

A Patient's Guide to WATCHMAN[®] Left Atrial Appendage Closure

What is the left atrial appendage?



The *left atrial appendage (LAA)* is a pouch-like extension of the left atrium (a chamber of the heart). The LAA is about the size of a thumb and has a narrow opening into the left atrium. In patients with *atrial fibrillation* (defined below), blood tends to pool and form clots in this appendageⁱ. A blood clot (thrombus) that breaks loose (embolus) may travel through the blood vessels and eventually plug a smaller vessel in the brain or heart. The result may be pain, heart attack, or *stroke*.

Studies in humans show that about 90% of all blood clots in patients with atrial fibrillation (AF) are found in the LAAⁱⁱ. Clot formation likely occurs because of abnormal blood flow and the tendency of the blood to pool or collect within the muscle ridges of the appendage.

What is atrial fibrillation and how is it usually treated?

Atrial fibrillation is the irregular beating of the right and left *atria*, the upper chambers of the heart. In AF, the heart gives off electrical impulses so fast that the atrial muscle quivers or fibrillates. Episodes of AF may last a few minutes or several days.

The symptoms of AF vary from mild tiredness to dizziness to chest pain or difficulty breathing. Some patients feel their heart palpitating (racing or beating very fast); others are unaware of the change in their heart rate. AF can be caused by medical conditions such as coronary artery disease, high blood pressure, or an overactive thyroid. Sometimes there is no identifiable cause of AF.

Atrial fibrillation is not itself life-threatening but can lead to life-threatening problems. Treatment depends on patient symptoms and the underlying medical conditions. It may include anti-arrhythmic drugs to stabilize the heart rate, electrical cardioversion (shock) to restore the normal heart rhythm, or surgery to isolate (block off) the electrical circuit that causes an AF episode.

The most serious risk from AF is *thromboembolic stroke*. The American Heart Association (AHA) estimates that up to 15-20% of all strokes are related to AFⁱⁱⁱ. Most AF patients, regardless of how serious the symptoms or frequency of episodes, require treatment to reduce the risk of stroke.

How do physicians treat the stroke risk in patients with atrial fibrillation?

Current guidelines recommend *anticoagulation* with warfarin (Coumadin[®]) to thin the blood and delay clotting (coagulation) in patients with AF. A test called the *International Normalized Ratio (INR)* is used to assess the time it takes for the blood to clot and to determine the correct dose of warfarin. Too high a dose increases the risk of bleeding. Too low a dose increases the risk of clotting. Because the correct warfarin dose may change over time, it's important to test the INR at regular intervals.

In some patients, the level of warfarin is difficult to control. In others, the side effects of warfarin are not well tolerated. Physicians may consider alternatives to the long-term use of warfarin. One alternative is WATCHMAN LAA closure.

Note: *Antiplatelets* such as aspirin and clopidigrel (Plavix®) can increase the effect of anticoagulation by preventing blood cells from clumping together. Antiplatelets alone are not enough to reduce the stroke risk in AF patients.

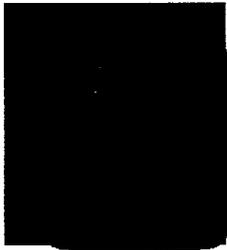
What is the WATCHMAN?



The WATCHMAN is a small, fabric-covered device permanently placed in the opening of the LAA. It prevents harmful-sized blood clots from exiting the LAA and entering the bloodstream. The WATCHMAN may reduce the risk of a stroke caused by a blood clot and eliminate the need for long-term warfarin. It is made of materials well-tolerated by most patients.

The WATCHMAN device is intended for patients with non-valvular AF, who require treatment for potential blood clotting and can take warfarin therapy. It is not suitable for patients who are unable to tolerate warfarin, aspirin, or clopidigrel.

What's involved in left atrial appendage closure with the WATCHMAN?



