WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device

Patient Information Guide

WATCHMAN FLX Pro Left Atrial Appendage Closure Device

PATIENT INFORMATION GUIDE

Your doctor thinks that you should get a WATCHMAN FLX Pro Implant or you have already had one put in a part of your heart called the left atrial appendage (LAA). Here is some important information about the implant that will answer many of your questions.

UNDERSTANDING YOUR HEART

This section explains how a normal heart works and what happens when the heart gets a condition known as atrial fibrillation.

The Normal Heart

The heart has four parts: two upper atrial chambers (a right and left atrium) and two lower ventricular chambers (a right and left ventricle). The chambers fill with blood when the heart is resting then pump blood out

to the body with each heartbeat (or contraction).

The heart has special cells that make electrical signals to help the heart muscle beat and pump blood. Usually, your heart's pumping rate is controlled by the heart's internal pacemaker located in the upper part of the right atrium. The heartbeat spreads through both the right and left atrium and then travels to the right and left ventricles. This electrical signal makes the heart muscle contract and pump blood through the blood vessels. After each beat, the heart rests and fills with blood until the next beat. This cycle occurs millions of times in a year.

Atrial Fibrillation

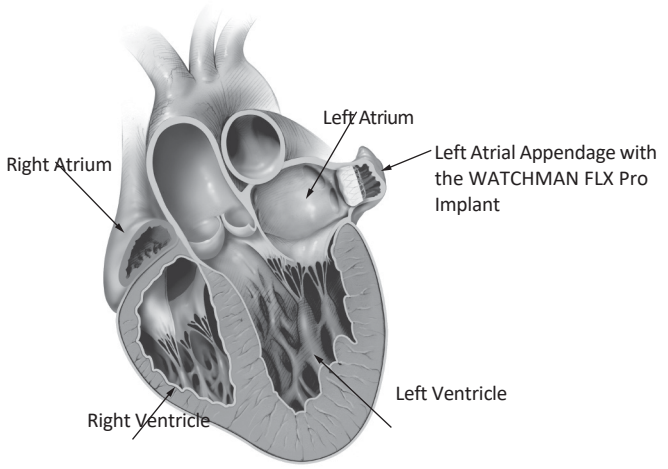
In atrial fibrillation, the right and left atria do not contract together properly making the heartbeat (pulse) irregular. This can cause symptoms like feeling tired (fatigue), lightheaded, short of breath, or have a fluttering feeling in your chest (palpitations). Sometimes you might have no symptoms at all.

Doctors often give medications to keep the heart rate from getting too fast.

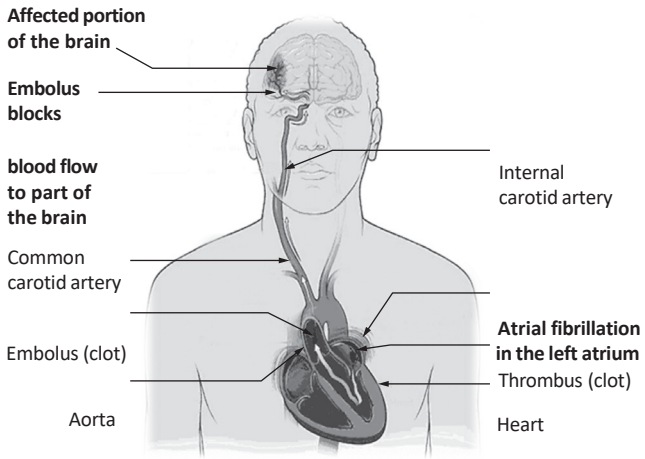
These medications usually help patients feel well and do normal activities even with atrial fibrillation. However, some patients still feel unwell despite taking these medications and need extra medications or special heart procedures (called cardioversion and ablation) to try to stop atrial fibrillation and keep the heart beating normally.

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

Because right and left atria don't contract normally in atrial fibrillation, the blood flow within the atria can be slower than normal. This slower blood flow can cause blood clots to form. Most blood clots that start in the heart during atrial fibrillation 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 it breaks loose and blocks a blood vessel in the brain, it can cause a stroke, which can damage the brain within minutes. A stroke can result in the loss of a body function, weakness, a change in sensation, problems speaking, or even death. A thromboembolus can travel to other areas of the body and cause organ damage by blocking blood flow.



Not all people with atrial fibrillation have the same risk of getting blood clots and stroke. The risk is higher for those who are older (especially over 75 years), have high blood pressure, heart failure, diabetes, heart disease, or have had a stroke or mini-stroke before.

Current Treatment to Prevent Stroke in Atrial Fibrillation Patients

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

However, some patients find that blood thinners are hard to tolerate or risky. Since they thin the blood to prevent clots, they can increase the risk of bleeding problems. Often the bleeding is minor like a cut taking longer to stop bleeding and can be easily treated. But sometimes, the bleeding can be serious needing hospitalization and transfusion and can even be life-threatening or fatal like when a stroke is caused by bleeding in the brain.

