FDA Approves Expanded Use of Innovative Trial System for Incontinence Therapy

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Medtronic

Discreet, Wireless Touch-Screen System Allows for Shorter Evaluations Expediting the Potential for Long-Term Restoration of Bladder or Bowel Function

DUBLIN - September 30, 2015 - The U.S. Food and Drug Administration (FDA) recently approved the use of the Verify(TM) Evaluation System for basic evaluations, which last 3-7 days, thereby expediting the potential for long-term restoration of bladder or bowel function. Before making a long-term commitment, the Verify System allows patients to test the benefits of Medtronic Bladder or Bowel Control Therapy (Sacral Neuromodulation), delivered by the InterStim® System for the chronic symptoms of overactive bladder, non-obstructive urinary retention or bowel incontinence in patients who did not have success with more conservative therapies. More than 37 million adults in the United States - almost one in six - suffer from overactive bladder (OAB),[i,ii] and nearly 18 million Americans - about one in 12 - have bowel incontinence.[iii]

Overactive bladder often causes embarrassment and can dramatically affect the quality of daily living;[i,ii] patients limit activities, avoid social engagements, and restrict their diet.[iv,v] Many believe the misconception that incontinence is a normal part of aging that one must just live with. There is a significant unmet need in the treatment of OAB: among those who do seek treatment, studies show that 80 percent of patients prescribed oral medications to treat their OAB symptoms stop taking them by 12 months.[vi]

"Many patients suffering from OAB have failed multiple treatments and the Verify System for Basic Evaluations uses new technology to make it easier and faster for patients to assess the potential for effective long-term bladder control," said Steven Siegel, M.D., Director, Metro Urology Centers for Female Urology and Continence Care, Minneapolis, Minnesota. "Trying sacral neuromodulation before committing to the therapy allows patients to make a long-term decision with confidence and with an excellent chance to get their lives back."

Both the Verify System and the long-term InterStim System provide mild electrical stimulation to the sacral nerves, which are located near the tailbone and help bladder or bowel function. The therapy helps to normalize communication between the bladder or bowel and the brain, and it is clinically proven to eliminate or greatly reduce bladder or bowel control symptoms and significantly improve quality of life[vii]. The InterStim System consists of a pacemaker-like device called a neurostimulator and a lead (thin wire), which are implanted under the skin during a minimally invasive procedure following a successful trial with the Verify System.

"My overactive bladder symptoms ran my life. I quit going places and couldn't sleep through the night," said Peggy Smith, who underwent a 4-day trial with the Verify System for Basic Evaluations. "Oral medications didn't work for me and I was skeptical about trying this. But after this simple trial, I knew the therapy could work."

Peggy went on to receive Medtronic Bladder Control Therapy and has been pleased with her results. "Now with this therapy I can go places again and not worry about wetting myself," said Peggy. "It's a chance to be normal."

The Verify System includes a simple, wireless touch-screen controller and a small, concealable external neurostimulator device. It is discreet, easy to use and allows patients to perform many normal daily activities while undergoing the evaluation. There are two types of evaluations: the basic evaluation, initiated through a simple, in-office procedure, uses a temporary lead and lasts 3-7 days; and the advanced evaluation, which is initiated through a minimally invasive outpatient procedure performed in a hospital or surgical center and may last up to 14 days. The trial can be considered a success if a patient experiences a significant reduction in bladder control symptoms, such as going from 14 bathroom visits per day to 7.

The Verify System allows physicians to personalize treatment and provides real-time results and insights to help make informed decisions about long-term therapy. The Verify System includes a usage log that allows physicians to effectively manage patient evaluations by reviewing the operation of the system and matching it against a patient's diary of daily bladder or bowel episodes.

"Medtronic developed the Verify System as part of our commitment to provide meaningful innovations that restore health and advance the treatment of overactive bladder, urinary retention and bowel incontinence," said Linnea Burman, vice president and general manager, gastro/urology therapies at Medtronic. "Our goal is to provide long-term benefits to patients and the Verify System was designed to deliver clinical value by being easy for patients to use and helping physicians make informed treatment decisions with their patients along the continuum of care."

The InterStim System was developed by Medtronic and has been available in the United States since 1997. More than 175,000 patients worldwide have received Medtronic Bladder or Bowel Control Therapy.

Results of the therapy vary, and not every patient's response is the same. People should consult their physicians to decide whether InterStim therapy is appropriate. A prescription is required. In addition to risks related to a medical procedure, complications from this therapy can include pain, infection, sensation of electrical shock, device problems, undesirable change in voiding function, and lead migration, among others. Additional safety information can be found at www.everyday-freedom.com. For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com.

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 more than 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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