TREATING PAROXYSMAL ATRIAL FIBRILLATION WITH CRYOBALLOON ABLATION
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.

**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

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**Normal Heartbeat**
Flow of electrical signals in a normal heartbeat.

**Atrial Fibrillation**
Atrial fibrillation with abnormal signals originating in the atria.
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. 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.

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

“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
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.

During the Procedure

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.
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 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 cardiac cryoablation catheter 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 manipulation of the catheter within the heart would be unsafe (e.g., severe cardiomyopathy).

Warnings/Precautions: Do not resterilize this device for purpose of reuse. Use only the 12 Fr FlexCath™ steerable sheath family with the Arctic Front Advance cryoballoon because using another sheath may damage the balloon or balloon segment. Do not inflate the balloon inside the sheath. Always inflate the balloon, 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 deploy the cryoballoon inside 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 and perform phrenic nerve pacing 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 catheter catheterization and ablation include, but are not limited to the following: Vasovagal reaction; Visual changes; Transient ischemic attack; Urinary infection; Shortness of breath; Sore throat; Tachycardia; Effusion; Pulmonary vein stenosis; Shivering; Nausea/vomiting; Nerve injury; Pericardial effusion; Pulmonary vein stenosis; Shivering; Shortness of breath; Sore throat; Tachycardia; Transient ischemic attack; Urinary infection; Vascular injury; embolization; Thrombus; Aneurysm; Myocardial ischemia; Myocardial infarction; Stenosis; Numbness; Fatigue; Fever; Headache; Hypesthesia; Hypotension/hypertension; Life-threatening hemorrhage or other severe bleeding; 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.