CAUTION: FEDERAL LAW (USA) RESTRICTS CARDIAC ARRHYTHMIA MANAGEMENT DEVICES TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.

Brief Summary: Please review the appropriate literature accompanying the device for a complete listing of warnings and precautions.

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Atrial fibrillation (also called AF or A Fib) is the most common abnormal heart rhythm, affecting about 5 million people worldwide. It is a very fast, uncontrolled rhythm caused when the upper chambers of the heart (the atria) quiver instead of beating in an organized manner. During AF, the atrial rate can jump to between 350 and 600 beats per minute (bpm). The lower chambers of the heart, the main pumping chambers or ventricles, do not beat this fast; however, they often beat much higher than a normal heart rate, which is between 60 and 100 bpm at rest.

When AF continues for a period of time, the physician will often prescribe medications to control the rate of the ventricles, while using other medications that attempt to terminate the AF and restore normal rhythm in the atrium.

What exactly happens during AF?

To understand AF, it is helpful to first understand how a healthy heart works.

The heart is a pump with four chambers: two small upper chambers called the atria (you have a right and a left atrium) and two larger, more powerful pumping chambers called ventricles (again you have a right and a left ventricle). In a healthy heart, blood is pumped efficiently through the body, controlled by a unique electrical system in the heart itself. The electrical impulse that begins each heartbeat originates from an area in the upper right side of the heart. This area is called the sinoatrial (SA) node, or the heart’s natural pacemaker. Once originated, an electrical impulse travels through the atria causing them to contract. Then it moves down a pathway to the ventricles, causing them to contract and move the blood out of the heart to the rest of the body.

Every normal heartbeat actually has four steps. When the atria contract, they squeeze (pump) blood into the ventricles. There is a very short pause (a fraction of a second) giving the blood time to move into the ventricles and then the ventricles contract, pumping blood to the body. Thus the four parts of each heartbeat include an atrial beat, a short pause, a ventricular beat, and another pause before the beginning of the next heartbeat. This last pause allows the blood that has returned to the heart and is being collected in the atrium to then enter and help fill the ventricle. For every atrial beat, there is a ventricular beat at a set time right afterward. This is called synchrony.

When a patient suffers from AF, there is an abnormality in the heart's electrical system; impulses are initiated in a chaotic and irregular manner from various locations in the atria, not in a regular manner from the SA node. This
is why there is a quivering effect in the atria, instead of an orderly pattern for each heartbeat. These multiple impulses compete with each other and send the upper chambers into a disorganized rhythm. Because there are so many impulses, the atria try to keep up by responding to all of them, resulting in this quivering called fibrillation.

It is not just the atria that are affected, however. The ventricles also beat irregularly and sometimes rapidly (but not as fast as the atria), so they do not pump blood as they should to the rest of your body. This is what can cause symptoms like shortness of breath and more. Over time, this irregularity in the ventricles can lead to other complications, such as heart failure, a progressively worsening condition in which (most typically) the ventricles do not beat efficiently.

What are the symptoms of AF?

The symptoms of AF include palpitations, irregular heartbeat, shortness of breath, chest discomfort, and dizziness. Many patients experience feelings of weakness, caused by the heart’s diminished pumping ability. The awareness of a rapid and/or irregular heartbeat also may cause some patients to feel quite anxious. Patients who have otherwise healthy hearts may be better able to tolerate AF. People with underlying heart disease are generally less able to tolerate AF without complication. Once AF becomes symptomatic, it becomes more serious as it indicates that the heart is failing to pump adequate amounts of blood to the body.

Can I have AF and not know it?

Sometimes, AF occurs, but its symptoms, such as fatigue or lack of energy, can be hard to discern. Because of this, the patient can dismiss them as the result of too little sleep the night before, or stress at home or at work. It has been estimated that up to 90 percent of AF episodes are asymptomatic.

What causes AF?