When prescribing blood-thinning medications in atrial fibrillation patients, doctors weigh the risk of a stroke against the risk of a serious bleeding. Studies show that the *benefit* of reducing stroke risk from blood clots is greater than the *risk* of major bleeding (including brain bleeds). This means that anticoagulant medications prevent more strokes than they cause. Therefore, blood thinning medications are recommended for most patients. However, in some patients, the risk of major bleeding is believed to be too high, so they won't be prescribed these medications. Other atrial fibrillation patients might choose not to take blood thinners for a longer period of time because of minor bleeding, other side effects or worries about bleeding from injuries.

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

Your doctor has prescribed the WATCHMAN FLX Pro Implant for you because you have atrial fibrillation without significant heart valve disease, but with other risk factors that increase your stroke risk. While you might take blood thinning medication to reduce stroke risk, your doctor recommends the WATCHMAN FLX Pro Implant as an alternative to long-term use of these drugs. In making this recommendation, your doctor has considered the benefits and risks of the WATCHMAN FLX Pro Implant compared to those of approved blood thinning medication that are used to reduce stroke risk in atrial fibrillation patients.

Factors you and your doctor may consider are your overall stroke risk, the risk of stroke from a blocked blood vessel in the brain, and the risk of major bleeding while on blood thinners (including bleeding in the brain). For preventing a stroke caused by a blocked blood vessel in the brain, clot preventing medications may be better than the WATCHMAN FLX Pro Implant. On the other hand, anticoagulant medications increase risk of major bleeding episodes, including bleeding in the brain, and these medications can usually be stopped about 6 to 12 weeks after the WATCHMAN FLX Pro Implant is successfully placed in your heart, as long as the left atrial appendage is properly sealed. Your doctor will also consider your personal preferences regarding blood-thinning medications and procedures involved with the WATCHMAN FLX Pro Implant.

WATCHMAN FLX Pro implant following a catheter ablation for atrial fibrillation (either during the same procedure or following recent ablation procedure):

A catheter ablation is when your doctor destroys the tissue around the veins in the upper left chamber of your heart to try to get back to a normal heartbeat and reduce some symptoms of atrial fibrillation. If you have recently had a catheter ablation for atrial fibrillation, the WATCHMAN FLX Pro Implant is similar to blood-thinning medications in preventing stroke caused by blood clots from the heart. The WATCHMAN FLX Pro also has lower risk of non-procedural bleeding episodes than blood thinners and blood thinners can be stopped 3 months after successful placement of the WATCHMAN FLX Pro in your heart, provided the left atrial appendage is properly sealed.

When a blood clot forms in the heart of someone with atrial fibrillation, it is usually found in the left atrial appendage. The WATCHMAN FLX Pro Implant acts as a barrier to stop these clots from entering the bloodstream and cause a stroke by blocking a blood vessel in the brain. However, it is important to know that strokes can also be caused by other factors like high blood pressure and narrowing of the blood vessels to the brain. The WATCHMAN FLX Pro Implant will *not* prevent these other causes of stroke.

It is also important for you to understand that, like blood-thinning medications, the WATCHMAN FLX Pro Implant does not cure atrial fibrillation.

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

Patients Who Should Not be Considered for the WATCHMAN FLX Pro Implant

A patient with atrial fibrillation who currently has a blood clot in the heart should not receive a WATCHMAN FLX Pro 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 Pro 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 Pro Implant.
- Patients who cannot take blood-thinners, aspirin, or other medication to prevent blood clots.
- Patients who should not or cannot have a heart catheterization procedure.
- Patients who are allergic or sensitive to nickel, titanium, or any of the other materials in the WATCHMAN FLX Pro Implant.

There are risks of having an invasive heart procedure. Patients who are doing well on blood thinners but have had a recent catheter ablation could be considered for the WATCHMAN FLX Pro Implant. In general, a WATCHMAN FLX Pro Implant is not suitable for patients if the risks of the procedure are higher than the benefits. The WATCHMAN FLX Pro Implant is not recommended in patients whose atrial fibrillation is caused by serious heart valve disease.

WATCHMAN FLX PRO LEFT ATRIAL APPENDAGE CLOSURE DEVICE

The WATCHMAN FLX Pro Left Atrial Appendage Closure Device is placed at the opening of the left atrial appendage to stop blood clots from entering your blood stream and causing a stroke. It is made from materials that are commonly used in medical devices and is designed to be a one-time implant that does not need to be

replaced.

Information to Consider Prior to your WATCHMAN FLX Pro Implant

Before the WATCHMAN FLX Pro Device is implanted, your doctor will do a thorough check up. He/she will ask about your medical history, check your stroke risk, examine you, and take pictures of your heart. If you have a blood clot inside your heart, you should not get the WATCHMAN FLX Pro Implant until the clot is gone after taking blood thinners.

Your doctor will tell you which medications to take, like blood thinners and aspirin. Be sure to discuss any medication changes with your doctor.

Implanting the WATCHMAN FLX Pro Implant

The WATCHMAN FLX Pro Implant is placed into your heart using a minimally invasive procedure in a special lab by a trained doctor and their team. You will lie on a table and be monitored during the procedure. X-rays and ultrasound pictures will help guide the implant to the right spot in your heart. Dye will be used to help place the implant. You will get general and/or local anesthetic to reduce discomfort. Discuss the anesthesia method that is best for you with your doctor.

A small puncture is made into a vein in your groin. A long, thin tube, called a catheter, is inserted into the vein and moved 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 moved into the left atrium. A thinner catheter is watched with X-ray as it is moved into the left atrial appendage. The WATCHMAN FLX Pro Implant is compressed inside the catheter and is passed through the catheter into the left atrial appendage. Once the WATCHMAN FLX Pro Implant is in the right place, the doctor will then expand the implant and seal the left atrial appendage. After the procedure, the WATCHMAN FLX Pro Implant is the only material that stays in the body.

After the Procedure

After WATCHMAN FLX Pro is implanted, you will rest in the hospital and be monitored as you recover. You might stay one or more days and your doctor will decide how long you need to stay.

Your doctor will tell you to take a blood thinner or an antiplatelet and aspirin after your implant. After at least 45 days your doctor will use a test called a TEE (transesophageal echocardiogram), to take pictures of your heart and check if the implant has closed the opening of the left atrial appendage.

If you were first given blood thinners and aspirin, your doctor will consider the results of the TEE and ***may*** stop your blood thinner. If your doctor chooses to stop your blood thinner, they will give you an antiplatelet medication (such as Plavix™, Effient™ or Brilinta™) until 6 months after your implant procedure. If you were first given an antiplatelet and aspirin, your doctor may change your medicines based on the results of your TEE. Unless your doctor tells you differently, you should continue your antiplatelet and aspirin therapy (also known as `dual antiplatelet therapy' or DAPT) for 6 months. You continue to take aspirin indefinitely.

If the TEE that is done at around 45 days shows that the left atrial appendage is not fully closed or if there is a blood clot on the device, another TEE may be scheduled at around 6 months to check again At about 12 months after your WATCHMAN FLX Pro implant, your doctor will schedule another TEE to make sure the left atrial appendage is still closed and there is no blood clot on the device.

WATCHMAN FLX Pro implant following a catheter ablation for atrial fibrillation for atrial fibrillation (either during the same procedure or following recent ablation procedure):

Your doctor will tell you to take a blood thinner and aspirin after your implant. After at least 3 months, your doctor will use a test called a TEE (transesophageal echocardiogram), to take pictures of your heart and check if the implant has closed the opening of the left atrial appendage.

If you were first given blood thinners and aspirin, your doctor will consider the results of the TEE and *may* stop your blood thinner. If your doctor chooses to stop your blood thinner they will prescribe you aspirin only indefinitely. If the TEE that is done at around 3 months shows that the left atrial appendage is not fully closed, or if there is a blood clot on the device, another TEE may be scheduled at around 12 months to check again. You may continue to take your blood thinners until your doctor tells you to stop. At about 12 months after your WATCHMAN FLX Pro Implant, your doctor will schedule another TEE to make sure the left atrial appendage is still closed and there is no blood clot on the device.

It is very important to take your medications (blood thinners, antiplatelet medication, and aspirin) as recommended. If you stop or change the dosage without your doctor's advice, you risk blood clots, stroke, or even death. Talk to your doctor before stopping your medications or changing the dosage.

If you need surgery or dental work that requires stopping your medications early, you and your doctors should weigh the risks and benefits. Talk to your doctor about the timing of any medical procedures you may need.

If you do need to stop these medications early because of serious bleeding, your doctor will watch you closely for any problems. Once you are stable, your doctor may restart the medications. Talk to your doctor before restarting medications or changing their doses.

MRI SAFETY INFORMATION

A person with the Boston Scientific WATCHMAN FLX Pro Closure Device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	WATCHMAN FLX Pro Closure Device
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of up to 8 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

CLINICAL STUDIES

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

- Lowering the risk of stroke from a blood clot in the left atrial appendage

- Being able to stop long-term blood thinner therapy and a reduction in the risks associated with long-term blood thinner 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 blood thinner 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 procedure. 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 blood thinners. 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 blood thinners after first follow-up visit.

The OPTION study was designed to determine if WATCHMAN FLX is a reasonable alternative to blood thinners following catheter ablation in 1600 patients. Patients were randomized to receive either a device implant or blood thinners after catheter ablation. The results of the OPTION trial show a low rate of major complications in those patients that received the device. In the OPTION trial, 85.6% of device patients were able to stop taking blood thinners after first follow-up visit.

In all of the WATCHMAN clinical trials, greater than 92% patients were able to stop taking their blood thinners after their first follow-up visit, and over 95% 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.

In the OPTION study, patients who had an ablation and WATCHMAN FLX compared to patients who had an ablation and took blood thinners for three years all had a similar risk of stroke (either from a blocked vessel or bleeding within the brain), any death, or a blocked blood vessel in another part of the body besides the brain. Patients with WATCHMAN FLX bled less starting 3 days after the procedure compared to patients on blood thinners.

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 Pro Implant.

Potential harmful events (in alphabetical order) which may be associated with the use of the WATCHMAN FLX Pro 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 Pro 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 Pro 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 windpipe)
- 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)
- Myocardial Infarction (heart attack)
- 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)
- Radiation injury (tissue damage or burn from X-ray)
- 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 prevent blood clots from forming. After your WATCHMAN FLX Pro Implant has been in place for at least of 45 days, your doctor ***may*** modify your medications based on the results of your TEE test.

WATCHMAN FLX Pro implant following a catheter ablation for atrial fibrillation (either during the same procedure or following recent ablation procedure)):

Your doctor has prescribed medication to prevent blood clots from forming. After your WATCHMAN FLX Pro Implant has been in place for at least of 3 months, your doctor ***may*** modify your medications based on the results of your TEE test.

It is very important to follow your medication plan. If you stop or change your medications without your doctor's advice, you risk blood clot, stroke, or even death.

ACTIVITY

- Follow your doctor's recommendations.
- Gradually return to normal activities 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 Pro Implant.
- Keep all follow-up appointments, including laboratory blood testing.
- Carry your WATCHMAN FLX Pro Device Implant Card at all times. If you receive dental or medical care or report to an emergency room/center, show your WATCHMAN FLX Pro Device Implant Card.

FREQUENTLY ASKED QUESTIONS

Can the WATCHMAN FLX Pro 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 Pro 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 Pro Implant?

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

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.

Report any serious incident that occurs in relation to your device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country.

Symbol Definitions

The following symbols are used for patient information:

REF Catalog Number	LOT Lot Number	MR Conditional
Indicates the date the device must be implanted by.	Manufacturer	UDI Unique Device Identifier

REF

M635WU60200	M635WU60240	M635WU60270	M635WU60310	M635WU60350	M635WU60400

Information in this patient guide relates to the health care professional WATCHMAN FLX Pro Instructions for Use for this device. See www.IFU-BSCI.com for the health care professional Instructions for Use.

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.

Boston Scientific

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

2024-12

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Perforation

Boston Scientific

INSTRUCTIONS FOR USE

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The Instructions for Use (IFU) for this product are supplied in electronic form over the Internet.

Visit www.IFU-BSCI.com to access the IFU in Adobe® Portable Document Format (PDF), and be sure to have the product label available for reference.

If you have difficulty accessing the IFU online, or would prefer to receive a paper copy, please contact Boston Scientific Customer Service or your local country contact. A copy will be sent to you at no charge and should arrive within seven days.

2025-06

52038333-01

Patient Implant Card

Apply the peel-off label from the product onto patient implant card. Fill in implant date, patient name, healthcare institution and/or physician contact information. Tear off patient implant card along perforation and provide to patient.

Perforation

Place peel-off here

Score & Fold

Boston Scientific

Manufacturer
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001
www.IFU-BSCI.com

MR Conditional

2025-06 52038333-01

Score & Fold

Boston Scientific

Implant Card

WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device

Please carry this card at all times and show it to any medical personnel, including a MRI technician, that may be treating you.

Front

Perforation

Perforation

Score & Fold

Score & Fold

Back

Carte d'implant du patient

Appliquer l'étiquette pelable du produit sur la carte d'implant du patient. Indiquer la date de l'implantation, le nom du patient, les coordonnées de l'établissement de soins de santé et/ou du médecin. Détacher la carte d'implant du patient le long de la perforation et la remettre au patient.

MRI Safety Information

Non-clinical testing has demonstrated the WATCHMAN FLX Pro Device is MR Conditional. A patient with the Closure Device can be scanned safely, immediately after implantation, under the following conditions:

- Static magnetic fields of 3.0 Tesla or 1.5 Tesla
- Maximum spatial gradient field of 4000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2.0 W/kg (normal operating mode only)

If information about a specific MR system parameter is not included, there are no conditions associated with that parameter.

Under the scan conditions defined above, the WATCHMAN FLX Pro Device is expected to produce a maximum temperature rise of less than 3.0 °C after 15 minutes of continuous scanning. The maximum continuous scan duration is 60 minutes.

Presence of the WATCHMAN FLX Pro Device may produce an image artifact of up to 8 mm.

Scanning under different conditions may result in device malfunction, injury and/or death.

Full MRI safety information is available in the WATCHMAN FLX Pro Instructions for Use, which can be obtained at www.IFU-BSCI.com

PLEASE CARRY YOUR CARD AT ALL TIMES.

Your doctor has prescribed medication to thin the blood and prevent blood clots after your WATCHMAN FLX Pro 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 FLX Pro Implant or other procedures (e.g., MRI), please contact your implanting doctor.**

Follow-up Visit dates	

Patient Name and ID Code

Implanting Physician's Name

Date of Implant

Hospital Telephone Number

Hospital Name

Hospital Address

Register your card with WATCHMAN.com/implantcard to receive a new card in case of loss. This registration is voluntary for all WATCHMAN FLX Pro recipients. To view the WATCHMAN FLX Pro patient information guide, please visit www.IFU-BSCI.com. To receive a hard copy patient information guide, call 1.888.272.1001.

