WATCHMAN®
Left Atrial Appendage Closure Device

Patient Information Guide

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PATIENT INFORMATION GUIDE

Your doctor has recommended that you consider undergoing a procedure to receive the WATCHMAN Implant or you have recently had a WATCHMAN Implant procedure in a part of your heart called the left atrial appendage (LAA). The following information about the WATCHMAN Implant is important for you to know and will address many of the common questions you may have about your implant.

UNDERSTANDING YOUR HEART

This section will discuss the basic function of the normal heart and will also explain what happens when the heart develops the condition known as atrial fibrillation.

The Normal Heart

The heart is divided into four chambers: two upper atrial chambers (a right and left atrium) and two lower ventricular chambers (a right and left ventricle). The four chambers fill with blood when the heart is at rest and then pump the blood throughout the body with each heart beat (or contraction).

The heart has specialized cells which produce electrical impulses that stimulate the heart muscle cells to beat and pump blood. Normally, your heart's pumping rate is controlled by the heart's internal pacemaker that is located in the upper portion of the right atrium. The heart beat spreads throughout both the right atrium and left atrium and then travels through special pathways to both the right and left ventricles. This electrical stimulation causes the heart muscle to contract and pump blood through the blood vessels. The heart then rests and fills with blood until the next contraction occurs. This cycle occurs millions of times in a year.

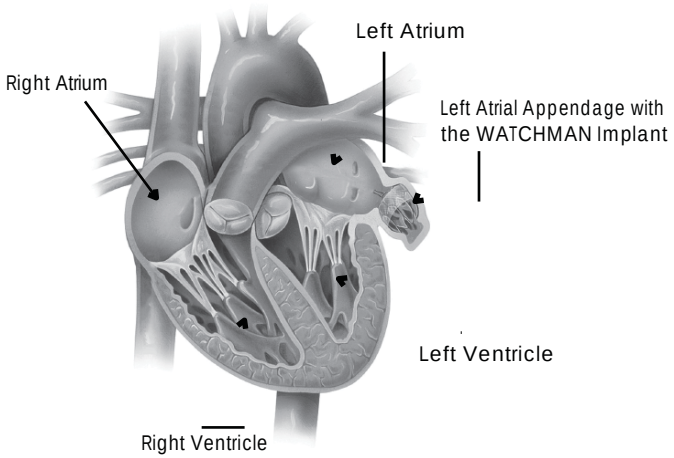
Atrial Fibrillation

In atrial fibrillation, the right and left atria no longer contract together in a coordinated fashion and the heart beat (pulse) becomes irregular. Atrial fibrillation can cause you to have symptoms such as feeling tired (fatigue), lightheaded, short of breath, or have a fluttering sensation in your chest (palpitations). It is also possible that you may have no symptoms.

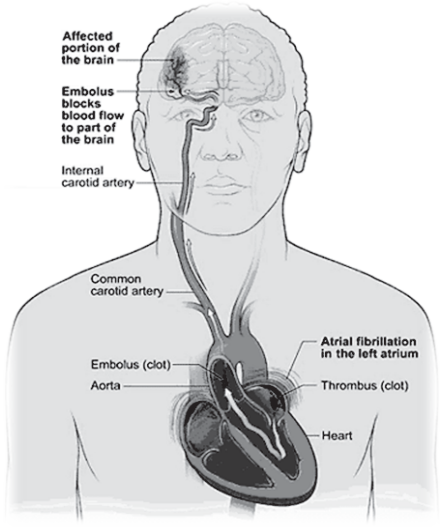
Doctors often prescribe medications to prevent the pulse rate from getting too fast. These medications typically help patients feel well and able to do normal activities despite having atrial fibrillation. However, despite taking these medications (or trying these medications) some patients still feel poorly due to atrial fibrillation and require additional medications or special heart procedures (known as cardioversion and ablation) to try to stop atrial fibrillation altogether and keep the heart in a normal rhythm.

Atrial Fibrillation, Heart Blood Clots, and the Risk of Stroke

Because right and left atria no longer contract normally in atrial fibrillation, the blood flow within the atria can be slower than normal. This change in blood flow may also cause blood clots to form. During atrial fibrillation, most blood clots that originate in the heart develop in the left atrial appendage, which is a pouch-like structure that is part of the left atrium.



A blood clot is called a "thrombus" when it stays in one place, and if it breaks loose and travels to another part of the body, it is then called a "thromboembolus." A thromboembolus can be dangerous if it blocks a blood vessel that supplies blood to an important body part. If a thromboembolus breaks loose from the left atrial appendage and blocks a blood vessel in the brain, the part of the brain that is supplied by that blood vessel can become permanently damaged within minutes. This type of brain damage is known as a stroke. A stroke can result in the loss of a body function, weakness, a change in sensation, problems speaking, or even death. Besides the brain, a thromboembolus can travel to other areas of the body and cause organ damage by blocking blood flow.



Not all atrial fibrillation patients are at equal risk for developing left atrial appendage blood clots and stroke. Factors that increase the risk include advancing age (particularly ages greater than 75 years), high blood pressure, heart failure, diabetes, other cardiovascular (heart) disease, and a prior stroke or mini-stroke ("transient ischemic attack" or TIA).

Current Treatment to Prevent Stroke in Atrial Fibrillation Patients

The current treatment for atrial fibrillation patients who are at increased risk for stroke is treatment with blood-thinning medications called **anticoagulants**, which reduce the chance that blood clots form. These medications (which include warfarin/Coumadin™, Pradaxa™, Xarelto™, Eliquis™, Savaysa™) are effective and recommended in lowering the risk of stroke in atrial fibrillation patients. Most patients can safely take these medications for years (and even decades) without serious side effects.

However, some patients find that anticoagulants can be difficult to tolerate or risky. Because they prevent blood clots by thinning the blood, anticoagulants can increase the risk of bleeding problems. When bleeding events occur, the events are often minor (like a skin cut taking longer to stop bleeding than normal) and easily treated. But in some cases, bleeding can be quite serious requiring hospitalization and transfusion and can even be life-threatening or fatal (such as when strokes are caused by bleeding into the brain).

