

A TREATMENT FOR YOUR ATRIAL FIBRILLATION



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A Patient's Guide

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This pamphlet is not intended to replace your doctor's advice and information. You should consult your doctor regarding the ALERT® procedure as it specifically relates to you.

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INTRODUCTION

Your doctor has recommended that you undergo treatment of your atrial fibrillation with the ALERT® System.

Now you probably have some questions and concerns about this procedure. This brochure can help answer many of your questions about this procedure.

What is Atrial Fibrillation?

Atrial fibrillation is an irregular, rapid heartbeat in which the upper chambers of your heart (the atria) beat irregularly, very quickly, and ineffectively. The walls of the atria begin to quiver and can't squeeze blood efficiently. Not everyone experiences the same symptoms. Some people may have this irregular heartbeat without knowing it. This irregular heartbeat can cause a sensation of pounding or fluttering in the chest, and/or you may feel tired, dizzy, short of breath, and/or pressure or discomfort in the chest. Atrial fibrillation may interrupt duties, work activities, and other activities.

What is the treatment for Atrial Fibrillation?

Your doctor has decided that your condition requires treatment to change your irregular heartbeat back to the normal rhythm. There are numerous ways to do this; some may or may not apply to you so your doctor will choose the best treatment/s for you.

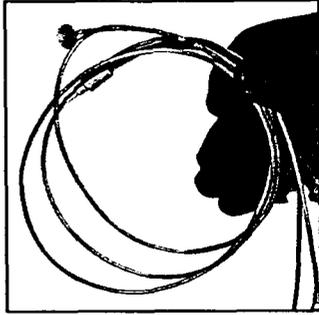
Your doctor can give you a medication that may convert your heart rhythm back to normal. However, many patients do not have their heartbeat restored to a normal rhythm with medications that are currently available. Your physician can further share this information with you.

You can be given general anesthesia (put to sleep), and have two patches placed on your chest to shock your heart back to normal rhythm. This procedure is called "external cardioversion". Although external cardioversion is usually very effective, not all patients with this type of irregular heartbeat can be restored to a normal rhythm with this treatment.

Another method of treating this condition uses the ALERT® system to deliver low energy shock to convert your heart back to a normal rhythm.

What is the ALERT® system?

The ALERT® system consists of a catheter (long flexible tube containing wires for electrical conduction) which will be inserted into your heart, and the Companion which is a piece of equipment placed by your bedside and connected to the catheter to deliver the shock energy through the catheter to stop your irregular heartbeat.



Tell me about the ALERT® procedure.

The catheter is temporarily inserted into your heart through a vein, in either your arm, neck, or groin. X-rays will be taken to guide the proper placement of the catheter in your heart.

After the catheter is properly positioned, the catheter is connected to the ALERT® Companion which is turned on, and one or more low energy shocks will be given to stimulate your heart into a normal rhythm. Your doctor will discuss this insertion procedure with you and answer any additional questions that you may have.

What can I expect?

Unless you are already hospitalized you will be admitted to the hospital for the ALERT® procedure. In some cases, it may also be done as an outpatient procedure. You may also be admitted as an inpatient for observation in case your physician needs to adjust any drug therapy that he has selected to help you. Several routine lab tests including blood work and an ECG (electrocardiogram; recording of your heart rhythm) may be performed sometime prior to this procedure.

On the day of the procedure you may be asked not to eat or drink anything before the test but you may take sips of water with your medications. The doctor may review your medical history and examine you. He will explain the procedure, its purpose, potential benefits, and possible risks. This is a good time to ask questions, and, most importantly share any feeling or concerns you may have about the procedure. As in many procedures done in the hospital, you will be asked to sign a consent form that gives the doctor permission to perform the procedure. You may be asked to change into a hospital gown and taken to a special room or laboratory where the procedure will be performed.

There is a chance this procedure may need to be repeated in the future just as with external high energy shocking procedures.

Who can get the ALERT® system?

The ALERT® System is designed to be used in patients who are candidates for external high energy shocking procedures of irregular heart rhythms. The system may be used for temporary pacing, as well as for low energy internal atrial defibrillation (≤ 15 joules). The system may also work much like a pacemaker. The ALERT® Catheter also allows for special measurements inside the heart, when connected to an external pressure monitor.

Who should not get the ALERT® system?

The ALERT® System should not be used in patients who can not have temporary pacing leads put inside the heart, and/or internal low energy shocks. Your doctor will also make the decision if they feel you are not suitable for this procedure. You should let your doctor know if you are on coumadin (blood thinners) medication, on aspirin, or if you have a mechanical heart valve or have a known allergy to latex.