MODE D'EMPLOI

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Le mode d'emploi de ce produit est fourni sous forme électronique par Internet.

Consultez le site www.IFU-BSCI.com pour accéder au mode d'emploi au format PDF (Portable Document Format) d'Adobe et assurez-vous d'avoir l'étiquette du produit à titre de référence.

Si vous avez des problèmes pour accéder au mode d'emploi en ligne ou que vous préférez recevoir une copie papier, contacter le service clientèle de Boston Scientific ou votre représentant local. Un exemplaire vous sera envoyé gratuitement et devrait vous parvenir dans les sept jours.

Boston Scientific (Patient Guide Template 8in x 8in), Patient Card, MR, Watchman FLX Pro, en/fr, 52038333-01A

WATCHMAN FLX™ Left Atrial Appendage Closure Device

Patient Information Guide

WATCHMAN FLX Left Atrial Appendage Closure Device

PATIENT INFORMATION GUIDE

Your doctor thinks that you should get a WATCHMAN FLX Implant or you have already had one put in a part of your heart called the left atrial appendage (LAA). Here is some important information about the implant that will answer many of your questions.

UNDERSTANDING YOUR HEART

This section explains how a normal heart works and when the heart gets a condition known as atrial fibrillation.

The Normal Heart

The heart has four parts: two upper atrial chambers (a right and left atrium) and two lower ventricular chambers (a right and left ventricle). The chambers fill with blood when the heart is resting then pump blood out

to the body with each heartbeat (or contraction).

The heart has special cells that make electrical signals to help the heart muscle beat and pump blood. Usually, your heart's pumping rate is controlled by the heart's internal pacemaker located in the upper part of the right atrium. The heartbeat spreads through both the right and left atrium and then travels to the right and left ventricles. This electrical signal makes the heart muscle contract and pump blood through the blood vessels. After each beat, the heart rests and fills with blood until the next beat. This cycle occurs millions of times in a year.

Atrial Fibrillation

In atrial fibrillation, the right and left atria do not contract together properly making the heartbeat (pulse) irregular. This can cause symptoms like feeling tired (fatigue), lightheaded, short of breath, or have a fluttering feeling in your chest (palpitations). Sometimes you might have no symptoms at all.

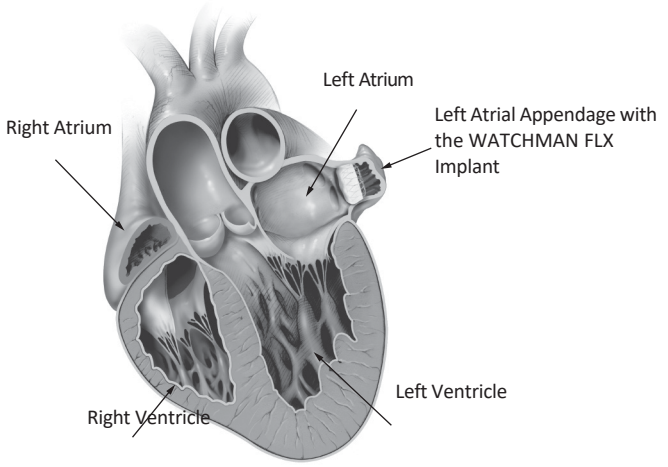
Doctors often give medications to keep the heartrate from getting too fast.

These medications usually help patients feel well and do normal activities even with atrial fibrillation. However, some patients still feel unwell despite taking these medications and need extra medications or special heart procedures (called cardioversion and ablation) to try to stop atrial fibrillation and keep the heart beating normally.

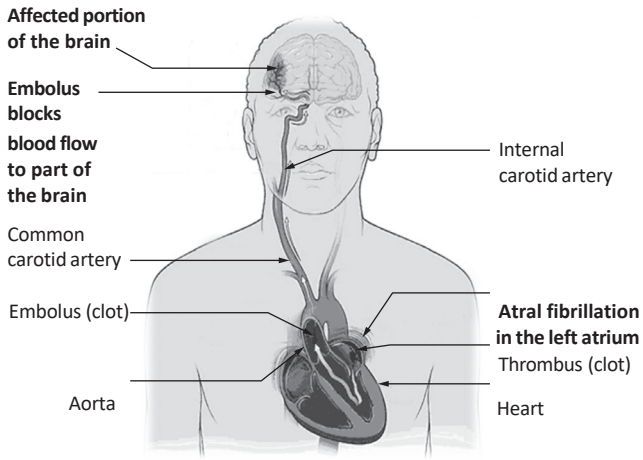
Atrial Fibrillation, Heart Blood Clots, and the Risk of Stroke

Because right and left atria don't contract normally in atrial fibrillation, the

blood flow within the atria can be slower than normal. This slower blood flow can cause blood clots to form. Most blood clots that start in the heart during atrial fibrillation 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 it breaks loose and blocks a blood vessel in the brain, it can cause a stroke, which can damage the brain within minutes. A stroke can result in the loss of a body function, weakness, a change in sensation, problems speaking, or even death. A thromboembolus can travel to other areas of the body and cause organ damage by blocking blood flow.