When prescribing anticoagulant medications in atrial fibrillation patients, doctors consider the risk of a stroke versus the risk of a serious bleeding problem. In studies of atrial fibrillation patients, the *benefit* of a reduced risk of stroke caused by a blood clot traveling from the left atrial appendage is greater than the *risk* of major bleeding (including strokes caused by bleeding into the brain). This means that more strokes are prevented by anticoagulant medications than are caused by anticoagulant medications. Therefore, anticoagulant medications are recommended for most patients. However, in select patients, the risk of major bleeding is believed to be too high, so that anticoagulants will not be prescribed. Other atrial fibrillation patients, even though they may be able to take anticoagulant medications without major bleeding, may choose not to take the medication because of minor bleeding episodes, other medication side effects, or concerns about bleeding due to trauma.

Treatment with the WATCHMAN® Implant to Prevent Stroke in Atrial Fibrillation Patients

Your doctor has prescribed the WATCHMAN Implant for you because you have atrial fibrillation without significant heart valve disease, but with other risk factors that put you at an increased risk of stroke. Although you may take an anticoagulant (blood thinning medication) to reduce the risk of stroke, your doctor has recommended that you undergo implantation of the WATCHMAN Implant as an alternative to long-term use of this drug. In making this recommendation, your doctor has considered the benefits and risks of the WATCHMAN Implant compared to the benefits and risks of approved anticoagulant medication that are used to reduce the risk of stroke in atrial fibrillation patients.

Among the factors you and your doctor may consider are your overall risk of stroke, your risk of stroke caused by a blockage of a blood vessel in the brain, and your risk of a major bleeding problem (including bleeding in the brain) while taking anticoagulant medications. In the case of preventing a stroke caused by a blockage of a blood vessel in the brain, anticoagulant medications may be better than the WATCHMAN Implant. On the other hand, anticoagulant medications increase the risk of major bleeding episodes (including bleeding in the brain), and anticoagulant medications can usually be stopped about 6 weeks after successful placement of the WATCHMAN Implant in your heart, provided the left atrial appendage has been adequately sealed. Your doctor will also consider your personal preferences regarding anticoagulant medications and heart procedures associated with implanting and monitoring the WATCHMAN Implant.

When a blood clot develops in the heart of a patient with atrial fibrillation, it is most often found within the left atrial appendage. The WATCHMAN Implant acts as a barrier to prevent left atrial appendage blood clots from entering the bloodstream and blocking a blood vessel in the brain resulting in a stroke. However, it is important for you to know that a stroke can be due to factors not related to a clot traveling to the brain from the left atrial appendage. Other causes of stroke can include high blood pressure and narrowing of the blood vessels to the brain. The WATCHMAN Implant will *not* prevent these other causes of stroke.

It is also important for you to understand that, like anticoagulant medications, the WATCHMAN Implant does not cure atrial fibrillation.

Be sure to discuss your specific situation with your doctor as you consider all options to reduce your risk of stroke.

Patients Who Should Not be Considered for the WATCHMAN Implant

A patient with atrial fibrillation who currently has a blood clot in the heart should not receive a WATCHMAN Implant until the blood clot is successfully treated with blood thinning medications. Patients who have had an atrial septal repair or closure device should not receive the WATCHMAN Implant. Other patients who should not receive the implant include:

- Patients with a left atrial appendage that is too large or too small to fit the WATCHMAN Implant.
- Patients who cannot take anticoagulants, aspirin, or clopidogrel.
- Patients who should not or cannot undergo heart catheterization procedures.
- Patients who have an allergy or sensitivity to nitinol (nickel and titanium) or any of the other materials in the WATCHMAN Implant.

Additionally, due to the upfront risk of undergoing an invasive heart procedure, patients should not be considered for the WATCHMAN Implant if they are doing well and anticipate continuing to do well with anticoagulant medications. In general, a WATCHMAN Implant is not appropriate for those patients for whom the risk of the implantation procedure is expected to exceed the benefit from receiving the implant. The WATCHMAN Implant is not recommended in patients whose atrial fibrillation is due to significant heart valve disease.

WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE DEVICE

The WATCHMAN Left Atrial Appendage Closure Device is implanted at the opening of the left atrial appendage and is intended to prevent left atrial appendage blood clots from entering your blood stream and potentially causing a stroke. It is made of materials that are common to many medical devices. The implant is designed to be a one-time implant that does not need to be replaced.

Information to Consider Prior to your WATCHMAN® Implant

Before the WATCHMAN Device is implanted, your doctor will perform a thorough assessment. He/she will ask you about your medical history, assess your stroke risk, perform a physical examination, and take pictures of your heart based on your circumstances using appropriate techniques. A thrombus inside your heart may be detected. A patient with atrial fibrillation who currently has a thrombus within the heart should not be considered for a WATCHMAN Implant until the thrombus goes away after a course of blood thinners.

Your doctor will provide specific instructions on what medications to take, such as anticoagulant medications and aspirin. Be sure to discuss any medication changes with your doctor.

Implanting the WATCHMAN Implant

The WATCHMAN Implant is placed into your heart using a minimally invasive procedure in a cardiac catheterization laboratory or electrophysiology laboratory by a physician and his/her team who have experience and training in the WATCHMAN implantation technique. In preparation for the implant, you will be lying on your back on a table while you are continuously monitored throughout the procedure by medical personnel. X-rays and echocardiograms (a special type of ultrasound picture) will be used to help visualize the heart while the implant is being advanced into the correct position in your heart. Contrast media will also be injected to help guide the implant placement. You will be given a general and/or local anesthetic by your doctor to minimize any discomfort during the procedure. Discuss the anesthesia method that is best for you with your physician.

A small puncture is made into a vein in your groin. A long, thin tube, called a catheter, is inserted into the vein and advanced into the right atrium of the heart. Another puncture is made through a thin muscle wall between the right atrium and the left atrium so that the catheter can be advanced into the left atrium. A thinner catheter is then advanced into the left atrial appendage under X-ray guidance. The WATCHMAN Implant is tightly compressed within the catheter and is passed through the catheter into the left atrial appendage. Once the WATCHMAN Implant is in the right place, the doctor will then deploy the implant which will expand and seal the left atrial appendage. After the procedure, the WATCHMAN Implant is the only material that remains in the body. A thin layer of tissue will grow over the surface of the WATCHMAN Implant within about 45 days.

