Medtronic News

# Medtronic Announces FDA Approval of InterStim(R) Therapy for Bowel Control

*Unique Sacral Nerve Stimulation Therapy Now Available for Treatment of Chronic Fecal Incontinence*

MINNEAPOLIS, Apr 01, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) approval of InterStim(R) Therapy for Bowel Control. InterStim Therapy, previously available to treat the symptoms of overactive bladder and non-obstructive urinary retention, is now also approved for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments. InterStim Therapy for Bowel Control is a new, minimally invasive option proven to improve or restore bowel control in more than 80 percent of patients who received the therapy in a multi-center clinical trial.

The implantable InterStim system uses mild electrical stimulation of the sacral nerves to influence the behavior of the pelvic floor muscles and bowel. As a result, the therapy significantly reduced fecal incontinent episodes for a high percentage of clinical trial patients. 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.

"Bowel control problems can have a significant, detrimental effect on a person's emotional well-being and quality of life. Standard treatments often fail due to both the inherent challenges of the condition and the fact that few effective treatment options are available," said Steven D. Wexner, M.D., chief academic officer at Cleveland Clinic Florida, professor and chair of the Department of Colorectal Surgery, and president-elect of the American Society of Colon and Rectal Surgeons. "I applaud the application of promising technology to advance treatment options for many who suffer with chronic fecal incontinence." Dr. Wexner was the lead principal investigator during the Medtronic-sponsored pivotal trial that served as the basis for the application to the FDA. After completion of the study, he began working as a paid consultant assisting Medtronic in the development of educational materials relating to this 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 will 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 85,000 people have received InterStim Therapy worldwide.

"Medtronic's InterStim Therapy is an important advance for patients who see their quality of life diminished by bowel control problems," said Tom Tefft, president of the Neuromodulation business and senior vice president at Medtronic. "Medtronic has been the pioneer and long-time leader in neuromodulation technologies; this approval reflects our ongoing commitment to extend our expertise to additional serious, chronic diseases where there are few other current treatment options for patients."

Data from the Medtronic-sponsored pivotal study that led to FDA approval show InterStim Therapy for Bowel Control reduced fecal incontinent episodes and increased quality of life in patients with the condition. The 120-patient, multi-center study - the largest trial of its kind in the world - examined the efficacy of InterStim Therapy in patients with chronic fecal incontinence who had failed or were not candidates for more conservative treatments. The results were published in the March 2010 issue of the *Annals of Surgery.*

At 12 months of follow-up, 83 percent of patients experienced therapeutic success, defined as a greater than 50 percent reduction in the number of fecal incontinent episodes per week. Furthermore, complete continence (no incontinent episodes)

was achieved in more than 40 percent of the patients. In addition, patients in the study showed significant improvement in quality of life as measured by the Fecal Incontinence Quality of Life (FIQOL) Index.

In the study, the most common device or therapy-related adverse events that occurred during the implant phase included implant site pain (25.8 percent), paraesthesia - a sensation of tingling, pricking, or numbness of the skin (12.5 percent), and implant site infection (10.8 percent). The majority of the events were successfully handled by minimal interventions. No adverse device effects were unanticipated.

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.

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.

SOURCE: Medtronic, Inc.

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