Medtronic News

FDA Approves Smart Programmer for the InterStim System

Intuitive and Discreet Device Provides Sacral Neuromodulation Therapy for Overactive Bladder and Bowel Incontinence

DUBLIN - December 17, 2018 - Medtronic plc (NYSE:MDT) today announced U.S. Food and Drug Administration (FDA) approval of the InterStim(TM) smart programmer for use with the InterStim system, which provides sacral neuromodulation therapy for the treatment of overactive bladder (OAB), chronic fecal incontinence (FI) and non-obstructive urinary retention. The new smart programmer streamlines multiple devices into a single, intuitive, touch screen Samsung mobile device and enables clinicians to personalize each patient's care and allows patients to manage their therapy simply and discreetly. OAB and FI are treatable, extremely common and embarrassing conditions. More than 37 million adults in the United States - almost one in six - suffer from OAB and nearly 20 million Americans - about one in 12 - have bowel incontinence.1-4

"In addition to simplified programming and ongoing management of InterStim therapy, the smart programmer is discreet, which is meaningful to patients because OAB can greatly impact confidence, intimacy and activities," said Steven Siegel, M.D., Metro Urology Centers for Female Urology and Continence Care, Minneapolis, Minn. "It takes courage to seek treatment and many struggle to find long-term relief. My goal is to address OAB symptoms and help restore my patients' quality of life, and I'm pleased to have a tool like the InterStim smart programmer for patients who may benefit from neuromodulation."

Designed to deliver easy, streamlined programming, the smart programmer provides a single, intuitive app-based platform for implant and long-term therapy management. Physicians can instantly check Magnetic Resonance Imaging (MRI) eligibility, which is critical given the growing need for MRI scans in the U.S. The smart programmer also provides physicians with insights and access to a detailed, accurate view of the patient's therapy experience, which may help facilitate constructive patient conversations. To help optimize efficacy and tailor treatment based on patient needs, patients are able to adjust their therapy themselves, within clinician-defined limits in seven standard preset programs. The smart programmer also leverages Samsung Knox, Samsung's proprietary mobile security platform.

"Medtronic pioneered sacral neuromodulation two decades ago and we continue to innovate to improve the patient and physician experience and make it easier for more patients to find effective relief from both OAB and FI with the InterStim system," said Linnea Burman, vice president and general manager of the Pelvic Health & Gastric Therapies business, part of the Restorative Therapies Group at Medtronic. "The advanced technology of the smart programmer paves the way for future digital health solutions, like digital symptom tracking, and should give physicians and patients confidence that relief and restored quality of life are possible."

"The incorporation of consumer technology in medical device solutions, such as the InterStim system, is not only helping patients integrate these solutions into their daily lives, it's also empowering clinicians to evolve and digitally transform their practice," said Dr. David Rhew, chief medical officer and VP/GM, Enterprise (B2B) Healthcare, Samsung Electronics America. "Medtronic continues to lead the market in these types of healthcare innovations, and we are proud to partner with them to bring these important solutions to patients and clinicians."

About Overactive Bladder

OAB significantly impacts quality of life and can negatively affect social activities, exercise and cause disruptive nighttime voiding.5,6 Many sufferers are frustrated and embarrassed and limit their lives socially, professionally, and personally.7 However, 45 percent don't seek treatment and as many as seven in 10 stop using medications within six months due to intolerable side effects or unsatisfying results.8,9,10

Evidence points to OAB being caused by a miscommunication between the bladder and brain.11 Sacral neuromodulation

therapy, or gentle stimulation of the sacral nerves, delivered by the InterStim system is thought to normalize the brain-bladder communication pathway thereby restoring bladder function and alleviating symptoms. Restore is defined as >=50 percent reduction in dysfunctional voiding symptoms from baseline. The InterStim system is the only sacral neuromodulation solution proven to demonstrate sustained five-year efficacy and quality of life improvements for OAB.12

About Fecal Incontinence

FI is a distressing and disruptive chronic condition that is characterized by the inability to control bowel movements, which results in frequent accidents and leakage. People with FI report more depression and embarrassment, as well as lower quality of life compared to those without FI.13 Even through FI is treatable, 8.5 out of 10 adults haven't even told their doctor about their FI.14

About Medtronic InterStim Therapy for Bladder and Bowel Control

Medtronic is the first and leading provider of neuromodulation solutions for bladder and bowel control issues. Sacral neuromodulation therapy delivered by the InterStim system was first approved twenty years ago and has helped more than 250,000 patients worldwide.

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 86,000 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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