There is still much we do not know about the causes of AF; however, there are risk factors that can contribute to its onset. The prevalence of AF increases strikingly with advancing age. Less than one percent of men and women in the U.S. younger than 60 experience AF, whereas it occurs in about 1 out of every 10 adults over 80 years. Smoking, stimulants (including caffeine), high blood pressure, heart failure, heart valve disease, hyperthyroidism (too much thyroid hormone in the body), and other factors can increase the likelihood of AF.

(http://www.cdc.gov/dhdsp/library/fs_atrial_fibrillation.htm)
Is AF life-threatening?
AF, by itself, is not life-threatening, and it was once thought that AF was not even necessarily serious. More recently, however, studies have shown that AF may increase your risk of stroke or heart failure and decrease your quality of life.

How does AF increase my risk of stroke?
Because the pumping function of the upper chambers is not working properly, the blood is not completely emptied from the heart’s chambers, causing it to pool and sometimes clot. If part of a clot dislodges from inside the heart and moves to the brain or an artery, it can cause a stroke. A person with AF may be up to five times more likely to suffer a stroke than someone who does not have AF.

What can be done to help prevent stroke due to AF?
If it is discovered that you have episodes of AF that are recurrent and last for hours, if not days at a time, your doctor will most likely recommend blood thinners (anticoagulants). Blood thinners have been shown to significantly reduce the incidence of a stroke due to AF.

How does AF increase my risk of heart failure?
If the heart beats in a very rapid and disorganized way for a long period of time, the heart muscle may weaken. The weakened heart muscle can become enlarged, such that it is unable to pump efficiently, regardless of the rate. This condition is known as heart failure, and it refers to the progressive weakening of the heart muscle. People with AF are more likely to develop heart failure than people without AF.

Is all AF the same?
There are several types of AF. Paroxysmal AF is characterized by brief episodes of the arrhythmia, which can resolve by themselves. In persistent AF, the episodes require some form of intervention to return the heart rhythm back to normal. For those with permanent AF, normal rhythm cannot be restored. Instead, the focus becomes controlling the response of the heart’s ventricles to the AF. This is most commonly accomplished through medication.

How is AF treated?
There are a number of treatment options for AF, and there is no single way to treat AF that is right for everybody. Every patient is unique, as there are many causes of AF. You should discuss your treatment options with your doctor; however, there are a few standard approaches of which you should be aware. The first line of treatment usually involves medications, but there are other treatments that might be appropriate, including cardioversion, ablation, surgery and, more recently, implantation of a pacemaker to suppress AF by regulating the atrial rhythm. Sometimes a pacemaker is also implanted after certain ablation procedures to regulate the heart rate.
What medications might be used to manage my AF?

Many AF patients are successfully treated using cardiac drugs. Depending on your condition, your doctor may prescribe medications from up to three main categories:

- Those used to prevent the ventricular rate from becoming too fast and that may reduce symptoms; these are called beta blockers (like atenolol or metoprolol) and calcium channel blockers (like verapamil or diltiazem)
- Those used to help restore a normal heart rhythm (amiodarone, dronedarone, sotalol or dofetilide)
- Those used to “thin” the blood and reduce the risk of clot formation, called anticoagulants (such as Coumadin® or heparin); not all AF patients require blood thinners

There are many AF drugs on the market, so your physician is your best source of advice for the right medication for your condition. Because every patient is different, your doctor may have to prescribe different medications, or a combination of medications, in order to find the right one(s) that work best for you.

Be sure to follow your physician’s advice carefully for such medications, as there can be interactions with other medications or side effects that have no outward manifestations (such as issues with liver or kidney function). For this reason, your doctor might perform periodic blood tests and, if problems are identified, he or she might decide to change your medication regimen.

What is cardioversion?

The word cardioversion means to change an abnormal heart rate back to a normal one. Cardioversion can be done chemically through medication designed to restore normal rhythm, as mentioned previously, or through electricity. In electrical cardioversion, energy is applied to the heart to “jolt” it out of AF. It is typically used to treat cases of persistent or permanent AF, and it is often used with medication.

