Medtronic the First to Offer Complete Portfolio of Full-Body MR Conditional Neurostimulation Systems for Chronic Pain

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Medtronic

FDA Approval of Medtronic Specify® SureScan® MRI Surgical Leads Rounds Out Exclusive Portfolio Designed for Access to Full-Body MRI[*]

DUBLIN - March 3, 2016 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) approval of Specify® SureScan® MRI surgical leads, which are indicated for use as part of Medtronic implanted neurostimulation (also known as spinal cord stimulation, or SCS) systems for chronic pain. In 2013, Medtronic introduced the only implantable neurostimulation systems for use in the treatment of chronic, intractable back and/or limb pain that are FDA approved for full-body Magnetic Resonance Imaging (MRI) scans under specified conditions. The approval of SpecifySureScan MRI surgical leads establishes Medtronic as the only company with a full portfolio of SCS systems FDA approved for full-body MRI.* This means physicians can now offer a Medtronic full-body MR Conditional SCS system best suited for their patients regardless of the type of neurostimulator (rechargeable or non-rechargeable) or lead type (percutaneous or surgical). The new Specify SureScan MRI leads will be available to physicians and their patients later this month.

Studies show that 82 percent of patients implanted with a spinal cord stimulator are expected to need an MRI within five years of receiving their implant,[1] and Medtronic SureScan MRI neurostimulation systems offer patients the confidence of knowing that they can receive optimal diagnostic imaging anywhere in the body should the need arise. 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, muscles, 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. 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]

"All patients with a spinal cord stimulation system should have the ability to be offered the same imaging options as those without one," said Steven Falowski, M.D., neurosurgeon at St. Luke's University Health Network in Bethlehem, Pennsylvania. "Now more than ever, patients and other health care providers are concerned about access to MRI when considering an implantable device. This approval means I can offer a neurostimulation system that helps manage my patients' pain and gives them access to the diagnostic benefits of MRI."

Back pain is estimated to affect 8 out of 10 people at some point during their lives.[3] For some people, noninvasive options, such as medication and physical therapy, provide adequate relief; others may require surgery, nerve blocks, or medical devices, such as spinal cord stimulators or drug pumps. Spinal cord stimulators are medical devices implanted under the skin that send mild electrical pulses to an area near the spine. These pulses disrupt the pain signals traveling between the spinal cord and the brain, offering patients effective pain relief and improved function.[4]

"The use of MRI as a diagnostic tool has grown significantly. Medtronic appreciates the opportunity to offer physicians the only full portfolio of SCS systems that allow patient access to full-body MRIs, facilitating optimal patient care and timely interventions," said Julie Foster, vice president and general manager of the Pain Therapies business, which is part of the Restorative Therapies Group at Medtronic. "Medtronic remains committed to the advancement of spinal cord stimulation therapy overall and continues to ensure greater access to MRIs across many of our implanted Medtronic systems, such as pacemakers, ICDs and deep brain stimulation systems."

While the benefits of neurostimulation therapy are well documented, some individuals with an SCS system have traditionally been limited when receiving MRI scans, as the scans produce electromagnetic fields that can damage the

device or cause injury to the patient. These patients have the option of undergoing computerized tomography (CT) scans, which work well for imaging bones and other hard materials, but are less effective in examining soft tissue. In some cases, people needing an MRI have had the system explanted prior to imaging.

Additional benefits of the Medtronic Spinal Cord Stimulation Therapy include:

- Technology that is proven to significantly relieve pain for the long term[5] and help patients get back to the everyday activities they enjoy.[4]
- The opportunity for patients to "test drive" spinal cord stimulation with an external stimulator for a 3 to 10 day trial period during which they can assess how well the therapy relieves their pain during daily activities before committing to long-term therapy.
- RestoreSensor® SureScan MRI systems feature Medtronic's AdaptiveStim® technology, which adjusts stimulation automatically. Patients no longer have to use their programmer to make manual adjustments every time they change position.
- Personalization that empowers patients to manage their own pain therapy by adjusting their stimulation within pre-set limits.

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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References

1 Desai MJ, Hargens LM, Breitenfeldt MD, Doth AH, Ryan MP, Gunnarsson C, Safriel Y. The rate of magnetic resonance imaging in patients with spinal cord stimulation. Spine. 2015 May 1;40(9):E531-7.
2 IMV Benchmark Report 2012. IMV Medical Information Division. Des Plaines, Illinois. Page 1.
3 Web site: https://www.nlm.nih.gov/medlineplus/backpain.html Accessed: February 10, 2016
4 Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomized controlled trial in patients with failed back surgery syndrome. Pain. 2007;132:179-188.
5 Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. Neurosurgery. 2008;63(4):762-770.

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[*] Under specific conditions. Refer to approved labeling.

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