#1 Doctor Recommended LAAC Implant

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

A lifetime of stroke risk reduction, without the lifelong risks of OACs.

One Time. For a Lifetime.

For healthcare professional use.

AFib doesn't have to mean a lifetime of oral anticoagulation therapy.

Falls, active lifestyles, GI issues, medical procedures, and more can leave patients vulnerable to bleeds.

Living with restrictions and worry prevents patients from living life to the fullest.

The WATCHMAN™ Implant can help.

Protected by the WATCHMAN™ Implant. For Life.

The WATCHMAN Left Atrial Appendage Closure (LAAC) Implant is a one-time procedure that delivers a lifetime of stroke risk reduction, without the bleeding risks associated with lifelong oral anticoagulation (OAC) therapy. It's **One Time. For a Lifetime.**

The PINNACLE FLX US IDE Clinical Trial was designed to establish the procedural safety and closure efficacy of the WATCHMAN FLX™ Implant.

Proven

99%

Patients successfully implanted (395/400)[1,*]

Safe

0.5%

Major adverse event rate[1,†]

Effective

100%

Effective LAA closure[1,‡]

* 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 ≤5 mm per core laboratory-assessed TEE.

600,000+

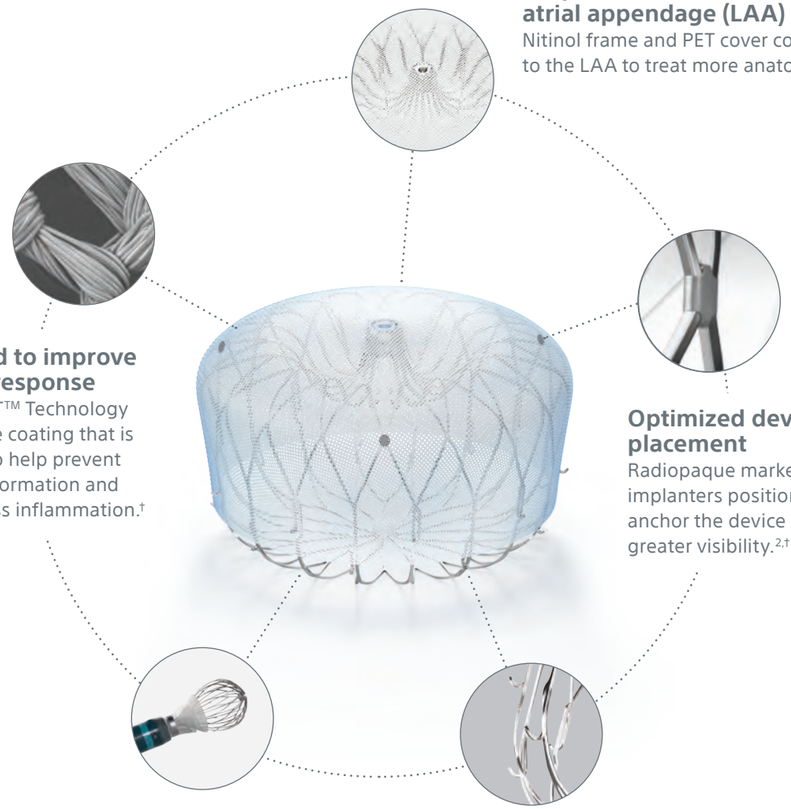
Lives Changed and Counting

The Leader in LAAC

The world's most studied LAAC device safely treats more patients than ever.

WATCHMAN FLX™ Pro is built on the proven performance of the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Implant, and introduces features designed to promote faster healing.*

WATCHMAN FLX Pro Implant design



Purpose-built for the left atrial appendage (LAA)
Nitinol frame and PET cover conform to the LAA to treat more anatomies.

Designed to improve healing response
HEMOCOAT™ Technology is a durable coating that is intended to help prevent thrombus formation and result in less inflammation.†

Optimized device placement
Radiopaque markers help implanters position and anchor the device with 57% greater visibility.[2,†]

Engineered for safety
Fully rounded ball for safe advancement and maneuvering in the LAA.

