

## Medtronic First to Receive FDA Approval for MR-Conditional Implantable Cardioverter Defibrillator System

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*Evera MRI ICD System Approved for Use During Full Body MRI Scans for Patients at Risk of Sudden Cardiac Arrest*

**DUBLIN - Sept. 14, 2015** - Medtronic plc (NYSE: MDT) today announced that it has received the first U.S. Food and Drug Administration (FDA) approval for an implantable cardioverter defibrillator (ICD) system for use with magnetic resonance imaging (MRI) scans. The Medtronic Evera MRI(TM) SureScan® ICD System is approved for MRI scans on any part of the body without positioning restrictions, which means that patients in the U.S. who depend on life-saving ICDs also now have access to MRI scans if and when they need them. The newly approved system, which will be commercially available this month, includes the Evera MRI ICD and Sprint Quattro® Secure MRI SureScan® DF4 leads, which must be used together to be considered MR-conditional.

"Patients at risk for sudden cardiac arrest have long relied on ICDs to monitor their hearts, detect dangerous arrhythmias and deliver the life-saving therapy needed to survive," said Michael R. Gold, M.D., Ph.D., chief of cardiology, Michael E Assey Professor of Medicine at the Medical University of South Carolina, and principal investigator in the Evera MRI Clinical Trial. "Many of these patients also need access to MRIs, so the approval of an ICD that can be used in an MRI environment is crucial, and can help provide patients with the peace of mind that they are receiving the best care available."

Sudden cardiac arrest (SCA) is a sudden, abrupt loss of heart function that can result in death if not treated within minutes with an electrical cardioverter shock, which can be delivered by an ICD. MRI is considered the gold standard in soft-tissue imaging and is used regularly for the diagnosis of conditions such as stroke, cancer, Alzheimer's disease, and muscle, bone and joint pain.

Until now, patients with ICD systems have been contraindicated by the FDA from receiving MRI scans because of potential interactions between the MRI and device function, which might result in risk to patients. These MRI restrictions have resulted in a critical unmet need as data have shown that, within four years, more than one-third of patients with ICDs - 36 percent - are likely to need an MRI.<sup>1</sup>

The Evera MRI ICD system includes hardware and software design enhancements from previous generation devices that allow it to safely undergo full-body MRIs, while maintaining the same longevity, proven shock reduction and physiological size and shape of the original Evera ICD. The device is paired with the Sprint Quattro® Secure MRI SureScan® DF4 leads, part of the only ICD lead family with more than 10 years of proven performance with active monitoring,<sup>2</sup> now tested for safe use in an MRI environment.

The FDA approval of the Evera MRI ICD system was based on safety and efficacy data from the Evera MRI Clinical Trial, a multicenter, prospective, randomized, controlled clinical trial that enrolled 275 patients at 42 centers around the world. Presented during a late-breaking clinical trial session at Heart Rhythm 2015, the Heart Rhythm Society's 36<sup>th</sup> Annual Scientific Sessions, and published simultaneously in the *Journal of the American College of Cardiology (JACC)*, these data demonstrated that the Evera MRI ICD system is safe and effective, and that full-body MRI scans did not affect its ability to deliver life-saving therapy.<sup>3</sup>

"The Evera MRI ICD system underwent comprehensive computer modeling of more than 2.3 million clinical scenarios and this information, combined with the safety data from the clinical trial, has resulted in this critical regulatory approval," said Marshall Stanton, M.D., vice president and general manager of the Tachycardia business, which is part of the Cardiac Rhythm and Heart Failure division at Medtronic. "As pioneers in the development of implantable cardiac devices that can be used in an MRI environment, Medtronic is committed to ongoing innovation to address the clinical needs of physicians

and patients."

### **About the Evera MRI ICD**

The Evera MRI ICD is part of the Evera family of ICDs and includes the following key features and benefits:

- A contoured shape with thin, smooth edges that better fits inside the body, increasing patient comfort by reducing skin pressure by 30 percent<sup>4</sup>
- Industry-leading projected battery longevity (up to 11 years) compared with previous devices<sup>5-12</sup>
- SmartShock(TM) 2.0, the Medtronic exclusive, industry-leading shock reduction algorithm that enables the device to better differentiate between dangerous and harmless heart rhythms<sup>13</sup>
- OptiVol® 2.0 Fluid Status Monitoring and complete diagnostics, which is designed to identify patients at risk of worsening heart failure and atrial fibrillation

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. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

### **Multimedia Release**

A multimedia version of this release, with links to graphics and additional background information can be found at:

<https://medtronicmediacap.gcs-web.com/medtronic-first-receive-fda-approval-mr-conditional-implantable-cardioverter>

### **About Medtronic**

Medtronic plc ([www.medtronic.com](http://www.medtronic.com)), headquartered in Dublin, Ireland, 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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<sup>1</sup> Nazarian S, Reynolds M, Ryan M, et al. Estimating the Likelihood of MRI in Patients After ICD Implantation: A 10-Year Prediction Model. *J Am Coll Cardiol*. 2015;65(10S)

<sup>2</sup> Medtronic Product Performance Report, 2012 Second Edition, Issue 66.

<sup>3</sup> Gold MR, Torsten S, Schwitter J, et al. Full-Body MRI Scanning in Patients with an ICD: Primary results of the randomized Evera MRI Study. *J Am Coll Cardiol*. Published online May 14, 2015.

<sup>4</sup> Flo, Daniel. Device Shape Analysis. January 2013. Medtronic data on file.

<sup>5</sup> Knops P, Theuns DA, Res JC, et al. Analysis of implantable defibrillator longevity under clinical circumstances: implications for device selection. *Pacing Clin Electrophysiol*. October 2009;32(10):1276-1285.

<sup>6</sup> Schaer BA, Koller MT, Sticherling C, et al. Longevity of implantable cardioverter defibrillators, influencing factors, and comparison to industry-projected longevity. *Heart Rhythm*. December 2009;6(12):1737-1743.

<sup>7</sup> 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.

<sup>8</sup> Kallinen L, et al. 2009. <http://spo.escardio.org/eslides/view.aspx?eevtid=33&id=1913>.

<sup>9</sup> 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.

<sup>10</sup> Shafat T, Baumfeld Y, Novack V, et al. Significant differences in the expected versus observed longevity of implantable cardioverter defibrillators (ICDs). *Clin Res Cardiol*. Published online July 14, 2012.

<sup>11</sup> Horlbeck FW, Mellert F, Kreuz J, et al. 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.

<sup>12</sup> Evera XT DR/VR Manual.

<sup>13</sup> Auricchio, Angelo et al. Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results. Heart Rhythm. Published online: January 27, 2015

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