

Stroke Prevention by Occlusion of the Left Atrial Appendage

What is Atrial Fibrillation?

Atrial fibrillation is the most common heart rhythm disturbance, affecting over 2 million individuals in the United States. A normal heart rhythm is regulated by sequential electrical activity in the heart from the natural pacemaker (sinoatrial node) in the upper chambers (atria) to the main pumping chambers (ventricles) through a specialized conduction system. In atrial fibrillation, a more chaotic and disorganized electrical activity replaces the normal regular rhythm. The electrical activity through the conduction system to the ventricles occurs normally, though activations occur irregularly often resulting in a rapid and irregular heart rhythm. Atrial fibrillation can be asymptomatic, or cause symptoms like chest palpitations, shortness of breath, exercise intolerance and lightheadedness.

Did you know atrial fibrillation is associated with stroke?

A stroke is the most feared complication of atrial fibrillation. When the atria are fibrillating, blood may stagnate in parts of the atria, often in a structure known as the left atrial appendage. The left atrial appendage (LAA) is a small structure of the heart originating in the left atrium. This structure is responsible for excreting hormones and normally contracts with each heartbeat allowing blood to move freely in and out of the appendage. Atrial fibrillation or low left atrial appendage velocities cause sluggish blood flow inside the appendage. Sluggish blood flow results in blood pooling and the formation of blood clots. These clots can break loose and are the cause of 90% of all strokes in patients with non-valvular atrial fibrillation. Young patients who are otherwise healthy have a low risk of blood clots and stroke, but the risk increases in older patients especially those with conditions such as high blood pressure, diabetes mellitus, heart failure and prior strokes.

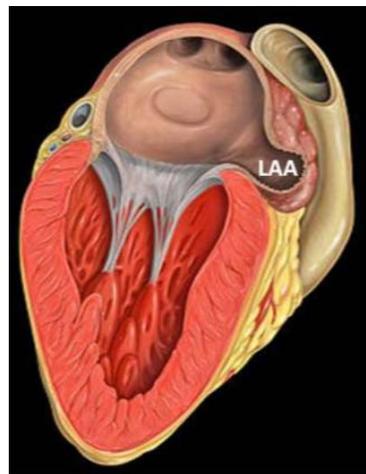


Illustration of left atrial appendage

How can you reduce your risk of stroke?

Various options are available for eligible patients to reduce the risk of atrial fibrillation related strokes. Blood thinners like warfarin, apixaban, dabigatran, rivaroxaban and edoxaban may be considered. Your doctor will help you choose the correct treatment based on your individual risk of stroke and other medical conditions.

Despite the excellent record of blood thinners like warfarin in preventing strokes in patients with atrial fibrillation, there are circumstances when blood thinners may not be suitable. These may include a prior major bleeding event or an unacceptable risk of bleeding with blood thinners. In such situations mechanical exclusion of the left atrial appendage from the blood circulation offers an alternative strategy for stroke prevention. This can be performed non-surgically with use of flexible tubes (catheters) introduced through tiny punctures in the skin. There are two approaches to exclusion of the left atrial appendage: The Watchman Implant™ and The Lariat Procedure™ .

What is Watchman?

The Watchman Implant™ (Boston Scientific) is an alternative for patients with a valid reason to not take long-term blood thinners to reduce risk of atrial fibrillation related stroke.⁴ It is a device designed to occlude the left atrial appendage and keep stroke causing blood clots from entering your blood stream. It is made of materials that are common to many medical devices, is about the size of a quarter and cannot be seen outside the body.

The Watchman Implant was studied in two randomized clinical trials and several clinical registries that include more than 2,400 patients. The Watchman Implant has been approved in Europe since 2005 and is FDA-approved in the United States.⁶ It has been implanted in more than 10,000 patients around the world.



Watchman™ Device

How is the Watchman device implanted?

A Watchman is a one-time implant typically performed under general anesthesia. Similar to a stent procedure, your doctor will guide the Watchman device into your heart through a flexible catheter inserted through a vein in your upper leg. The implant does not require open heart surgery and does not need to be replaced.

