Medtronic News

Medtronic Announces Clinical Trial for Breakthrough Technology in Neurostimulation Therapy for Intractable Chronic Pain

RestoreSensor Neurostimulator Designed to Optimize Pain Relief for Patients Regardless of Body Position

MINNEAPOLIS, May 06, 2010 (BUSINESS WIRE) --Medtronic, Inc. (NYSE: MDT) today announced the initiation of a prospective, multi-center, randomized U.S. clinical trial for the RestoreSensorTM neurostimulator that adapts therapy to the changing needs of chronic pain patients by responding automatically to changes in body position and activity in an upright position. The RestoreSensor neurostimulator received CE Mark approval in Europe and is under investigational use in the United States. The U.S. clinical trial will evaluate the benefits of the unique AdaptiveStimTM feature of the RestoreSensor device that uses a cutting-edge, proprietary smart technology for the first time in an implantable medical device for the treatment of chronic pain. Physicians at ten U.S. medical centers will be enrolling patients in this study. The first implant of a RestoreSensor neurostimulator in the study was performed by David Schultz, M.D., at MAPS Pain Clinic in Minneapolis.

"Neurostimulation offers patients a therapy that has been clinically proven to provide pain relief, but there is variance in the device settings required to maximize the pain relief and comfort based on a patient's activity," said David Schultz, M.D., founder and medical director of MAPS Pain Clinics and MAPS Applied Research Center (MARC) in Minneapolis, and investigator in the RestoreSensor clinical trial. "We are pleased to be involved in the clinical efforts to study a device that could address an unfulfilled need for a neurostimulation system. This device is designed to allow automatic response to changes in position and maintenance of a consistent, optimal level of stimulation for patients."

The level of stimulation required to manage a patient's pain at any given time is dependent on the distance between the spinal cord and implanted electrodes. However, this distance changes depending on whether the patient is upright or lying down in various positions. Currently, most patients have to use a remote control device to adjust the level of stimulation to maximize pain control and comfort after they change body positions. This often includes turning the stimulation up when a person is upright and active, or turning it down when they are lying down. The RestoreSensor device with AdaptiveStim technology is the first device to sense a change in body position and automatically optimize the pain therapy settings.

AdaptiveStim technology uses a proprietary sensor and algorithm that leverage the latest advancements in motion detection technology. Similar to the sensing mechanism used in innovative technologies like automobile airbags and popular consumer electronics, the sensing capabilities of the RestoreSensor neurostimulator involve the use of an accelerometer to sense changes in body position. Once the AdaptiveStim feature is activated, programming parameters based on a patient's optimal stimulation settings are correlated to certain positions or activity. When the programming is complete, the device is designed to improve pain relief regardless of body position by automatically adjusting the device settings.

The RestoreSensor neurostimulator also records and stores the frequency of these posture and activity changes. These objective data provide feedback to the clinician to understand whether the patient's individual stimulation requirements are changing over time.

The inspiration for the AdaptiveStim technology comes from Medtronic's pioneering work in responsive (or adaptive) technology in cardiac pacemakers. Medtronic was the first to develop rate responsive pacemakers that could sense and respond to a patient's changing need for cardiac output, which are the standard of care today. The RestoreSensor study will pursue a similar adaptive therapy for the field of neuromodulation.

"We have long been committed to finding new and innovative ways to improve the lives of patients suffering from chronic pain," said Don Deyo, vice president of Product Development and Technology in Medtronic's Neuromodulation business. "We are

proud to be developing this breakthrough technology that will continue to help patients with chronic pain return to a more full life. We expect the RestoreSensor neurostimulator with cutting-edge AdaptiveStim technology will set a new precedent for using neurostimulation to manage chronic pain."

About Spinal Cord Stimulation for Chronic Pain

Spinal cord stimulation, developed by Medtronic in partnership with physicians, uses an implantable medical device similar to a pacemaker connected to thin, flexible wires to deliver electrical pulses to the epidural space in order to block pain signals from reaching the brain. Spinal cord stimulation is approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic, intractable pain in the trunk and/or limbs. To date, more than 250,000 people worldwide have received Medtronic spinal cord stimulation therapies for intractable, chronic pain.

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 offers innovative therapies for chronic pain, movement disorders, obsessive-compulsive disorder, spasticity, overactive bladder, enlarged prostate and gastroparesis.

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.

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