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# FDA nod for Medtronic's single-chamber ICDs

03 May 2016 | News | By BioSpectrum Bureau

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Medtronic has received the US Food and Drug Administration (US FDA) approval for the Visia AF MRI SureScan and Visia AF 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 monitors. When left untreated, patients with AF are five times more likely to have a stroke and three times more likely to develop heart failure.

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 US are single-chamber devices.

Built on the proven performance of the Medtronic Evera 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 percent
Greater Battery Longevity: Industry-leading battery longevity (up to 11 years)
Sprint Quattro Leads: Paired with the Sprint Quattro family of leads, the most frequently prescribed lead, with more than 10 years of proven performance with active monitoring
SmartShock 2.0: An exclusive shock reduction algorithm that enables the device to better differentiate between dangerous

and harmless heart rhythms, delivering a 98 percent inappropriate shock-free rate at one year.

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 Dr John Liddicoat, 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).