After the Procedure

After WATCHMAN is implanted, you will rest in the hospital where you will be monitored during your recovery from the procedure. It may be one or more days before you are discharged home, and your doctor will determine how long you need to be in the hospital.

Your doctor will instruct you to take anticoagulation therapy and aspirin after your implant. After your WATCHMAN Implant has been in place for a minimum of 45 days, your doctor will take pictures of your heart by means of a test called a TEE (transesophageal echocardiogram) to determine if the implant has closed the opening of the left atrial appendage. Your doctor ***may*** stop your anticoagulation therapy medication at that time, depending on the result of this test. If your doctor chooses to stop your anticoagulant, he/she will prescribe a second antiplatelet medication (such as Plavix™, Effient™ or Brilinta™) until 6 months after your implant procedure, and your aspirin dose may increase.

At about 12 months after your WATCHMAN Implant, your doctor will schedule another TEE to check on the device and make sure that your LAA is still closed.

If the TEE that is performed at around 45 days shows that the opening of the left atrial appendage is not adequately closed, another TEE may be scheduled at around 6 months to re-evaluate whether adequate closure of the left atrial appendage has occurred.

It is extremely important for you to take the recommended medications (anticoagulant, antiplatelet medication, and aspirin) at the recommended time. If you stop taking these medications or change their dosage before being instructed to do so by your doctor, the chances of blood clot formation, subsequent stroke, or even death are increased. Talk to your doctor before stopping your medications or changing the dosage.

If surgery or dental work is needed which would require you to stop taking these medications prematurely, you and your doctors should carefully consider the risks and benefits of this additional surgery or dental work versus the possible risks from stopping these medications early. Talk to your doctor about the timing of any medical procedures you may need.

If you do require premature discontinuation of these medications because of significant bleeding, your doctor will carefully monitor you for possible complications. Once your condition has stabilized, your doctor may restart these medications. Talk to your doctor before restarting medications or changing their doses.

CLINICAL STUDIES

The potential benefits of the WATCHMAN Implant for a patient with atrial fibrillation without heart valve disease are as follows:

- Reducing the risk of stroke from a blood clot originating in the left atrial appendage
- Being able to stop long-term anticoagulation therapy and a reduction in the risks associated with long-term anticoagulation use

In the PROTECT AF study, which lasted five years and studied 707 atrial fibrillation patients, the WATCHMAN Implant was compared to warfarin. The WATCHMAN Implant was found to be as effective as warfarin in reducing the risk of the combination of stroke (either from a blocked vessel or bleeding within the brain), cardiovascular death, or a blocked blood vessel in another part of the body besides the brain. A second study of the WATCHMAN Implant compared to warfarin called the PREVAIL study enrolled 407 atrial fibrillation patients. The PREVAIL study has lasted 5 years. In the PREVAIL study, the combined rate of stroke, death, and a blocked blood vessel in a part of the body outside of the brain in patients treated with the WATCHMAN Implant were generally similar to what was seen in PROTECT AF. In this study, it could *not* be concluded that the combined outcomes in the WATCHMAN patients were as good as warfarin, however, the ischemic stroke protection was found to be as good as warfarin.

Overall, the two clinical studies (PROTECT AF and PREVAIL) suggested that warfarin was better than the WATCHMAN Implant in preventing *strokes caused by a blocked blood vessel in the brain*, but the WATCHMAN Implant was better than warfarin in terms of the number of *strokes caused by bleeding into the brain*. In making treatment recommendations, doctors should consider the benefits and risks of anticoagulant medications and the WATCHMAN Implant for each individual patient, including the chance that either kind of stroke (a stroke caused by a blocked blood vessel or a stroke caused by bleeding) might occur.

The PREVAIL study also tested a new training program that was designed for doctors who had not previously performed a WATCHMAN Implant. The PREVAIL

study found that these new operators could safely implant the WATCHMAN Implant. Two more studies of 566 and 576 patients called the CAP and CAP2 Registries also confirmed that the WATCHMAN® Implant could be implanted successfully and safely.

The PINNACLE FLX study was designed to assess the safety and effectiveness of the next generation WATCHMAN device, WATCHMAN FLX, in 400 patients. After receiving the WATCHMAN FLX, patients took non-warfarin anticoagulants. The new device was designed to improve the implant procedure and device sealing, allowing more patients to come off lifelong OAC. The results of the PINNACLE FLX trial show a low rate of major complications. In the PINNACLE FLX trial, 96% of patients were able to stop taking OAC after first follow-up visit.

In all of the WATCHMAN clinical trials, greater than 92% patients were able to stop taking their anticoagulant after their first follow-up visit, and over 99% were able to stop taking an anticoagulant by 1 year.

In the studies that compared patients who received the WATCHMAN Implant to those who continued on warfarin, the overall risk of serious bleeding was similar between WATCHMAN patients and warfarin patients, but beyond 7 days after the implantation procedure, the risk of bleeding was lower for WATCHMAN patients.

As with any procedure, there are risks associated with the implant, the implant procedure itself, and the medications that are prescribed during and after the implant procedure. You should discuss with your doctor if these risks outweigh the benefit you may receive from a WATCHMAN Implant.

