

FIRE AND ICE Analysis: Lower Healthcare System Costs with Medtronic Cryoballoon

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Late Breaking Clinical Trial Demonstrates Favorable Health Economics and Positive Clinical Outcomes for AF Patients

DUBLIN AND SEOUL, REPUBLIC OF KOREA - Oct. 13, 2016 - Medtronic plc (NYSE:MDT) today unveiled new health economic analysis data from the FIRE AND ICE trial that favor cryoballoon catheter ablation over radiofrequency (RF) ablation related to trial period cost savings as a result of fewer cardiovascular (CV) rehospitalizations and repeat ablations. The data were presented at a late-breaking clinical trial session at the Asia Pacific Heart Rhythm Society's Scientific Sessions in Seoul, Republic of Korea.

The new analyses show that the Arctic Front® Cryoballoon Catheter Family reduces payer costs across multiple healthcare systems, compared to the ThermoCool® line of RF ablation catheters. Investigators also examined the association between baseline patient demographics and CV rehospitalizations to determine if the primary and secondary trial results were consistent across patient subgroups.

"The cryoballoon technology demonstrates cost savings across multiple health systems, driven by a reduction in post-procedure rehospitalizations and reinterventions due to their underlying disease state," said Prof. Karl-Heinz Kuck, M.D., director of cardiology at Asklepios Klinik St. Georg, Hamburg, Germany, and principal investigator of the trial. "These analyses highlight the real-world patient outcomes and health system benefits of the cryoballoon."

The primary results from the FIRE AND ICE trial 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.

Health Economic Supplementary Analysis

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. This analysis revealed the cryoablation group used fewer post-procedure healthcare resources and experienced fewer repeat ablations and reinterventions compared to the RF group (205 healthcare utilization events vs. 268), demonstrating favorable health economics across three major healthcare systems:

- €244,607 total trial savings under the German system (p=0.012)
- £139,603 total trial savings under the United Kingdom system (p=0.013)
- \$355,005 total trial savings under the United States system (p=0.016)

"We are committed to leading the global shift to value-based healthcare, which means we want to be measured by the impact we have both on patient outcomes as well as the economic value we create for the healthcare system," said Colleen Fowler, vice president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic. "Today's findings further underscore the ability of the cryoballoon to make a difference in care across patients, physicians and healthcare systems."

"Predictors of Outcomes": Patient Demographic-Based Clinical Outcomes

Investigators also evaluated baseline patient characteristics and their association with CV rehospitalizations - one of the trial's predefined secondary endpoints - to determine whether certain subgroups may respond more favorably to treatment with the cryoballoon or RF ablation. Patients with a CHA₂DS₂-VASC (stroke risk) score of 0-1, and/or patients with prior direct current cardioversion were associated with a significantly lower risk of CV rehospitalization with cryoablation

vs. RF ablation.

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, published in *The New England Journal of Medicine*, enrolled 769 patients. The trial met its primary efficacy endpoint of showing noninferiority for cryoballoon compared to RF catheter ablation in reducing arrhythmia recurrence and the need for antiarrhythmic drug therapy and/or repeat 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.

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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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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