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

*Saliba, W., et al. JACC EP, May 2023. Bench testing or pre-clinical study results may not necessarily be indicative of clinical performance. N=12 in a pre-clinical canine study.
†Bench study performed under CT by Boston Scientific.

Broad range of anatomies

Designed to treat the widest range of patient anatomies with greater device sizing overlap and less appendage depth needed for deployment.

With sizes up to 40 mm to accommodate a wide range of patient anatomies, WATCHMAN FLX Pro expands the treatable patient population by 6%.[2]

> *[WATCHMAN is] very easy to use. It's flexible. It fits into a wide range of appendages … all of the nooks and crannies the different appendages present to us because that's a very unique personal aspect of physiology and anatomy.*
>
> **— Electrophysiologist**

How the WATCHMAN™ Implant works

In non-valvular atrial fibrillation (AFib), >90% of stroke-causing clots that come from the left atrium are formed in the LAA.[3] The WATCHMAN Implant is a minimally invasive, one-time procedure designed to reduce the risk of strokes that originate in the LAA.

Permanent implant

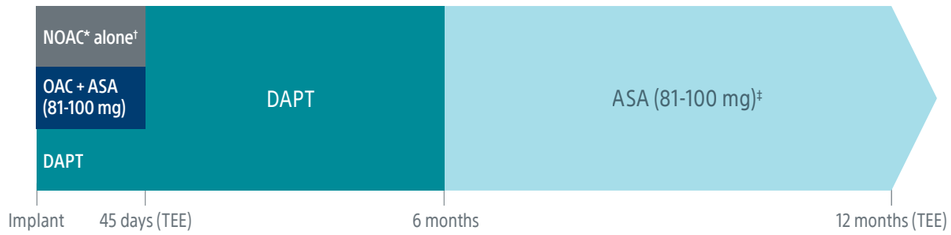
Minimally invasive

1 day or less average hospital stay

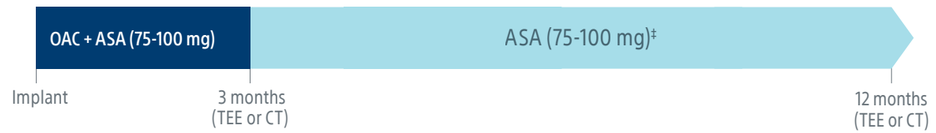
The only LAAC implant that offers post-implant drug regimen options for standalone and post-AF ablation procedures.

Post-implant drug regimen options

Standalone LAAC



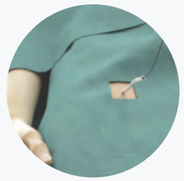
Post-catheter ablation with LAAC



*Excludes Warfarin.
†Pre-procedure ASA is per physician discretion if the physician intends to prescribe NOAC alone for the patient post-procedure.
‡Continued indefinitely.

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).

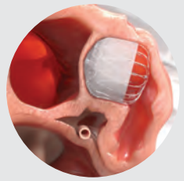
2 Cross

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 LAA over a pigtail catheter.

3 Deploy

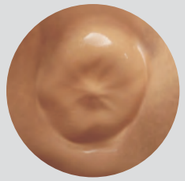
The WATCHMAN™ Implant is deployed and released in the LAA.

4 Heal



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

5 Protect



The implant is fully endothelialized.

In the PINNACLE FLX clinical trial

>96% of patients were able to stop OACs at 45 days[1]

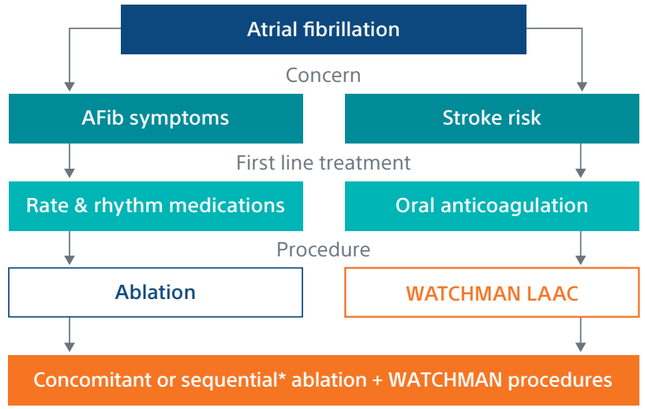
Combined procedure options for comprehensive AFib management

AFib adversely affects cardiac rhythm and elevates stroke risk.

