Medtronic News

Study Shows Medtronic InterStim(R) Therapy Improves Bowel Control and Related Quality of Life Issues at Three Years

InterStim Therapy for Bowel Control Recently Approved by the U.S. FDA

MINNEAPOLIS, Aug 15, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) announced today that newly published data from a multicenter, prospective trial show that sacral nerve stimulation using Medtronic InterStim(R) Therapy reduced incontinent episodes and increased quality of life in a majority of patients with chronic fecal incontinence at three years of follow up. The U.S. Food and Drug Administration recently approved the minimally invasive therapy for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

This analysis published in the September issue of *Diseases of the Colon and Rectum,* provides three-year safety and effectiveness data from a study of 120 patients who had sacral nerve stimulation with implantable InterStimTherapy to treat more than twice-weekly episodes of fecal incontinence.

Among the 77 study participants completing all of the three-year follow-up assessments, 86 percent ($p<0.0001$) reported at least a 50 percent reduction in the number of incontinent episodes per week compared to baseline. Additionally, the number of incontinent episodes per week for these patients decreased from a mean of 9.4 at baseline to 1.7. Complete continence (100 percent reduction in episodes) was seen in 40 percent of patients. Results remained robust in an analysis where missing three-year data were imputed using the last-observation-carried-forward method, with 79 percent of patients experiencing greater-than or equal to 50% reduction in the number of incontinent episodes per week.

Patients also experienced significant improvements in overall quality of life at 12, 24 and 36 months of follow up as defined by the Fecal Incontinence Quality of Life scale, a questionnaire composed of 29 questions, grouped into four domains: lifestyle, coping/behavior, depression/self-perception and embarrassment. This improvement included reduced worry about incontinent episodes and a beneficial effect on planning of daily activities.

"Most people can't begin to fathom the challenges of living with fecal incontinence, and these patients deserve to find effective treatment solutions," said Anders Mellgren, M.D., Ph.D., lead author of the study and clinical professor of surgery at the University of Minnesota. "This large study demonstrates the dramatic long-term impact InterStim Therapy can have on the daily lives of patients dealing with chronic bowel control issues."

The study, sponsored by Medtronic, was conducted in 16 centers, including 14 in the U.S., one in Canada and one in Australia from 2002 to 2010. All patients had failed or were not candidates for more conservative medical treatments and suffered from chronic fecal incontinence.

"Medtronic's innovative neurostimulation technologies have been shown to have a significant impact on a broad range of chronic, medically refractory conditions," said Cindy Kent, vice president and general manager, Gastro/Urology Therapies in Medtronic's Neuromodulation division. "This research provides important evidence to support increased physician consideration of InterStim Therapy for patients struggling with bowel control problems. We are pleased to now offer the therapy to appropriate patients in the United States."

The most common device-related adverse events in the study included implant site pain (28 percent), paresthesia (15 percent), change in sensation of stimulation (12 percent) and infection (10 percent). There were no reported unanticipated adverse device effects.

About InterStim Therapy

InterStim Therapy uses an implantable system, consisting of a thin wire lead and a neurostimulator, or pacemaker-like device, as well as external clinician and patient programmers. Physicians who implant InterStim Therapy for Bowel Control include colorectal surgeons, urologists, gynecologists and urogynecologists who receive appropriate training. Originally approved by the FDA in 1997 for urinary urge incontinence, InterStim Therapy now can be used for both urinary control and bowel control in many geographies, including the United States, Europe, Canada and Australia. To date, more than 100,000 people have received InterStim Therapy worldwide. InterStim Therapy is the only bowel control treatment option that allows patients and physicians to determine probable success of the therapy through a test stimulation procedure prior to committing to long-term therapy.

About Fecal Incontinence

Fecal incontinence is the inability to control the bowels and is a debilitating condition that is often underreported and stigmatized. According to a National Institutes of Health (NIH)-funded study, more than 18 million Americans have fecal incontinence1. It is more common in adults, predominately women, but it is not a normal part of aging. Fecal incontinence can be caused by a variety of factors, including damage to the nerves or muscles in the rectum from trauma such as childbirth or other pelvic health disorders.

More information on InterStim Therapy for Bowel Control can be found at www.medtronic.com/bowelcontrol.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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.

1 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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