

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 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 re-sterilize 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 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. 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; 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.

www.medtronic.com

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Treating Atrial Fibrillation with Catheter Ablation

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What is atrial fibrillation?

Atrial fibrillation, also known as AF, is an irregular heart rhythm that affects the upper chambers (atria) of the heart.

In AF, the atria quiver instead of beating normally. AF can also lead to rapid heart rhythm, where the heart can beat as much as 300 times a minute or more in the atria and up to 150 times a minute or more in the lower chambers (ventricles).

The importance of treating atrial fibrillation

As a result of the quivering rhythm in the atria during AF, blood is not completely pumped out of the upper chambers of the heart, which may cause it to pool and clot. Treating AF is important because it may negatively impact your quality of life or even cause a stroke. While the condition is not considered life-threatening, people with AF are five to seven times more likely to form blood clots and suffer a stroke.

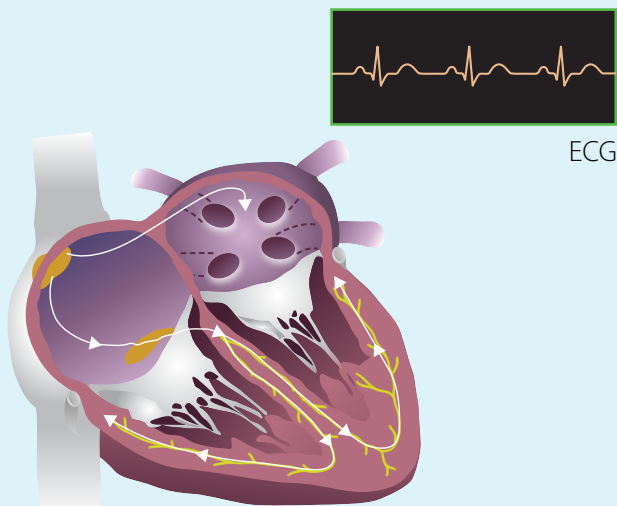
Atrial fibrillation is also associated with fatigue and heart failure. The rapid and irregular heartbeats associated with atrial fibrillation can make your heart larger and weaker over time. A larger and weaker heart does not pump blood to all the areas of your body very efficiently. This is what we mean by the term heart failure.

Fortunately, these risks can be reduced dramatically if they are monitored and treated. By working closely together, patients and physicians can choose the most appropriate course of care for the treatment of atrial fibrillation.

When does atrial fibrillation occur?

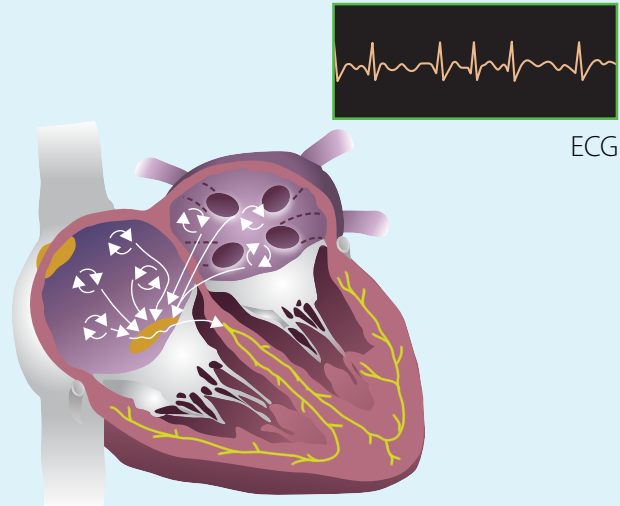
When atrial fibrillation occurs unrelated to any other heart condition, it is called **lone atrial fibrillation**. However, it may also occur along with other structural heart disease, such as heart valve disease.

Normal Heartbeat



Flow of electrical signals in a normal heartbeat.

Atrial Fibrillation



Atrial fibrillation with abnormal signals originating in the atria.

How do I know if I might have AF?

Some people experience these symptoms of atrial fibrillation:

- Heart sensations, sometimes called palpitations, which may include irregular, thumping, or pounding heartbeats
- A feeling that the heart is racing
- Chest discomfort or pain
- Fainting or lightheadedness
- Fatigue, shortness of breath, or weakness

Others have no symptoms and discover that they have AF at a doctor's appointment. Even without symptoms, atrial fibrillation is a serious medical condition.

Make an appointment with your doctor if you have symptoms such as those above. Your doctor can help determine if the symptoms are related to AF or another health concern.

Are there different types of AF?