What happens during the cardioversion procedure?

There are two types of electrical cardioversion: external and internal. For both procedures, you will go to the hospital or clinic and you may be given some medication to help you relax.

For external cardioversion, two external patches will be placed on your chest, or one will be placed on your chest and the other on your back. An electrical shock is sent through the paddles and travels through your body to the heart.

Cardioversion shocks the heart out of AF and back into normal rhythm. External cardioversion is often effective at stopping an episode of AF, but it is possible that the AF will recur.

Internal cardioversion uses a similar approach, but instead of using patches on the outside of the body, a small wire, called a catheter, is inserted through a vein and maneuvered to your heart. The electrical energy is delivered through the catheter to the inside of the heart to stop the AF. Cardioversion does not prevent the arrhythmia from recurring. That is accomplished with medication, special pacing techniques, other ablation procedures or a combination of these therapies.
What is ablation?

Ablation is a technique—usually performed on an outpatient basis—that interrupts the abnormal electrical pathways in the heart that enable AF. Not all patients should have ablation. It is sometimes used on patients who did not respond to other therapies; however, every patient is unique, so you should discuss your treatment options with your physician. If your physician is not an electrophysiologist (a cardiologist who specializes in the electrical problems in the heart), he or she may refer you to an electrophysiologist for a second opinion as to how the AF should be best managed in your case.

What happens during the ablation procedure?

There are two types of ablation procedures used to restore sinus rhythm: surgical ablation and catheter ablation. Surgical ablation requires a general anesthetic. An incision is made in your chest so that your heart can be accessed. In traditional procedures, a precise pattern of incisions are made in the heart tissue and then sutured back together. The scar tissue created by these lesions provides a block in the abnormal pathway that contributes to the AF. Surgical ablation is most often performed if you have AF and also need another heart surgery, such as valve replacement or repair.

For catheter ablation, you will most likely receive some medication to help you relax, and a small incision is made (usually in your leg). A thin, flexible wire, called a catheter, is maneuvered until it enters your heart. The doctor then uses the catheter to burn (ablate) specific areas in the heart tissue, in essence damaging them and disrupting the electrical impulses contributing to AF.

Is it true that I will need a pacemaker after ablation?

There is another type of ablation procedure that is used to help control how the ventricles respond during AF. This is called an AV node ablation, and it generally requires the use of a pacemaker after the procedure. AV nodal ablation is usually used when medication is unsuccessful in restoring normal rhythm or in controlling the ventricular response to the AF. It involves ablating tissue at the AV node, specialized cardiac tissue that conducts electrical impulses from the atria to the ventricles, and is designed to act as a gatekeeper to prevent the ventricles from beating too fast in the presence of an abnormal atrial rhythm like AF. With AV nodal ablation, the goal is to stop the frequent atrial impulses from traveling down the normal pathway between the atria and the ventricles, thus driving the ventricles to rapid and persistent irregular rates. Because conduction may be disrupted, an implantable pacemaker is generally needed to help regulate your heartbeat.
In some cases, only a very small portion of tissue is ablated. These procedures are called focal catheter ablation or linear catheter ablation. Because only a small section of the atrium is affected, you may not need a pacemaker.

**How can a pacemaker or implantable cardioverter defibrillator (ICD) help my AF?**

Some pacemakers (used to treat slow or irregular rhythms) or ICDs (also used to treat dangerously fast rhythms) have special features, designed to help patients with AF. As with all AF management options, device-based therapy is monitored on a regular basis by your doctor.

**How do I know which treatment option is right for me?**

Every person is unique. Your doctor is your best resource for learning about the treatment options available to you and the best course for your condition. Talk to your doctor and follow his or her advice for your care. Remember that AF is a serious medical condition that progressively worsens and is associated with unpleasant symptoms and increased health risks. With proper care, however, AF is generally manageable, and those with AF live quality, productive lives.
My additional notes and questions: