Medtronic News

Medtronic Receives FDA Approval for New Single-Chamber ICDs That Detect Atrial Fibrillation

Visia AF MRI(TM) SureScan® and Visia AF(TM)ICDs Treat Dangerous Heart Rhythms and Enable Physicians to Identify Patients at Increased Risk for Stroke and Heart Failure Due to AF

DUBLIN - May 2, 2016 - Medtronic plc (NYSE: MDT) today announced it has received U.S. Food and Drug Administration (FDA) approval for the Visia AF MRI(TM) SureScan® and Visia AF(TM) single-chamber implantable cardioverter defibrillators (ICDs). The Visia AF devices can detect previously undiagnosed and/or asymptomatic atrial fibrillation (AF) and monitor recurrent AF, while treating life-threatening rhythms in the lower chambers of the heart. The Visia AF ICD systems will be commercially available in early summer.

AF is a condition that involves an irregular quivering or rapid heart rhythm in the upper chambers (atria) of the heart. Because many patients do not experience symptoms, the condition frequently goes undetected, even with traditional external monitors1-2. When left untreated, patients with AF are five times more likely to have a stroke3 and three times more likely to develop heart failure4.

The Visia AF ICDs include a proprietary algorithm that detects AF episodes (without a lead in the atrium) and captures AF frequency and duration, information that helps physicians identify AF and tailor treatment for these patients. More than half of all new ICD implants in the U.S. are single-chamber devices.

"Approximately 75 percent of ICD patients have no history of atrial fibrillation at the time they receive a device," said Edward J. Schloss, MD, director of cardiac electrophysiology, The Christ Hospital, Cincinnati. "After device implant, we've seen about 20 percent of these patients go on to have newly discovered AF. Until now, we haven't been able to detect these arrhythmias with single chamber ICD diagnostics. The Visia AF ICDs give physicians a new tool to monitor for AF in patients with VR ICDs, which may allow them to identify and treat AF earlier to potentially help avoid other serious conditions."

Built on the proven performance of the Medtronic Evera(TM) family of ICDs, the Visia AF ICDs include:

- SureScan® Labeling: Approved for MRI scans on any part of the body without positioning restrictions, as well as for MRI scans in 1.5 Tesla (magnet strength) machines
- Physio Curve® Design: A contoured shape with thin, smooth edges that increases patient comfort by reducing skin pressure by 30 percent5
- Greater Battery Longevity: Industry-leading battery longevity (up to 11 years)6-13
- Sprint Quattro(TM) Leads: Paired with the Sprint Quattro(TM) family of leads, the most frequently prescribed lead, with more than 10 years of proven performance with active monitoring14
- SmartShock(TM) 2.0: An exclusive shock reduction algorithm that enables the device to better differentiate between dangerous and harmless heart rhythms,15 delivering a 98 percent inappropriate shock-free rate at one year16

In addition, remote monitoring through the Medtronic CareLink® Network is available with the Visia AF ICDs, connecting patients to their clinics from home or away.

"Early detection of AF is vital to assist physicians in making treatment decisions that can reduce stroke and heart failure risk," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Cardiac Rhythm and Heart Failure division. "These single chamber defibrillators with AF detection capabilities, utilizing our proven Quattro lead - alongside our overall portfolio of AF detection devices - demonstrate our commitment to providing cardiac patients with the latest technology to improve their health."

The Visia AF ICDs received CE Mark in 2015. This FDA approval further expands the Medtronic portfolio of MR-conditional cardiac rhythm and heart failure devices, which includes MR-conditional pacemakers, ICDs, insertable cardiac monitors (ICMs) and cardiac resynchronization therapy defibrillators (CRT-Ds).

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.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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