THE NEW CHOICE FOR PERSISTENT AF

Arctic Front™ Family of Cardiac Cryoablation Catheters

The Arctic Front Advance™ cardiac cryoablation catheter is indicated for the treatment of drug-refractory, recurrent, symptomatic, paroxysmal, and persistent atrial fibrillation (episode duration less than 6 months).

SAFE

< 1% Complication Rate

Only 1 primary safety event unrelated to study device occurred in 1 patient during a repeat ablation procedure.

EFFECTIVE

- Cryoballoon PVI only
- No Class I or III AAD initiation or dose increase after blanking period

> 1 out of every 2 patients
free from atrial arrhythmia recurrence 12 months post-ablation

Significant improvements in quality of life, reduced symptoms, and
~9 out of every 10 patients
free from repeat ablation by 12 months post-ablation

EFFICIENT[1]

Short & Predictable Procedure Times ~2 hours

- Procedure time: 121 ± 46 minutes
- Cryoballoon LA dwell time: 66 ± 25 minutes
- Fluoroscopy time: 19 ± 16 minutes

Medtronic

Reference
[1] Su WW, Reddy VY, Bhasin K, et al. Cryoballoon Ablation of Pulmonary Veins for Persistent Atrial Fibrillation: Results From the Multicenter STOP Persistent AF Trial. *Heart Rhythm*. Published online June 23, 2020.

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Brief Statement
Arctic Front™ Family of Cardiac Cryoablation Catheters
Indications: The Arctic Front family of cardiac cryoablation catheter systems are indicated for the treatment of drug-refractory recurrent, symptomatic paroxysmal and persistent atrial fibrillation (episode duration less than 6 months).

Contraindications: Use of the cryoballoon is contraindicated: 1) In the ventricle because of the danger of catheter entrapment in the chordae tendineae, 2) In patients with one or more pulmonary vein stents, 3) In patients with cryoglobulinemia, 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/Precautions: Do not resterilize this device for purpose of reuse. Use only a compatible Medtronic 12 Fr inner diameter sheath with the Arctic Front family of cardiac cryoablation catheters. 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 veins 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 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 pull 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. Esophageal ulcerations have been observed in some subjects who have undergone left atrial ablation with the Arctic Front family. As with other forms of left atrial ablation, the physician should consider appropriate medical strategies to minimize the risk of esophageal injury.

Damage to the lung or tracheobronchial tree has been observed in some subjects who have undergone left atrial ablation with the Arctic Front family. The physician should consider appropriate medical strategies to minimize the risk of damage to the lung or tracheobronchial tree. 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 family of cardiac cryoablation catheters were 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: Access site complications (e.g., bruising, ecchymosis); Anemia; Anxiety; Arrhythmia (e.g., atrial flutter, bradycardia, heart block, tachycardia); Back pain; Bleeding from puncture sites; Bronchial constriction; Bronchial fistula; Bronchitis; Bruising; Cardiac tamponade; Cardiopulmonary arrest; Cerebral vascular accident; Chest discomfort/pain/pressure; Cold feeling; Coronary artery spasm; Cough; Death; Diarrhea; Dizziness; Embolism; Esophageal damage (including esophageal fistula); Fatigue; Fever; Headache; Hemoptysis; Hypotension/Hypertension; Infection (e.g., pericarditis, sepsis, urinary); Lightheadedness; Myocardial infarction; Nausea/vomiting; Perforation; Pericardial effusion; Phrenic nerve injury; Pleural effusion; Pneumonia; Pneumothorax; Pseudoaneurysm; Pulmonary edema; Pulmonary hemorrhage; Pulmonary vein dissection; Pulmonary vein stenosis; Shivering; Shortness of breath; Sore throat; Transient ischemic attack; Vagal nerve injury (e.g., gastroparesis); Vasovagal reaction; Visual Changes (e.g., blurred vision).

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 the Medtronic website at medtronic.com.

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

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