Medtronic News

Medtronic Announces CE Mark and European Launch of First Implantable Cardioverter-Defibrillator System to Allow for Full-Body MRI Scans

Evera MRI(TM) ICD System Is First to Combine Proven Treatment Performance, Increased Longevity, Improved Comfort with Full-Body MRI Access

MINNEAPOLIS - April 9, 2014 - Medtronic today announced CE (Conformité Européenne) Mark and European launch of the Evera MRI(TM) SureScan® implantable cardioverter-defibrillator (ICD) System, the first and only ICD system approved for magnetic resonance imaging (MRI) scans positioned on any region of the body. The Medtronic Evera MRI ICD is not approved in the United States.

It is estimated that as many as 63 percent 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.

"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. "An ICD that allows for full-body access to MRI will help patients get the diagnostic answers they need."

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 monitoring[11] 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.

"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," said Stanton. "Patients suffering from debilitating heart rhythm disorders who need an ICD also are likely to need an MRI over the lifetime of their device and this technology allows them to do so."

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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[1] Turakhia M, Reynolds M, Wolff S, et al. Medtronic Data on File 2013. Data from 2011 MarketScan® Commercial and Medicare database, Truven Analysis, Inc. were used for this research. Patient cohort represents ICD patients in terms of age, gender, and major comorbidities (N = 10,778).

[2] Flo, Daniel. Device Shape Analysis. January 2013. Medtronic data on file.

[3] Knops P, Theuns DA, Res JC, Jordaens L. Analysis of implantable defibrillator longevity under clinical circumstances:implications for device selection. Pacing Clin Electrophysiol. October 2009;32(10):1276-1285.

[4] Schaer BA, Koller MT, Sticherling C, Altmann D, Joerg L, Osswald S. Longevity of implantable cardioverterdefibrillators,influencing factors, and comparison to industry-projected longevity. Heart Rhythm. December 2009;6(12):1737-1743.

[5] Biffi M, Ziacchi M, Bertini M, et al. Longevity of implantable cardioverter-defibrillators: implications for clinical practice and health care systems. Europace. November 2008;10(12):1288-1295.

[6] Kallinen L, et al. 2009. http://spo.escardio.org/eslides/view.aspx?eevtid=33&id=1913.

[7] Thijssen J, Borleffs CJ, van Rees JB, et al. Implantable cardioverter-defibrillator longevity under clinical circumstances: an analysis according to device type, generation, and manufacturer. Heart Rhythm. April 2012;9(4):513-519.

[8] Shafat T, Baumfeld Y, Novack V, Konstantino Y, Amit G. Significant differences in the expected versus observed longevity of implantable cardioverter defibrillators (ICDs). Clin Res Cardiol. Published online July 14, 2012.

[9] Horlbeck FW, Mellert F, Kreuz J, Nickenig G, Schwab JO. Real-world data on the lifespan of implantable cardioverter-defibrillators depending on manufacturers and the amount of ventricular pacing. J Cardiovasc Electrophysiol. December 2012;23(12):1336-1342.

[10] Evera XT DR/VR Manual.

[11] Medtronic Product Performance Report, 2012 Second Edition, Issue 66.

[12] Models 6935M (55cm, 62cm) and 6947M (55cm, 62cm)

[13] Poole JE, Johnson GW, Hellkamp AS, et al. Prognostic importance of defibrillator shocks in patients with heart failure. N Engl J Med. 2008 Sep 4;359(10):1009-17. Doi: 10.1056/NEJMoa071098.

[14] E.J. Schloss et al. Painfree sst trial primary results low shock rates in patients with dual and triple chamber icd's using novel detection algorithms late breaking clinical trial session - May 10, 2013 at HRS 2013

[15] Meijer et al PainFree SmartShock technology: Trial primary results: Inappropriate shock rates in patients with single

chamber ICD's using a novel suite of detection algorithms. Late Breaking Clinical Trial Session - June 25, 2013 at Europace 2013

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