What could happen?

With a catheter being placed inside of your heart the following complications or side effects could occur: an allergic reaction to the cleaning fluid used to clean the catheter insertion site, an allergic reaction to the anesthetics, an allergic reaction to the latex in the catheter balloon tip, bleeding at the site where the catheter is inserted, blood clot formation, tenderness/ bruising at the catheter insertion site, infection, spasm of the vein, perforation of a blood vessel or heart chamber, puncture of a lung, bursting of the tiny balloon which is at the tip of the catheter, heart attack, pulmonary infarction, (damaged tissue in lung) heart valve injury, or death.

It is also possible that the catheter may become dislodged during therapy and require repositioning. It is possible that the top chambers of the heart may continue to beat too fast (therapy failure), that the bottom chambers of the heart may be stimulated in beating too fast (ventricular fibrillation), or that another type of abnormal heart rhythm may occur.

It is also possible that if you have a blood clot inside your heart, it may become dislodged during or after the procedure and travel to your brain, causing a stroke. Your doctor has taken precautions to prevent the possibility of a stroke by giving you blood thinning medication. Also, there are certain tests that he can do prior to the procedure to check for the presence of clots. Therefore, the probability of this complication is low.

In addition, your doctor will minimize allergic reaction risks by asking you before the procedure if you ever had any reaction to medications, anesthesia or any other specific allergic reactions.

Since this procedure is typically performed in a special lab, equipment is available and along with your physician, also specially trained personnel experienced in treating heart rhythm irregularities as well as other emergencies.

Benefits:

Your heart's rhythm may be returned to normal, and you may feel relief from symptoms associated with these irregular heartbeats. It is possible that the ALERT® system may be able to stop the irregular heartbeat in patients who cannot be successfully treated with external high energy shocks. It is also possible that patients treated with the ALERT® system will have little or no muscle or joint injury due to the use of much lower energies than those used in external high energy shocks. Patients treated with the ALERT® system have not experienced any skin burns which may occur with external high energy shocks. In addition, it is possible that you will not experience any of the numerous side effects that can be experienced with drug treatment which your physician can discuss with you.

Alternatives to Treatment:

Additional methods of treatment, as previously mentioned, are available to you. These include external cardioversion (electrical shocks applied to the surface of the chest) and pharmacological cardioversion (drugs that reduce or eliminate abnormal heart rhythms). You should discuss these alternatives with your doctor, and he will decide which treatment option is best for you.

Clinical Studies:

A comparison clinical study done in the United States on the ALERT® System and external cardioversion demonstrated no difference in the success rates between these treat-

ments. The most common complications experienced by patients treated with the ALERT® System were bruising, bleeding/hematoma, and abnormal rhythm. The most common complications experienced with external cardioversion were skin burns, skin rash, and pain after the procedure.

Should you have additional questions about the ALERT® system, please be sure to ask your doctor about the procedure.

Glossary:

ALERT® System – The ALERT® (Atrial Low Energy Reversion Therapy) System is a catheter system that is put into the heart to provide a low-energy shock (5-15 joules) to stop irregular heart rhythms in the atria.

ALERT® Companion – Electrical energy source, which is connected to the ALERT® catheter and used to supply the shock for internal cardioversion.

Atrial Fibrillation – Irregular rapid heartbeat in which the upper chambers of the heart (the atria) beat irregularly, very quickly and ineffectively.

Cardioversion – The conversion of an irregular heart rate to a normal rhythm.

Catheter – Long flexible tube containing wires for electrical conduction which is inserted into the heart.

Defibrillator – Electrical energy source that is applied to the heart, either externally through skin patches or paddles on the chest or internally through a catheter, to convert irregular heart rates (fast) to a normal rhythm.

ECG – Electrocardiogram recording of the heart rhythm using patch electrodes applied to the patient's skin.

External Cardioversion – A method of converting and abnormally fast heart rate to a normal rhythm using high energy shocks (200 joules and above) applied through electrode patches or paddles placed over the chest.

Fluoroscopy – Real-time x-radiographic images of the heart that may be used to guide a catheter into the main heart chamber(s).

Internal Cardioversion – A method of converting an abnormally fast heart rate to a normal rhythm using low energy shocks (3 to 15 joules) applied through a catheter inserted into the main chamber(s) of the heart.

Pharmacological Cardioversion – A method of converting and abnormally fast heart rate to a normal rhythm using medication that slows the heart rate.

Pulmonary Infarct – An area of damaged tissue in the lung typically as a result of a blood clot.