Potential adverse events (in alphabetical order) which may be associated with the use of the WATCHMAN Implant or implantation procedure include but are not limited to:

- Air embolism (leak of air bubbles into the bloodstream which may cause damage to organs)
- Airway trauma (damage to your airways)
- Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medications
- Altered mental status (change in mental status)
- Anemia (thin blood) requiring transfusion
- Anesthesia risk
- Angina (chest pain)
- Anoxic encephalopathy (change in mental status from a lack of oxygen reaching the brain)
- Arrhythmias (heart rhythm abnormalities)
- Atrial septal defect (hole in wall between upper chambers of the heart)
- Bruising, hematoma (blood collection) or seroma (fluid collection) near the catheter insertion site
- Cardiac perforation (perforation of the heart muscle)
- Chest pain/discomfort
- Confusion post procedure
- Congestive heart failure (decreased ability of your heart to pump blood)
- Contrast-related nephropathy (kidney damage from contrast media)
- Cranial bleed (bleeding inside the skull)
- Death
- Decreased hemoglobin (lack of red blood cells in your blood)
- Deep vein thrombosis (blood clot in a vein)
- Device embolization (implant moves from the intended location)
- Device fracture (damage to the WATCHMAN Implant)
- Device thrombosis (clot on the implant)
- Edema (fluid collection in the tissue)
- Embolism
- Excessive bleeding
- Fever
- Fistula (e.g., abnormal connection between blood vessels)
- Groin pain
- Groin puncture bleed
- Hematuria (blood in the urine)
- Hemoptysis (blood in the sputum)
- Hypotension (low blood pressure)
- Hypoxia (low oxygen level in the bloodstream)
- Improper wound healing
- Inability to reposition, recapture, or retrieve device
- Infection/Pneumonia
- Interatrial septum thrombus (blood clot on wall between heart's upper chambers)
- Intratracheal bleeding (bleeding in the wind pipe)
- Major bleed requiring transfusion
- Misplacement of the device / improper seal of the appendage / movement of the device from appendage wall
- Myocardial erosion (erosion through heart wall)
- Nausea (feeling sick)
- Oral bleeding (bleeding from the mouth)
- Pericardial effusion / tamponade [accidental heart puncture causing fluid collection in the heart sack (pericardial effusion) which may lead to increased pressure in the heart sack (tamponade)]
- Pleural effusion (collection of fluid around the lungs)
- Prolonged bleeding from a laceration (prolonged bleeding from a cut)
- Pseudoaneurysm (abnormal collection of blood between the outer two layers of the arterial wall)
- Pulmonary edema (collection of fluid in the lung tissue)
- Renal failure (kidney failure)
- Respiratory insufficiency/failure (breathing failure)
- Surgical removal of the device
- Stroke – Hemorrhagic (stroke from bleeding inside the brain)
- Stroke – Ischemic (stroke from lack of blood supply to a part of the brain)
- TEE (Transesophageal echocardiogram) complications (throat pain, bleeding, esophageal trauma)
- Thrombocytopenia (low platelet count)
- Thrombosis (clot formation)
- Transient Ischemic Attack (TIA) (temporary loss of body function that results from lack of blood supply to part of the brain)
- Valvular or vascular damage (damage to heart valve or blood vessel)
- Vasovagal reactions (change in blood pressure and/or heart rate)

There may be other potential adverse events that are unforeseen at this time.

MEDICATIONS

Your doctor has prescribed medication to thin the blood and prevent blood clots from forming. Current guidelines recommend oral anticoagulant medications to thin the blood and delay blood clotting (coagulation) in patients with atrial fibrillation. Your doctor will also have you take aspirin after your WATCHMAN has been implanted. After your WATCHMAN Implant has been in place for a minimum of 45 days, your doctor ***may*** stop your anticoagulation medication as described in the **After the Procedure** section. If your doctor chooses to stop your anticoagulant, he/she will prescribe a second antiplatelet medication (such as Plavix™, Effient™ or Brilinta™) until 6 months after your implant procedure and may increase your aspirin dose.

It is extremely important to follow your medication regimen. If you stop taking these medications or change their dosage before being instructed to do so by your doctor, the chances of blood clot formation, subsequent stroke, or even death are increased.

ACTIVITY

- Follow your doctor's recommendations.
- Return to normal activities gradually, pacing your return to activity as you feel better. Check with your doctor about strenuous activities.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Report side effects from medications immediately. These may include bleeding, headaches, nausea, vomiting or rash.
- Do not stop taking your medications, or change their dose, unless it is recommended by the doctor who implanted your WATCHMAN Implant.
- Keep all follow-up appointments, including laboratory blood testing.
- Carry your WATCHMAN Device Implant Card at all times. If you receive dental or medical care or report to an emergency room/center, show your WATCHMAN Device Implant Card.

FREQUENTLY ASKED QUESTIONS

Can the WATCHMAN Implant move or rust?

Once positioned by your doctor, the implant should not move on its own. It is manufactured so it will not rust.

Can I walk through metal detectors with the WATCHMAN Implant?

Yes, without any fear of setting them off.

How soon can I resume normal daily activities?

The majority of people return to normal daily activities within a few days following the procedure. Check with your doctor before resuming your usual activities.

What if I experience pain?

If you experience pain, immediately inform your doctor or the center where the procedure was performed.

What if I miss taking my medication?

Call your doctor.

Can I undergo MRI or scanner testing with the WATCHMAN Implant?

MRI safety testing has shown that the WATCHMAN Left Atrial Appendage Closure Device is "MR Conditional" and that a patient with a WATCHMAN Implant may safely undergo an MRI scan under certain conditions listed on the WATCHMAN Device Implant Card. Prior to undergoing an MRI scan, inform your doctor or MRI technologist that you have a WATCHMAN Left Atrial Appendage Closure Device, and show them the WATCHMAN Device Implant Card.

Indications, contraindications, warnings and instructions for use can be found in the labeling supplied with each product. CAUTION: Federal (U.S.A.) law restricts these products to sale by or on the order of a physician.

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2019-10 50879598-02A

WATCHMAN® Left Atrial Appendage Closure Device

WATCHMAN® Left Atrial Appendage Closure Device

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician/technologist that you have a left atrial appendage closure implant. Non-clinical testing has demonstrated the WATCHMAN Implant is MR Conditional. A patient with the WATCHMAN Implant can be scanned safely under the following conditions:

- Static magnetic fields of 1.5 Tesla or 3 Tesla
- Spatial gradient field of 2500 Gauss/cm or less
- The maximum whole body averaged specific absorption rate (SAR) shall be limited to 2.0 W/kg (normal operating mode only) for 15 minutes of scanning
- Normal operating mode of the MRI scanner

The WATCHMAN Implant should not migrate in this MRI environment.