Your doctor will cross from the right side of the heart to the left side of the heart. Once the position is confirmed, your doctor will release the implant to leave it permanently fixed in your heart. You would then need to stay in the hospital overnight and recovery typically takes about twenty-four hours. After a few months, you may be able to stop taking your warfarin (blood thinner).



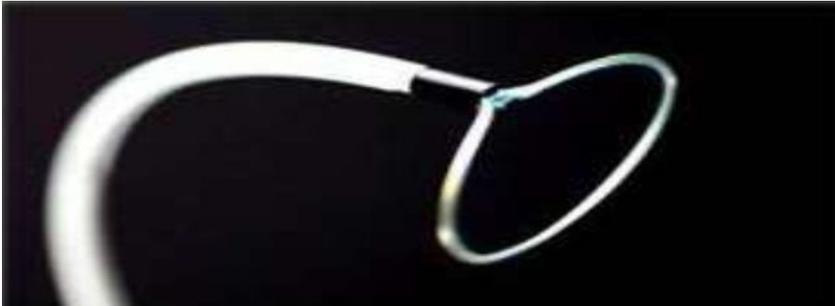
What are the potential risks and complications of the Watchman Implant?

Any invasive procedure is associated with risks of unintended complications. Risks with Watchman implant include:

- Bleeding
 - In the sac around the heart (which could require surgery)
 - At the access site in the upper leg
- Cardiac tamponade (external compression of the heart by blood in the heart sac)
- Stroke
- Heart attack
- Pericarditis (inflammation around the heart)
- Infection
- Inability to place the Watchman device
- Ineffective occlusion of the left atrial appendage due to residual leak around the Watchman Implant
- Dislodgement of the Watchman device

What is the Lariat procedure?

The Lariat is a device that is used to suture the left atrial appendage closed in patients who are at risk for developing clots in the left atrial appendage. The Lariat is made by SentreHEART, Inc., in Redwood City, CA. The device was approved by the U.S. Food & Drug Association (FDA) in 2009.



LARIAT device (image courtesy of SentreHEART, Inc.)

The procedure is done in the Cardiovascular Procedure Center (CPC) under sterile conditions using fluoroscopy and trans-esophageal echocardiogram (TEE) guidance

The procedure takes approximately two hours and is done with the patient under general anesthesia

How is the Lariat device implanted?

The Lariat procedure involves two small puncture sites: right groin and under the breastbone (sub-xiphoid). The design of this instrument includes two magnetically tipped guide wires (endocardial and epicardial), a suture delivery system and an endocardial balloon.

- Epicardial: The epicardial catheter is inserted just below the xiphoid process, through the pericardial sac and advanced to the left atrial appendage. This is the lasso portion of the device
- Endocardial: The endocardial catheter and balloon are inserted in the right groin and are advanced to the right atrium. The catheter is then passed transseptal to the left atrium.

The magnetic wire tip within the left atrial appendage (endocardial) attracts the magnet wire tip in the lasso device that is on the outside of the heart (epicardial), allowing the

Lariat suture loop to be advanced over the appendage. The balloon is inflated and utilized to confirm position. The endocardial catheter and balloon are removed from the left atrial appendage just prior to deployment of the suture. The lasso suture knot is then tightened around the base of the appendage. Once sutured off, the appendage will over time shrink into scar tissue.

What are the potential risks and complications of the Lariat Procedure?

Bleeding: pericardial or femoral (which could require surgery)
Cardiac tamponade
Blood transfusion
Heart attack
Stroke
Infection
Pericarditis
Pain

Inability to place the Lariat device
Failure to close the left atrial appendage

What is the best strategy for your atrial fibrillation?

Every person with atrial fibrillation has different needs. If you've been diagnosed with atrial fibrillation, talk with your doctor about treatment options available to you. The Washington University cardiovascular specialists in electrophysiology will help you understand the risks associated with each option. *Together we can choose the treatment that is right for you.*

To seek further advice on whether or not occlusion of the left atrial appendage is appropriate for you, please schedule an appointment with Dr. Amit Noheria at (314) 362-1291.