Medtronic News

New ESC Guidelines Support Recent Medtronic Innovations for Patients with Atrial Fibrillation

Clinical Practice Guidelines from European Society of Cardiology 2016 Reinforce Benefits of Cryoballoon Ablation and Long-Term Cardiac Monitoring

DUBLIN - September 12, 2016 - Two Medtronic plc (NYSE: MDT) innovations were acknowledged in updated guidelines published by the European Society of Cardiology (ESC): cryoballoon ablation for patients with diagnosed atrial fibrillation (AF), and long-term cardiac monitoring for survivors of stroke who do not have an established diagnosis of AF.

The Clinical Practice Guidelines on Atrial Fibrillation were issued by the ESC at its meeting in Rome, and were developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). The guidelines also were published online in the *European Heart Journal* and the *European Journal of Cardio-Thoracic Surgery*.

Cryoballoon Ablation for Patients with Atrial Fibrillation

ESC's guidelines now recognize the strong evidence supporting the use of pulmonary vein isolation as the preferred ablation intervention for patients with AF. Catheter ablation is recommended as the first-line treatment in select patients*, with cryoenergy as effective as radio frequency energy for isolating the pulmonary veins.

More than 400 peer-reviewed publications on Cryoballoon ablation, including the landmark FIRE AND ICE Trial published in *The New England Journal of Medicine* and *European Heart Journal*, and the STOP AF pivotal trial, have reported on the clinical experience of the cryoballoon.

The new ESC Guidelines on Ablation for Atrial Fibrillation Patients state, "Catheter Ablation is recommended as a first-line treatment in selected patients after research showed it was not less safe than antiarrhythmic drugs."

More than 220,000 patients have been treated with Medtronic cryoballoon ablation worldwide.

Long-term Cardiac Monitoring for Stroke Patients Without a Diagnosis of AF

The new ESC guidelines support screening for AF with long-term cardiac monitoring in patients who have had an ischemic stroke, the most common type of stroke (approximately 85 percent of all strokes). Ischemic strokes are caused when an obstruction in a blood vessel prevents adequate blood flow to the brain.

The benefits of long-term cardiac monitoring in stroke are supported by a strong body of clinical evidence. The CRYSTAL AF Study, which was published in the June 2014 issue of *The New England Journal of Medicine,* found that long-term cardiac monitoring with the Reveal® Insertable Cardiac Monitor (ICM) detected AF at a rate of more than seven times higher than standard care (at one year) in patients with an unknown cause of stroke. Also, recent data presented at the 2016 American Academy of Neurology Annual Meeting showed that in a real-world population of these stroke patients, 72 percent of AF patients would have gone undiagnosed if cardiac monitoring had been limited to only 30 days.

According to the new ESC Clinical Practical Guidelines on AF, prolonged monitoring "seems reasonable in all survivors of an ischemic stroke without an established diagnosis of AF."

"Because AF often has no symptoms and may occur infrequently, we have advocated for continuous long-term monitoring as the standard of care for detecting AF in these patients," said John Camm, professor of clinical cardiology at St. George's University of London. "We look forward to raising awareness about this important guideline update so that patients everywhere have access to the diagnostic tools they need so they can lead healthier lives."

About Atrial Fibrillation

Atrial fibrillation is a common cardiac condition in which the heart beats irregularly or rapidly; patients with AF are five times more likely to have a stroke1 due to small blood clots that may form in the heart and subsequently travel to the brain. Worldwide, it is estimated that more than 33.5 million people suffer from atrial fibrillation2.

"At Medtronic, one of our goals is to develop industry-leading technologies, validated by clinical evidence, that improve peoples' lives," said John Liddicoat, M.D., senior vice president at Medtronic and president of the Cardiac Rhythm and Heart Failure Division. "Cryoablation therapy and long-term cardiac monitoring represent the meaningful innovations needed by patients with diagnosed AF, and by patients who've had a stroke and don't know if it was caused by AF but need to find out so they can be treated effectively."

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 of the highest quality 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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* The Medtronic Arctic Front Advance(TM) Cryoablation System is approved in the U.S. for the treatment of drug-refractory, recurrent, symptomatic paroxysmal atrial fibrillation and in Europe for the treatment of atrial fibrillation.

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

2 Chugh S, Havmoeller R, Narayanan K, et al. Worldwide epidemiology of atrial fibrillation: a global burden of disease 2010 study. Circulation. 2014; 129:837-847.

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