MR imaging within these conditions may be performed immediately following the implantation of WATCHMAN. MR image quality may be compromised if the area of interest is relatively close to the WATCHMAN Implant. Optimization of MR imaging parameters is recommended. This implant has not been evaluated to determine if it is MR Conditional beyond these parameters.

PLEASE CARRY YOUR CARD AT ALL TIMES.

Your doctor has prescribed medication to thin the blood and prevent blood clots after your WATCHMAN® Implant. It is extremely important to take the blood thinning medications as prescribed by your doctor. Before considering any surgery or dental work which would require you to stop taking prescribed blood thinning medications, you and your doctors should consider the risks from premature discontinuation of these medications. **For questions regarding your WATCHMAN Implant or other procedures (e.g., MRI), please contact your implanting doctor.**

Follow-up visit dates	
45-day visit	
6-month visit	
12-month visit	

WATCHMAN® Left Atrial Appendage Closure Device

Patient Name

Implanting Physician's Name

Date of Implant

Hospital

Device Lot Number

Contact Information

Register your card with WATCHMAN.com/register to receive a new card in case of loss. This registration is voluntary for all WATCHMAN recipients.

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WATCHMAN FLX™
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Patient Information Guide

WATCHMAN FLX™

Left Atrial Appendage Closure Device

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The Normal Heart

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The heart has specialized cells which produce electrical impulses that stimulate the heart muscle cells to beat and pump blood. Normally, your heart's pumping rate is controlled by the heart's internal pacemaker that is located in the upper portion of the right atrium. The heart beat spreads throughout both the right atrium and left atrium and then travels through special pathways to both the right and left ventricles. This electrical stimulation causes the heart muscle to contract and pump blood through the blood vessels. The heart then rests and fills with blood until the next contraction occurs. This cycle occurs millions of times in a year.

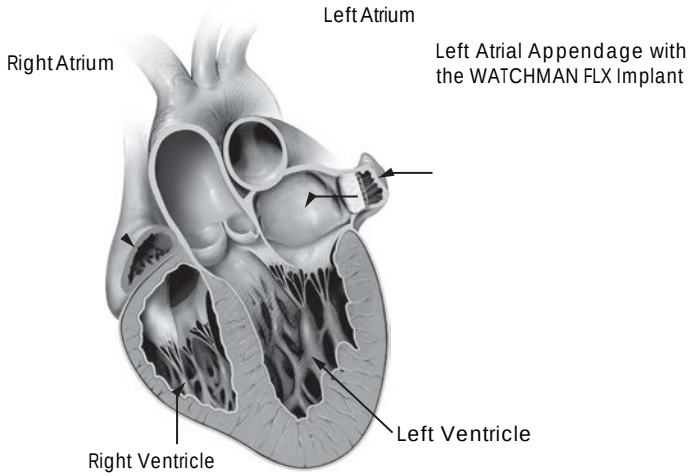
Atrial Fibrillation

In atrial fibrillation, the right and left atria no longer contract together in a coordinated fashion and the heart beat (pulse) becomes irregular. Atrial fibrillation can cause you to have symptoms such as feeling tired (fatigue), lightheaded, short of breath, or have a fluttering sensation in your chest (palpitations). It is also possible that you may have no symptoms.

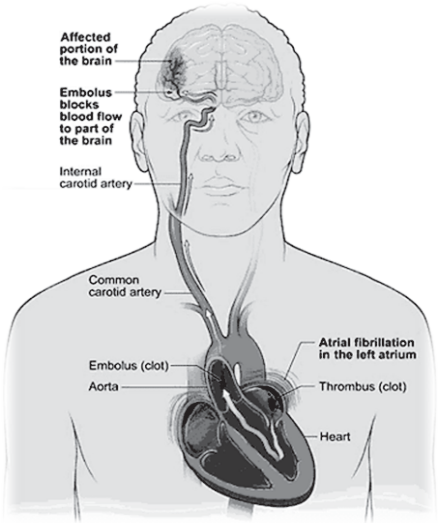
Doctors often prescribe medications to prevent the pulse rate from getting too fast. These medications typically help patients feel well and able to do normal activities despite having atrial fibrillation. However, despite taking these medications (or trying these medications) some patients still feel poorly due to atrial fibrillation and require additional medications or special heart procedures (known as cardioversion and ablation) to try to stop atrial fibrillation altogether and keep the heart in a normal rhythm.

Atrial Fibrillation, Heart Blood Clots, and the Risk of Stroke

Because right and left atria no longer contract normally in atrial fibrillation, the blood flow within the atria can be slower than normal. This change in blood flow may also cause blood clots to form. During atrial fibrillation, most blood clots that originate in the heart develop in the left atrial appendage, which is a pouch-like structure that is part of the left atrium.



A blood clot is called a "thrombus" when it stays in one place, and if it breaks loose and travels to another part of the body, it is then called a "thromboembolus." A thromboembolus can be dangerous if it blocks a blood vessel that supplies blood to an important body part. If a thromboembolus breaks loose from the left atrial appendage and blocks a blood vessel in the brain, the part of the brain that is supplied by that blood vessel can become permanently damaged within minutes. This type of brain damage is known as a stroke. A stroke can result in the loss of a body function, weakness, a change in sensation, problems speaking, or even death. Besides the brain, a thromboembolus can travel to other areas of the body and cause organ damage by blocking blood flow.



Not all atrial fibrillation patients are at equal risk for developing left atrial appendage blood clots and stroke. Factors that increase the risk include advancing age (particularly ages greater than 75 years), high blood pressure, heart failure, diabetes, other cardiovascular (heart) disease, and a prior stroke or mini-stroke ("transient ischemic attack" or TIA).

Current Treatment to Prevent Stroke in Atrial Fibrillation Patients

The current treatment for atrial fibrillation patients who are at increased risk for stroke is treatment with blood-thinning medications called **anticoagulants**, which reduce the chance that blood clots form. These medications (which include warfarin/Coumadin™, Pradaxa™, Xarelto™, Eliquis™, Savaysa™) are effective and recommended in lowering the risk of stroke in atrial fibrillation patients. Most patients can safely take these medications for years (and even decades) without serious side effects.

