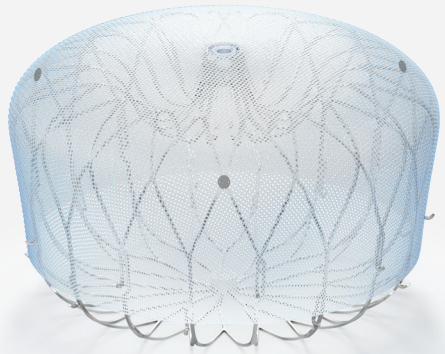


Boston Scientific
Advancing science for life™

WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

#1 Doctor Recommended LAAC Implant

MOST STUDIED AND IMPLANTED LAAC DEVICE IN THE WORLD

Evolved from 20 years of innovation and the experience gained from 400,000+ successful implants and 10+ clinical studies, WATCHMAN™ is the LAAC technology with proven safety and trusted patient outcomes.

PROVEN[1]

+400K
Patients Successfully Implanted

10+
Clinical Trials

SAFE[2]

99%
Implant Success Rate (395/400)*

0.5%
Major Adverse Event Rate**

- **0.5%** Ischemic Stroke (2/400)
- **0%** Device Embolization
- **0%** All-cause Death
- **0%** Pericardial Effusions Requiring Open Cardiac Surgery

EFFECTIVE[2]

100%
Effective LAA Closure at 12 Months†

>96%
Discontinued OAC at 45 Days in Clinical Trial

The PINNACLE FLX US IDE Clinical Trial was designed to establish the procedural safety and closure efficacy of the WATCHMAN FLX Implant.
* Procedure success defined as successful delivery and release of a WATCHMAN FLX device into the LAA.
**Occurrence of one of the following events between the time of implant and within 7 days following the procedure or by hospital discharge, whichever is later: all-cause death, ischemic stroke, systemic embolism, or device or procedure related events requiring open cardiac surgery or major endovascular intervention.
† LAA closure at 12 months is defined as any peri-device flow with jet size <5mm per core laboratory-assessed TEE.

Protected By WATCHMAN. For Life.

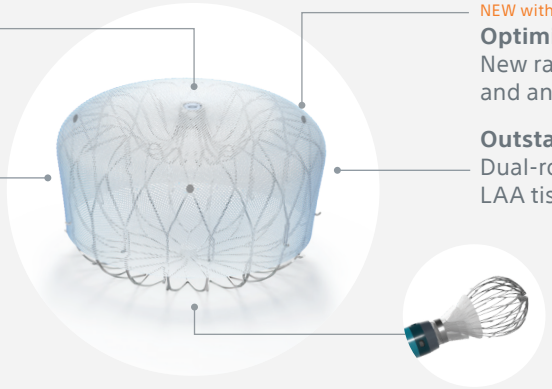
The WATCHMAN LAAC Implant is a one-time procedure that delivers a lifetime of stroke risk reduction, without the bleeding risks associated with lifelong oral anticoagulation therapy.

One Time. For a Lifetime.

The WATCHMAN FLX™ Pro LAAC Implant is built on the safety and procedural success of the WATCHMAN FLX Implant.

Purpose-built for the LAA
Nitinol frame and PET cover conform to the LAA to treat more anatomies.

NEW with WATCHMAN FLX Pro
Improved healing response
HEMOCOAT™ Technology is a durable coating that is designed to help prevent thrombus formation and result in less inflammation.[3]



NEW with WATCHMAN FLX Pro
Optimized device placement
New radiopaque markers help implanters position and anchor the device with 57% greater visibility.[4]

Outstanding Stability
Dual-row anchors or optimal engagement with LAA tissue for long-term stability.

Engineered for safety
Fully rounded ball for safe advancement and maneuvering.

The WATCHMAN Implant may be suitable for a broad range of non-valvular Afib (NVAF) patients and may be an appropriate option for your NVAF patients who:

1	Have an increased risk for stroke and be recommended for oral anticoagulation (OAC) (CHA_2DS_2-VASc ≥ 2 for men, ≥ 3 for women)*
2	Are suitable for short-term OAC therapy
3	Have an appropriate reason to seek a non-pharmacologic alternative to OACs

*CHA_2DS_2-VASc score – Congestive heart failure = 1, Hypertension (SBP >160) = 1, Age > 75 yrs = 2, Diabetes mellitus = 1, Prior stroke, TIA, or thromboembolism = 2, Vascular disease (PAD, MI) = 1, Age 65-74 yrs = 1, Sex category (female) = 1.

CMS coverage criteria requires a CHA_2DS_2-VASc score ≥ 3. Providers are encouraged to read the decision memo in its entirety for additional detail. Commercial Policies' medical criteria may vary.

Brief Summary WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED 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 CHA2 DS2-VASc1 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 in the IFU).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section in the IFU) 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 in the IFU) 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.

ADVERSE EVENTS
Potential adverse events which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to:
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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References:
1. Represents the combination of data for all WATCHMAN models.
2. Boston Scientific data on file. Bench study performed under CT by Boston Scientific.
3. Saliba, W., et al. JACC EP, May 2023. Based on preclinical testing. Bench testing or pre-clinical study results may not necessarily be indicative of clinical performance. N=12 in a pre-clinical canine study.
4. Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.