Medtronic News

FIRE AND ICE Trial Analysis Shows Medtronic Cryoballoon Reduces Healthcare System Costs and Utilization

Data from Landmark Trial Published in the Journal of the American Heart Association

DUBLIN - August 1, 2017 - *A n*ew health economic analysis from the landmark FIRE AND ICE Trial, sponsored by Medtronic plc (NYSE: MDT), was published today in the *Journal of the American Heart Association*. The data show that treating paroxysmal atrial fibrillation (AF) with cryoballoon catheter ablation may result in substantial cost savings as compared to radiofrequency (RF) ablation. These findings were driven by fewer repeat ablations and cardiovascular (CV) rehospitalizations in patients treated with the cryoballoon and were consistently observed in multiple healthcare systems internationally included in the analysis.

The analysis - building on data originally presented as a late-breaking clinical trial at the 2016 Asia Pacific Heart Rhythm Society Scientific Sessions - supports the economic value of cryoballoon ablation with the Medtronic Arctic Front(TM) Cryoballoon Catheter Family compared to RF ablation with the ThermoCool® line of RF ablation catheters.

"These findings show that patients treated with the cryoballoon have positive clinical outcomes such as fewer rehospitalizations and ablations, leading to decreased burden on health systems and lower costs," said Prof. Karl-Heinz Kuck, M.D., director of cardiology at Asklepios Klinik St. Georg, Hamburg, Germany, and principal investigator of the trial. "The latest analysis further validates cryoablation as an effective treatment option for AF patients with real economic value across health systems."

Health Economic Supplementary Analysis

In the FIRE AND ICE Trial, investigators randomly assigned patients into the cryoballoon (n=374) or RF (n=376) treatment group. Total rehospitalization and reintervention events observed during the trial (average follow up of 1.5 years) were assigned payer costs based on the healthcare systems and currencies from Germany (Euro), the United Kingdom (British Pound) and the United States (USD), respectively. The analysis showed the cryoablation group used fewer post-procedure healthcare resources, including fewer repeat ablations and reinterventions compared to the RF group (205 healthcare utilization events vs. 268 HCEs), demonstrating favorable health economics across three major healthcare systems:

- €640 trial savings per patient / €245,000 total trial savings under the German system (p=0.012)
- £364 trial savings per patient / £140,000 total trial savings under the United Kingdom system (p=0.013)
- $925 trial savings per patient /$ 355,000 total trial savings under the United States system (p=0.016)

"This analysis illustrates the Medtronic cryoballoon's sustained economic impact across multiple healthcare systems - improving patient outcomes with reduced healthcare utilization and lowering healthcare system costs," said Colleen Fowler, vice president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic.

About FIRE AND ICE

FIRE AND ICE is the largest multicenter, prospective, randomized study to compare cryoballoon ablation and point-by-point RF ablation for the treatment of paroxysmal AF. This landmark, head-to-head, non-inferiority study enrolled 769 patients. Primary results were published in *The New England Journal of Medicine* and showed comparable safety and effectiveness of cryoballoon ablation and RF catheter ablation1. Secondary analyses, which demonstrated significantly fewer repeat ablations and lower cardiovascular hospitalization rates with cryoablation, were published in the *European Heart Journal*2.

About the Arctic Front Advance Cryoballoon

Cryoballoon ablation is used in a minimally invasive procedure to isolate the pulmonary veins, which are a source of erratic electrical signals that cause AF. The device uses cold energy (freezing) rather than heat (radiofrequency) to create scar tissue, delivering refrigerant through an inflatable balloon to freeze tissue to interrupt unwanted electrical pathways in the heart. More

than 250,000 patients in more than 50 countries worldwide have been treated with the cryoballoon.

The 2016 European Society of Cardiology's (ESC) guidelines and recent 2017 Heart Rhythm Society (HRS) Consensus Statement for the management of atrial fibrillation both acknowledge cryoablation therapy for AF, and recognize pulmonary vein isolation (PVI) as an effective and preferred treatment option for select patients with AF.

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 91,000 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 Kuck KH, Brugada J, Fürnkranz A, et al. N Engl J Med 2016; 374:2235-2245 June 9, 2016 DOI: 10.1056/NEJMoa1602014

2 Kuck KH, Fürnkranz A, Chun J, et al. Eur Heart J (2016) ehw285 DOI: http://dx.doi.org/10.1093/eurheartj/ehw285 First published online: 5 July 2016

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