TREATING PAROXYSMAL ATRIAL FIBRILLATION WITH CRYOBALLOON ABLATION

Medtronic
Atrial fibrillation (AF or Afib) is an irregular heart rhythm that affects the upper chambers (atria) of the heart. This arrhythmia prevents blood from being pumped efficiently to the rest of your body.

AF may impact your quality of life, energy level, and physical activity and if left untreated, it may increase the risk of heart failure, stroke, and death. In fact, AF increases the likelihood of having a stroke by 5 times. Even without symptoms, AF can be a serious medical condition.

That’s why your doctor is working with you to make sure you get the right treatment for your heart condition.

**Your symptoms**
AF symptoms vary depending on how advanced your AF is, its cause, and your overall health. You may notice...

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

**Why did I get AF?**
The causes of atrial fibrillation are often unclear. AF may be the result of:

- Heart abnormality from birth
- Damage to the heart structure from a heart attack
- Heart valve problems

People with otherwise normal hearts may also develop AF.

**Risk Factors**
- High cholesterol
- High blood pressure
- Heart disease
- Smoking
- Excess weight
- Caffeine
- Alcohol abuse
- Lack of physical activity
- Some medications
- Sleep apnea
- Family history
- Advancing age
- Heart disorder
Why now?
There are several reasons your physician may be recommending ablation:

- Patients with PAF have better outcomes when treated with ablation earlier.\(^7\)
- AF is a progressive disease.\(^8\)
- Some patients who received ablation therapy had a lower rate of PAF disease progression compared with drug therapy alone.\(^9\)

THE NEXT STEP: CRYOBALLOON ABLATION

If you have spoken to your physician and are considering cryoballoon ablation for your paroxysmal atrial fibrillation (PAF), you’ve taken an important step.

Why ablation?
Cryoballoon ablation is a safe and effective alternative after antiarrhythmic drugs (AADs) taken to control heart rate and rhythm.\(^6\) It’s a minimally invasive procedure with a short recovery time, that may make a big difference in the way you feel.

The procedure your doctor has suggested for you is cryoballoon pulmonary vein isolation (PVI) ablation. PVI is a minimally invasive procedure performed by an electrophysiologist (EP). It helps correct your arrhythmia by disabling unwanted electrical signals in the pulmonary veins.

“Getting rid of the AF is more than just getting activity back and being off meds. It’s regaining my total being — freedom of life and lifestyle”
— Richard, PAF Patient
TREATING YOUR PAF

The goal of your PAF treatment is to:

- Relieve PAF symptoms and improve your quality of life
- Prevent blood clots to decrease the risk of stroke
- Control the heart rate to allow the ventricles (lower heart chambers) enough time to fill with blood
- Reset the heart rhythm to allow the atria (upper chambers of the heart) and ventricles to work together more efficiently

Why Cryoballoon?

Your doctor has chosen cryoballoon ablation for your PVI procedure. The inflatable balloon uses cold energy to remove heat from the tissue and disables unwanted electrical signals by creating a line of scar tissue.

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.
YOUR CRYOBALLOON PROCEDURE

Your doctor will discuss your procedure with you in detail, but here is a general overview of what you can expect.

**Before**
Your doctor will probably tell you not to eat or drink after midnight the night before your procedure. You may need to stop certain medications. You will also want to tell your doctor immediately about any changes in your health. You may be under general anesthesia for the procedure.

**After**
You will need to limit your activities for a couple of days. Minor soreness in the chest or bruising at the insertion site is normal. Let your physician know if you experience any symptoms that are bothering you.

Your doctor will probably arrange follow-up visits to monitor your healing and heart rhythms.

**Access**
The doctor makes a small incision in the groin area through which to insert the catheter (small tube). To access the left atrium, the doctor must create a puncture in the wall that separates the left and right sides of the heart. The cryoballoon is then advanced to the left atrium.

**Inflate**
The doctor inflates the balloon and moves it to the opening of the pulmonary vein. The goal is to temporarily close off the opening of the pulmonary vein completely, stopping blood flow between the atrium and the vein (this is called occlusion).

