Medtronic News

Medtronic Receives CE Mark for Pacemaker Lead That Will Expand Patient Access to MRI Technology

CapSure Sense MRI™ SureScan® Passive Fixation Leads Gives Physicians More MR-Conditional Options

MINNEAPOLIS--(BUSINESS WIRE)--Mar. 5, 2012--Medtronic, Inc. (NYSE: MDT) today announced the receipt of CE Mark (Conformité Européenne) and launch of the CapSure Sense MRI™ SureScan® pacing leads, which are approved for use during Magnetic Resonance Imaging (MRI). Medtronic introduced the first MR-Conditional pacemaker system in the world in 2008 and in the U.S. in 2011.

The newly approved leads are the smallest MR–Conditional leads available in the world. As passive-fixation leads (which attach to the heart with small tines), they will give physicians an additional option that is MR-Conditional, or designed to be safe for the MRI environment when used per the specified MR Conditions for Use.i Previously approved Medtronic MR–Conditional leads are active fixation leads, which fasten directly into the cardiac tissue.

With approximately 60 million MRI procedures performed worldwide each year,ii there has been increasing demand for MR–Conditional pacing systems. MRI procedures are indicated for 17 percent of pacemaker patients within 12 months of device implant.iii

“The CapSure Sense MRI SureScan® leads address an unmet clinical need for thoroughly tested MRI conditional passive fixation leads," said Gianluca Botto, M.D., director of EPS Unit atSt. Anna Hospital in Como, Italy. “With this new lead, there is now a full portfolio of options available for physicians and their patients, when this lead is combined with an MR–Conditional device.”

To assure the safety of patients and the effectiveness of the patients’ pacing therapy, the CapSure Sense MRI leads were tested in more than 400,000 scenarios that evaluated different patient body types, scanning locations, MRI scanner types and lead lengths.

“Now patients and physicians will have access to MRI passive leads approved for full body MRI scans,” saidPat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. “This is a major step forward in addressing both patient access and providing physician options.”

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.

i Wilkoff B, et al. Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment. Heart Rhythm 2011; 8(1): 65-73.

ii Sutton R, Kanal E, Wilkoff BL, Bello D, et al. Safety of magnetic resonance imaging of patients with a new Medtronic EnRhythm MRI SureScan pacing system: clinical study design. Trials 2008, 9:68

iii Sommer T, Naehle CP, Yang A, Zeijlemaker V, et al. Strategy for safe performance of extrathoracic magnetic resonance imaging at 1.5 Tesla in the presence of cardiac pacemakers in non–pacemaker-dependent patients: A prospective study with 115 examinations. Circulation, Sep 2006; 114: 1285 - 1292.

Source: Medtronic, Inc.

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