Medtronic News

New Evaluation System Leads to Incontinence Relief

FDA-Approved System Provides Patients with Added Benefits While Testing Innovative Therapy for Bladder and Bowel Incontinence

MINNEAPOLIS - October 7, 2014 - After living with overactive bladder and urinary retention symptoms for 11 years, Jennifer LaForest, a 26-year-old woman from Auburn Hills, Michigan, recently became one of the first in the U.S. to receive a test evaluation with the new Verify(TM) Evaluation System from Medtronic, and subsequently received Medtronic Bladder Control Therapy.

The Verify System, which was recently approved by the U.S. Food and Drug Administration (FDA), is used temporarily to determine if Medtronic Bladder Control or Bowel Control Therapies, delivered by the InterStim® System, may provide long-term relief for a patient suffering from chronic symptoms of overactive bladder, non-obstructive urinary retention or bowel incontinence who failed, could not tolerate or were not candidates for more conservative therapies. More than 37 million adults in the United States - one in six - suffer from overactive bladder,i,ii and nearly 18 million Americans - about one in 12 - have bowel incontinence.iii

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 and bowel function. The therapy is thought to help normalize communication between the bladder or bowel and the brain. The implantable components of the InterStim System consist of a pacemaker-like device called a neurostimulator and a lead (thin wire). These are implanted under the skin during a minimally invasive procedure following a successful trial stimulation period with Verify, which typically lasts up to 14 days.

While an evaluation system has been available to patients previously, the new, easy-to-use Verify Evaluation System offers a more discreet and unobtrusive experience to patients during the evaluation period. The system uses two advanced components: a small, external neurostimulator weighing less than two ounces and concealed securely in a soft belt worn at the waist under clothing; and a mobile phone-sized wireless controller with a touch-screen for easy stimulation adjustments. The Verify Evaluation System is used following a minimally invasive outpatient procedure to place the lead.

"In the short time that I've received this therapy, my overactive bladder and retention issues have dramatically improved. Previously, I rarely left my house feeling comfortable, and my self-esteem was very low. Now I have more confidence, and my worries about hygiene and odor have been reduced," said LaForest, who received Medtronic Bladder Control Therapy after a 14-day trial stimulation period with the Verify System. "Not only did the evaluation system confirm that the therapy works for me, but it was easy to use, was concealed easily beneath my clothes, and didn't get in the way of my normal daily activities."

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. Ken Peters, M.D., chief of urology at Beaumont Hospital in Royal Oak, Michigan was the first in the U.S. to use the Verify System.

"Mild stimulation of the sacral nerves can have a significant impact on patients suffering from overactive bladder, urinary retention or bowel control issues. The trial stimulation period allows them to try the therapy before having a neurostimulator implanted," said Dr. Peters. "This new trial system provides me with vital

information so I can determine if the long-term therapy is right for individual patients."

"More than 150,000 patients worldwide have received Medtronic Bladder Control or Bowel Control Therapies, and we are excited to bring the latest advancement in evaluation technology to physicians and patients," said Linnea Burman, vice president and general manager, gastro/urology therapies at Medtronic. "The Verify System reinforces Medtronic's commitment to innovative solutions for the treatment of overactive bladder, urinary retention and bowel incontinence."

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. 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/.

About Medtronic
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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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References:

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

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iii 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.

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