Medtronic Receives FDA Approval, CE Mark for Arctic Front Advance(TM) Cardiac Cryoballoon to Treat Atrial Fibrillation

The Associated Press

Next-Generation Technology Reinforces Safety and Efficacy While Improving Procedure Efficiency

MINNEAPOLIS - Aug. 24, 2012 - Medtronic, Inc. (NYSE:MDT) today announced that its Arctic Front Advance(TM) Cardiac Cryoballoon has received both U.S. Food and Drug Administration (FDA) approval and CE (Conformité Européenne) Mark for the treatment of paroxysmal atrial fibrillation (PAF). With the only cryoballoon system currently on the market worldwide, Medtronic's second-generation system provides a more efficient approach to treating PAF than point-by-point, radiofrequency (RF) ablation.

Arctic Front Advance features the new EvenCool(TM) Cryo Technology, which optimizes the delivery of coolant inside the balloon. As a result, the larger, more uniform cold surface reduces the effort needed to isolate the pulmonary veins, the target of most AF ablation procedures, and improves physicians' ability to treat patients with complicated anatomies compared to the original Artic Front® CryoAblation System.

"With Arctic Front Advance, we are now able to more effectively treat a broader range of pulmonary vein anatomies with less effort, which can potentially reduce procedure times," said Vivek Reddy, M.D., director of Electrophysiology Laboratories at The Mount Sinai Medical Center in New York.

Medtronic's cryoballoon treatment involves a minimally invasive procedure that isolates the pulmonary vein, a source of erratic electrical signals that cause AF, using coolant rather than heat (RF ablation). Delivered via a catheter, cryoballoon technology is associated with faster procedure times versus point-by-point, RF ablation. Additionally, 73 percent of Medtronic cryoablation patients achieved freedom from AF at one year1,2, a clinically significant increase in success over AF drug therapy1,2.

"The original Arctic Front technology has become a standard for AF ablation based on its safety, efficacy and relative ease of use," said Karl-Heinz Kuck, M.D., director of cardiology, Asklepios Klinik St. Georg, Hamburg, Germany. "The second-generation system builds on this solid foundation, while offering more sophisticated features that should benefit both the physician and patient."

The first-generation Arctic Front Cardiac CryoAblation Catheter System, currently

approved in both the United States and Europe, is the world's leading cryoballoon system indicated for the treatment of PAF. The system has experienced rapid worldwide adoption and clinical experience since its introduction onto the market, having been used to treat approximately 35,000 patients in more than 400 medical centers in 25 countries.

"We anticipate this next generation balloon will be enthusiastically received by physicians worldwide. Our aim is to offer physicians the best solutions for treating serious cardiovascular diseases such as atrial fibrillation, and improving overall patient quality-of-life, while delivering economic value," said Reggie Groves, vice president and general manager of Medtronic's AF Solutions division. "Our cadence of product launches showcases significant enhancements: This is the second revolutionary balloon-based medical technology we've launched in the past 18 months in the U.S. to treat AF."

About the Arctic Front Advance System The Arctic Front Advance Cardiac CryoAblation Catheter System is designed to be used with fluoroscopy and does not require the use of complex, three-dimensional mapping systems. The technologies currently offered in the system include:

The Arctic Front Advance Cryoballoon, which inflates and fills with coolant to ablate the tissue where the pulmonary veins enter the left atrium;

The FlexCath® Steerable Sheath, which helps deliver and position the cryocatheter 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 7 million people worldwide. It is estimated that half of all diagnosed atrial fibrillation patients fail drug therapy3, and if left untreated, patients have up to a five times higher risk of stroke4 and an increased chance of developing heart failure. PAF is a type of atrial fibrillation in which irregular heartbeats in the upper chambers start and stop suddenly on their own, usually for minutes or days at a time.

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, Inc. (www.medtronic.com), headquartered in Minneapolis, 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.

-end-

1 Andrade JG, Khairy P, Guerra PG, et al. Efficacy and safety of cryoballoon ablation for atrial fibrillation: a systematic review of published studies. Heart Rhythm. September 2011;8(9):1444-1451. 2 Calkins H, Reynolds MR, Spector P, et al. Treatment of atrial fibrillation with antiarrhythmic drugs or radiofrequency ablation: two systematic literature reviews and meta-analyses. Circ Arrhythm Electrophysiol. August 2009;2(4):349-361. 3JAMA 2001; 285:2370-5. 4 Fuster et al. Journal of the American College of Cardiology. 2006; 48:854-906.

Contacts: Kathleen Janasz Public Relations +1-763-526-3676 Jeff Warren Investor Relations +1-763-505-2696

This announcement is distributed by Thomson Reuters on behalf of Thomson Reuters clients. The owner of this announcement warrants that: (i) the releases contained herein are protected by copyright and other applicable laws; and (ii) they are solely responsible for the content, accuracy and originality of the information contained therein. Source: Medtronic, Inc. via Thomson Reuters ONE

HUG#1635073

Source URL (retrieved on *09/03/2014 - 1:45am*):
http://www.mdtmag.com/news/2012/08/medtronic-receives-fda-approval-ce-mark-arctic-front-advancetm-cardiac-cryoballoon-treat-atrial-fibrillation?qt-most_popular=0&qt-recent_content=0