**Freeze (Ablate)**
When occlusion is confirmed, the doctor introduces cold energy into the balloon. The cold energy freezes the tissue where the balloon touches the opening of the pulmonary vein. This scars the tissue, stopping the transmission of electrical signals that cause atrial fibrillation.
YOU MAY BE WONDERING...

Is cryoballoon ablation safe?
Cryoballoon ablation is generally considered to be a safe and effective treatment for PAF after antiarrhythmic drugs (AADs). It is a minimally invasive procedure, meaning there is no need to open the chest or make large incisions. The most common problem is local irritation or bleeding at the site of the incision. The risk of more serious complications is small, but you should talk to your doctor about whether the procedure is right for you.

How effective is ablation?
Both cryoballoon and radiofrequency ablation have been shown to effectively treat PAF, improving symptoms and quality of life for many patients. Generally, after AADs, the earlier your PAF is treated with ablation, the more successful it may be. Of course every patient’s experience is different. Sometimes after the procedure you will continue to have arrhythmia and may need a repeat procedure. It’s also possible that you may need to continue with some type of medication. Be sure to discuss this and any other concerns you might have with your doctor.

My symptoms come and go. Do I need to have a procedure?
Atrial fibrillation can be a serious medical condition that should be treated no matter what level of symptoms you experience. Without effective treatment, AF may lead to a stroke, heart failure, or other health complications. If your AF does not improve after the use of an antiarrhythmic medication, speak to your doctor about whether or not catheter ablation is the next step for you.

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.

What patients say

“I could feel my heart beating in a normal rhythm right away, and I was thrilled.”
— Dawn

“My emotional state is back to normal because I’m not having to constantly worry about how I’m going to take care of my family.”
— Nathan

“After the cryoablation the quality of my life improved tremendously.”
— Norma

Where can I get more information?
For more information about atrial fibrillation or to read more stories of people who have had a cryoablation procedure, visit www.medtronic.com/Afib, or call the toll-free Medtronic Lifeline Patient Services line: 1-877-526-7890.
References

Brief Statement: Arctic Front Advance™ Cardiac Cryoballoon Catheter

Indications: The Arctic Front Advance cryothermal cardiac cryoballoon catheter system is intended for the treatment of drug refractory, symptomatic paroxysmal atrial fibrillation.

Contraindications: Use of Arctic Front cryothermal balloon catheter is contraindicated in patients with 1) the presence of a metallic valve because of the danger of catheter entrapment in the chordal tendinæ, 2) In patients with one or more pulmonary vein stents, 3) in patients with cryoglobulinemia, 4) in patients with a history of damage to the heart or aorta, 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 future use. Use only the 12 Fr FlexCath™ steerable sheath family with the Arctic Front Advance cryoballoon catheter system in the sheath configuration. Do not advance the balloon beyond the guide wire to reduce the risk of tissue damage. Do not advance the balloon through a sheath after the balloon has been inflated as this may lead to tissue injury. Do not connect the cryoballoon to a radiofrequency (RF) generator or use it to deliver RF energy because this may create a hazard to the patient or the device.

Potential Complications: Potential complications/adverse reactions associated with cryoballoon ablation include, but are not limited to the following: Anemia; Anxiety; Atrial flutter/ fibrillation; Back pain; Bleeding from puncture sites; Blurred vision; Bradycardia; Bronchiolitis; Carotid artery dissection; Cardiac tamponade; Cardiovascular collapse; Cardiopulmonary arrest; Cerebral vascular accident; Chest discomfort/pain/breathlessness; Cold feeling; Cough; Death; Dizziness; Dizziness; Epileptic seizure (including status epilepticus) and syncope; Fever; Headache; Hemoptysis; Hypotension/hypertension; Lightheadedness; Myocardial infarction; Myocardial ischemia; Nausea/vomiting; Pain; Pulmonary vein stenosis; Shivering; Shortness of breath; Stroke; Thrombosis; Transient ischemic attack; Urinary infection; Vasovagal reaction; Visual changes. Refer to the device technical manual for detailed information regarding the procedures, indications, contraindications, warnings, precautions, and postprocedure care. For further information, please call Medtronic at 1-800-328-2581 and consult the Medtronic website at medtronic.com.

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