Medtronic News

Medtronic Receives FDA Approval for First and Only Pacemaker System in the U.S. Designed for Use in the MRI Environment

Revo MRI(TM) SureScan(R) Pacing System Offers Pacemaker Patients Access to MRI Scans

MINNEAPOLIS, Feb 08, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced that the U.S. Food and Drug Administration (FDA) approved its Revo MRI(TM) SureScan(R) pacing system, the first and only pacemaker in the U.S. specifically designed for use in an Magnetic Resonance Imaging (MRI) environment and approved as MR-Conditional. Shipments of Revo MRI will begin immediately.

Until now, MRI procedures had been contraindicated for patients with implanted pacemakers due to the potential for serious adverse events.1,2,3,4 Each year, an estimated 200,000 pacemaker patients in the United States have to forgo MRI scans, which are critical for making a wide range of health diagnoses.iv

"The new Revo MRI pacemaker is a major technological breakthrough for patients who need access to MRI," said Dr. J. Rod Gimbel of Cardiology Associates of East Tennessee in Knoxville, Tenn. "Providing pacemaker patients with access to MRI allows detection and treatment of serious medical conditions such as stroke, cancer, and a wide variety of important neurologic and orthopedic conditions."

As the population ages, the use of pacemakers is growing, with approximately 5 million patients worldwide who currently are implanted with a pacemaker or implantable cardioverter-defribrillator. 5 At the same time, the use of MRI as a diagnostic tool is increasing, with approximately 30 million scans completed in 2007.6,7 Individuals over age 65 are twice as likely to need an MRI compared with younger patients, and between 50 and 75 percent of patients with electronic cardiac devices will likely need an MRI over their device's lifetime.8

"For the first time, patients will have access to a state-of-the-art pacemaker that is designed to work safely and effectively in an MRI environment," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "This milestone underscores Medtronic's ongoing commitment to develop pacemaker technology that provides meaningful differences in patients' lives."

Prior to the introduction of Revo MRI, pacemaker patients could face serious complications if they were exposed to the powerful magnetic fields generated by MRI machines, which can be as much as 30,000 times more powerful than the Earth's magnetic field.9 Complications to exposure could include interference with pacemaker operation, damage to system components, or a change in pacing capture threshold, which is the minimum amount of current required to evoke a cardiac contraction.10,11,12,13 Revo MRI, when programmed into SureScan mode prior to an MRI scan, is designed to be safe for the MRI environment when used per the specified MR Conditions for Use.14 Revo MRI is considered MR-Conditional, a term used to indicate that a device may be used in the MRI environment under certain conditions, such as a particular type of MRI scanner and scanner settings.

About Revo MRI(TM) SureScan(R) Pacing System

Revo MRI was designed from the ground up to address safety concerns around MRI procedures for patients who have implanted pacemakers. The pacemaker system includes hardware modifications to the device and leads that are designed to reduce or eliminate several hazards produced by the MRI environment. In addition, since MRI scanners may cause other current pacemakers to misinterpret MRI-generated electrical noise and withhold pacing therapy or deliver unnecessary pacing therapy, this new pacemaker includes a proprietary SureScan feature that sets the device into an appropriate mode for the MRI environment.

The Revo MRI pacing system must consist solely of a Medtronic Revo MRI SureScan device and two CapSureFix MRI(TM) SureScan Model 5086MRI leads. Prior to scanning a patient, refer to the Revo MRI Pacing System MR Conditions for Use located in the device manuals. Consult Medtronic's website at www.medtronic.com or call Medtronic at 1 (800) 328-2518. For more information about Revo MRI go to www.medtronic.com/patient/revomri.

"We are continuing to work with FDA toward a final resolution to the Mounds View warning letter and are optimistic that we are making progress toward this goal," concluded Pat Mackin.

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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