Medtronic News

Medtronic Arctic Front® Cryoballoon Catheters Meet Non-Inferiority Goal in Head-to-Head Trial Presented at ACC Scientific Sessions and Published in The New England Journal of Medicine

Cryoballoon Comparable in Safety and Effectiveness as Current Standard of Care Ablation Technology

DUBLIN and CHICAGO - April 4, 2016 - Medtronic plc (NYSE: MDT) today announced positive results from the landmark *FIRE AND ICE* clinical trial, which demonstrated comparable safety and effectiveness for its Arctic Front® Cryoballoon Catheter Family compared to the ThermoCool® line of radiofrequency (RF) ablation catheters for the treatment of symptomatic paroxysmal atrial fibrillation (AF). The study, presented today in a late-breaking session at the American College of Cardiology's 65th Annual Scientific Sessions and published simultaneously in *The New England Journal of Medicine*, provides further clinical validation that Cryoballoon ablation is a safe and effective option for ablation treatment, with shorter and more consistent procedure times.

"Through this rigorously designed trial, we found that Cryoballoon catheter technology is not only comparable to RF ablation - the current standard of care - but also delivered key procedural efficiencies," said Prof. Karl-Heinz Kuck, M.D., director of cardiology at Asklepios Klinik St. Georg, Hamburg, Germany, and principal investigator of the trial. "The simple, straightforward cryoablation procedure may allow us to treat more patients with AF."

The trial met its primary efficacy endpoint of showing non-inferiority for the Arctic Front Cryoballoon catheters without 3D mapping compared to ThermoCool® RF ablation catheters using 3D mapping (p=0.0004) in reducing arrhythmia recurrence and the need for antiarrhythmic drug therapy and/or re-ablation. It also met its primary safety endpoint of time to first all-cause death, all-cause stroke/TIA, or treatment-related serious adverse events (p=0.24); both technologies had similarly low complication rates. The Cryoballoon demonstrated shorter procedure times (mean=124 minutes) compared to the RF ablation treatment arm (mean=141 minutes; p=0.0001), and fluoroscopy times were shorter with the RF catheter (mean=17 minutes with RF; mean=22 minutes with cryoballoon; p=0.0001).

Isolating the pulmonary veins (pulmonary vein isolation, or PVI), which are a source of erratic electrical signals that cause AF, is a standard approach for treating AF patients: the Cryoballoon uses coolant to create contiguous, circumferential lesions to achieve PVI; RF ablation uses heat (RF energy) and requires 3D mapping as well as point-by-point application to achieve PVI.

FIRE AND ICE is the largest, randomized, multinational, clinical study to compare two AF ablation techniques: Cryoablation (ICE) with the Medtronic Arctic Front or Arctic Front Advance® Cryoballoons, and RF (FIRE) ablation and 3D mapping with one of three Biosense Webster ThermoCool® catheters: ThermoCool® irrigated catheters, ThermoCool® SF Surround Flow irrigated catheters, or ThermoCool® SmartTouch® contact force sensing catheters. A total of 769 patients from 16 medical centers throughout Europe were enrolled in the trial. All subjects were diagnosed with paroxysmal AF, had failed at least one antiarrhythimic drug and were followed for up to 33 months (mean = 1.54 years) following initial ablation. A non-inferiority design is often used to demonstrate that a newer technology is comparable to the currently accepted and existing technology.

"As the largest head-to-head study comparing these two technologies to treat AF, the FIRE AND ICE results provide important clinical insights on safety and effectiveness, and also show Cryoablation with more consistent procedure times, which benefits both patients and physicians," said Colleen Fowler, vice president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic. "As the world's population continues to age, the demand for safe, clinically effective and efficient advanced treatment options will only increase. Today's findings further support the rapid global adoption of Cryoablation and serve as a significant milestone in helping guide optimal patient care."

The Arctic Front Cryoablation system has been used in more than 180,000 procedures conducted to date in more than 50

countries worldwide. The Arctic Front Advance 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.

About Atrial Fibrillation

Atrial fibrillation is the most common and one of the most undertreated heart rhythm disorders, affecting more than 33.5 million people worldwide.[i] It is estimated that half of all diagnosed atrial fibrillation patients fail drug therapy[ii] and if left untreated, patients have up to a five times higher risk of stroke and an increased chance of developing heart failure.[iii]

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.

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 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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[i] 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.

[ii] Wyse, et. al Circ. 1996; 93:1262-1277.

[iii] Fuster et al. Journal of the American College of Cardiology. 2006; 48:854-906

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