There are three types of AF:

Paroxysmal AF

Paroxysmal AF refers to AF that occurs sometimes and then stops. The AF stops by itself and the heart returns to its normal rhythm. The AF may last for seconds, minutes, hours, or up to seven days before the heart returns to its normal rhythm. People with this type of AF usually have more symptoms than others. As the heart goes in and out of AF, the pulse rate may change from slow to fast and back again in short periods of time.

Persistent AF

Persistent AF occurs when the AF does not stop by itself. Medications and/or cardioversion (a special type of electrical shock) may be used to help the heart return to its normal rhythm. If no treatment is given, the heart will stay out of rhythm.

AF lasting from seven days to 12 months is called **short lasting persistent**. AF lasting 12 months or more is called **long standing persistent**.

Permanent AF

Permanent AF occurs when the AF cannot be fixed. Medications and cardioversion alone cannot help return the heart to its normal rhythm.

What are my treatment options if I have AF?

Treating atrial fibrillation is important since AF may increase the risk of blood clots and stroke. The American Heart Association recommends proactive treatment for AF whether you can feel symptoms or not. You and your doctor can discuss which treatment would be best for you and your heart condition.

The major goals in treating atrial fibrillation are to:

- Relieve AF symptoms and improve a patient's 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

The following treatments may be prescribed to treat atrial fibrillation:

- Anticoagulation or “blood thinning” therapy to prevent clots from forming
- Medication to control the heart rate or rhythm
- Restoration of normal heart rhythm either through an electrical cardioversion or medication. Electrical cardioversion itself does not generally have lasting effects.
- Radiofrequency catheter ablation or cryoablation. (These therapies are further discussed in the following pages.)
- Pacemakers and defibrillators, although not used as stand-alone treatment, may be used in conjunction with medication or catheter ablation. Some pacemakers and defibrillators have features that detect AF early and help suppress episodes.
- Open-heart surgery to create lines of scar tissue to block abnormal electrical circuits causing AF

The remainder of this guide will focus on the treatment of atrial fibrillation using catheter ablation.

What is catheter ablation?

Catheter ablation is a minimally invasive procedure that can be used when medication fails to control the heart rhythm. Catheter ablation is performed in an electrophysiology lab in the hospital by a team of highly skilled nurses and technicians who work alongside the electrophysiologist (a doctor who specializes in treating heart rhythm conditions).

In paroxysmal AF, 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.

The standard ablation technique for accomplishing this goal is called pulmonary vein isolation. During the procedure, catheters are used to terminate (ablate) these abnormal electrical circuits and stop them from spreading and continuing to cause AF.

There are two main techniques used to perform pulmonary vein isolation: **Radiofrequency (RF) ablation** and **Cryoablation**. One of the main differences between these techniques is the energy source used during the procedure. In RF ablation, heat is applied to the tissue, where in Cryoablation, heat is removed from the tissue by introducing cold temperatures. Both types of ablation result in the formation of scar tissue around the pulmonary veins.

Treating paroxysmal atrial fibrillation with the Arctic Front Advance™ Cardiac CryoAblation Catheter

One method for treating paroxysmal atrial fibrillation (PAF) is cryoablation using the Arctic Front Advance Cryoballoon catheter. As its name indicates, 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 is considered a safe and effective medical device for treating PAF. It is safe because it has a low risk of complications. Cryoballoon ablation catheters have been used to treat over 30,000 patients in 400 centers worldwide.

Because of its balloon shape, Arctic Front Advance allows physicians to reach and treat pulmonary veins quickly and efficiently. Due to its balloon shape, an advantage of cryoablation with Arctic Front Advance is the ability for 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.

The next section will discuss, in detail, what to expect with the cryoablation procedure using Arctic Front Advance.



What can I expect to experience with a cryoablation procedure?

Before the ablation procedure

Preparing for ablation is like preparing for any other type of elective procedure. Typical instructions include not drinking or eating after midnight the night before the procedure. Certain medications may need to be stopped; your doctor will advise you accordingly. As well, you will need to tell your doctor immediately of any health changes before the scheduled procedure, as infections can increase the risk of the procedure.

During the ablation procedure

During the procedure, you will receive fluids and any necessary medication through an intravenous (IV) line inserted in your arm. You may be anesthetized ('put to sleep') or sedated for the procedure.

A local anesthetic will be applied to the site where the ablation catheters will be inserted. In most cases, the blood vessels in your groin are used for catheterization.

In the procedure, the physician makes a needlestick or a small cut in the groin area through which to insert the catheter. The physician threads the catheter to the right atrium of the heart. Then he or she crosses the wall that separates the left and right sides of the heart. This provides access to the left atrium. You will receive anticoagulants (blood thinners) to help prevent blood clots during the procedure.

