Boston Scientific
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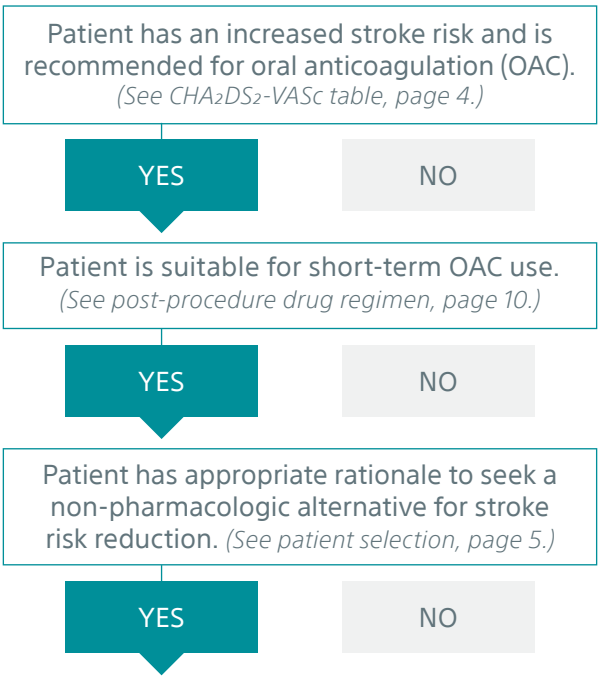
# WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

# Referring Pocket Guide

# FDA Indications for Use*

The WATCHMAN Implant is indicated to reduce the risk of thromboembolism originating in the left atrial appendage (LAA) for patients with non-valvular AFib who meet these criteria:




*See full indication on page 14.

# CMS Coverage Criteria

## CMS will cover LAAC with the WATCHMAN Implant when the following criteria are met:*†

1 **Increased risk for stroke**

$CHADS_2$ score ≥2
or a $CHA_2DS_2$-VASc score ≥3

2 **Suitable for Short-Term OAC Therapy**

But deemed unable to take long-term oral anticoagulation

3 **Formal Shared Decision-Making Interaction**

**Independent non-interventional physician** using an OAC evidence-based decision**

* *Providers are encouraged to read the decision memo in its entirety for additional detail. Commercial Policies' medical criteria may vary.*

** *Documented in patient medical record*

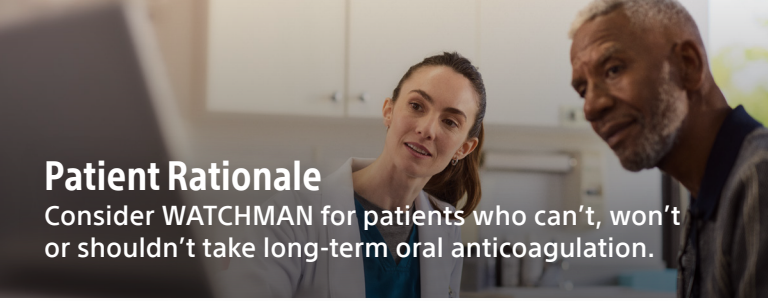
† *98% of Commercial Plans also cover LAAC. Numbers derived from DRG, Part of Clarivate, 2023. May not include employer sponsored plans.*

# $CHA_2DS_2$-VASc Score (Stroke Risk)[a]

| | Condition | Points |
|---|---|---|
| C | Congestive heart failure | 1 |
| H | Hypertension | 1 |
| A | Age ≥ 75 years | 2 |
| D | Diabetes mellitus | 1 |
| $S_2$ | Prior stroke, TIA, or thromboembolism | 2 |
| V | Vascular disease (PAD, MI) | 1 |
| A | Age 65-74 years | 1 |
| Sc | Sex category (Female) | 1 |
| **Total Points** | | |

| Score | Yearly Stroke Risk (%) | | |
|---|---|---|---|
| | No Warfarin | With Aspirin[b] | With Warfarin[b] |
| 0 | 0 | 0 | 0 |
| 1 | 1.3 | 1.0 | 0.5 |
| 2 | 2.2 | 1.8 | 0.8 |
| 3 | 3.2 | 2.6 | 1.1 |
| 4 | 4.0 | 3.2 | 1.4 |
| 5 | 6.7 | 5.4 | 2.3 |
| 6 | 9.8 | 7.8 | 3.4 |

*a. $CHA_2DS_2$-VASc: Chest. 2010;137(2):263-272.*
*b. Warfarin Stroke Reduction: Ann Intern Med. 2007;146:857-867.*
*Elevated Risk = $CHA_2DS_2$-VASc ≥ 2 in men, ≥ 3 in women.*
*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.*



# Patient Rationale

Consider WATCHMAN for patients who can't, won't or shouldn't take long-term oral anticoagulation.