Not all people with atrial fibrillation have the same risk of getting blood clots and stroke. The risk is higher for those older (especially over 75 years), have high blood pressure, heart failure, diabetes, other heart disease, or have had a stroke or mini-stroke before.

Current Treatment to Prevent Stroke in Atrial Fibrillation Patients

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

However, some patients find that blood thinners are hard to tolerate or risky. Since they thin the blood to prevent clots, they can increase the risk of bleeding problems. Often the bleeding is minor like a cut taking longer to stop bleeding and can be easily treated. But sometimes, the bleeding can be serious needing hospitalization and transfusion and can even be life-threatening or fatal like a when stroke is caused by bleeding in the brain.

When prescribing blood-thinning medications in atrial fibrillation patients, doctors weigh the risk of a stroke against the risk of serious bleeding. Studies show that the *benefit* of reducing stroke risk from blood clots is greater than the *risk* of major bleeding (including brain bleeds). This means that anticoagulant medications prevent more strokes than they cause. Therefore, blood thinner medications are recommended for most patients. However, in some patients, the risk of major bleeding is believed to be too high, so they won't be prescribed these medications. Other atrial fibrillation patients might choose not to take blood thinners for a longer period of time because of minor bleeding, other side effects or worries about bleeding from injuries.

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 increase your stroke risk. While you might take blood thinning medication to reduce stroke risk, your doctor recommends the WATCHMAN FLX Implant as an alternative to long-term use of these drugs. In making this recommendation, your doctor has considered the benefits and risks of the WATCHMAN FLX Implant compared to those of approved blood thinning medication that are used to reduce stroke in atrial fibrillation patients.

Factors you and your doctor may consider are your overall stroke risk, the risk of stroke from a blocked blood vessel in the brain, and the risk of major bleeding while on blood thinners (including bleeding in the brain). For preventing a stroke caused by a blocked blood vessel in the brain, clot preventing medications may be better than the WATCHMAN FLX Implant. On the other hand, anticoagulant medications increase risk of major bleeding episodes, including bleeding in the brain, and these medications can usually be stopped about 6 to 12 weeks after the WATCHMAN FLX Implant is successfully placed in your heart, as long as the left atrial appendage is properly sealed. Your doctor will also consider your personal preferences regarding blood-thinning medications and procedures involved with the WATCHMAN FLX Implant.

WATCHMAN FLX implant following a catheter ablation for atrial fibrillation (either during the same procedure or following recent ablation procedure):

A catheter ablation is when your doctor destroys the tissue around the veins in the upper left chamber of your heart to try to get back to a normal heartbeat and reduce some symptoms of atrial fibrillation. If you have recently had a catheter ablation for atrial fibrillation, the WATCHMAN FLX Implant is similar to blood-thinning medications in preventing stroke caused by blood clots from the heart. The WATCHMAN FLX also has a lower risk of non-procedural bleeding episodes than blood thinners and blood thinners can be stopped 3 months after successful placement in your heart, provided the left atrial appendage is properly sealed.

When a blood clot forms in the heart of someone with atrial fibrillation, it is usually found in the left atrial appendage. The WATCHMAN FLX Implant acts as a barrier to stop these clots from entering the bloodstream and cause a stroke by blocking a blood vessel in the brain. However, it is important to know that strokes can also be caused by other factors like 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 blood-thinning 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 stroke risk.

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 blood-thinners, aspirin, or other medication to prevent blood clots.
- Patients who should not or cannot have a heart catheterization procedure.
- Patients who are allergic or sensitive to nickel, titanium, or any of the other materials in the WATCHMAN FLX Implant.

There are risks of having an invasive heart procedure. Patients who are doing well on blood thinners but have had a recent catheter ablation could be considered for the WATCHMAN FLX Implant. In general, a WATCHMAN FLX Implant is not suitable for patients if the risks of the procedure are higher than the benefits. The WATCHMAN FLX Implant is not recommended in patients whose atrial fibrillation is caused by serious heart valve disease.

WATCHMAN FLX LEFT ATRIAL APPENDAGE CLOSURE DEVICE

The WATCHMAN FLX Left Atrial Appendage Closure Device is placed at the opening of the left atrial appendage to stop blood clots from entering your blood stream and causing a stroke. It is made from materials that are commonly used in medical devices and 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 do a thorough check up. He/she will ask about your medical history, check your stroke risk, examine you, and take pictures of your heart. If you have a blood clot inside your heart, you should not get the WATCHMAN FLX Implant until the clot is gone after taking blood thinners.

Your doctor will tell you which medications to take, like blood thinners 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 special lab by a trained doctor and their team. You will lie on a table and be monitored during the procedure. X-rays and ultrasound pictures will help guide the implant to the right spot in your heart. Dye will be used to help place the implant. You will get a general and/or local anesthetic to reduce discomfort. Discuss the anesthesia method that is best for you with your doctor.

