Medtronic News

NICE Issues Medtech Innovation Briefing Recognizing Medtronic Reveal LINQ in the Detection of Atrial Fibrillation After Stroke of Unknown Cause

DUBLIN - February 21, 2018 - Today, the United Kingdom's National Institute for Health and Care Excellence (NICE) issued a Medtech Innovation Briefing on the use of the Medtronic Reveal LINQ(TM) insertable cardiac monitor (ICM) with the Medtronic CareLink® Network, highlighting the device's benefits in detecting suspected atrial fibrillation (AF) after a stroke of unknown cause (cryptogenic stroke), which includes cryptogenic transient ischaemic attack (TIA) and embolic stroke of undetermined source (ESUS).1 The NICE briefing also states the potential for downstream savings if Reveal LINQ detects AF, leading to effective treatment and possible stroke prevention.

Cryptogenic stroke patients have a high risk of recurrent strokes and require confirmed AF diagnoses to receive appropriate preventive therapy, such as blood thinners.2 The NICE briefing identifies several exclusive features of Reveal LINQ that help physicians diagnose and monitor AF including:

- A proprietary AF detection algorithm for reducing false positives
- Small device size that allows for insertion outside a catheterization lab
- Large memory capacity, which offers enough recording time to find symptom-rhythm correlations
- Ability to provide continuous monitoring for up to three years

"People who have suffered a stroke understandably want to know what caused the stroke in the first place," commented Professor Dame Caroline Watkins, professor of Stroke Care and faculty director of Research and Innovation at the University of Central Lancashire. "The Reveal LINQ helps patients and their physicians hone in on the reason behind their stroke, so they can receive appropriate treatment. This is an incredibly important technology, as it provides these people, their families, and their caregivers, a degree of reassurance and reduces the likelihood and fear of recurrent strokes, thereby significantly improving their quality of life."

The NICE briefing also states the Reveal LINQ can result in resource savings as it uses remote monitoring and can be inserted outside the catheterization lab. Physicians insert the device, which is approximately one-third the size of an AAA battery (~1 cc), just beneath the skin through a small incision in the upper left side of the chest. The device communicates wirelessly with a patient's bedside monitor, which uploads device data to the Medtronic CareLink Network.

AF, a condition that often has no symptoms and may occur infrequently, may not be detected by conventional cardiac monitoring techniques such as in-hospital monitoring, electrocardiography (ECG) or traditional ambulatory monitors such as a Holter monitor. Unlike these short-term monitoring methods, the Reveal LINQ ICM continuously detects and wirelessly records abnormal heart rhythms for up to three years.

"We welcome the news that NICE has recognized the importance of a device that helps to detect AF," said Trudie Lobban MBE, founder and trustee of the Arrhythmia Alliance and AF Association. "There are thousands of patients in the UK unknowingly living with a potentially life-threatening and often extremely debilitating condition, because AF remains undiagnosed. Now, with the announcement from NICE, more people will understand and appreciate the benefits and evidence supporting this minimally invasive diagnostic device."

Patients with AF are five times more likely to have a stroke due to blood clots that may form in the heart and make their way to the brain.3 Undiagnosed AF is believed to be responsible for a significant portion of the 30,000 cryptogenic strokes that occur each year in the United Kingdom.4

About NICE Medtech Innovation Briefings

NICE Medtech Innovation Briefings (MIBs) are designed to support NHS and social care commissioners and staff who are considering using new medical devices and other medical or diagnostic technologies. The information provided includes a description of the technology, how it's used and its potential role in the treatment pathway, as well as a review of relevant published evidence and the likely costs of using the technologies. MIBs are designed to be fast, flexible and responsive to the need for information on innovative technologies.5

About Reveal LINQ Insertable Cardiac Monitor System

The Reveal LINQ ICM, which received CE Mark in November 2013 and was cleared by the U.S. Food & Drug Administration (FDA) in February 2014, allows physicians to continuously and wirelessly monitor a patient's heartbeat for up to three years. Approximately one-third the size of an AAA battery (~1 cc) it is placed just beneath the skin through a small incision of less than 1 cm in the upper left side of the chest, and its presence is often nearly undetectable to the naked eye once the incision has healed. The device communicates wirelessly with a patient bedside monitor that uploads device data to the Medtronic CareLink Network; it is MR-Conditional, allowing patients to undergo magnetic resonance imaging (MRI), if needed.

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 84,000 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 NICE Medtech Innovation Briefing

2 NICE CG 180 Atrial Fibrillation: Management https://www.nice.org.uk/guidance/cg180

3 Wolf PA, et al. *Stroke*. 1991; 22: 983-988.

4 According to Health Episodes Statistics in 2015-2016, the hospital admission reports were 112,101 hospital admissions for ischemic stroke. The cause remains unexplained after routine evaluation in 20 to 40 percent of those cases (Grau AJ et al 2001 and Adams HP 1993), resulting in the classification, by exclusion, of 33,630 cryptogenic or embolic stroke of undetermined source in 2015-2016.

5 Medtech innovation briefings: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-advice/medtech-innovation-briefings Last accessed January 2018.

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