Medtronic News

Medtronic Receives FDA Approval for First and Only Cryoballoon Ablation Treatment in the U.S. for Paroxysmal Atrial Fibrillation

New Arctic Front(R) Cardiac CryoAblation Catheter System Reduces Symptoms for Patients with Common Heart Rhythm Disorder

MINNEAPOLIS, Dec 17, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE:MDT) today announced that the U.S. Food and Drug Administration (FDA) has approved its Arctic Front(R) Cardiac CryoAblation Catheter system, the first and only Cryoballoon in the United States indicated for the treatment of drug refractory paroxysmal atrial fibrillation (PAF). The Cryoballoon treatment involves a minimally-invasive procedure that efficiently creates circumferential lesions around the pulmonary vein, which is the source of erratic electrical signals that cause the irregular heartbeat.

Balloon-based technology is novel because it ablates or blocks the conduction of atrial fibrillation (AF) in cardiac tissue through the use of a coolant rather than heat, which is delivered through a catheter. This freezing technology allows the catheter to adhere to the tissue during ablation, allowing for greater catheter stability.

"This technology represents a significant improvement over currently used focal ablation treatment for atrial fibrillation," said Vivek Reddy, MD, director of Electrophysiology Laboratories at The Mount Sinai Medical Center in New York, NY. "This unique ablation approach fills an unmet need in AF ablation by providing a straightforward and efficient approach to pulmonary vein isolation, while giving patients a new, minimally-invasive treatment approach proven to be safe and effective."

The FDA approval of the Arctic Front System was based on the pivotal STOP AF (Sustained Treatment of Paroxysmal Atrial Fibrillation) trial, which demonstrated the safety and efficacy of the device in treating and eradicating paroxysmal atrial fibrillation. The study showed that 69.9 percent of patients treated with Arctic Front were free from atrial fibrillation at one year, compared to 7.3 percent of patients treated with drug therapy only. The study also demonstrated that treatment with the device is safe, with limited procedure-related adverse events (3.1 percent), and patients enrolled in the study displayed a significant reduction of symptoms, a decrease in the use of drug therapy and substantial improvements in both physical and mental quality-of-life factors.

"This next-generation technology demonstrates Medtronic's commitment to providing physicians with innovative solutions proven to help them efficiently, effectively and safely treat patients suffering from Atrial Fibrillation," said Reggie Groves, vice president and general manager of Medtronic's AF Solutions division. "We are now able to offer this novel technology, which has already been used to treat more than 10,000 patients in more than 200 centers outside of the U.S., to physicians and patients in this country."

Medtronic acquired U.S.-based Ablation Frontiers, Inc., and Montreal-based CryoCath Technologies, Inc. to form Medtronic's AF Solutions division within the Cardiac Rhythm Disease Management business. When combined with Medtronic's existing EP Systems product portfolio, AF Solutions offers an extensive line of diagnostic, cryoablation (freezing technology) and radiofrequency ablation tools to diagnose and treat a broad spectrum of cardiac arrhythmias.

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 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 in America. Approximately 3 million Americans are estimated to have the disease, and about 40 percent don't exhibit symptoms and may be under-diagnosed. Half of all diagnosed atrial fibrillation patients fail drug therapy1, and if left untreated patients have up to a five times higher risk of stroke2 and an increased chance of developing heart failure. Additionally, since atrial fibrillation is often age-related, as the U.S. population continues to grow older, the need for more effective treatment options is escalating.

Paroxysmal atrial fibrillation (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.

Vivek Reddy, MD has received financial compensation as a lecturer for Medtronic.

1 JAMA 2001; 285:2370-5.

2 Fuster et al. *Journal of the American College of Cardiology*. 2006; 48:854-906.

SOURCE: Medtronic, Inc.

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