



**WATCHMAN™**

LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

# Referring Pocket Guide

## FDA Indications\*

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:

Patient has an increased stroke risk and is recommended for oral anticoagulation (OAC).\*\*  
(See CHA<sub>2</sub>DS<sub>2</sub>-VASc table, page 4.)

YES



NO

Patient is suitable for short-term OAC use.†  
(See post-procedure drug regimen, page 12.)

YES



NO

Patient has an appropriate rationale to seek a non-pharmacologic alternative to OACs.

*Note: Does not apply to patients who receive the WATCHMAN Implant concomitantly or sequentially with an AFib ablation.†  
The CMS National Coverage Determination (NCD) remains unchanged.  
The patient must be deemed unable to take long-term OAC and meet all criteria in NCD 20.34 to be eligible for coverage.*

YES



NO

**Patient may be a candidate for the  
WATCHMAN Implant**

\*Scan the QR code on page 16 for full indications.

\*\*Increased Risk = CHA<sub>2</sub>DS<sub>2</sub>-VASc  $\geq 2$  in men,  $\geq 3$  in women. CMS coverage criteria requires a CHA<sub>2</sub>DS<sub>2</sub>-VASc score  $\geq 3$ . Providers are encouraged to read the decision memo in its entirety for additional detail. Commercial Policies' medical criteria may vary.

† Option for immediate DAPT-only post-implant drug regimen for standalone WATCHMAN procedures.

‡ In the OPTION trial, sequential LAAC was a minimum of 90 days post AF ablation (as a protocol-driven blanking period) and less than 6 months post-AF ablation.

# CMS Coverage Criteria

CMS will cover LAAC with the WATCHMAN™ Implant when the following criteria are met:<sup>\*†</sup>

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## 1 Increased risk for stroke

CHADS<sub>2</sub> score  $\geq 2$   
or a CHA<sub>2</sub>DS<sub>2</sub>-VASc score  $\geq 3$

## 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 tool<sup>\*\*</sup>

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\* 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<sub>2</sub>DS<sub>2</sub>-VASc Score (Stroke Risk)<sup>a</sup>

	Condition	Points
C	Congestive heart failure	1
H	Hypertension	1
A	Age ≥ 75 years	2
D	Diabetes mellitus	1
S <sub>2</sub>	Prior stroke, TIA, or thromboembolism	2
V	Vascular disease (PAD, MI)	1
A	Age 65-74 years	1
Sc	Sex category (Female)	1
<b>Total Points</b>		

Score	Yearly Stroke Risk (%)		
	No Warfarin	With Aspirin <sup>b</sup>	With Warfarin <sup>b</sup>
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<sub>2</sub>DS<sub>2</sub>-VASc: *Chest*. 2010;137(2):263-272.

b. Warfarin Stroke Reduction: *Ann Intern Med*. 2007;146:857-867.

Elevated Risk = CHA<sub>2</sub>DS<sub>2</sub>-VASc ≥ 2 in men, ≥ 3 in women.

CMS coverage criteria requires a CHA<sub>2</sub>DS<sub>2</sub>-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?



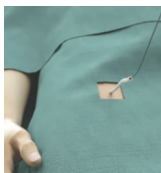
## Increased risk of future bleed

- 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:

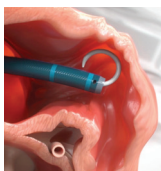
- Do you have concerns about falling?
- Do you live with someone who is able to help you in case of a fall?
- What other medications are you taking?
- Does being on a blood thinner interfere with your daily tasks or activities?
- Have you had to change your diet or lifestyle?

# Implant Procedure Overview



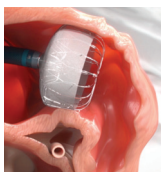
## 1. Access

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).



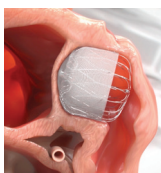
## 2. Cross

The interatrial septum is crossed using a standard transeptal 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.

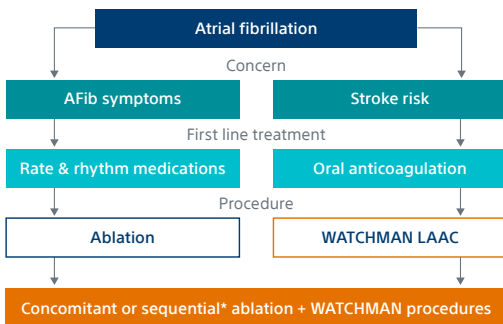
# Comprehensive management of AFib patients



While atrial fibrillation (AFib) management typically begins with rhythm control medications and oral anticoagulants (OACs), some AFib patients require both rhythm control and the freedom from OACs.

