Medtronic News

Medtronic Announces FDA Clearance and First Patient Procedure with the Achieve(TM) Mapping Catheter

New Technology Adds Diagnostic Capability to the Arctic Front(R) Cardiac CryoAblation Catheter System in Treating Paroxysmal Atrial Fibrillation

MINNEAPOLIS, May 02, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE:MDT) today announced the U.S. Food and Drug Administration (FDA) approval for use, and the first patient procedure using the Achieve(TM) Mapping Catheter, an intra-cardiac electrophysiology diagnostic catheter that can be used to assess pulmonary vein isolation when treating paroxysmal atrial fibrillation (PAF). The new catheter technology is approved for use with Medtronic's Arctic Front(R) Cardiac CryoAblation Catheter System to provide a more straightforward treatment approach by combining pulmonary vein diagnostic and ablation capabilities in a single system. The first patient procedure in the United States using the new Achieve Mapping Catheter was performed last week by Robert Kowal, M.D., Ph.D., an electrophysiologist at the Baylor Heart & Vascular Hospital in Dallas.

"In many cases, this new mapping catheter will allow real-time assessment of pulmonary vein isolation and provide valuable information regarding time-to-effect during the cryoablation procedure," said Dr. Kowal.

The Arctic Front Cardiac CryoAblation Catheter, approved by the FDA in December 2010, is the first and only cryoballoon in the United States indicated for the treatment of PAF. Baylor Heart and Vascular Hospital was the first in North Texas to offer the Arctic Front CryoAblation Catheter. The cryoablation treatment involves a minimally-invasive procedure that creates circumferential lesions around the pulmonary vein (the source of erratic electrical signals that cause atrial fibrillation) and blocks the conduction of atrial fibrillation in cardiac tissue through the use of a coolant.

The Achieve Mapping Catheter is deployed through the Arctic Front guide wire lumen enabling the Arctic Front procedure to be performed using a single transseptal puncture with minimal catheter exchanges. It is available in 15 mm and 20 mm loop diameters, enabling physicians to map electrical conduction between the left atrium and pulmonary veins in order to assess pulmonary vein potentials before, during and after cryoablation with Arctic Front.

Approximately 15,000 Arctic Front procedures have been performed worldwide, including 1,000 procedures with the Achieve Mapping Catheter in Europe.

"The Achieve Mapping Catheter, which enables physicians to engage in real-time evaluation of pulmonary vein isolation during the Arctic Front procedure, underscores Medtronic's commitment to providing physicians with a comprehensive medical solution for treating atrial fibrillation and improving patient quality of life," said Reggie Groves, vice president and general manager of Medtronic's AF Solutions division.

Medtronic will be introducing the Achieve Mapping Catheter at Heart Rhythm 2011, the Heart Rhythm Society's 32nd Annual Scientific Sessions, in San Francisco, May 4-7, 2011.

About the Arctic Front Cardiac CryoAblation Catheter System
The Arctic Front 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 Cryoballoon, which inflates and fills with coolant to ablate the tissue where the pulmonary veins enter the left atrium;
- The FlexCath(R) Steerable Sheath, which helps deliver and position the cryocatheter in the left atrium;

- The Freezor(R) 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 therapy, and if left untreated, patients have up to a five times higher risk of stroke and an increased chance of developing heart failure. Additionally, since atrial fibrillation is often age-related, the need for more effective treatment options is escalating as the global population grows older. 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.

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.

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