However, some patients find that anticoagulants can be difficult to tolerate or risky. Because they prevent blood clots by thinning the blood, anticoagulants can increase the risk of bleeding problems. When bleeding events occur, the events are often minor (like a skin cut taking longer to stop bleeding than normal) and easily treated. But in some cases, bleeding can be quite serious requiring hospitalization and transfusion and can even be life-threatening or fatal (such as when strokes are caused by bleeding into the brain).

When prescribing anticoagulant medications in atrial fibrillation patients, doctors consider the risk of a stroke versus the risk of a serious bleeding problem. In studies of atrial fibrillation patients, the *benefit* of a reduced risk of stroke caused by a blood clot traveling from the left atrial appendage is greater than the *risk of* major bleeding (including strokes caused by bleeding into the brain). This means that more strokes are prevented by anticoagulant medications than are caused by anticoagulant medications. Therefore, anticoagulant medications are recommended for most patients. However, in select patients, the risk of major bleeding is believed to be too high, so that anticoagulants will not be prescribed. Other atrial fibrillation patients, even though they may be able to take anticoagulant medications without major bleeding, may choose not to take the medication because of minor bleeding episodes, other medication side effects, or concerns about bleeding due to trauma.

Treatment with the WATCHMAN FLX™ Implant to Prevent Stroke in Atrial Fibrillation Patients

Your doctor has prescribed the WATCHMAN FLX Implant for you because you have atrial fibrillation without significant heart valve disease, but with other risk factors that put you at an increased risk of stroke. Although you may take an anticoagulant (blood thinning medication) to reduce the risk of stroke, your doctor has recommended that you undergo implantation of the WATCHMAN FLX Implant as an alternative to long-term use of this drug. In making this recommendation, your doctor has considered the benefits and risks of the WATCHMAN FLX Implant compared to the benefits and risks of approved anticoagulant medication that are used to reduce the risk of stroke in atrial fibrillation patients.

Among the factors you and your doctor may consider are your overall risk of stroke, your risk of stroke caused by a blockage of a blood vessel in the brain, and your risk of a major bleeding problem while taking anticoagulant medications (including bleeding in the brain). In the case of preventing a stroke caused by a blockage of a blood vessel in the brain, anticoagulant medications may be better than the WATCHMAN FLX Implant. On the other hand, anticoagulant medications increase the risk of major bleeding episodes (including bleeding in the brain), and anticoagulant medications can usually be stopped about 6 weeks after successful placement of the WATCHMAN FLX Implant in your heart, provided the left atrial appendage has been adequately sealed. Your doctor will also consider your personal preferences regarding anticoagulant medications and heart procedures associated with implanting and monitoring the WATCHMAN FLX Implant.

When a blood clot develops in the heart of a patient with atrial fibrillation, it is most often found within the left atrial appendage. The WATCHMAN FLX Implant acts as a barrier to prevent left atrial appendage blood clots from entering the bloodstream and blocking a blood vessel in the brain resulting in a stroke. However, it is important for you to know that a stroke can be due to factors not related to a clot traveling to the brain from the left atrial appendage. Other causes of stroke can include high blood pressure and narrowing of the blood vessels to the brain. The WATCHMAN FLX Implant will *not* prevent these other causes of stroke.

It is also important for you to understand that, like anticoagulant medications, the WATCHMAN FLX™ Implant does not cure atrial fibrillation.

Be sure to discuss your specific situation with your doctor as you consider all options to reduce your risk of stroke.

Patients Who Should Not be Considered for the WATCHMAN FLX Implant

A patient with atrial fibrillation who currently has a blood clot in the heart should not receive a WATCHMAN FLX Implant until the blood clot is successfully treated with blood thinning medications. Patients who have had an atrial septal repair or closure device should not receive the WATCHMAN FLX Implant. Other patients who should not receive the implant include:

- Patients with a left atrial appendage that is too large or too small to fit the WATCHMAN FLX Implant.
- Patients who cannot take anticoagulant, aspirin, or second antiplatelet medication.
- Patients who should not or cannot undergo heart catheterization procedures.
- Patients who have an allergy or sensitivity to nitinol (nickel and titanium) or any of the other materials in the WATCHMAN FLX Implant.

Additionally, due to the upfront risk of undergoing an invasive heart procedure, patients should not be considered for the WATCHMAN FLX Implant if they are doing well and anticipate continuing to do well with anticoagulant medications. In general, a WATCHMAN FLX Implant is not appropriate for those patients for whom the risk of the implantation procedure is expected to exceed the benefit from receiving the implant. The WATCHMAN FLX Implant is not recommended in patients whose atrial fibrillation is due to significant heart valve disease.

WATCHMAN FLX LEFT ATRIAL APPENDAGE CLOSURE DEVICE

The WATCHMAN FLX Left Atrial Appendage Closure Device is implanted at the opening of the left atrial appendage and is intended to prevent left atrial appendage blood clots from entering your blood stream and potentially causing a stroke. It is made of materials that are common to many medical devices. The implant is designed to be a one-time implant that does not need to be replaced.

Information to Consider Prior to your WATCHMAN FLX Implant

Before the WATCHMAN FLX Device is implanted, your doctor will perform a thorough assessment. He/she will ask you about your medical history, assess your stroke risk, perform a physical examination, and take pictures of your heart based on your circumstances using appropriate techniques. A thrombus inside your heart may be detected. A patient with atrial fibrillation who currently has a thrombus within the heart should not be considered for a WATCHMAN FLX Implant until the thrombus goes away after a course of blood thinners.

Your doctor will provide specific instructions on what medications to take, such as anticoagulant medications and aspirin. Be sure to discuss any medication changes with your doctor.

Implanting the WATCHMAN FLX™ Implant

The WATCHMAN FLX Implant is placed into your heart using a minimally invasive procedure in a cardiac catheterization laboratory or electrophysiology laboratory by a physician and his/her team who have experience and training in the WATCHMAN FLX implantation technique. In preparation for the implant, you will be lying on your back on a table while you are continuously monitored throughout the procedure by medical personnel. X-rays and echocardiograms (a special type of ultrasound picture) will be used to help visualize the heart while the implant is being advanced into the correct position in your heart. Contrast media (dye) will also be injected to help guide the implant placement. You will be given a general and/or local anesthetic by your doctor to minimize any discomfort during the procedure. Discuss the anesthesia method that is best for you with your physician.

