed each year.<sup>1</sup>

When programmed to appropriate settings, MR Conditional Medtronic DBS systems allow patients to continue to receive therapy during MRI scans. Previously, patients receiving an MRI scan had their DBS systems turned off before the scan.

"MRI is commonly the method of choice to image the body to diagnose disease or monitor existing conditions, but MRI use has often been limited in patients receiving DBS therapy," said Dr. John Thornton, medical physicist at the National Hospital for Neurology and Neurosurgery in London. "Patients receiving DBS therapy can now receive more advantages of MRI technology."

"Most patients who we consider for a DBS implant have other conditions which may require MRI," said Mr. Ludvic Zrinzo, neurosurgeon at the National Hospital for Neurology and Neurosurgery in London. "The MR Conditional Activa systems mean patients can receive DBS care, and still may have the option of MRI when needed to manage other conditions."

To receive approval for MR Conditional DBS systems, Medtronic developed proprietary test and measurement systems, in conjunction with advanced electromagnetic modeling tools. Existing Activa DBS systems were rigorously tested and evaluated across millions of simulated patient scans spanning over 38,000 unique implant conditions to demonstrate patient safety.

"Medtronic is proud to be the only company to offer DBS systems to patients across Europe allowing them access to full-body MRI technology," 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. "Additionally, now patients with MR Conditional systems will be able to continue to receive the benefits of the therapy during the scanning procedure. Continuous advancements such as these set Medtronic apart and reinforce our commitment to the field of brain modulation."

### **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 125,000 patients worldwide have received Medtronic

DBS Therapy.

The therapy is currently approved in many locations around the world, including Europe and the United States, for the treatment of the disabling symptoms of essential tremor, advanced Parkinson's disease and chronic intractable primary dystonia, 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](http://www.medtronic.com)), headquartered in Dublin, Ireland, 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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### **Reference**

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.

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\* Under specific conditions of use. 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](http://www.medtronic.com/mri).

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