

Medtronic Announces Launch of FlexCath Advance(TM) Steerable Sheath, Enhancing the Arctic Front Advance(TM) Cryoballoon System

The Associated Press

Second-Generation Sheath May Facilitate Easier Access to the Inferior Veins When Treating Paroxysmal Atrial Fibrillation

MINNEAPOLIS - Jan. 15, 2013 - Medtronic, Inc. (NYSE: MDT) today announced Food and Drug Administration (FDA) clearance and U.S. launch of the FlexCath Advance(TM) Steerable Sheath, a new enhancement to the Arctic Front Advance(TM) Cryoballoon System. This second-generation sheath has an increased degree of deflection and response, providing greater ease compared to the previous generation in reaching the inferior veins of the heart when delivering and positioning the cryoballoon catheter in the left atrium to treat paroxysmal atrial fibrillation (PAF).

The Arctic Front Advance System is used in minimally invasive procedures to isolate the pulmonary veins using coolant. Delivered via a catheter, the cryoballoon technology is associated with faster procedure times than point-by-point radiofrequency ablation^{1, 2}, and better treatment outcomes than drug therapies on the market³. Additionally, the Arctic Front Advance cryoballoon features the new EvenCool(TM) Cryo Technology, which optimizes the delivery of coolant inside the balloon; the larger, more uniform cold surface reduces the effort needed to isolate the pulmonary veins, and improves physicians' ability to treat patients with complicated anatomies as compared to the original Arctic Front® Cryoballoon.

"The FlexCath Advance sheath's ability to maneuver the catheter with a greater range of deflection may help reach the inferior veins and facilitate placement of the cryoballoon, which is a critical step to ensuring treatment success," said Suneet Mittal, M.D., director, Electrophysiology Laboratory, Arrhythmia Institute of the Valley Health System, Ridgewood, NJ.

The FlexCath Advance Steerable Sheath has a deflection of 135 degrees, compared to the 90 degree deflection rate of its first-generation predecessor. This greater degree of deflection may allow the cryoballoon to be better maneuvered and positioned within the heart to achieve maximum treatment benefit. The sheath includes the following features:

Radiopaque marker band at 5 millimeters to provide enhanced visibility under fluoroscopy; Deflection mechanism with an ergonomic handle that optimizes the movement of the sheath; and Hemostasis valve that allows for introduction, withdrawal and exchanging of catheters and guidewires, while preventing air insertion and minimizing blood loss.

"Building upon the Arctic Front System's proven platform, the FlexCath Advance Steerable Sheath augments the overall efficiency of the procedure," said Reggie Groves, vice president and general manager of Medtronic's AF Solutions division. "It completes the Arctic Front Advance System and is the fourth new product we have launched in the U.S. market in two years."

About the Arctic Front Advance System The Arctic Front Advance Cryoballoon System and its predecessor have been used to treat more than 50,000 patients in approximately 500 centers across 32 countries. The technologies currently offered include:

The Arctic Front Advance Cryoballoon, which inflates and fills with coolant to isolate the pulmonary veins for the treatment of PAF; 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 7 million people worldwide. It is estimated that half of all diagnosed atrial fibrillation patients fail drug therapy⁴, and if left untreated, patients have up to a five times higher risk of stroke⁵ and an increased chance of developing heart failure. PAF is a type of disease 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 Kojodjojo P, O'Neill MD, Lim PB, et al. Pulmonary venous isolation by antral ablation with a large cryoballoon for treatment of paroxysmal and persistent atrial fibrillation: medium-term outcomes and non-randomised comparison with pulmonary venous isolation by radiofrequency ablation. *Heart*. September 2010;96(17):1379-1384. 2 Sorgente A, Chierchia GB, Capulzini L, et al. Atrial

Medtronic Announces Launch of FlexCath Advance(TM) Steerable Sheath, E

Published on Medical Design Technology (<http://www.mdtmag.com>)

fibrillation ablation: a single center comparison between remote magnetic navigation, cryoballoon and conventional manual pulmonary vein isolation. Indian Pacing Electrophysiol J. December 26, 2010;10(11):486-495. 3 Medtronic, Inc. Arctic Front Cardiac CryoAblation Catheter clinical reports, in support of FDA premarket approval. 4 JAMA 2001; 285:2370-5. 5 Fuster et al. Journal of the American College of Cardiology. 2006; 48:854-906.

Contacts: Tracy McNulty Public Relations +1-763-526-2492 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#1669664

Source URL (retrieved on 01/29/2015 - 1:20am):

http://www.mdtmag.com/news/2013/01/medtronic-announces-launch-flexcath-advancetm-steerable-sheath-enhancing-arctic-front-advancetm-cryoballoon-system?qt-video_of_the_day=0