A small puncture is made into a vein in your groin. A long, thin tube, called a catheter, is inserted into the vein and advanced into the right atrium of the heart. Another puncture is made through a thin muscle wall between the right atrium and the left atrium so that the catheter can be advanced into the left atrium. A thinner catheter is then advanced into the left atrial appendage under X-ray guidance. The WATCHMAN FLX Implant is tightly compressed within the catheter and is passed through the catheter into the left atrial appendage. Once the WATCHMAN FLX Implant is in the right place, the physician will then deploy the implant which will expand and seal the left atrial appendage. After the procedure, the WATCHMAN FLX Implant is the only material that remains in the body. A thin layer of tissue will grow over the surface of the WATCHMAN FLX Implant within about 45 days.

After the Procedure

After WATCHMAN FLX is implanted, you will rest in the hospital where you will be monitored during your recovery from the procedure. It may be one or more days before you are discharged home, and your doctor will determine how long you need to be in the hospital.

Your doctor will instruct you to take anticoagulant and aspirin after your implant. After your WATCHMAN FLX Implant has been in place for a minimum of 45 days, your doctor will take pictures of your heart, by means of a test called a TEE (transesophageal echocardiogram), to determine if the implant has closed the opening of the left atrial appendage. Your doctor ***may*** stop your anticoagulant medication at that time, depending on the result of this test. If your doctor chooses to stop your anticoagulant, he/she will prescribe a second antiplatelet medication (such as Plavix™, Effient™ or Brilinta™) until 6 months after your implant procedure, and your aspirin dose may increase.

If the TEE that is performed at around 45 days shows that the opening of the left atrial appendage is not adequately closed, another TEE may be scheduled at around 6 months to re-evaluate whether adequate closure of the left atrial appendage has occurred.

At about 12 months after your WATCHMAN Implant, your doctor will schedule another TEE to check on the device and make sure that your LAA is still closed.

It is extremely important for you to take the recommended medications (anticoagulant, antiplatelet medication, and aspirin) at the recommended time. If you stop taking these medications or change their dosage before being instructed to do so by your doctor, the chances of blood clot formation, subsequent stroke, or even death are increased. Talk to your doctor before stopping your medications or changing the dosage.

If surgery or dental work is needed, which would require you to stop taking these medications prematurely, you and your doctors should carefully consider the risks and benefits of this additional surgery or dental work versus the possible risks from stopping these medications early. Talk to your doctor about the timing of any medical procedures you may need.

If you do require premature discontinuation of these medications because of significant bleeding, your doctor will carefully monitor you for possible complications. Once your condition has stabilized, your doctor may restart these medications. Talk to your doctor before restarting medications or changing their doses.

CLINICAL STUDIES

The potential benefits of the WATCHMAN FLX Implant for a patient with atrial fibrillation without heart valve disease are as follows:

- Reducing the risk of stroke from a blood clot originating in the left atrial appendage
- Being able to stop long-term anticoagulation therapy and a reduction in the risks associated with long-term anticoagulation use

In the PROTECT AF study, which lasted five years and studied 707 atrial fibrillation patients, the WATCHMAN™ Implant was compared to warfarin. The WATCHMAN Implant was found to be as effective as warfarin in reducing the risk of the combination of stroke (either from a blocked vessel or bleeding within the brain), cardiovascular death, or a blocked blood vessel in another part of the body besides the brain. A second study of the WATCHMAN Implant compared to warfarin called the PREVAIL study enrolled 407 atrial fibrillation patients. The PREVAIL study has lasted 5 years. In the PREVAIL study, the combined rate of stroke, death, and a blocked blood vessel in a part of the body outside of the brain in patients treated with the WATCHMAN Implant were generally similar to what was seen in PROTECT AF. In this study, it could not be concluded that the combined outcomes in the WATCHMAN patients were as good as warfarin, however, the ischemic stroke protection was found to be as good as warfarin. Overall, the two clinical studies (PROTECT AF and PREVAIL) suggested that warfarin was better than the WATCHMAN Implant in preventing strokes caused by a blocked blood vessel in the brain, but the WATCHMAN Implant was better than warfarin in terms of the number of strokes caused by bleeding into the brain. In making treatment recommendations, doctors should consider the benefits and risks of anticoagulant medications and the WATCHMAN Implant for each individual patient, including the chance that either kind of stroke (a stroke caused by a blocked blood vessel or a stroke caused by bleeding) might occur.

The PREVAIL study also tested a new training program that was designed for doctors who had not previously performed a WATCHMAN Implant. The PREVAIL study found that these new operators could safely implant the WATCHMAN Implant. Two more studies of 566 and 576 patients called the CAP and CAP2 Registries also confirmed that the WATCHMAN Implant could be implanted successfully and safely.

The PINNACLE FLX study was designed to assess the safety and effectiveness of the next generation WATCHMAN device, WATCHMAN FLX, in 400 patients. The new device was designed to improve the implant procedure and device sealing, allowing more patients to come off lifelong OAC. The results of the PINNACLE FLX trial show a low rate of major complications. In the PINNACLE FLX trial, 96% of patients were able to stop taking OAC after first follow-up visit.

In all of the WATCHMAN clinical trials, greater than 92% patients were able to stop taking their anticoagulant after their first follow-up visit, and over 99% were able to stop taking an anticoagulant by 1 year.

In the studies that compared patients who received the WATCHMAN™ Implant to those who continued on warfarin, the overall serious bleeding rates were similar in WATCHMAN patients and warfarin patients. The risk overall of serious bleeding was similar between WATCHMAN patients and warfarin patients, but beyond 7 days after the implantation procedure, the risk of bleeding was lower for WATCHMAN patients.

As with any procedure, there are risks associated with the implant, the implant procedure itself, and the medications that are prescribed during and after the implant procedure. You should discuss with your doctor if these risks outweigh the benefit you may receive from a WATCHMAN FLX™ Implant.

