Medtronic News

Medtronic Receives CE Mark for New Single-Chamber ICDs That Can Detect Atrial Fibrillation

Diagnosing AF with Visia AF(TM) and Visia AF MRI(TM) SureScan® ICDs Enables Physicians to Manage Patients at Increased Risk for Stroke and Heart Failure

DUBLIN - October 21, 2015 - Medtronic plc (NYSE: MDT) today announced it has received CE (*Conformité Européenne*) Mark for the Visia AF(TM) and Visia AF MRI(TM) SureScan® single-chamber implantable cardioverter defibrillators (ICDs), which can detect and monitor new onset, asymptomatic, and previously undiagnosed atrial fibrillation (AF). Early detection of AF can help a physician better tailor treatment to the needs of the patient. The Visia AF devices include a proprietary algorithm that accurately detects AF episodes, captures AF burden frequency and duration1, and alerts the physician from the patient's home.

An estimated 33 million people worldwide have AF, making it the most common cardiac rhythm disorder in the world.2 AF is a condition that involves an irregular quivering or rapid heart rhythm in the upper chambers (atria) of the heart, and patients with AF are five times more likely to have a stroke3 and three times more likely to have heart failure.4 Approximately 20 percent of patients who experience ventricular arrhythmias (irregular heart rhythms in the lower chambers) later develop AF5, which often goes undetected with traditional external monitors.6-7

Built on the proven performance of the Medtronic Evera(TM) family of ICDs, the Visia AF ICDs also feature a contoured shape with thin, smooth edges that increases patient comfort by reducing skin pressure by 30 percent.8 The devices include the same industry-leading battery longevity (up to 11 years) compared to previous devices.9-16 And when 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 monitoring17 - the Visia AF MRI SureScan device allows patients to undergo full-body MRI scans.

The Visia AF ICDs include SmartShock(TM) 2.0, an exclusive shock reduction algorithm that enables the device to better differentiate between dangerous and harmless heart rhythms.18 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.19-22 SmartShock technology helps to eliminate these inappropriate shocks, and delivers a 98 percent inappropriate shock-free rate at one year.23

"Medtronic is committed to continuing to develop a wide range of technologies to help patients with AF," 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. "With devices like the Visia AF ICDs and the Reveal LINQ(TM) Insertable Cardiac Monitor, which detects and monitors abnormal heart rhythms for up to three years, we aim to increase AF detection and enable physicians to manage a patient's risk for strokes and heart failure."

In the U.S., the Visia AF ICDs are not yet approved for commercial use.

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 more than 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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Contacts:
Tracy McNulty
Public Relations
+1-763-526-2492

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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