A small puncture is made into a vein in your groin. A long, thin tube, called a catheter, is inserted into the vein and moved 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 moved into the left atrium. A thinner catheter is watched with X-ray as it is moved into the left atrial appendage. The WATCHMAN FLX Implant is compressed inside the catheter and is passed through the catheter into the left atrial appendage. Once the WATCHMAN FLX Implant is in the right place, the doctor will then expand the implant and seal the left atrial appendage. After the procedure, the WATCHMAN FLX Implant is the only material that stays in the body.

After the Procedure

After WATCHMAN FLX is implanted, you will rest in the hospital and be monitored as you recover. You might stay one or more days and your doctor will decide how long you need to stay.

Your doctor will tell you to take a blood thinner or an antiplatelet and aspirin after your implant. After at least 45 days, your doctor will use a test called a TEE (transesophageal echocardiogram), to take pictures of your heart and check if the implant has closed the opening of the left atrial appendage.

If you were first given blood thinners and aspirin, your doctor will consider the results of the TEE and ***may*** stop your blood thinner. If your doctor chooses to stop your blood thinner, they will give you an antiplatelet medication (such as Plavix™, Effient™ or Brilinta™) until 6 months after your implant procedure. If you were first given an antiplatelet and aspirin, your doctor may change your medicines based on the results of your TEE. Unless your doctor tells you differently, you should continue your antiplatelet and aspirin therapy (also known as `dual antiplatelet therapy' or DAPT) for 6 months. You continue to take aspirin indefinitely.

If the TEE that is done at around 45 days shows that the left atrial appendage is not fully closed or if there is a blood clot on the device, another TEE may be scheduled at around 6 months to check again. At about 12 months after your WATCHMAN FLX Implant, your doctor will schedule another TEE to make sure the left atrial appendage is still closed and there is no blood clot on the device.

WATCHMAN FLX implant following a catheter ablation for atrial fibrillation for atrial fibrillation (either during the same procedure or following recent ablation procedure):

Your doctor will tell you to take a blood thinner and aspirin after your implant. After at least 3 months, your doctor will use a test called a TEE (transesophageal echocardiogram), to take pictures of your heart and check if the implant has closed the opening of the left atrial appendage.

If you were first given blood thinners and aspirin, your doctor will consider the results of the TEE and may stop your blood thinner. If your doctor chooses to stop your blood thinner, they will prescribe you aspirin only indefinitely. If the TEE that is done at around 3 months shows that the left atrial appendage is not fully closed, or if there is a blood clot on the device, another TEE may be scheduled at around 12 months to check again. You may continue to take your blood thinners until your doctor tells you to stop. At about 12 months after your WATCHMAN FLX Implant, your doctor will schedule another TEE to make sure the left atrial appendage is still closed and there is no blood clot on the device.

It is very important to take your medications (blood thinners, antiplatelet medication, and aspirin) as recommended time. If you stop or change the dosage without your doctor's advice, then you risk blood clots, stroke, or even death. Talk to your doctor before stopping your medications or changing the dosage.

If you need surgery or dental work that requires stopping your medications early, you and your doctors should weigh the risks and benefits. Talk to your doctor about the timing of any medical procedures you may need.

If you do need to stop these medications early because of serious bleeding, your doctor will watch you closely for any problems. Once you are stable, your doctor may restart these medications. Talk to your doctor before restarting medications or changing their doses.

MRI SAFETY INFORMATION

A person with the Boston Scientific WATCHMAN FLX Closure Device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	WATCHMAN FLX Closure Device
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	25 T/m (2,500 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/ scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of up to 8 mm.

If information about a specific parameter is not included, there are no conditions associated with parameter.

CLINICAL STUDIES

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

- Lowering the risk of stroke from a blood clot in the left atrial appendage
- Being able to stop long-term blood thinner therapy and a reduction in the risks associated with long-term blood thinner 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 blood thinner 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 blood thinners. 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 blood thinners after first follow-up visit.

The OPTION study was designed to determine if WATCHMAN FLX is a reasonable alternative to blood thinners following catheter ablation in 1600 patients. Patients were randomized to receive either a device implant or blood thinners after catheter ablation. The results of the OPTION trial show a low rate of major complications in those patients that received the device. In the OPTION trial, 85.6% of device patients were able to stop taking blood thinners after first follow-up visit.

In all of the WATCHMAN clinical trials, greater than 92% patients were able to stop taking their blood thinners after their first follow-up visit, and over 95% 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.

In the OPTION study, patients who had an ablation and WATCHMAN FLX compared to patients who had an ablation and took blood thinners for three years all had a similar risk of stroke (either from a blocked vessel or bleeding within the brain), any death, or a blocked blood vessel in another part of the body besides the brain. Patients with WATCHMAN FLX bled less starting 3 days after the procedure compared to patients on blood thinners.

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 windpipe)

- 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)
- Myocardial Infarction (heart attack)
- 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)
- Radiation injury (tissue damage or burn from X-ray)
- 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 prevent blood clots from forming. After your WATCHMAN FLX Implant has been in place for at least 45 days, your doctor ***may*** modify your medications based on the results of your TEE test.