The following three images describe what happens specifically with the Cryoballoon catheter:



The Cryoballoon catheter enters the left atrium.



The physician inflates the balloon and moves it to the opening of the pulmonary vein.



The goal is to close off the opening of the pulmonary vein completely, which stops the flow of blood between the atrium and the vein (this is called occlusion).

Once occlusion is confirmed, the physician introduces liquid refrigerant into the balloon. The refrigerant evaporates and removes heat from the heart tissue at the opening of the pulmonary vein where the balloon is in contact with it. As a result, the tissue is scarred and may no longer spread the electrical currents that cause atrial fibrillation.

What happens *after* the procedure?

Soon after the procedure is completed, the catheter will be removed and pressure will be applied to the insertion site to reduce any bleeding. You will likely stay overnight in the hospital for observation. While activities will need to be limited for a couple of days, most patients return to their normal routine within a few days. You may feel some minor soreness in your chest, or bruising or soreness at the insertion site. Your doctor will talk to you about any activities you may have to curtail or stop while you are healing.

In most cases, you will be able to return home the day following the procedure but some patients may be in the hospital a little longer. Some patients may experience a slight cough following the procedure. Let your physician know any time you have symptoms causing you discomfort.

Follow-Up Visits

Your doctor will likely want to see you to check on your healing and monitor your heart rhythms. One catheter ablation is usually enough to treat atrial fibrillation. In some cases, individuals need a repeat procedure to achieve full success.

It's important to have check-ups as recommended by your physician. In addition, many patients may continue anticoagulation medication following an ablation procedure. Monitoring for this therapy may be required.

What are the benefits and risks of catheter ablation?

Benefits

Catheter ablation may treat atrial fibrillation. In combination with a complete program of treatment, catheter ablation may improve your quality of life and eliminate or reduce the unpleasant symptoms of atrial fibrillation like shortness of breath, fatigue, or weakness. Some patients may require more than one catheter ablation procedure. In some cases, patients may not require further drug treatment after receiving the catheter ablation procedure. Be sure to speak with your doctor about your condition.

Risks

As with any medical procedure, there are risks with catheter ablation. Some of the risks include stroke, pericardial tamponade, narrowing of pulmonary veins, damage to the phrenic nerve, damage to the blood vessels in your groin area, and a serious but rare risk of atrio-esophageal fistula. Other risks include irritation, infection, or bleeding occurring where the catheter was inserted; the heart could be punctured; fluid may build up around the heart, or in rare cases death may occur.

Remember to talk to your doctor about all benefits and risks that are specific to your condition, and any concerns or questions you have. Although many patients benefit from catheter ablation, results may vary.

Dick's Story

Not Ready to Slow Down

Turning 70 and retiring certainly didn't slow Dick's pace of living. Besides competitive tennis in the Open Circuit, golfing, and biking, Dick consults for multiple companies and recently acquired his real estate license. He still finds time for multiple visits to his children and grandchildren scattered across the country.

Accustomed to a high level of activity, Dick was surprised when he couldn't finish his tennis match one day. "I felt like I just ran out of gas on the court," Dick recalled, "but I attributed the extreme fatigue to the long tournament, the heat, the wine – anything but a heart problem." Dick began to experience episodes of inconsistent, pounding heartbeats which came on intermittently, lasted

anywhere from a few minutes to 36 hours, and would stop suddenly on their own.

His primary doctor referred Dick to a cardiologist who diagnosed AF and prescribed medication to treat it. "Although the medication reduced the number of episodes at first, the side effects interfered with my life," said Dick. "I was on blood thinners to prevent a stroke which meant that I had to have my blood checked regularly. Plus my doctor advised no hard physical activity which I loved." The AF medications also left Dick feeling lethargic and less alert.

A More Permanent Solution

As the months went on, Dick's AF worsened.



It lasted longer and became more debilitating, despite changing medications and dosage levels. It was also very unpredictable, making babysitting for the grandchildren no longer an option. Dick felt he needed a more permanent solution. He and his cardiologist discussed catheter ablation with the Arctic Front Cryoballoon.

“Fast forward to after the cryoablation procedure,” chuckled Dick. “I felt my heart run like a freshly tuned Chevy V8. There was an immediate difference in how I felt.” Dick had a short stint of AF about five weeks after his catheter ablation but nothing since. “Getting rid of the AF is more than just getting activity back and being off meds,” emphasized Dick. “It’s regaining my total being – freedom of life and lifestyle.”

This story reflects one person’s experience. Not every person will receive the same results. Talk to your doctor about your treatment options.

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, www.medtronic.com/afablation, or call the toll-free Medtronic Lifeline Patient Services line: 1 (877) 526-7890.



