Medtronic News

Medtronic Expands Leadership in Treating Bladder and Bowel Control Conditions with Two New FDA-Approved Products: InterStim™ Micro Neurostimulator and InterStim™ SureScan™ MRI Leads

World's Smallest Rechargeable Bladder/Bowel Control System — InterStim Micro — Features Trusted MRI Technology for Full-Body 1.5 and 3 Tesla MRI Scans
Only Medtronic Offers Patients Personalized Therapy with the Choice of Rechargeable or Recharge-Free Sacral Neuromodulation Devices

DUBLIN, Aug. 03, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received approval from the United States Food and Drug Administration (FDA) for its InterStim™ Micro neurostimulator and InterStim™ SureScan™ MRI leads. InterStim Micro — the market's smallest rechargeable device to deliver sacral neuromodulation (SNM) therapy — is used for treating overactive bladder (OAB), fecal incontinence (FI) and non-obstructive urinary retention. The InterStim SureScan MRI leads are used with InterStim Micro and with the recharge-free InterStim II, and allow full-body 1.5 and 3 Tesla MRI-conditional scans.[1] The two new products make Medtronic the only company to offer patients and physicians a choice in SNM systems to match their preferences, lifestyle and treatment goals. Product is available for order immediately and will be delivered for patient procedures within days.

"I'm excited about the new InterStim technology because it will allow so many more patients to be able to pursue SNM therapy and get back to living life their way," said Dr. Steve Siegel, urologist at the Centers for Female Urology and Continence Care at Minnesota Urology. "The new technology by Medtronic allows me and my patients a choice between a rechargeable or a recharge-free system to best suit their lifestyle, and assures them they can have an MRI. Medtronic has left no box unchecked."

The new InterStim Micro:

- Is 50% smaller than the market's other rechargeable SNM device, making it the world's smallest.
- Allows patients to choose how and when they want to charge their device — from a quick charge once a week, or as infrequent as once per month, depending on the patient's preference or device settings.
- Features SureScan MRI technology, which does not require impedance checks prior to an MRI scan, providing more efficiency in patient care versus the other SNM system on the market.
- Can recharge from zero to 100% in less than an hour, making it the fastest battery available.
- Reduces the need for battery replacement surgeries due to its life of 15 years.

SureScan™ MRI technology is a known and trusted brand by MRI technicians. Built on more than 19 years of full-body MRI research, 10 million simulated patient scans, and more than 1.2 million unique scanning scenarios, Medtronic SureScan™ MRI systems prioritize patient safety.[1]

"The new InterStim portfolio brings the best choice in SNM therapy, offering MRI conditional recharge and recharge-free options for patients who have tried other therapies with little or no results," said Brooke Story, vice president and general manager of the Pelvic Health & Gastric Therapies business, which is part of the Restorative Therapies Group at Medtronic. "We have the only five-year data for four indications to demonstrate the safety and efficacy of InterStim systems and 25 years' experience in sacral neuromodulation therapy. We're committed to partnering with physicians to bring life-enhancing technologies to patients."

Medtronic has seen rapid adoption of the new InterStim portfolio in Europe since receiving CE mark in January 2020.

More than 37 million adults in the United States — almost one in six — suffer from overactive bladder (OAB),[2,3] and nearly 18 million Americans — about one in 12 — have bowel incontinence.[4,5] Many sufferers limit their lives socially, professionally, and personally.[6] 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.[7-9]

About Sacral Neuromodulation

Sacral neuromodulation (SNM) uses a small device to send electrical impulses to the sacral nerves located in the lower back to improve bladder and bowel control. Unlike oral medications that target the muscular component of bladder control, SNM offers control of symptoms through direct modulation of the nerve activity, normalizing the communication between the bladder and the brain.[10,11]

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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