Potential harmful events (in alphabetical order) which may be associated with the use of the WATCHMAN FLX Implant or implantation procedure include but are not limited to:

- Air embolism (leak of air bubbles into the bloodstream which may cause damage to organs)
- Airway trauma (damage to your airways)
- Allergic reaction to the contrast media, anesthetic, WATCHMAN FLX Implant material, or medications
- Altered mental status (change in mental status)
- Anemia (low blood count) requiring transfusion
- Anesthesia risk
- Angina (chest pain)
- Anoxic encephalopathy (change in mental status from a lack of oxygen reaching the brain)
- Arrhythmias (heart rhythm abnormalities)
- Atrial septal defect (hole in wall between upper chambers of the heart)
- Bruising, hematoma (blood collection) or seroma (fluid collection) near the catheter insertion site
- Cardiac perforation (perforation of the heart muscle)
- Chest pain / discomfort
- Confusion post procedure
- Congestive heart failure (decreased ability of your heart to pump blood)
- Contrast-related nephropathy (kidney damage from contrast dye)
- Cranial Bleed (bleeding inside the skull)
- Death
- Decreased hemoglobin (lack of red blood cells in your blood)
- Deep vein thrombosis (blood clot in a vein)
- Device Embolization (implant moves from the intended location)
- Device fracture (damage to the WATCHMAN FLX Implant)
- Device thrombosis (clot on the implant)
- Edema (fluid collection in the tissue)
- Embolism
- Excessive bleeding
- Fever
- Fistula (e.g., abnormal connection between blood vessels)
- Groin pain
- Groin puncture bleed
- Hematuria (blood in the urine)
- Hemoptysis (blood in the sputum)
- Hypotension (low blood pressure)
- Hypoxia (low oxygen level in the bloodstream)
- Improper wound healing
- Inability to reposition, recapture, or retrieve device
- Infection/Pneumonia
- Interatrial septum thrombus (blood clot on wall between heart's upper chambers)
- Intratracheal bleeding (bleeding in the wind pipe)
- Major bleed requiring transfusion
- Misplacement of the device / improper seal of the appendage / movement of the device from appendage wall
- Myocardial Erosion (erosion through heart wall)
- Nausea (feeling sick)
- Oral bleeding (bleeding from the mouth)
- Pericardial effusion / tamponade [accidental heart puncture causing fluid collection in the heart sack (pericardial effusion) which may lead to increased pressure in the heart sack (tamponade)]
- Pleural Effusion (collection of fluid around the lungs)
- Prolonged bleeding from a laceration (prolonged bleeding from a cut)
- Pseudoaneurysm (abnormal connection between your blood vessels due to the procedure)
- Pulmonary Edema (collection of fluid in the lung tissue)
- Renal failure (kidney failure)
- Respiratory insufficiency/failure (breathing failure)
- Surgical removal of the device
- Stroke – Ischemic (stroke from lack of blood supply to a part of the brain)
- Stroke – Hemorrhagic (stroke from bleeding inside the brain)
- TEE (Transesophageal echocardiogram) complications (throat pain, bleeding, esophageal trauma)
- Thrombocytopenia (low platelet count)
- Thrombosis (clot formation)
- Transient Ischemic Attack (TIA) (temporary loss of body function that results from lack of blood supply to part of the brain)
- Valvular or vascular damage (damage to heart valve or blood vessel)
- Vasovagal Reactions (change in blood pressure and/or heart rate)

There may be other potential adverse events that are unforeseen at this time.

MEDICATIONS

Your doctor has prescribed medication to thin the blood and prevent blood clots from forming. Current guidelines recommend oral anticoagulant medications to thin the blood and delay blood clotting (coagulation) in patients with atrial fibrillation. Your doctor will also have you take aspirin after your WATCHMAN FLX™ has been implanted. After your WATCHMAN FLX Implant has been in place for a minimum of 45 days, your doctor ***may*** stop your anticoagulation medication as described in the **After the Procedure section**. If your doctor chooses to stop your anticoagulation, he/she will prescribe a second antiplatelet medication (such as Plavix™, Effient™ or Brilinta™) until 6 months after your implant procedure and may increase your aspirin dose.

It is extremely important to follow your medication regimen. If you stop taking these medications or change their dosage before being instructed to do so by your doctor, the chances of blood clot formation, subsequent stroke, or even death are increased.

ACTIVITY

- Follow your doctor's recommendations.
- Return to normal activities gradually, pacing your return to activity as you feel better. Check with your doctor about strenuous activities.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Report side effects from medications immediately. These may include bleeding, headaches, nausea, vomiting or rash.
- Do not stop taking your medications, or change their dose, unless it is recommended by the doctor who implanted your WATCHMAN FLX Implant.
- Keep all follow-up appointments, including laboratory blood testing.
- Carry your WATCHMAN FLX Device Implant Card at all times. If you receive dental or medical care or report to an emergency room/center, show your WATCHMAN FLX Device Implant Card.

FREQUENTLY ASKED QUESTIONS

Can the WATCHMAN FLX Implant move or rust?

Once positioned by your doctor, the implant should not move on its own. It is manufactured so it will not rust.

Can I walk through metal detectors with the WATCHMAN FLX Implant?

Yes, without any fear of setting them off.

How soon can I resume normal daily activities?

The majority of people return to normal daily activities within a few days following the procedure. Check with your doctor before resuming your usual activities.

What if I experience pain?

If you experience pain, immediately inform your doctor or the center where the procedure was performed.

What if I miss taking my medication?

Call your doctor.

Can I undergo MRI or scanner testing with the WATCHMAN FLX Implant?

MRI safety testing has shown that the WATCHMAN FLX Left Atrial Appendage Closure Device is "MRI Conditional" and that a patient with a WATCHMAN FLX Implant may safely undergo an MRI scan under certain conditions listed on the WATCHMAN FLX Device Implant Card. Prior to undergoing an MRI scan, inform your doctor or MRI technologist that you have a WATCHMAN FLX Left Atrial Appendage Closure Device, and show them the WATCHMAN FLX Device Implant Card.

Indications, contraindications, warnings and instructions for use can be found in the labeling supplied with each product. CAUTION: Federal (U.S.A.) law restricts these products to sale by or on the order of a physician.

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2019-11
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