Medtronic News

Medtronic Receives FDA Approval of AdaptiveStim(TM) with RestoreSensor(TM) for the Management of Chronic Pain

Neurostimulator Uses Innovative Motion Sensor Technology to Provide Patient Comfort and Convenience

MINNEAPOLIS--(BUSINESS WIRE)--Nov. 17, 2011-- Medtronic, Inc. (NYSE: MDT) today announced the U.S. Food & Drug Administration (FDA) approval of its AdaptiveStim™ with RestoreSensor™ neurostimulation system, the first and only chronic pain treatment that harnesses motion sensor technology found in smart phones and computer gaming systems to provide effective pain relief and convenience by automatically adapting stimulation levels to the needs of people with chronic back and/or leg pain.

“Medtronic is pleased to introduce AdaptiveStim technology, and we look forward to helping address the many concerns we’ve heard from physicians and patients about traditional neurostimulation systems,” said Julie Foster, vice president and general manager of the Pain and Drug Delivery Therapy businesses in the Neuromodulation division at Medtronic. “It is our intent that this breakthrough technology will help transform pain management and enable people suffering with chronic pain to feel better and get back to their normal activities.”

Neurostimulation systems consist of an implantable medical device similar to a pacemaker to interrupt pain signals from reaching the brain. The treatment has become a mainstay of chronic pain management; however, a change in body position (e.g., sitting up or lying down) can result in an increase or decrease in the intensity of stimulation as a patient’s spinal cord moves closer or further away from the stimulation site. As a result, patients may need to make frequent manual adjustments to their stimulation levels as they move, using a handheld patient programmer.

AdaptiveStim with RestoreSensor reduces the need for manual programming changes by automatically adapting stimulation levels to the needs of people with chronic back and/or leg pain by recognizing and remembering the correlation between a change in body position and the level of stimulation needed. It also records and stores the frequency of posture changes, providing objective feedback to clinicians to help them understand how a patient’s individual stimulation requirements are changing over time. Additionally, AdaptiveStim with RestoreSensor is approved by the FDA for use in MRI head scans if recommended by a physician.1Medtronic is the only company to offer neurostimulators with this approved labeling for use in MRI head scans.

Data from the U.S. RestoreSensor clinical trial demonstrate that the AdaptiveStim with RestoreSensor neurostimulator provides effective pain relief and convenience. At the end of the study, 86.5 percent of study participants with chronic pain, who were included in an intent-to-treat analysis (n=74), experienced somewhat better or much better pain relief with no loss of convenience, or somewhat more or much more convenience with no loss of pain relief, when the device’s AdaptiveStim technology was turned on, compared to a control period when the participants manually adjusted neurostimulation settings using a patient programmer. With AdaptiveStim, study participants reported functional improvements, including improved comfort during position changes (80.3 percent).

The multicenter, prospective, open-label, randomized, crossover study enrolled 79 study participants at 10 U.S. centers. Participants were randomized to receive either stimulation from the RestoreSensor device for six weeks with the AdaptiveStim technology turned on followed by six weeks with AdaptiveStim turned off, or six weeks

with AdaptiveStim turned off followed by six weeks with AdaptiveStim turned on. When AdaptiveStim was turned off, participants manually adjusted stimulation levels using a patient programmer.

“This research provides important clinical evidence that demonstrates this innovative, position-sensing technology improves pain management and makes it easier for patients suffering from chronic pain to better manage their symptoms when compared to systems that require manual changes in stimulation,” said David Schultz, M.D., founder and medical director of MAPS Pain Clinics and MAPS Applied Research Center (MARC) in Minneapolis, and RestoreSensor clinical trial investigator.

The profile of adverse events reported during the U.S. clinical trial was similar with and without the AdaptiveStim technology activated.

Nearly 200,000 people worldwide have received Medtronic neurostimulation therapy for intractable, chronic pain. Additional information on current Medtronic neurostimulation pain therapies is available at www.tamethepain.com or 1-888-430-PAIN (7426).

About Chronic Pain

Chronic pain affects an estimated 116 million American adults – more than the total affected by heart disease, cancer, and diabetes combined2. Chronic pain, which is defined as pain that lasts for more than three to six months, is a disabling condition, not simply a symptom of another disease or condition, and it can be either intermittent or continuous. For some, chronic pain is so severe that it interferes with working, eating, participating in physical activity and enjoying life3.

Medtronic’s Leadership in Neuromodulation

Medtronic developed and leads the field of neuromodulation, the targeted and regulated delivery of electrical pulses and pharmaceuticals to specific sites in the nervous system. The company’s Neuromodulation business includes implantable neurostimulation and targeted drug delivery systems for the management of chronic pain, common movement disorders, spasticity and urologic and gastrointestinal 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 Under specific conditions of use. Refer to approved labeling.

2 Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research; Consensus Report, Institute of Medicine (IOM), June 2011.

3 Consumer Guide to Pain Medication and Treatment, 2011 Edition. American Chronic Pain Association. http://www.theacpa.org/uploads/ACPA_Consumer_Guide_2011%20final.pdf. Accessed August 4, 2011.

Source: Medtronic, Inc.

Medtronic, Inc.
Donna Marquard, 763-526-6248
Public Relations
or
Jeff Warren, 763-505-2696
Investor Relations

---

https://news.medtronic.com/2011-11-17-Medtronic-Receives-FDA-Approval-of-AdaptiveStim-TM-with-RestoreSensor-TM-for-the-Management-of-Chronic-Pain