

# Medtronic

## Arctic Front Advance® System

### Overview

Catheter ablation is a minimally invasive procedure that aims to treat atrial fibrillation (AF), an irregular quivering or rapid rhythm in the upper chambers (atria) of the heart. The goal of the treatment is to stop the rapid beating of the upper heart chambers by ablating, or blocking the conduction of AF by isolating the pulmonary veins.

Building on the demonstrated safety and efficacy of its predecessor<sup>1</sup>, the Arctic Front Advance® System is the leading cryoballoon approved in the U.S. to treat drug refractory, symptomatic, paroxysmal atrial fibrillation, and in Europe for the treatment of atrial fibrillation. Eighty-two percent of patients treated with the Cryoballoon achieved freedom from AF at one year, and 79 percent were free from AF, symptomatic atrial flutter and atrial tachycardia, as seen in a recent analysis.<sup>2</sup>

The Arctic Front Advance system utilizes coolant to freeze and ablate the heart tissue around the pulmonary veins, rather than creating lesions with radiofrequency or heated energy with a point-by-point catheter.

### Physician and Patient Benefits

The Arctic Front Advance Cryoablation Catheter isolates the pulmonary veins in AF patients who have previously failed drug therapy. The Arctic Front System has been shown to improve quality of life for patients and significantly reduce atrial fibrillation symptoms, with patients experiencing reduction in atrial fibrillation episodes, palpitations, fatigue, rapid heartbeat, swelling, and syncope.<sup>3</sup>

### About the Medtronic Arctic Front Advance System

The Arctic Front Advance System has been used to treat more than 160,000 patients in 1,000 centers across more than 50 countries. The technologies currently offered include:

- The Arctic Front Advance Cryoablation Catheter, used to isolate the pulmonary veins;
- The FlexCath Advance 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;
- 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.

### Atrial Fibrillation Overview and Statistics

- Atrial fibrillation is an irregular quivering or rapid heart rhythm in the upper chambers (atria) of the heart.
- AF causes inefficient pumping of the heart and can lead to other rhythm problems as well as chronic fatigue, difficulty breathing and heart failure.
- AF is one of the most common and undertreated heart rhythm disorders, affecting more than 33.5 million people worldwide.<sup>4</sup>
- It is estimated that half of all diagnosed AF patients fail drug therapy.<sup>5</sup>
- Untreated AF patients have a five times higher risk of stroke and an increased chance of developing heart failure.<sup>6</sup>

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<sup>1</sup> Packer DL, Kowal RC, Wheelan KR, et al. Cryoballoon ablation of pulmonary veins for paroxysmal atrial fibrillation: first results of the North American Arctic Front (STOP AF) pivotal trial. *Journal of the American College of Cardiology*. April 23, 2013.61(16)1713-1723.

<sup>2</sup> Knight BP, Novak PG, Sangrigoli R, et al. 12-Month Clinical Outcomes Following Pulmonary Vein Isolation (PVI) Using the Arctic Front Advance® Cryoballoon: Interim Results from the STOP-AF Post Approval Study. Presented at HRS May 2016 (Abstract).

<sup>3</sup> Packer D, et al. *Journal of the American College of Cardiology*. 2013 Mar 13 doi: 10.1016/j.jacc.2012.11.064.

<sup>4</sup> 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.

<sup>5</sup> Wyse, et al. *Circulation*. 1996; 93:1262-1277.

<sup>6</sup> Fuster, et al. *Journal of the American College of Cardiology*. 2006; 48:854-906.