WATCHMAN FLX implant following a catheter ablation for atrial fibrillation (either during the same procedure or following recent ablation procedure):

Your doctor has prescribed medication to prevent blood clots from forming. After your WATCHMAN FLX Implant has been in place for at least of 3 months, your doctor **may** modify your medications based on the results of your TEE test.

It is very important to follow your medication plan. If you stop or change your medications without your doctor's advice, you risk blood clot, stroke, or even death.

ACTIVITY

- Follow your doctor's recommendations.
- Gradually return to normal activities, 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. See the MRI Safety Information section for more information.

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.

Report any serious incident that occurs in relation to your device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country.

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Symbol Definitions

The following symbols are used for patient information:

REF Catalog Number	LOT Lot Number	MR Conditional
Indicates the date the device must be implanted by.	Manufacturer	UDI Unique Device Identifier

REF

M635WU50200	M635WU50240	M635WU50270	M635WU50310	M635WU50350

Information in this patient guide relates to the health care professional WATCHMAN FLX Instructions for Use for this device. See www.IFU-BSCI.com for the health care professional Instructions for Use.

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.

Boston Scientific

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

2024-12

51973973-01

Perforation

Boston Scientific

INSTRUCTIONS FOR USE

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The Instructions for Use (IFU) for this product are supplied in electronic form over the Internet.

Visit www.IFU-BSCI.com to access the IFU in Adobe® Portable Document Format (PDF), and be sure to have the product label available for reference.

If you have difficulty accessing the IFU online, or would prefer to receive a paper copy, please contact Boston Scientific Customer Service or your local country contact. A copy will be sent to you at no charge and should arrive within seven days.

2025-06

52038325-01

Patient Implant Card

Apply the peel-off label from the product onto patient implant card. Fill in implant date, patient name, healthcare institution and/or physician contact information. Tear off patient implant card along perforation and provide to patient.

Perforation

Place peel-off here

Score & Fold

Boston Scientific

Manufacturer
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001
www.IFU-BSCI.com

MR Conditional

2025-06 52038325-01

Score & Fold

Boston Scientific

Implant Card

WATCHMAN FLX™ Left Atrial Appendage Closure Device

Please carry this card at all times and show it to any medical personnel, including a MRI technician, that may be treating you.

Front

Boston Scientific (Patient Guide Template 8in x 8in), Patient Card, MB, Watchman FLX, en/fr, 52038325-01A

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Perforation

Perforation

Score & Fold

Score & Fold

Back

Carte d'implant du patient

Appliquer l'étiquette pelable du produit sur la carte d'implant du patient. Indiquer la date de l'implantation, le nom du patient, les coordonnées de l'établissement de soins de santé et/ou du médecin. Détacher la carte d'implant du patient le long de la perforation et la remettre au patient.

MRI Safety Information

Non-clinical testing has demonstrated the WATCHMAN FLX Device is MR Conditional. A patient with the Closure Device can be scanned safely, immediately after implantation, under the following conditions:

- Static magnetic fields of 3.0 Tesla or 1.5 Tesla
- Maximum spatial gradient field of 2500 Gauss/cm (25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2.0 W/kg (normal operating mode only)

If information about a specific MR system parameter is not included, there are no conditions associated with that parameter.

Under the scan conditions defined above, the WATCHMAN FLX Device is expected to produce a maximum temperature rise of less than 3.0 °C after 15 minutes of continuous scanning. The maximum continuous scan duration is 60 minutes.

Presence of the WATCHMAN FLX Device may produce an image artifact of up to 8 mm.

Scanning under different conditions may result in device malfunction, injury and/or death.

Full MRI safety information is available in the WATCHMAN FLX Instructions for Use, which can be obtained at www.IFU-BSCI.com

PLEASE CARRY YOUR CARD AT ALL TIMES.

Your doctor has prescribed medication to thin the blood and prevent blood clots after your WATCHMAN FLX 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 FLX Implant or other procedures (e.g., MRI), please contact your implanting doctor.**

Follow-up Visit dates	

Patient Name and ID Code

Implanting Physician's Name

Date of Implant

Hospital Telephone Number

Hospital Name

Hospital Address

Register your card with WATCHMAN.com/implantcard to receive a new card in case of loss. This registration is voluntary for all WATCHMAN FLX recipients. To view the WATCHMAN FLX patient information guide, please visit www.IFU-BSCI.com. To receive a hard copy patient information guide, call 1.888.272.1001.

MODE D'EMPLOI

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Le mode d'emploi de ce produit est fourni sous forme électronique par Internet.

Consultez le site www.IFU-BSCI.com pour accéder au mode d'emploi au format PDF (Portable Document Format) d'Adobe et assurez-vous d'avoir l'étiquette du produit à titre de référence.

Si vous avez des problèmes pour accéder au mode d'emploi en ligne ou que vous préférez recevoir une copie papier, contacter le service clientèle de Boston Scientific ou votre représentant local. Un exemplaire vous sera envoyé gratuitement et devrait vous parvenir dans les sept jours.

Boston Scientific (Patient Guide Template 8in x 8in), Patient Card, MR, Watchman FLX, en/fr, 52038325-01A