Boston Scientific
Advancing science for life™

WATCHMAN™
INTEGRATED LAAC SOLUTIONS

MRI Information with the WATCHMAN Left Atrial Appendage Closure Devices

Non-clinical testing has demonstrated the WATCHMAN LAAC Device is MR Conditional. A patient with the WATCHMAN Implant can be scanned safely, immediately after implantation, under the defined conditions by device generation.

Refer to the patient's implant card to identify the WATCHMAN Implant device generation (i.e. WATCHMAN, WATCHMAN FLX™, WATCHMAN FLX™ Pro).

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

Frequently Asked Questions

Where can I find MRI safety guidelines for the WATCHMAN Implant?

Full safety information for the WATCHMAN Implant is in the IFU, available at IFU-BSCI.com. Refer to your patient's implant card to identify their device generation.

What should I do if my patient has lost or does not have an implant card?

In cases where the patient's device generation is not known, refer to the MRI safety guidance in the WATCHMAN FLX LAAC Device IFU. If the patient received their implant before 2022, also limit continuous scan duration to 15 minutes per the WATCHMAN LAAC Device IFU. These instructions will ensure the most stringent MRI criteria among the potentially implanted device generations are applied.

Do I need to know my patient's device lot number?

Lot number is not required. Refer to your patient's implant card to identify their device generation. If the patient does not have their implant card but the lot number is known, you can contact Boston Scientific with the patient present, and our representatives may be able to determine the device generation based on the lot number.

How soon can a patient have an MRI after the WATCHMAN Implant procedure?

A patient can be scanned safely anytime following implantation, as long as the correct safety guidelines are followed.

I'm looking for a parameter I don't see listed in the IFU. What should I use?

The WATCHMAN Implant is not an active implantable, so some MRI criteria that apply to other implanted devices (ex. leads) do not apply for the WATCHMAN Implant. If information about a specific parameter is not included in the IFU, then there are no conditions associated with that parameter. In other words, you may use any desired setting for MRI parameters that are not listed in the MRI safety table, provided the parameters that are listed in the MRI safety table are still met.

Can I proceed with an MRI if my patient has multiple medical devices? For example, a pacemaker and the WATCHMAN Implant.

Follow the MRI safety guidelines for all medical devices a patient has. Refer to the most stringent MRI guidelines.

Who should I contact with additional questions not addressed here?

If you have questions regarding the MRI safety guidelines in the IFU, please consult your radiologist.

The following is an overview of MRI safety information by device.

A person with a Boston Scientific WATCHMAN LAAC Device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	WATCHMAN LAAC Device*	WATCHMAN FLX™ LAAC Device	WATCHMAN FLX™ Pro LAAC Device
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T	1.5 T or 3.0 T	1.5 T or 3.0 T
Maximum Spatial Field Gradient	25 T/m (2,500 Gauss/cm)	25 T/m (2,500 Gauss/cm)	40 T/m (4,000 Gauss/cm)
RF Excitation	Unspecified (can reference WATCHMAN FLX or FLX Pro)	Circularly Polarized (CP)	Circularly Polarized (CP)
RF Transmit Coil Type	Unspecified (no restrictions)	There are no Transmit Coil restrictions	There are no Transmit Coil restrictions
RF Receive Coil Type	Unspecified (Any)	Any	Any
Operating Mode	Unspecified (can reference WATCHMAN FLX or FLX Pro)	Normal Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)	2 W/kg (Normal Operating Mode)	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Unspecified (can reference WATCHMAN FLX or FLX Pro)	3.2 W/kg (Normal Operating Mode)	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 15 minutes of scanning	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)	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 5mm.	The presence of this implant may produce an image artifact of up to 8mm.	The presence of this implant may produce an image artifact of up to 8mm.

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

***Additional WATCHMAN LAAC Device MRI information:**

The WATCHMAN Device should not migrate in this MRI environment. This device has not been evaluated to determine if it is MR Conditional beyond these parameters.

3.0 Tesla Temperature Information

In non-clinical testing, the WATCHMAN Device produced a temperature rise of <1.1 oC at a maximum MR system-reported SAR of 2.0 W/kg as measured by calorimetry for 15 minutes of continuous MR scanning in a 3.0 Tesla MR system (Excite, Software G3.0-052B, GE Healthcare, Milwaukee, WI).

These calculations do not take into consideration the cooling effects of blood flow.

