Medtronic News

Data Shows Medtronic AdaptiveStim™ with RestoreSensor™ Provides Pain Relief and Convenience

Neurostimulator with Innovative Motion Sensor Technology Was Recently Approved by the FDA for the Management of Chronic Pain

MINNEAPOLIS--(BUSINESS WIRE)--Dec. 9, 2011-- Clinical trial data presented at the 15th Annual Meeting of the North American Neuromodulation Society demonstrate the AdaptiveStim™ with RestoreSensor™ neurostimulation system from Medtronic (NYSE: MDT) provides clinical benefits for many patients, including effective pain relief and convenience, compared to systems without position-adaptive stimulation technology.

AdaptiveStim with RestoreSensor, approved by the U.S. Food and Drug Administration in November 2011, is the first chronic pain management system to harness motion sensor technology found in smart phones and computer gaming systems to provide effective pain relief and convenience for treating chronic back and/or leg pain, compared to conventional stimulation. The system uses proprietary motion sensor technology to automatically adapt 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 position changes, providing feedback to clinicians to help them understand how a patient's individual stimulation requirements are changing over time.

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 also reported functional improvements, including improved comfort during position changes (80.3 percent). When the study ended, 90.1 percent of the participants said they intended to use AdaptiveStim, either by leaving it on all or most of the time or by turning it on or off as needed.

Additionally, when AdaptiveStim was turned on, a 41 percent reduction in the average number of manual programming changes needed to adjust stimulation throughout the day was noted. Physicians reported a clinical benefit for 88.7 percent of participants with AdaptiveStim.

The multicenter, prospective, open-label, randomized, crossover study enrolled 79 study participants at 10 U.S. centers. Seventy-six participants received implants and 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 study clearly demonstrates the effectiveness of position-adaptive stimulation technology in providing pain relief and convenience to patients suffering from chronic pain, so they can lead more normal lives," 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.

Worldwide, nearly 200,000 people 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).

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 neurostimulation and implantable, 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 inMedtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

Source: Medtronic, Inc.

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

---

https://news.medtronic.com/2011-12-09-Data-Shows-Medtronic-AdaptiveStim-TM-with-RestoreSensor-TM-Provides-Pain-Relief-and-Convenience