Medtronic News

Medtronic Initiates Study Of 'In-Office' Insertion Of Reveal LINQ™ Cardiac Monitor

RIO 2 Study Evaluates Safety and Effectiveness of Moving the Insertion Procedure from Hospital to Office Setting

DUBLIN – May 7, 2015 – Medtronic plc (NYSE: MDT) today announced the first inoffice implant of its miniaturized cardiac monitor as part of the Medtronic Reveal LINQ In-Office 2 (RIO 2) Study. The world's smallest cardiac monitor was successfully implanted in an office setting at Scripps Clinic in La Jolla, California, by cardiologist John Rogers, M.D. The RIO 2 study will determine if the Reveal LINQ™ Insertable Cardiac Monitor (ICM) procedure, performed in an in-office setting, is as safe as procedures performed in a traditional hospital setting, such as an operating room, cardiac catheterization laboratory or electrophysiology laboratory.

"Studies such as RIO 2 may enable physicians to provide their patients with even greater access to the latest diagnostic tools and therapies," said Dr. Rogers. "In-office procedures have the potential to help patients and reduce costs to the healthcare system."

RIO 2 is enrolling approximately 540 patients in 30 centers across the U.S. in a two-arm, prospective, un-blinded study in which patients will be randomized 1:1 to either receive the Reveal LINQ ICM in an office setting or in a traditional hospital setting. Patients will be followed for approximately three months and evaluated for procedure and device-related complications, and also for procedure time and resources required to perform the procedure.

The RIO 2 study also is enrolling approximately 150 patients in 15 centers across Europe, Australia and Canada. This observational study will examine clinical evidence to support moving the LINQ insertion procedure from the traditional hospital setting to new locations within the hospital, or "out-of-lab."

"Physicians have embraced Reveal LINQ ICM for its ease of use, and moving the insertion procedure to the office setting has the potential to improve patient access to cardiac monitoring while enhancing the overall patient experience," said Nina

Goodheart, vice president and general manager of the Diagnostics business in Medtronic's Cardiac Rhythm and Heart Failure division.

Cleared by the U.S. Food and Drug Administration (FDA) in 2014, the Reveal LINQ

ICM System is the newest generation of ICM and the smallest cardiac monitor available (~1 cc, or one-third the size of a AAA battery). The device is placed under the skin of the chest using a minimally invasive insertion procedure and allows physicians to continuously and wirelessly monitor a patient's heart through the Carelink[®] Network for up to three years. Common uses include monitoring syncope (fainting) patients for potential episodes of bradycardia (slow heartbeat), monitoring patients who have had cryptogenic strokes (strokes of unknown cause) for possible episodes of atrial fibrillation, and monitoring patients suffering from intermittent chest palpitations for potential episodes of atrial or ventricular arrhythmias.

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 (<u>www.medtronic.com</u>), 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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