- Cardiac Ablation: Restoration of normal heart rhythm when patients experience AF symptoms
- WATCHMAN™ Left atrial appendage closure (LAAC): Reduction of stroke risk when AF patient has a reason to seek alternatives to OAC therapy

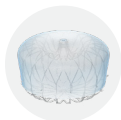
## Journey to a combined procedure



*\*In the OPTION trial, sequential LAAC was a minimum of 90 days (as a protocol-driven blanking period) and less than 6 months post-AFib ablation.*

## WATCHMAN procedure options for comprehensive AFib management

For AFib patients suitable for the WATCHMAN™ LAAC Device, implanting physicians may suggest one of three procedure options, depending on their eligibility and the physician's discretion:



**Standalone.** A WATCHMAN device is implanted in a single procedure.



**Concomitant.** An AFib ablation is performed, and a WATCHMAN device is implanted within a single procedural event.\*



**Sequential.** An AFib ablation is performed, and a WATCHMAN device is implanted in a later procedure.\*\*

## Boston Scientific provides two industry-leading solutions to help patients manage their AFib:



### FARAPULSE™ Pulsed Field Ablation System

#1 utilized pulse field ablation (PFA) system in the US. Treats rate and rhythm symptoms in AFib patients with minimal risk of post-procedural complications.



### WATCHMAN Implant

Most-studied and implanted LAAC device globally. Delivers a lifetime of stroke risk reduction, without the bleeding risks associated with long-term oral anticoagulation (OAC) therapy.

*NOTE: FARAPULSE PFA Catheter pictured as representative example for AFib ablation, though any modality may be used.*

*\* Two distinct procedures delivered during one operative episode/coordinated intervention.*

*\*\* In the OPTION trial, sequential LAAC was a minimum of 90 days (as a protocol-driven blanking period) and less than 6 months post-AFib ablation.*

# 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.<sup>1</sup> WATCHMAN is the only LAAC device without a requirement of an overnight stay post-procedure.

## Procedure Overview



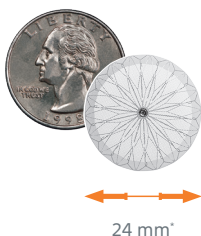
Permanent implant



Minimally invasive



1 day or less average hospital stay



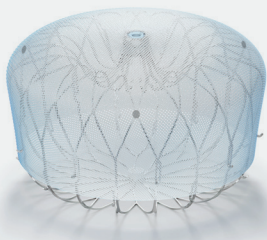
Learn more about the WATCHMAN LAAC Implant procedure



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<sup>1</sup>

99%

Implant Success Rate  
(395/400)\*

0.5%

Major Adverse  
Event Rate<sup>†</sup>

#### PROVEN EFFICACY<sup>1</sup>

100%

Effective LAA Closure  
at 12 Months<sup>‡</sup>

>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  $\leq 5$ mm per core laboratory-assessed TEE.

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

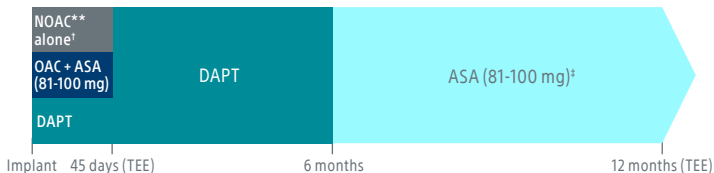
# Post-Procedure Drug Regimen

## What to expect after a WATCHMAN™ Implant procedure

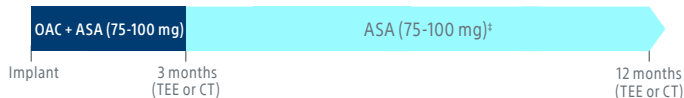
### Post-Procedure Drug Regimen Options

The only LAAC implant that offers post-implant drug regimen options for standalone and post-AFib ablation with LAAC ablation procedures.

#### Standalone LAAC



#### Post-catheter ablation with LAAC



\*\* Excludes Warfarin.

† Pre-procedure ASA is per physician discretion if the physician intends to prescribe NOAC alone for the patient post-procedure.

‡ Continued indefinitely.

## Patient Cost

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

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

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

**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.



## **WATCHMAN FLX™ Pro**

Indications, Safety, and Warnings

[www.watchman.com/en-us-hcp/  
watchman-flx-pro-brief-summary.html](http://www.watchman.com/en-us-hcp/watchman-flx-pro-brief-summary.html)

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