Medtronic News

Medtronic Receives CE Mark for InterStim™ Micro Neurostimulator and InterStim™ SureScan™ MRI Leads

Full-Body MRI-Conditional InterStim II and InterStim Micro Systems Offer Lifestyle-Friendly Choices in Sacral Neuromodulation Therapy to Europeans Suffering from Incontinence

DUBLIN, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced it has received CE Mark for its InterStim™ Micro neurostimulator and InterStim™ SureScan™ MRI leads — clearing the technologies for commercial sale and clinical use in Europe. The availability of the new technologies on January 15 will expand access to sacral neuromodulation (SNM) therapy for thousands of potential European patients by offering full-body MRI scan eligible, lifestyle-friendly choices with either the InterStim Micro or InterStim II neurostimulators.

InterStim Micro is a rechargeable device that delivers sacral neuromodulation therapy to treat overactive bladder (OAB), fecal incontinence (FI) and non-obstructive urinary retention. It is 80% smaller than the existing recharge-free InterStim II neurostimulator and could reduce the need for battery replacement surgeries due to its life of 15 years. It also features proprietary Overdrive™ battery technology — a battery with virtually no loss in capacity over time1 — that provides simple and rapid recharging. The SureScan leads, which will be used in both the InterStim Micro system and in future implants of the existing recharge-free InterStim II, are designed to allow for full-body 1.5 and 3 Tesla MRI-conditional scans.

Between 4% and 8% of the world's population — almost 400 million people worldwide2 — suffer from incontinence. In addition, at least half of patients with pacemakers or neurostimulators will have a clinical indication for an MRI examination over their lifetime3, and up to 23% of SNM explants are currently due to the need for an MRI scan4. Medtronic has treated more than 300,000 patients with recharge-free InterStim systems and, now, the rechargeable InterStim Micro and SureScan leads for the InterStim Micro and InterStim II systems will allow even more patients to access the therapy. In addition, Medtronic is the only company in Europe to offer patients a choice between rechargeable and recharge-free systems that are both full-body MRI-conditional.

"We're excited our most recent technology advances in sacral neuromodulation will allow physicians to treat more patients who need relief from their symptoms," said Brooke Story, vice president and general manager of the Pelvic Health and Gastric Therapies business, which is part of the Restorative Therapies Group at Medtronic. "We pioneered this therapy 25 years ago in partnership with physicians, and we have the only five-year data for all indications to demonstrate its safety and efficacy. We know from deep experience that it's important the therapy accommodates the lifestyle of the patient to produce the best outcome, and our latest innovations will now offer them a lifestyle-friendly choice in Medtronic SNM systems."

OAB significantly impacts quality of life and can negatively affect social activities, exercise and intimacy.5,6 Many sufferers limit their lives socially, professionally, and personally.7 However, as many as 45% who suffer from symptoms do not seek treatment and as many as seven in 10 stop using medications within six months due to intolerable side effects or unsatisfying results.7-10

"Effective long-term bladder and bowel control is an under-met medical need for many who experience regular accidents and/or frequency issues associated with OAB and FI," said Philip E.V. Van Kerrebroeck, M.D., Ph.D., MMSc; professor of Urology, Maastricht University Medical Centre, Maastricht, the Netherlands. "The new capabilities offered by MRI-conditional InterStim II and InterStim Micro will give patients the ability to choose a system that is compatible with their lifestyle, and they can have an MRI without being explanted. I'm excited because it allows me to offer the trusted experience and support of Medtronic to help give my patients their lives back."

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 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 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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