WATCHMAN LAA closure is performed under local or general anesthesia in the catheterization laboratory (cath lab) of the hospital. The heart is reached through a hole made in the *femoral vein* in the upper thigh. The WATCHMAN is delivered to the LAA through a *catheter* (long tube) under fluoroscopic (x-ray) and echo (ultrasound) guidance. The procedure is monitored by trained medical staff who are prepared to respond if there is a complication or emergency.

WATCHMAN LAA closure takes about an hour and requires an overnight hospital stay. Recovery from the procedure usually takes 24 to 48 hours.

Before the procedure: Transesophageal echo (TEE) images are used to evaluate the shape and size of your LAA, confirm your eligibility for LAA closure, and select the proper device size for your LAA anatomy. To acquire a TEE image, the *sonographer* inserts a flexible instrument, called an ultrasound probe (sensor), through your mouth and throat and into your esophagus. Because the probe is placed near your heart, TEE provides clear images of the heart chambers and the LAA.



One day before surgery, your warfarin dose will be adjusted and you'll be asked to take an aspirin. You'll be given specific instructions on food and liquid intake prior to the procedure.

During the procedure: The catheter insertion site in your upper thigh will be cleaned, shaved, and covered with sterile drapes. The physician will insert a needle into your femoral vein, introduce the

WATCHMAN delivery catheter, and guide it through the left atrium and into the LAA. TEE images are used to confirm the position, stability, and seal of the WATCHMAN before the delivery catheter is removed. Intravenous (IV) *heparin*, a fast acting anticoagulant, is used to keep the appropriate blood clotting time throughout the procedure.

After the procedure: It takes at least 45 days for the heart tissue to heal. During that time, it's important to continue taking warfarin and a daily aspirin. Your physician may also prescribe an antibiotic to prevent infection after surgery. INR monitoring will continue at weekly intervals until the 45-day follow-up visit.

At 45-days, TEE images will be used to check the WATCHMAN device. At this time your physician may stop warfarin and prescribe clopidogrel. At six months, your physician may stop clopidogrel. Because you have AF, you'll likely remain on aspirin indefinitely.



What are the risks of WATCHMAN LAA closure?

Studies in humans show that the WATCHMAN device can be safely implanted. Certain risks, however, are associated with the procedure and placement of the WATCHMAN device. The risks include an accidental heart puncture causing fluid collection in the heart sac (pericardial effusion) which may lead to increased pressure in the heart sac (tamponade), bruising (hematoma) or fluid collection (seroma) at the catheter insertion site, bleeding or throat pain from the TEE probe, stroke or transient ischemic attack (TIA), clot formation on the WATCHMAN device, allergic reaction to the contrast dye, anesthetic, WATCHMAN material, or surgical equipment, irregular heartbeats, a blood clot or air bubbles in the lungs or other organs, device misplacement, or death.

Although studies show that WATCHMAN LAA closure may reduce the stroke risk in AF patients, there is no guarantee that WATCHMAN therapy will benefit all eligible patients.

MR Conditional

The WATCHMAN is *MR conditional*. This means you can safely undergo an MRI scan after WATCHMAN device placement. More information about MRI scans can be found at www.atritech.net

Glossary

Antiarrhythmic Drug used to prevent or correct a heart rhythm disturbance such as atrial fibrillation.

Anticoagulant Drug used to delay blood clotting or prevent clots from becoming larger. Warfarin (Coumadin®) is an oral anticoagulant (pill). Heparin is injected into a vein (IV tube).

Antiplatelet Drug used to prevent platelets (blood cells) from binding together to form blood clots. Aspirin and clopidogrel (Plavix) are antiplatelets.

Atria Upper right and left chambers of the heart.

Atrial fibrillation Heart rhythm disturbance characterized by the rapid, irregular beating of the left and right atria.

Biocompatible Posing little risk to living cells, tissues, or organs.

Catheter Flexible tube inserted into a body cavity or blood vessel for diagnosis or treatment.