1.5 Tesla Temperature Information

Non-clinical testing of RF-induced heating in the WATCHMAN Device was performed at 64 MHz in a 1.5 Tesla whole body coil MR scanner (Intera, Software release 10.6.2.4, 2006-03-10, Philips Medical Systems, Andover, MA) and produced a temperature rise of <1.5 oC at an MR extrapolated SAR of 2.0 W/kg for 15 minutes of continuous MR scanning.

These calculations do not take into consideration the cooling effects of blood flow.

Image Artifact Information

In non-clinical testing, the image artifact caused by the device extends less than 3 mm from the WATCHMAN Device when imaged with a spin echo pulse sequence and a 3-Tesla MRI system. The image artifact caused by the device extends less than 5 mm from the WATCHMAN Device when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system. MR image quality may be compromised if the area of interest is relatively close to the WATCHMAN Device. Optimization of MR imaging parameters is recommended.

WATCHMAN FLX Pro Device | Brief Summary

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Intended Use/Indications for Use

WATCHMAN FLX Pro is intended for percutaneous, transcatheter closure of the left atrial appendage.

Indications for Use

The WATCHMAN FLX Pro Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy.
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

Contraindications

Do not use the WATCHMAN FLX Pro Device if:

- Intracardiac thrombus is present.
- An atrial septal defect repair or closure device is present.
- A patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a Closure Device (see Step 7).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN FLX Pro Device is contraindicated.
- Any of the customary contraindications for other percutaneous catheterization procedure (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.
- There are contraindications to the use of anticoagulation therapy, aspirin, or P2Y12 inhibitor.

Warnings

Implantation of the WATCHMAN FLX Pro Device should only be performed by interventional cardiologists and/or electrophysiologists who are proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized and who have completed the WATCHMAN FLX Pro Physician Training program.

- For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the Closure Device and/or lead to Closure Device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the Closure Device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Closure Device may lead to injury, illness, or death of the patient.
- This device has not been studied in pregnant or breastfeeding women. Careful consideration should be given to use of the Closure Device in pregnant and/ or breastfeeding women due to the risk of significant exposure to x-rays and the use of anticoagulation medication.
- Device selection should be based on accurate LAA measurements obtained using transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]; For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium.
- Do not release (i.e., unscrew) the WATCHMAN FLX Pro Device from the core wire unless all release criteria (Step 15) are satisfied to avoid suboptimal results.
- Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period.
- If thrombus is observed on the device, anticoagulation therapy is recommended until resolution of thrombus is demonstrated by TEE.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section for further detail.
- Do not use if the temperature exposure indicator dot on the pouch label is red or missing, indicating Closure Device performance may have been compromised

Precautions

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Pro Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.
- The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying, recapturing, and repositioning the Closure Device.
- Use caution when introducing a WATCHMAN Access System to prevent damage to cardiac structures.
- Use caution when introducing the Delivery System to prevent damage to cardiac structures.
- To prevent damage to the Delivery Catheter or Closure Device, do not allow the WATCHMAN FLX Pro Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath.
- If using a power injector, the maximum pressure should not exceed 690 kPa (100 psi).
- Use caution when manipulating the Delivery System. Excessive counterclockwise rotation of the deployment knob or Delivery System hub independent from the rest of the Delivery System can cause premature implant detachment.

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.

Potential Adverse Events

Air embolism, Airway trauma, Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medication, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, Bruising, hematoma, or seroma near the catheter insertion site, Cardiac perforation, Chest pain/discomfort, Confusion post-procedure, Congestive heart failure, Contrast-related nephropathy, Cranial bleed, Death, Decreased hemoglobin, Deep vein thrombosis, Device embolism, Device fracture, Device thrombosis, Edema, Embolism, Excessive bleeding, Fever, Fistula, Groin pain, Groin puncture bleed, Hematuria, Hemoptysis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection/pneumonia, Interatrial septum thrombus, Intratracheal bleeding, Major bleeding requiring transfusion, Misplacement of the device/improper seal of the appendage/movement of device from appendage wall, Myocardial erosion, Myocardial infarction, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Radiation injury, Renal failure, Respiratory insufficiency/failure, Stroke - Hemorrhagic, Stroke - Ischemic, Surgical removal of the device, TEE complications (e.g., throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular or vascular damage, Vasovagal reactions

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

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Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.