DO YOU HAVE PAROXYSMAL ATRIAL FIBRILLATION?
**Do you have atrial fibrillation (AF)? Do you think you might have it?**

If so, the time to take control is now. There are three important things to do.

1. If you haven't been diagnosed, but think you might have AF, see a doctor and get it checked.

2. If you have been diagnosed with AF, discuss treatment options with your doctor.

3. If your treatment isn’t working, talk to your doctor about making a change. You have options.

**About AF**

Atrial fibrillation (AF or Afib) is an irregular, rapid heart rhythm in the upper chambers of the heart, or atria. This prevents blood from being pumped efficiently to the body, causing symptoms such as:

- Irregular, rapid, fluttering or pounding heartbeat
- Fatigue, shortness of breath, or weakness
- Chest discomfort or pain
- Dizziness

**Discuss treatment options with your doctor.**

Whether your symptoms are mild or severe, atrial fibrillation can be a serious medical condition that should be treated. It may impact your quality of life, energy level, and physical activity.\(^1\) If left untreated, AF may increase the risk of heart failure, stroke, and death.\(^2,5\) In fact, AF increases the likelihood of having a stroke by 5 times.\(^4\)

**Seeking treatment earlier is important.**

AF is a progressive disease.\(^6\) That's why it's important to begin treatment promptly. If one type of treatment isn't working for you, talk to your doctor about an alternative therapy.

**Treatments for AF include:**

- Medications
- Minimally invasive cryoballoon or RF ablation
- Electrical cardioversion
- Pacemaker and defibrillators
- Surgery
If drugs don’t work.
Talk to your doctor if you are taking medication for your paroxysmal AF (PAF) and still have symptoms or are experiencing side effects. There are other treatments, such as ablation of the pulmonary veins, often referred to as pulmonary vein isolation (PVI).

PVI for Paroxysmal AFib.
PVI is considered the cornerstone of treatment for PAF. PVI is performed by a specialist (an electrophysiologist or EP) using a minimally invasive procedure called ablation to form scar tissue that blocks the irregular signals.

Cryoballoon PVI ablation.
There are two primary ablation tools used for PVI:
- Cryoballoon ablation freezes the tissue and disables unwanted electrical signals by creating a line of scar tissue (Fig. A).
- Radiofrequency (RF) ablation uses heat at the tip of a catheter to disable unwanted signals through several point-by-point applications around the pulmonary vein (Fig. B).

Cryoballoon was made for PVI.
A large clinical study (FIRE AND ICE Trial) demonstrated that cryoballoon ablation is comparable to radiofrequency (RF) ablation. A predefined secondary analysis showed that cryoablation resulted in 33% fewer repeat ablations (a second procedure). Additionally, patients treated with cryoballoon experienced 34% fewer cardiovascular hospitalizations compared to patients treated with RF ablation.

If you are considering an ablation for PAF, be sure to go to a specialist who is experienced with both procedures.

Risks and complications.
Cryoballoon ablation is generally a safe procedure. Complications are rare, but can be serious. They include irritation, bleeding, or infection at catheter insertion site; damage to blood vessels in groin area; narrowing of pulmonary veins; phrenic nerve damage; pericardial tamponade; atrio-esophageal fistula; heart punctures; fluid buildup around heart; and in rare cases, death. Be sure to talk to your doctor about the benefits and risks of cryoballoon ablation for you.
References


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 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 the 12 Fr FlexCat™ Steerable Sheath family 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 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. 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/pressure; Cold feeling; Cough; Death; Diarrhea; Dizziness; Esophageal damage (including esophageal fistula); Fatigue; Fever; Headache; Hemoptyis; 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 the Medtronic website at medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
“After the cryoablation the quality of my life improved tremendously.”
— Norma, PAF Patient

Take action today.

- Learn more online at medtronic.com/Afib.
- Contact the Medtronic Lifeline Patient Services line: 1-877-526-7890.
- Download free iPad® app from iTunes® called “Treating AF Patient Education.”

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