Medtronic News

Medtronic Receives FDA Approval and CE Mark for Arctic Front Advance® ST Cryoballoon to Treat Atrial Fibrillation

Third-Generation Cryoballoon Designed to Allow Enhanced Positioning and Help Improve Capture of Real-Time Data with Achieve® Mapping Catheter

DUBLIN - May 12, 2015 - Medtronic plc (NYSE: MDT) today announced the Arctic Front Advance® ST Cryoablation Catheter has received U.S. Food and Drug Administration (FDA) approval for the treatment of patients with drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation. In Europe, where the Cryoballoon has a broader indication, Arctic Front Advance ST Cryoballoon has received CE (*Conformité Européenne*) Mark for the treatment of patients with atrial fibrillation. An integral part of the Arctic Front Advance® System, the third-generation cryoballoon has a 40 percent shorter tip than the previous generation, designed to help physicians visualize ablation success in real-time with the Achieve® Mapping Catheter, as well as allow increased maneuverability for accessing some pulmonary vein anatomies.

The first patient was recently treated with the Arctic Front Advance ST Cryoballoon by Prof. Karl-Heinz Kuck, M.D., director of cardiology at Asklepios Klinik St. Georg, Hamburg, Germany. The product will be broadly available to physicians in fall 2015 following a limited market release.

The Arctic Front Advance ST Cryoballoon is used in a minimally invasive procedure to isolate the pulmonary veins, which are a source of erratic electrical signals that cause atrial fibrillation. The device uses coolant rather than heat (radiofrequency). Cryoballoon technology is associated with shorter procedure times than point-by-point radiofrequency ablation1, 2, and better treatment outcomes than drug therapies on the market3. The Arctic Front Advance System has been shown to improve quality of life for patients and significantly reduce paroxysmal (sporadic) atrial fibrillation symptoms, with patients experiencing reduction in atrial fibrillation episodes, palpitations, fatigue, rapid heartbeat, swelling, and syncope4, and has become a widely adopted treatment for atrial fibrillation.

"I have had the opportunity to utilize the cryoballoon technology since its inception more than a decade ago," said Prof. Kuck. "By building upon clinical feedback from physicians worldwide, the third-generation system offers the potential for more real-time data and even better maneuverability that may further enhance the procedure."

"The next-generation Arctic Front Advance ST Cryoballoon builds upon the successful performance of the Arctic Front Advance System, and its shorter tip was designed in response to physicians' needs in a real-world, clinical setting," said Reggie Groves, vice president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic.

About the Arctic Front Advance System

The Arctic Front Advance System is the only cryoballoon system approved in the U.S. for the treatment of paroxysmal atrial fibrillation and in Europe for treatment of atrial fibrillation. It has been used to treat more than 120,000 patients in more than 50 countries worldwide. The technologies currently offered as part of the system include:

- The Artic Front Advance ST Cryoballoon, which isolates the pulmonary veins for the treatment of atrial fibrillation;
- The FlexCath Advance(TM) Steerable Sheath, which helps deliver and position the cryoballoon in the left atrium;
- The Achieve® Mapping Catheter, an intra-cardiac electrophysiology recording catheter used to assess pulmonary vein isolation when treating paroxysmal atrial fibrillation;
- The Freezor® MAX Cardiac Cryoablation Catheter, which is a single-point catheter used to provide additional ablations, as needed; and
- The CryoConsole, which houses the coolant, electrical and mechanical components that run the catheters during a cryoablation procedure.

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.5 It is estimated that half of all diagnosed atrial fibrillation patients fail drug therapy6, and if left untreated, patients have up to a five times higher risk of stroke and an increased chance of developing heart failure7.

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 the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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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2 DeVille JB, Comparison of Resource Utilization of Pulmonary Vein Isolation: Cryoablation versus RF ablation with Three-Dimensional Mapping in the Value PVI Study. JIC. June 2014
3 Medtronic, Inc. Arctic Front Cardiac CryoAblation Catheter clinical reports, in support of FDA premarket approval.
4 Packer D. et al, Journal of the American College of Cardiology. 2013 Mar 13 doi: 10.1016/j.jacc.2012.11.064.
5 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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Contacts:
Tracy McNulty
Public Relations
+1-763-526-2492

Jeff Warren
Investor Relations
+1-763-505-2696

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