Boston Scientific
Advancing science for life™

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

Referring Pocket Guide

One Time. For a Lifetime.

LAA Indications

The LAA Closure Therapy is an innovative one-time minimally-invasive procedure designed to reduce the risk of stroke that originates in the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation suffering from bleeding, who are contraindicated or eligible for oral anticoagulants.

The average procedure time is approximately 60 minutes, and patients typically stay in the hospital for 24 hours.

LAAC has been included in the European Society of Cardiology (ESC) guidelines for AF management since 2012.

It is consistently recognized in the latest 2024 ESC AF management guidelines[1].

It is also included in the most recent 2023 US guidelines from leading cardiology societies (ACC/AHA/ACCP/HRS)[2].

Recommendation	Class[a]	Level[b]
Percutaneous LAA occlusion may be considered in patients with AF and contraindications for long-term anticoagulant treatment to prevent ischaemic stroke and thromboembolism.	IIb	C

AF, atrial fibrillation; LAA, left atrial appendage. | a Class of recommendation. b Level of evidence.

1 Van Gelder et al. (2024). "2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)". European Heart Journal. 45, 3314-3414
2 Joglar, J, Chung, M. et al. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol.

PATIENT RATIONALE

Consider a WATCHMAN implant for patients who can't, won't, or shouldn't take long-term OACs.

PAST BLEED

A major or minor bleeding episode
And if **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 OACs, such as bleeding risk based on HAS-BLED score or other factors

INCREASED RISK OF STROKE

A minor or disabling past stroke event
With history of stroke due to:

- Non-compliance
- Inability to maintain internal normalized ratio (INR) if patient on warfarin

ACC, HRS, and SCAI, the three leading cardiology and cardiovascular societies in the U.S., recognize 12 appropriate patient rationales to seeking an alternative to anticoagulation.[1]

1 ACC, HRS, SCAI LAAC NCD consensus memo to CMS. https://www.cms.gov/medicare-coverage-database/staticpages/public-comment.aspx?commentID=29406&ReportType=nca.

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

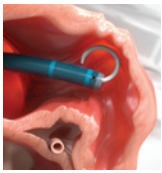
Questions to ask your patients:

- 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

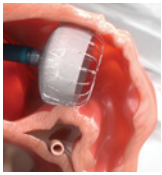
1. Access

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).



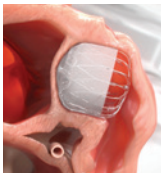
2. Cross

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.



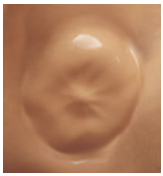
3. Deploy

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

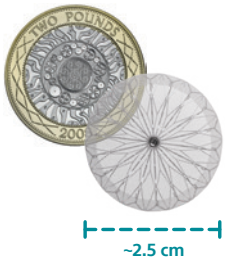
The implant is fully endothelialized.

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 Solution
- Minimally invasive
- 1 day 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.

Post-Procedure Drug Regimen

What to expect after a WATCHMAN™ Implant procedure

Post-implant drug regimen options

A Post-implant drug regimen for patients prescribed **dual anti-platelet therapy (DAPT)** only

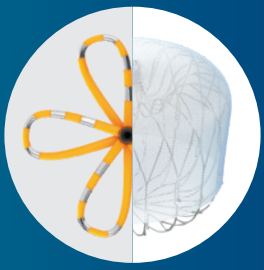
B Post-implant drug regimen for patients prescribed short-term **Oral Anticoagulant (OAC) therapy**

If a patient remains on OAC and aspirin for at least 3 months after implantation and then ceases use of OAC, the patient should not require clopidogrel.

**(INR 2.0-3.0)

NOTE: If thrombus is observed on the device, use of anticoagulation is at physician discretion. **Talk to your cardiologist to choose the best path for you.**

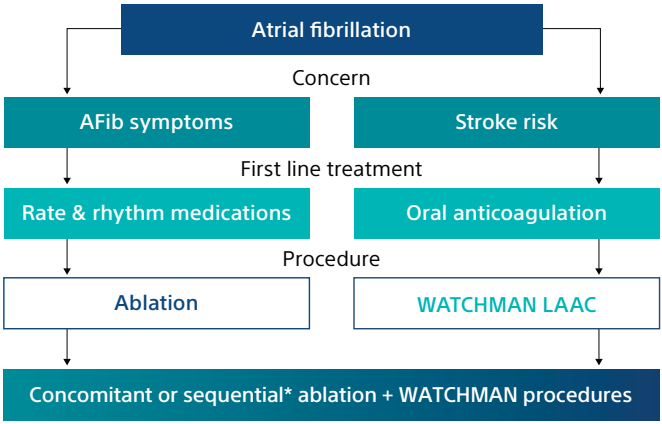
COMBINED PROCEDURE OPTIONS FOR COMPREHENSIVE AFIB MANAGEMENT



While AFib management typically begins with rhythm control medications and oral anticoagulants (OACs), some patients with AFib require both rhythm control with an ablation, while also needing the freedom from OACs that LAAC can provide.

- 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.

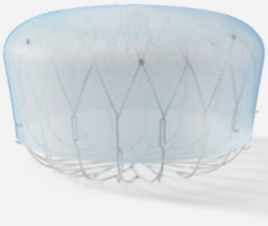
WATCHMAN Implant

Most-studied and implanted LAAC device globally. Delivers a lifetime of stroke risk reduction, without the bleeding risks associated with longterm 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.



#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.

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

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

To learn more about the WATCHMAN Implant, talk to your Boston Scientific representative, scan the QR code below, or visit WATCHMAN.COM/HCP

WATCHMAN FLX™ Pro
Indications, Safety, and Warnings

www.watchman.com/en-us-hcp/watchman-flx-pro-brief-summary.html

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CAUTION: The law restricts these devices to sale by or on the order of a physician. 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.

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