Medtronic News

Medtronic Announces Japanese Approval and Launch of Implantable Cardioverter-Defibrillator System to Allow for Full-Body MRI Scans

Evera MRI(TM) ICD System Combines Proven Treatment Performance, Increased Longevity and Improved Comfort with Full-Body MRI Access

MINNEAPOLIS - Nov. 10, 2014 - Medtronic today announced Japanese regulatory approval and launch of the Evera MRI(TM) SureScan® implantable cardioverter-defibrillator (ICD) System for magnetic resonance imaging (MRI) scans positioned on any region of the body. Reimbursement also was approved by Japan's Ministry of Health, Labor and Welfare (MHLW). The Medtronic Evera MRI ICD is currently limited to investigational use in the United States.

It is estimated that more than half of ICD patients will need an MRI within 10 years of receiving a device.1 Until the availability of MR-Conditional ICD systems, patients with devices have been contraindicated from receiving MRI scans because of potential interactions between the MRI and device function.

The newly-approved Evera MRI device is available in both single chamber and dual chamber ICDs. Like its non-MR-Conditional predecessor, the Evera MRI features a contoured shape with thin, smooth edges that better fits inside the body, increasing patient comfort by reducing skin pressure by 30 percent.2 The Evera MRI maintains the same industry-leading battery longevity (up to 11 years) compared to previous devices.3,4,5,6,7,8,9,10 In addition, Evera MRI is paired with the Sprint Quattro® Secure family of ICD leads, which has 10 years of proven performance with active monitoring11 and is safe for use in an MRI environment.12

Evera MRI includes SmartShock(TM) 2.0 - an exclusive shock reduction algorithm that enables the device to better differentiate between dangerous and harmless heart rhythms. While the majority of shocks delivered are necessary to treat potentially fatal arrhythmias, studies estimate that approximately 20 percent of patients with implantable defibrillators may experience inappropriate shocks in response to a benign arrhythmia or electrical noise sensed by the device.13 SmartShock technology helps to eliminate these inappropriate shocks, and delivers a 98-percent inappropriate shock free rate at one year.14,15 Also included in the Evera MRI is OptiVol® 2.0 Fluid Status Monitoring and complete diagnostics, which helps to identify patients at risk of worsening heart failure and atrial fibrillation.

"This means that in addition to having the highest standard in modern ICD treatment, patients implanted with an Evera MRI defibrillator will now have improved access to one of the most important diagnostic tools - the MRI," said Marshall Stanton, M.D., vice president and general manager of the Tachycardia Business at Medtronic. "Compared to other ICDs available, the Evera MRI system gives patients the most unrestricted access to MRI scans, and ultimately allows them to get the diagnostic answers they need."

The Evera MRI system is the latest addition to a growing number of Medtronic devices which are designed for MRI access including the Medtronic SureScan® pacing systems, neurostimulation systems for the management of chronic pain and the SynchroMed® II programmable drug infusion system.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias.

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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Contacts:
Tracy McNulty
Public Relations
+1-763-526-2492

Jeff Warren
Investor Relations
+1-763-505-2696

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