Product Information for Patients

WATCHMAN FLX™

Atrial Implant

Device Information

The WATCHMAN FLX Device is for patients with non-valvular atrial fibrillation. The WATCHMAN FLX Device fits into a part of your heart called the left atrial appendage (LAA). 90 % of stroke-causing blood clots that come from the heart are formed in the LAA. The WATCHMAN FLX Device permanently closes off this part of your heart to keep those blood clots from escaping and possibly causing a stroke. The WATCHMAN FLX Device is meant to stay in your heart for the rest of your life.

Even though the LAA is a source of blood clots that may lead to a stroke, it is not the only source. Other possible causes of stroke include disease of blood vessels in and near the brain and conditions that cause the blood to clot very easily.

Your doctor should provide you with an implant card that identifies your particular implant, and should be carried with you at all times. Your implant card should be presented to all your health care providers (doctors, dentists, technicians) so they know that you have an implanted device.

Information on Safe Use

If you need an MRI scan, tell your doctor or MRI technician that you have a WATCHMAN FLX Device in your heart. You may safely have an MRI scan if the MRI uses the following conditions:

- Static magnetic fields of 3.0 Tesla or 1.5 Tesla
- Maximum spatial gradient field of 2500 Gauss/cm
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2.0 W/kg (normal operating mode only) for 15 minutes

Contact your health care professional if you believe that you are experiencing adverse events (side effects) related to the device or if you are concerned about risks. Possible adverse events that may happen with the use of the WATCHMAN FLX Device 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 the windpipe)
- Allergic reaction to contrast media/medications or device materials
- Altered mental status (change in mental status)
- Anemia (low blood count) requiring transfusion
- Anesthesia risks
- 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 between two heart chambers)
- Bruising, hematoma (blood collection), or seroma (fluid collection) near the catheter insertion site
- Cardiac perforation (puncture of the heart muscle)
- Chest pain/discomfort
- Confusion post-procedure
- Congestive heart failure (decreased ability of your heart to pump blood)
- Contrast-related nephropathy (kidney damage from contrast media)

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- Cranial bleed (bleeding inside the skull)
- Death
- Decreased hemoglobin (lack of red blood cells in your blood)
- Deep vein thrombosis (clot in the vein)
- Device embolization (implant moves from the intended location)
- Device fracture (damage to the WATCHMAN implant)
- Device thrombosis (clot on the implant)
- Edema (fluid collection in the tissue)
- Embolism (release of particles, blood clot, or air bubbles in bloodstream)
- Excessive bleeding
- Fever
- Fistula (abnormal connection between blood vessels or two hollow or tubular organs)
- Groin pain
- Groin puncture bleed
- Hematuria (blood in 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 the device
- Infection/pneumonia
- Interatrial septum thrombus (blood clot on wall between heart's upper chambers)
- Intratracheal bleeding (bleeding in the windpipe)
- Major bleeding requiring transfusion
- Misplacement of the device/improper seal of the appendage/movement of 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 (bleeding from tear or cut)
- Pseudoaneurysm (abnormal collection of blood between the outer two layers of the arterial wall)
- 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)
- Stroke – Hemorrhagic (stroke from bleeding inside the brain)
- Stroke – Ischemic (stroke from lack of blood supply to a part of the brain)
- Surgical removal of the device
- 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)

Warnings and/or Precautions

See Information on Safe Use section above.

Expected Lifetime and Follow-up

Your doctor will schedule a follow-up visit about 6 weeks (45 days) after your WATCHMAN FLX Device is put in your heart to check how it is working. Be sure to follow your doctor's instructions. Your doctor may change your medication plan at a follow-up visit.

The WATCHMAN FLX Device has been tested for at least 10 years for strength and quality to make sure it does not crack or break. The device is meant to stay in your heart for the rest of your life.

If any serious incident does occur in relation to your WATCHMAN FLX Device, first contact your doctor. Report any serious incident that occurs in relation to this device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country. Contact information for Boston Scientific can be found at the end of this document.

For customers in Australia, report any serious incident that occurs in relation to this device to Boston Scientific and to the Therapeutic Goods Administration (https://www.tga.gov.au).

Patient Contacting Materials

The WATCHMAN FLX Device is not meant for patients with a nickel allergy. Below are the materials used in the WATCHMAN FLX Device that are permanently placed in your heart. Tell your doctor if you think you are allergic or sensitive to any of these materials.

Material	Amount(s)*
Titanium Dioxide	0.000 4 g
Polyethylene terephthalate (PET)	0.094 g
Nickel-titanium alloy (Nitinol)	0.328 g
Titanium grade 2	0.031 g

During the WATCHMAN FLX procedure a stainless steel part touches the blood in your body. This part may contain more than 0.1 % cobalt. Cobalt has the possibility of causing cancer or reproductive effects (CMR 1B). Contact with the stainless steel part occurs only during the procedure. The WATCHMAN FLX Device, which is permanently placed in your heart, does not contain stainless steel. According to current scientific evidence, contact with stainless steel containing cobalt during a medical procedure does not increase your risk of cancer or reproductive effects.

*The WATCHMAN Device has multiple sizes. Your doctor picks the right size for your heart. Amounts listed are for the largest size. Some amounts will be less for smaller sizes.

Symbol Definitions

The following symbols are used for patient information:

Date	Health care center or doctor	Patient identification
Catalog Number	Lot Number	Unique Device Identifier
Use By — Indicates the date the device must be implanted by.	MR Conditional	

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MB Drawing 50818813

Black (K) ΔE ≤5.0

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M635WS50200	M635WS50240	M635WS50270	M635WS50310	M635WS50350

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