## Past bleed

A major or minor bleeding episode

**Questions to ask your patients:**

- Have you experienced side effects from your blood thinner?
- Have you noticed bruising or bleeding?

## Increased risk of stroke

History of stroke due to:

- Non-compliance
- Inability to maintain INR

**Questions to ask your patients:**

- Do you sometimes miss or forget to take your blood thinner?
- Do you struggle filling or picking up your prescription?
- Is the cost of your blood thinner a concern for you?

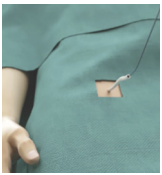
## Increased risk of future bleed

- Due to work or activities that increase risk of falling or bleeding
- Caused by other medications that increase bleeding risk
- Caused by side effects of oral anticoagulation (OACs), such as bleeding risk based on HAS-BLED score or other factors

### Questions to ask your patients:

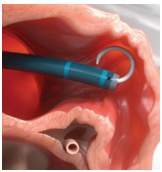
- Do you have concerns about falling?
- Do you live with someone who is able to help you in case of a fall?
- What other medications are you taking?
- Does being on a blood thinner interfere with your daily tasks or activities?
- Have you had to change your diet or lifestyle?

# Implant Procedure Overview



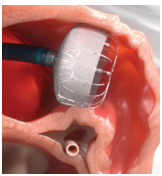
## 1. Access

Using a standard percutaneous technique, a guidewire and vessel dilator are inserted into the femoral vein. The implant procedure is performed with fluoroscopy and transesophageal echocardiography (TEE).



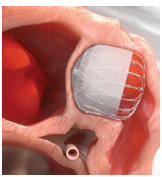
## 2. Cross

The interatrial septum is crossed using a standard transseptal access system. The access sheath is advanced over the guidewire into the left atrium and then navigated into the distal portion of the left atrial appendage (LAA) over a pigtail catheter.



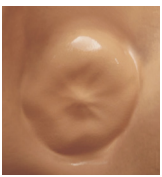
## 3. Deploy

The WATCHMAN Implant is deployed and released in the LAA.



## 4. Heal

Heart tissue grows over the implant and the LAA is permanently sealed; patients will then follow the post-procedure drug regimen as prescribed by their physician.



## 5. Protect

The implant is fully endothelialized.

# How the WATCHMAN LAAC Implant Works

The WATCHMAN LAAC Implant is a minimally invasive, one-time procedure designed to reduce the risk of strokes that originate in the LAA, where 90% of blood clots in the heart form.[1] WATCHMAN is the only LAAC device without a requirement of an overnight stay post-procedure.

## Procedure Overview

- Permanent implant
- Minimally invasive
- 1 day or less average hospital stay

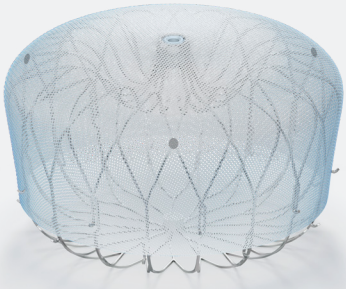
24 mm*

## Learn more about the WATCHMAN LAAC Implant procedure

*1. Blackshear JL., Odell JA. Annals of Thoracic Surg. 1996; 61: 755-759.*
**24 mm device shown for relative size comparison. WATCHMAN FLX Pro is available in six sizes to treat a broad range of patient LAA anatomies.*

**#1 DOCTOR RECOMMENDED LAAC IMPLANT**

# Most Studied and Implanted LAAC Device in the World



## Clinical Data

PINNACLE FLX IDE Clinical Study Results for the WATCHMAN FLX LAAC Implant

**PROVEN | SAFE | EFFECTIVE**

### ADVANCED SAFETY[1]

**99%**
Implant Success Rate (395/400)*

**0.5%**
Major Adverse Event Rate†

### PROVEN EFFICACY[1]

**100%**
Effective LAA Closure at 12 Months‡

**>96%**
of Patients Discontinued OAC After 45 Days

** 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.*

*1 Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.*

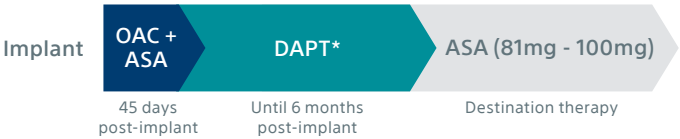
# Post-Procedure Drug Regimen

What to expect after a WATCHMAN Implant procedure

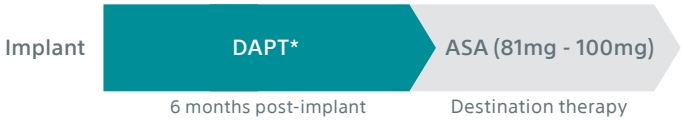
## Post-Procedure Drug Regimen Options

Only the WATCHMAN Implant provides you the flexibility to **choose the ideal drug regimen that is best for your patients** with clinical outcomes that support safety and efficacy in preventing thrombosis and consequent stroke.

