WATCHMAN® Left Atrial Appendage Closure Device

# 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 is 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 [commonly referred to as Coumadin®] and other newer approved anticoagulants) are very effective 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) called warfarin 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 warfarin and/or the benefits and risks of other 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 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.

In studies of the WATCHMAN Implant in patients with atrial fibrillation, the safety and effectiveness of the implant has been compared to warfarin. The WATCHMAN Implant has not been compared to newer anticoagulant medications that have also been approved to lower the rate of stroke in atrial fibrillation patients

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 warfarin, 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.

# 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 warfarin therapy and a reduction in the risks associated with long-term warfarin 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 been running for about 2 years and continues onward. 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. However, in this study, it could *not* be concluded that outcomes in the WATCHMAN patients were 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. Another study of 566 patients called the CAP Registry also confirmed that the WATCHMAN Implant could be implanted successfully and safely.

In all of the WATCHMAN**®** clinical trials, approximately 92% of patients were able to stop taking their warfarin 45 days after implant, and over 99% were able to stop taking warfarin by 1 year following the implant procedure.

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 of serious bleeding was higher in WATCHMAN patients versus warfarin patients within several months of the implantation procedure but lower beginning 6 months after the implantation procedure.

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 harmful 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 dye, 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)
* Arteriovenous (AV) fistula (abnormal connection between your blood vessels)
* 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)
* Decreased hemoglobin (lack of red blood cells in your blood)
* Deep vein thrombosis (blood clot in a vein)
* Death
* 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)
* Excessive bleeding
* Fever
* 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)
* Systemic Embolism
* 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.