Product Overview

The Arctic Front Advance Cryoballoon is the industry’s only cryoballoon to treat drug refractory recurrent symptomatic paroxysmal atrial fibrillation (PAF), a serious heart rhythm disorder that affects millions of Americans.

The Arctic Front Advance Cryoballoon delivers a refrigerant through an inflatable balloon to freeze tissue and disable unwanted electrical circuits that contribute to PAF.

Arctic Front Advance Cryoballoon is considered a safe and effective medical device for treating PAF. It is safe because it has a low risk of complications. The cryoballoon has been used to treat over 250,000 patients in more than 50 countries worldwide. Findings from a large clinical trial found that almost 70 percent of patients treated with cryoablation were free from atrial fibrillation at one year, compared to 7.3 percent of patients treated with drug therapy only. Additionally, patients treated with cryoablation displayed a significant reduction of symptoms, a decrease in the use of drug therapy, and substantial improvements in quality of life factors.

Due to its balloon shape, an advantage of cryoablation with the Arctic Front Advance Cryoballoon is the ability of the physician to create a continuous line of scar tissue all the way around the pulmonary vein with just a few applications. With other “point-to-point” catheter systems, repeated applications are made to create many small lesions in an attempt to form a continuous line of scar tissue.

WHAT IS CATHETER ABLATION?

Catheter ablation is a minimally invasive procedure that can be used when medication fails to control atrial fibrillation (AF), an irregular quivering or rapid heart rhythm in the upper chambers (atria) of the heart.

The goal of catheter ablation is to prevent unwanted electrical currents from traveling from the pulmonary veins and spreading to the upper chambers of the heart. The pulmonary veins are large blood vessels that carry blood from the lungs to the left atrium.
Complete Cryoablation System

Other Medtronic catheters and products that may be used in conjunction with the Arctic Front Advance Cryoballoon catheter are as follows:

- The **FlexCath Advance™ Steerable Sheath**, which helps deliver and position the Arctic Front Advance Cryoballoon in the left atrium.

- The **Freezor™ MAX Cardiac Cryoablation Catheter**, a single-point catheter used to provide additional ablations, as needed.

- The **Achieve™ Mapping Catheter**, a diagnostic catheter used to measure electrical signals pre and post the ablation procedure.

- The **CryoConsole**, which houses the coolant, electrical and mechanical components that run the catheters during a cryoablation procedure.

Sources:


Brief Statement

**Arctic Front Advance™ Cardiac Cryoablation Catheter**

**Indications:** The Arctic Front Advance Cardiac Cryoablation Catheter system is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation.

**Contraindications**

Use of Arctic Front Advance Cryoballoon is contraindicated 1) In the ventricle because of the danger of catheter entrapment in the chordae tendinae. 2) In patients with one or more pulmonary vein stents. 3) In patients with cryptoglobulinemia. 4) In patients with active systemic infections; and 5) In conditions where the manipulation of the catheter within the heart would be unsafe (e.g., intracardiac mural thrombus).

**Warnings and Precautions**

Do not re-sterilize this device for purpose of reuse. Use only the 12 Fr FlexCath™ Steerable Sheath with the Arctic Front Advance Cryoballoon because using another sheath may damage the catheter or balloon segment. Do not inflate the balloon inside the sheath. Always verify with fluoroscopy or by using the proximal shaft visual marker that the balloon is fully outside the sheath before inflation to avoid catheter damage. Do not position the Cryoballoon catheter within the tubular portion of the pulmonary vein to minimize phrenic nerve injury and pulmonary vein stenosis. Do not connect the Cryoballoon to a radiofrequency (RF) generator or use it to deliver RF energy because this may cause catheter malfunction or patient harm. The catheter contains pressurized refrigerant that can be released during operation; release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. Do not push on the catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, this may lead to tissue injury. Do not advance the balloon beyond the guide wire to reduce the risk of tissue damage. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue) to avoid damage to the valve, valvular insufficiency or premature failure of the prosthetic valve. Always inflate the balloon in the atrium then position it at the pulmonary vein ostium to avoid vascular injury. Do not ablate in the tubular portion of the pulmonary vein. Use continuous phrenic nerve pacing throughout each cryoablation application in the right pulmonary veins. To avoid nerve injury, place a hand on the abdomen in the location of the diaphragm to assess for changes in the strength of the diaphragmatic contraction or loss of capture. In case of no phrenic nerve capture, frequently monitor diaphragmatic movement using fluoroscopy. Stop ablation immediately if phrenic nerve impairment is observed. The Arctic Front Advance Cryoballoon was not studied for safety of changes in anticoagulation therapy in patients with paroxysmal atrial fibrillation. This equipment should be used only by or under the supervision of physicians trained in left atrial cryoablation procedures. Cryoablation procedures should be performed only in a fully equipped facility.

**Potential Complications**

Potential complications/adverse events from cardiac catheterization and ablation include, but are not limited to the following: Anemia; Anxiety; Atrial flutter; Back pain; Bleeding from puncture sites; Blurred vision; Bradycardia; Bronchitis; Bruising; Cardiac tamponade; Cardiopulmonary arrest; Cerebral vascular accident; Chest discomfort/pain; Cold feeling; Cough; Death; Diarrhea; Dizziness; Esophageal damage (including esophageal fistula); Fatigue; Fever; Headache; Hemoptysis; Hypotension; Hypertension; Lightheadedness; Myocardial infarction; Nausea/vomiting; Nerve injury; Pericardial effusion; Pulmonary vein stenosis; Shivering; Shortness of breath; Sore throat; Tachycardia; Transient ischemic attack; Urinary infection; Vasovagal reaction; Visual changes. Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

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