**Option 1:** Short-Term OAC




**Option 2:** Immediate DAPT-Only




As always, you should exercise clinical judgment based on individual patient characteristics in determining the most appropriate use of anti-thrombotic drugs for the post-implant medication regimen.

*ASA = Aspirin.*

*At TEE, if leak >5mm, patients remain on OAC + ASA until seal is documented (leak <5mm).*

**Any P2Y12 Inhibitor and Aspirin.*

# Patient Cost

Help your patient understand what they may expect in terms of cost and post-procedure regimen associated with the WATCHMAN Left Atrial Appendage Closure Implant.

## Estimated 2025 Medicare Patient Out-of-Pocket Costs for the WATCHMAN LAAC Implant

| | | Totals |
|---|---|---|
| **Preparing for WATCHMAN** | | |
| Pre-Screening TEE[1,2] | $130 | **$130** |
| **WATCHMAN Implant** | | |
| Inpatient Deductible[3] (Medicare Part A) | $1,676 | |
| Medical Services Deductible[3] (Medicare Part B) | $257 | |
| **Physician Professional Fee Co-Pays[2]** | | |
| Implanter | $148 | |
| Anesthesiologist | $85 | |
| Intraoperative TEE Operator | $43 | **$2,209** |
| **Post WATCHMAN Therapy Drug Regimen[4]** | | |
| Warfarin | $77 | |
| **OR** DOAC | $687 | |
| 45-day follow-up TEE[2] | $130 | **$336 - $947** |
| 1-year follow-up TEE[2] | $130 | |
| **Total Estimated Maximum Patient OOP Costs: $3,286** | | |

***NOTE:*** *Estimated costs are based on national averages of 2025 U.S. Medicare rates, and assume a 20% copay for Medicare Part B. These estimates will vary depending upon the patient's individual healthcare policy. Insurance coverage can vary significantly from one plan to another, even within the same insurance company. We therefore recommend that patients contact their insurance provider directly with questions regarding estimated patient-specific out-of-pocket costs.*

# Important Information

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies.

This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services.

It is always the provider's responsibility to determine medical necessity, to determine the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services rendered. It is also always the provider's responsibility to understand and comply with Medicare national coverage determinations (NCD), Medicare local coverage determinations (LCD), and any other coverage requirements established by relevant payers, which can be updated frequently. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters.

Boston Scientific does not promote the use of its products outside their FDA-approved label. Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements.

**REFERENCES**

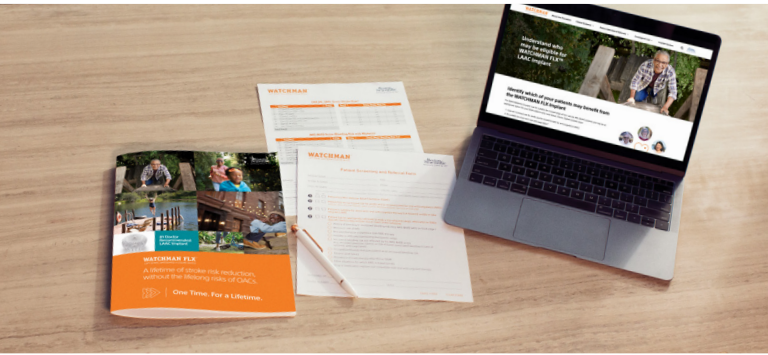

**1**. The pre-screen TEE cost will be different if it is completed within 72 hours before hospital admission due to the 3-Day Payment window. Source: CMS MLN Matters, SE20024, December 3, 2020.

**2**. Patient Costs are calculated based on Medicare beneficiaries 20% coinsurance payment for Part B services, for both hospital (where applicable) and physician work. Rates are CY2025 Medicare rates set by the CY2025 CMS Physician Fee Schedule and CY2025 CMS Hospital Outpatient Prospective Payment System Annual Rules. Payments from Optum, Inc. Accessed 02/04/2025.

**3**. Traditional Medicare beneficiaries 2025 Part A ($1,676), ($257) Part B, and ($590) Part D deductibles may have already been met for patients if they have had prior medical services unrelated to WATCHMAN procedures.

**4**. Post-procedure drug prices are sourced from GoodRx.com, using Xarelto and Eliquis. This scenario assumes that a traditional Medicare beneficiary has paid $0 towards their 2025 Medicare Part D deductible ($590) and a 25% copay.

# Resources for Your Patients




## Contact your Boston Scientific rep to learn more about:

- Ordering **patient education materials** (printed brochures, posters, and video brochures) for your office
- **Education Specialists** who can answer patients' questions during 1:1 phone calls
- **WATCHMAN Ambassadors** who volunteer to share their experience with prospective patients

Tell your patients to visit **WATCHMAN.com** to learn more.

# 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 CHA2DS2-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

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. 97097061.

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