WATCHMAN® Left Atrial Appendage Closure Device

Pre-Procedure Guide

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.

Before the WATCHMAN Implant, 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 using a technique called a TEE (trans-esophageal echocardiogram). A thrombus inside your heart may be detected by the TEE. 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.

# 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 (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 Implant is tightly compressed within the catheter and is passed through the catheter into the left atrial appendage. The physician will make sure that the implant is in the right place within the left atrial appendage and then deploy the implant (much like opening up a folded umbrella). 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 warfarin 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 warfarin medication at that time, depending on the result of this test. If your doctor chooses to stop your warfarin he/she will prescribe a new blood thinning medication called clopidogrel (Plavix®) 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 (warfarin, clopidogrel, 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.

# MEDICATIONS

Your doctor has prescribed medication to thin the blood and prevent blood clots from forming. Current guidelines recommend oral anticoagulant medications such as warfarin to thin the blood and delay blood clotting (coagulation) in patients with atrial fibrillation. A blood 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. A too high INR level increases the risk of bleeding. A too low level increases the risk of blood clots. Because the correct warfarin dose may change over time, it’s important to test your INR at regular intervals. 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 warfarin medication as described in the **After the Procedure section**. If your doctor chooses to stop your warfarin, he/she will prescribe clopidogrel (Plavix®) 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 physician, 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 “MRI 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.