Medtronic News

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

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.1

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,2 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 36th 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.3

"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 percent4
- Industry-leading projected battery longevity (up to 11 years) compared with previous devices5-12
- SmartShock(TM) 2.0, the Medtronic exclusive, industry-leading shock reduction algorithm that enables the device to better differentiate between dangerous and harmless heart rhythms13
- 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:

http://bit.ly/1KLJcnW

About Medtronic

Medtronic plc (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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