

Medtronic Announces Comprehensive U.S. Launch of New InterStim™ Micro Neurostimulator

First Patient Receives New Sacral Neuromodulation Device Implant at Cleveland Clinic

DUBLIN, Aug. 05, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced that its recently FDA-approved InterStim™ Micro neurostimulator for sacral neuromodulation (SNM) therapy is now available in the United States. Cleveland Clinic performed the first patient implant in the nation with the new device.

Sacral neuromodulation sends 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.^{1,2}

"Effective long-term bladder and bowel control is needed for almost 55 million adults^{3,4,5,6} in the United States who often experience regular accidents and/or frequency issues that are associated with overactive bladder (OAB) and fecal incontinence (FI)," said Sandip Vasavada, M.D., professor at the Glickman Urological and Kidney Institute and section head Female Pelvic Medicine and Reconstructive Surgery, Cleveland Clinic. "A new FDA-approved option for these patients is a step forward." Dr. Vasavada discloses compensation for speaker/trainer/educator activities.

About InterStim Micro

- At 2.8 cm³, it 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 enables full-body MRI conditional scans.
- 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.

"Patients unfortunately limit their lives socially, professionally and personally due to OAB and FI," said Howard Goldman, M.D., professor and vice chairman of Quality and Patient Safety, Glickman Urological and Kidney Institute, Cleveland Clinic. "With this newly FDA-approved device, we have a new option and can offer more patients sacral neuromodulation therapy and improve their quality of life." Dr. Goldman discloses compensation for speaker/trainer/educator and consulting activities.

"OAB and FI patients want to live a life without limits, and we designed our new rechargeable SNM system to advance this reality," 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 created our entire InterStim portfolio in partnership with physicians backed by a 25-year track record of experience in sacral neuromodulation including over 325,000 implanted patients, 5-year clinical data and more than 1,000 peer-reviewed articles. We are confident our InterStim systems give patients and physicians the best choice in SNM therapy."

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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¹ Leng WW, Morrisroe SN. Sacral nerve stimulation for the overactive bladder. Urol Clin N Am. 2006;33:491-501.

² Kenefick NJ, Emmanuel A, Nicholls RJ. Effect of sacral nerve stimulation on autonomic nerve function. British Journal of Surgery. 2003;90:1256-1260.

³ Stewart WF, et al. Prevalence and burden of overactive bladder in the United States. World J Urol. 2003 May;20(6):327-336.

⁴ United Nations, Department of Economic and Social Affairs, Population Division (2011). World Population Prospects: The 2010 Revision, CD-ROM Edition.

⁵ Whitehead WE, Borrud L, Goode PS, et al. Pelvic floor disorders network. Fecal incontinence in US adults: epidemiology and risk factors. Gastroenterology. 2009;137: 512-517

⁶ United States Quick Facts. United States Census Bureau Web site. Available at: <https://www.census.gov/quickfacts/table/PST045215/00>. Accessed July 19, 2016.

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