# WATCHMAN DEVICE
## for Atrial Fibrillation

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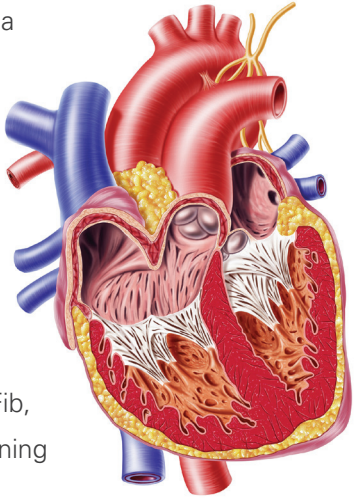
Atrial Fibrillation, or AFib, is a condition in which the heart beats irregularly. It is the most common form of heart rhythm problems, affecting an estimated 12.1 million people in the United States in 2030. Although the condition itself isn't life threatening, people who have AFib are at a greater risk of suffering a stroke.

## AFib and stroke risk

The heart has four chambers, or atria, and four valves that pump blood throughout the body. When the heart muscles contract, blood is pushed through the valves on the right side to the lungs to collect oxygen. The chamber on the left side receives the oxygen-rich blood from the lungs and pushes it into the aorta, the body's main artery, and then to the rest of the body.

When heart rhythm issues such as AFib occur, the pumping efficiency of the heart is decreased, and blood can pool inside the heart, specifically in an area called the left atrial appendage, a small space inside the left atrium that serves no known purpose. This pool of blood creates an ideal environment for blot clots to form, which may travel to the brain and cause a stroke.

One out of three people with AFib will have a stroke. Also, strokes that occur because of AFib are more frequently fatal or disabling.



AFib can be treated with medication, surgery, or by resetting the electrical impulses of the heart. However these treatments do not directly control the risk for stroke. In addition to treatment of AFib, most patients are also prescribed blood-thinning medication such as warfarin (also known as Coumadin) to control blood clots.

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## How can an AFib patient reduce the risk of stroke?

Today, a number of treatments are available to help protect AFib patients from stroke or related complications from blood clots. Appropriate treatments are chosen by the physician and patient based on the patient's heart rhythm, symptoms, stroke risk and any other medical conditions. Medications can reduce the risk of blood clots that could lead to stroke.

Medicines known as blood thinners, such as warfarin, affect the blood's ability to form clots. Blood thinners have been available for more than 50 years to reduce the risk of stroke in people with AFib and work well for many patients.

Newer medications such as Pradaxa, Xarelto, and Eliquis also lower the blood's ability to clot. These medicines have been proven to be effective and don't require the level of blood testing and diet restriction that warfarin does.

However, there are reasons why some patients do not take these medications. According to a report in the Journal of the American College of Cardiology (JACC), nearly half of AFib patients eligible for warfarin are untreated for their stroke risk due to tolerance and adherence issues.

## An alternative to blood thinners and anti-coagulants

Although blood-thinning medications are effective in preventing or dissolving blood clots, there can be issues with their use, including a chance of heavy bleeding, interactions with other medications, and frequent blood tests. There are also certain medical conditions that can prevent people from safely taking blood thinners.

WATCHMAN FX™

The WATCHMAN Device is a proven alternative to long-term warfarin therapy for stroke risk reduction in patients with non-valvular atrial fibrillation. It is implanted in the left atrial appendage to permanently close off this small pouch and to keep blood clots from entering the bloodstream.

By closing off the left atrial appendage—the source of more than 90% of stroke-causing blood clots that come from the heart in people with non-valvular AFib—the risk of stroke may be reduced and, over time, patients may be able to stop taking warfarin.

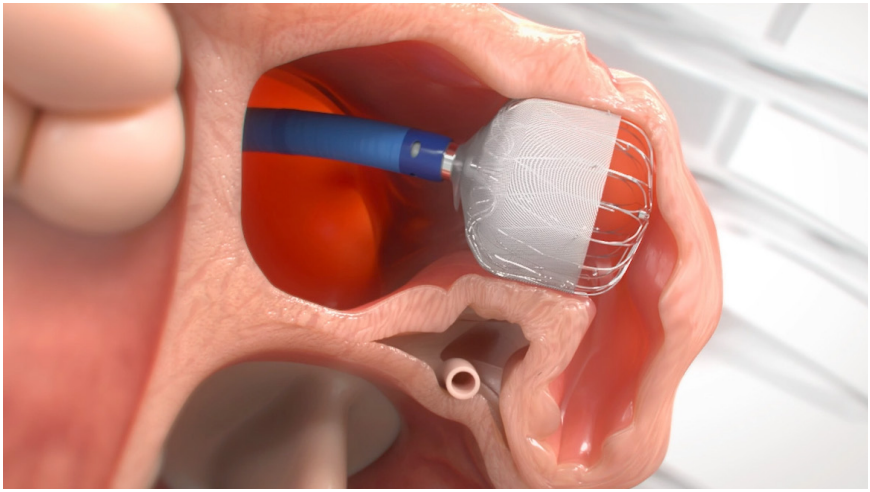
The WATCHMAN Device is designed to keep harmful blood clots from entering the blood stream, potentially causing a stroke.

