Medtronic News

# Medtronic Receives CE Mark for Ensura MRI(TM) SureScan(TM) Pacing System Approved for Use in MRI Machines as Labeled

*New Option in Second-Generation Pacing System Available in Select European Geographies Features Exclusive Technology and Allows Access to Critical Diagnostic Tool*

MINNEAPOLIS, Jun 30, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) announced today the company received CE (Conformité Européenne) Mark for Ensura MRI(TM) SureScan(TM) pacing system. Ensura MRI is the company's new option in the second-generation pacing system, available in select European geographies, in a portfolio of devices from Medtronic designed, tested, and approved for use as labeled with MRI machines. Patients with this new SureScan pacing system will have access to full body scans, without positioning restrictions in the MRI scanner. The Ensura MRI SureScan pacing system currently is not approved for sale in the United States.

"Half of the world's pacemaker implants are from Medtronic, and physicians say the number one unmet need is MRI compatibility," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "We are pleased to offer physicians a third option from the world's first portfolio of MR Conditional pacing systems with our exclusive technology for patients who may need access to the critical diagnostics available through MRI."

Approximately two million Europeans have implanted pacemakers; however, these patients are strongly discouraged from receiving MRI scans, a widely practiced diagnostic method for many common diseases and conditions, such as cancer, neurological disorders and orthopedic injuries. It is possible current pacing systems could interact with MRI machines, potentially affecting the device or patient safety. According to estimates, 50-75 percent of patients worldwide with implanted cardiac devices are expected to need an MRI scan during the lifetime of their devices.1 MRI is the standard of care in soft tissue imaging, providing information not seen with X-ray, ultrasound, or CT scan, and critical for early detection, diagnosis and treatment.

## About Ensura MRI Sure Scan Pacing System

Medtronic's new pacing system provides patients with innovative exclusive technology, MVP(R) (Managed Ventricular Pacing), which reduces right ventricular pacing by 99 percent2.

Data show every incremental 1 percent of unnecessary RV pacing increases the risk of atrial fibrillation (AF) by 1 percent and the risk of heart failure hospitalization by 5.4 percent.3 The European Society of Cardiology (ESC) guidelines state that in the selection of pacing mode and device, "the trend is towards dual chamber pacing with minimization of right ventricular stimulation."4 A strategy of minimizing ventricular pacing led to a 40 percent reduction in the relative risk of developing persistent AF compared to conventional dual chamber pacing.3

The Ensura MRI SureScan pacing system also features Atrial and Ventricular Capture management (ACM and VCM) with automatic threshold measurements and adjustments; and the pacing system is compatible with the Medtronic CareLink(R) Network, which allows remote device follow-ups by transmitting arrhythmia and diagnostic device data to a physician's clinic.

## 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 Kalin R, Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients.*Pacing Clin Electrophysiol*. April 2005;28(4):326-328.

2 Gillis, AM, et al. Reducing Unnecessary Right Ventricular Pacing with the managed Ventricular Pacing Mode in Patients with Sinus Node Disease and AV Block. *PACE*. July 2006;29(7):697-705.

3 Sweeney MO, Bank AJ, Nsah E, et al. Minimizing ventricular pacing to reduce atrial fibrillation in sinus-node disease*N Engl J Med*. September 6, 2007;357(10):1000-1008.

4 Vardas PE, Auricchio A, Blanc JJ, et al. ESC Guidelines for Cardiac Pacing and Cardiac Resynchronization Therapy.*Eur Heart J*. September 2007;28(18):2256-2295.

SOURCE: Medtronic, Inc.

Medtronic, Inc.
Yvan Deurbroeck, +41-21-802-7574
Public Relations
or
Jeff Warren, 763-505-2696
Investor Relations

---

https://news.medtronic.com/2010-06-30-Medtronic-Receives-CE-Mark-for-Ensura-MRI-TM-SureScan-TM-Pacing-System-Approved-for-Use-in-MRI-Machines-as-Labeled