Medtronic News

Medtronic Announces Approval and Launch of Reveal LINQ(TM) Insertable Cardiac Monitor in Japan

Miniaturized Device Now Available for Use in Patients with Unexplained Syncope and Stroke

DUBLIN - Sept. 14, 2016 - Medtronic plc (NYSE: MDT) today announced it has received Ministry of Health, Labor and Welfare (MHLW) approval of the Reveal LINQ Insertable Cardiac Monitor (ICM) System in Japan. In addition, MHLW has granted reimbursement approval for Reveal LINQ as a result of work with the Japanese regulatory body. The device will be available in Japan beginning this month.

The Reveal LINQ ICM System is the smallest insertable cardiac monitoring device available (~1 cc, or one-third the size of an AAA battery); it is designed to help physicians quickly and accurately diagnose irregular heartbeats. Placed just beneath the skin through a small incision of less than 1 cm in the upper left side of the chest, the Reveal LINQ ICM is inserted using a minimally invasive procedure; its presence is often nearly undetectable to the naked eye once the incision has healed.

In Japan, the Reveal LINQ ICM will be used by physicians in the diagnosis of unexplained syncope (unexplained fainting) and cryptogenic stroke (stroke of unknown cause). Approximately 200,000 Japanese patients each year suffer from episodes of syncope, and 20 to 30 percent of these cases are diagnosed as unexplained.1 In addition, 243,000 ischemic strokes are estimated to occur annually in Japan (the most common type of stroke, caused by an obstruction denying blood to part of the brain)2 and 20 to 40 percent are cryptogenic, as reported by modern stroke registries and databases.3-9

"Medtronic is the pioneer in the miniaturization of medical devices that improve the overall experience for patients," said Nina Goodheart, vice president and general manager of the Diagnostics and Monitoring business at Medtronic. "We are pleased that through our collaboration with MHLW, we can now offer this minimally invasive technology for Japanese patients with syncope and cryptogenic stroke."

The Reveal LINQ ICM automatically and continuously detects and records abnormal heart rhythms for up to three years and is MR-Conditional, allowing patients to undergo magnetic resonance imaging (MRI), if needed. The device communicates wirelessly with a patient bedside monitor that uploads device data to the Medtronic CareLink® network.

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 88,000 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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1 Japanese Guideline of Syncope 2012

2 Japanese Stroke Database 2015

3 Heart Disease and Stroke Statistics 2015 Update Circulation. 2015; 131:e29-e322 Published online before print December 17, 2014, doi: 10.1161/CIR.0000000000000152

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Contacts:
Ryan Mathre
Public Relations
+1-763-514-9625

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

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