In patients with AFib, more than 90% of stroke-causing blood clots that come from the heart originate in the left atrial appendage.

### WATCHMAN FLX™ Device

The next generation of innovation, the WATCHMAN FLX™, now expands to fit a wider range of patient valves, benefiting even more AFib patients. WATCHMAN FLX™ is a permanent implant that closes off a part of the heart where blood clots most commonly form and can cause strokes. This device effectively lowers the risk of bleeding associated with the long-term use of blood thinners. The procedure is completed within an hour and patients commonly stay in the hospital overnight and leave the next day.

A device called the WATCHMAN™ Left Atrial Appendage Closure (LAAC) was recently approved by the Food and Drug Administration (FDA) to help prevent strokes in patients with AFib. Implanting the WATCHMAN is done with a minimally invasive procedure through a vein in the patient's leg. It is a one-time procedure that does not require open-heart surgery and does not need to be replaced.



## The WATCHMAN procedure

The WATCHMAN Device doesn't require open-heart surgery and is typically performed under general anesthesia. You will have a breathing tube inserted, which will be removed prior to transferring you to the holding area for recovery.

Like in a stent procedure, the physician will make a small cut in the upper leg, insert a flexible tube (catheter) into a vein, and guide it into the right atrium of the heart. It will then cross from the right to the left side of the heart, where the WATCHMAN Device can be delivered into the left atrial appendage through the catheter.

Once WATCHMAN is in place, the physician will release the implant to permanently seal off the left atrial appendage and removes the catheter from the body. Over time, heart tissue will grow over the implant.

Because the left atrial appendage has no known purpose, permanently closing it off has no effect on the heart's ability to pump blood.

## AdventHealth's Expertise

AdventHealth cardiologists have extensive experience with the WATCHMAN device. In a recently published clinical trial, 96% of people were able to stop taking blood thinners just 45 days after the WATCHMAN procedure.

The FDA approved the use of device on March 13, 2015 and AdventHealth cardiologists performed Tampa Bay's first commercial implant of the WATCHMAN device that same year and in 2016 in Ocala. AdventHealth Ocala is the first in North Central Florida to successfully Implant the WATCHMAN FLX™ Device.

Currently, AdventHealth provides patients two different implants for closing off the left atrial appendage: WATCHMAN or FX.

## Are you a candidate for a Left Atrial Appendage Closure device?

If you answer yes to the questions below, the left atrial appendage closure device and WATCHMAN procedure may be the right choice for you:

Have you ever been diagnosed with atrial fibrillation not caused by a heart valve problem?

Are you currently taking or have you considered taking warfarin or other anticoagulant medication? (sold under brand names of Pradaxa, Eliquis, Xarelto, Savaysa, Jantoven or Coumadin)

Do you have a reason (bleeding, lifestyle, occupation or frequent falling) to look for a safe alternative to long-term use of a blood thinner that will provide a comparable reduction in risk of stroke?

If you did answer yes to these questions, you may be a candidate for the WATCHMAN procedure and should consult your AdventHealth cardiologist.

## How effective is the WATCHMAN?

The WATCHMAN Device was studied in two randomized clinical trials and several clinical registries that include more than 2,400 patients. It has been approved in Europe since 2005 and is FDA-approved in the United States. The device has been implanted in more than 10,000 patients worldwide.

Compared to warfarin, the WATCHMAN Device is comparable in the reduction of stroke risk, and has shown 85% reduction in hemorrhagic stroke, 63% reduction in disabling stroke, and 56% reduction in cardiovascular death. Patients treated with the WATCHMAN therapy had a 71% relative reduction in major bleeding after six months compared to patients treated with warfarin.

After 45 days, most patients were able to stop taking warfarin, and over 96% were off of warfarin at one year.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