Medtronic News

FIRE AND ICE Data Show Fewer Repeat Ablations and Hospitalizations for AF Patients Treated with Medtronic Cryoballoon

Secondary Analyses Presented at Cardiostim 2016 Highlight Positive, Real-World Patient Outcomes

DUBLIN AND NICE, FRANCE - June 10, 2016 - Medtronic plc (NYSE: MDT) today announced findings from the secondary analyses of the *FIRE AND ICE* clinical trial that demonstrate significantly fewer repeat ablations and lower hospitalization rates for patients with paroxysmal atrial fibrillation (PAF) treated with the Arctic Front® Cryoballoon Catheter Family compared to the ThermoCool® line of radiofrequency (RF) ablation catheters. The results were presented today at a late-breaking session at CARDIOSTIM-EHRA EUROPACE 2016.

Primary results from the FIRE AND ICE trial were previously published in *The New England Journal of Medicine* and showed comparable safety and effectiveness of Cryoballoon ablation and RF catheter ablation.

Predefined secondary endpoints presented at Cardiostim include cardiovascular-related hospitalizations, repeat ablations, and quality of life. Other analyses of interest focused on all-cause hospitalizations and direct current cardioversion.

Procedure Efficacy and Performance Results

The FIRE AND ICE trial demonstrated significant reductions in the Cryoballoon group in the areas important to patients, including 34 percent fewer cardiovascular-related hospitalizations and 33 percent fewer repeat ablations. Additional analyses showed 21 percent fewer all-cause hospitalizations and 50 percent fewer direct current cardioversions.

- The Cryoballoon group had 49 repeat ablations in 44 patients (44/374; 11.8 percent); the RF catheter group experienced 70 repeat ablations in 66 patients (66/376; 17.6 percent) (p=0.03).
- In the Cryoballoon group, 139 cardiovascular-related hospitalizations occurred in 89 patients (23.8 percent); by comparison, 203 cardiovascular-related hospitalizations occurred in 135 patients (35.9 percent) in the RF catheter group (p<0.01).
- With regard to all-cause hospitalizations, 122 patients in the Cryoballoon group were hospitalized 210 times (32.6 percent) compared to 156 patients in the RF ablation group who were hospitalized 267 times (41.5 percent) (p=0.01).
- Direct current cardioversion, a procedure that shocks the heart in an attempt to convert an abnormal heart rhythm back to a normal rhythm, was higher for patients treated by the RF catheter (6.4 percent) as compared to patients treated by the Cryoballoon (3.2 percent) (p=0.04).

Patient Quality of Life Results

Patient quality of life was assessed at baseline and every six months after the index ablation procedure for up to 30 months.The study showed an improvement in mental and physical quality of life for patients in both treatment groups at six months, which was maintained throughout the follow-up period.

"Today's findings continue to demonstrate the power of the Cryoballoon in making a difference to 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. "Offering a technology that has fewer hospitalizations, repeat procedures and shorter procedure times than conventional point-by-point technology is meaningful to patient care."

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 PAF. This landmark, head-to-head, non-inferiority study, published in *The New England Journal of Medicine*, enrolled 769 patients. The trial met its primary efficacy endpoint of showing non-inferiority for Cryoballoon compared to RF catheter ablation in reducing arrhythmia recurrence and the need for antiarrhythmic drug therapy and/or re-ablation, but with shorter and more consistent procedure times when using the Cryoballoon. It also met its primary safety endpoint of time to

first all-cause death, all-cause stroke/TIA, or treatment-related serious adverse events.

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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