Catheterization laboratory (cath lab) Examination room in a hospital or clinic equipped to support catheterization procedures such as WATCHMAN LAA closure.

Coumadin® Brand name for the anticoagulant, warfarin, manufactured by Bristol Myers Squibb.

Echocardiography (echo) Medical imaging technique that uses ultrasound energy and the acoustic (sound) properties of heart tissue to produce real-time images in multiple planes. *See also* transesophageal echo (TEE) and transthoracic echo (TTE).

Embolus Blood clot (thrombus) that breaks loose from the site of formation and circulates through the bloodstream until it plugs a small blood vessel and obstructs blood flow (oxygen delivery).

Femoral vein Largest vein in the groin at the junction of the legs and torso (upper body).

Fluoroscopy (fluoro) Medical imaging method that uses x-rays to acquire real-time images of motion. Fluoro is used in procedures that require immediate feedback, for example, catheter placement.

Hematoma Blood trapped in skin or organ tissue and existing as a bruise.

International normalized ratio (INR) Mathematical standard used to evaluate the time it takes for blood to clot and determine the effective warfarin dose in patients at risk for stroke.

Ischemia Pain caused by insufficient blood flow (oxygen delivery) to an organ. *See also* transient ischemic attack (TIA).

Left atrial appendage (LAA) Small pouch-like structure that arises from the left wall of the left atrium. The LAA is lined with muscle ridges that tend to collect blood in the presence of abnormal blood flow. In patients with atrial fibrillation (AF), blood clot formation in the LAA is common.

Magnetic resonance imaging (MRI) Medical imaging method that uses radio waves and a stable magnetic field to obtain images.

Pericardial effusion Increased fluid within the pericardial (heart) sac.

Seroma Pocket of clear fluid that sometimes develops after surgery.

Sonographer Health care professional with special training in the use of ultrasound equipment.

Stroke Rapid loss of brain function due to insufficient blood flow (oxygen delivery) to brain tissue, usually associated with complete obstruction of a blood vessel. The result may be weakness, speech defects, paralysis, or death.

Tamponade Compression of the heart sac caused by an accumulation of fluid that requires treatment.

Thromboembolic stroke Disruption of the blood supply to the brain caused by an embolus. Also called cerebrovascular accident (CVA).

Thrombus Blood clot that forms in a blood vessel or heart chamber. *See also* embolus.

Transesophageal echo (TEE) Echo imaging method in which an ultrasound probe is positioned in the esophagus to acquire heart images without interference from the ribs, chest wall, and lungs.

Transient ischemic attack (TIA) Temporary episode of insufficient blood flow to the brain, usually associated with partial obstruction of a blood vessel. Transient (temporary) symptoms include numbness or tingling, blurred vision, or impaired speech. Also called mini-stroke.

Transthoracic echo (TTE) Echo imaging method in which an ultrasound transducer is placed on the patient's chest and rotated or tilted to acquire heart images in various planes.

X-ray Form of electromagnetic radiation used primarily for diagnostic imaging.

Additional Resources

American Heart Association website. Available at <http://www.americanheart.org>. Accessed December 30, 2008.

American Stroke Association website. Available at <http://www.strokeassociation.org>. Accessed December 30, 2008.

Atritech website. Available at <http://www.atritech.net>. Accessed December 30, 2008.

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ML#### Rev. ## Month/Year

ⁱ Halperin JL, Gomberg-Maitland M. Obliteration of the LAA for Prevention of Thromboembolism, *J AM Coll Cardiol.* 2003(42): 1259-1261

ⁱⁱ Onalan O, Crystal E. Left Atrial Appendage Exclusion for Stroke Prevention in Patients with Nonrheumatic Atrial Fibrillation, *Stroke* 2007(38): 624

ⁱⁱⁱ Fuster Valentin MD PhD. Co-chair ACC/AHA/ESC Guidelines Writing Committee and Professor of Medicine and Director of the Mount Sinai Cardiovascular Institute in New York.