90% of strokes originate in the left atrial appendage (LAA)[1]

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.

Journey to a combined procedure



During the OPTION clinical trial, concomitant LAAC with WATCHMAN FLX™ at the time of ablation resulted in similar procedure related events compared to the ablation-only control arm. This shows no increase in procedural risk with the addition of the WATCHMAN FLX procedure to ablation.

2.1%
Ablation + WATCHMAN FLX
Procedural event rate (within 7 days)

vs

2.7%
Ablation (Only) + OAC
Procedural event rate (within 7 days)

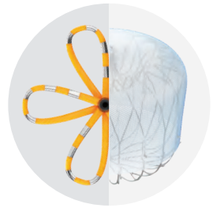
Concomitant procedures may mitigate risk of adverse events

1 in 7

14% of patients experienced ≥1 significant adverse event between staged cardiac ablation and LAAC procedures.[3]

WATCHMAN procedure options

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.†

Industry-leading AFib management solutions

Boston Scientific provides two solutions to help patients manage 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 OAC therapy.

Together, FARAPULSE and WATCHMAN offer a vital solution for AFib management.

Note: The FARAPULSE™ PFA Catheter is pictured as a 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.

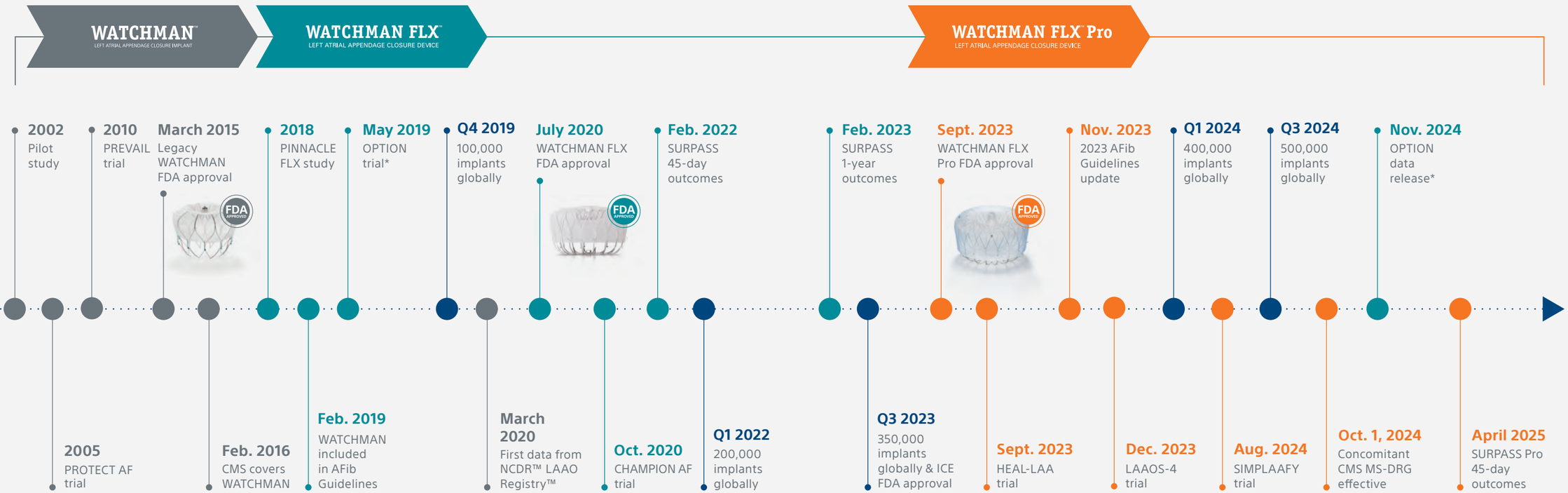
The WATCHMAN™ Implant is proven

600,000+
Patients implanted

20+ Years
Clinical trial and real-world experience

Included In
ACC/AHA/HRS AF Guidelines

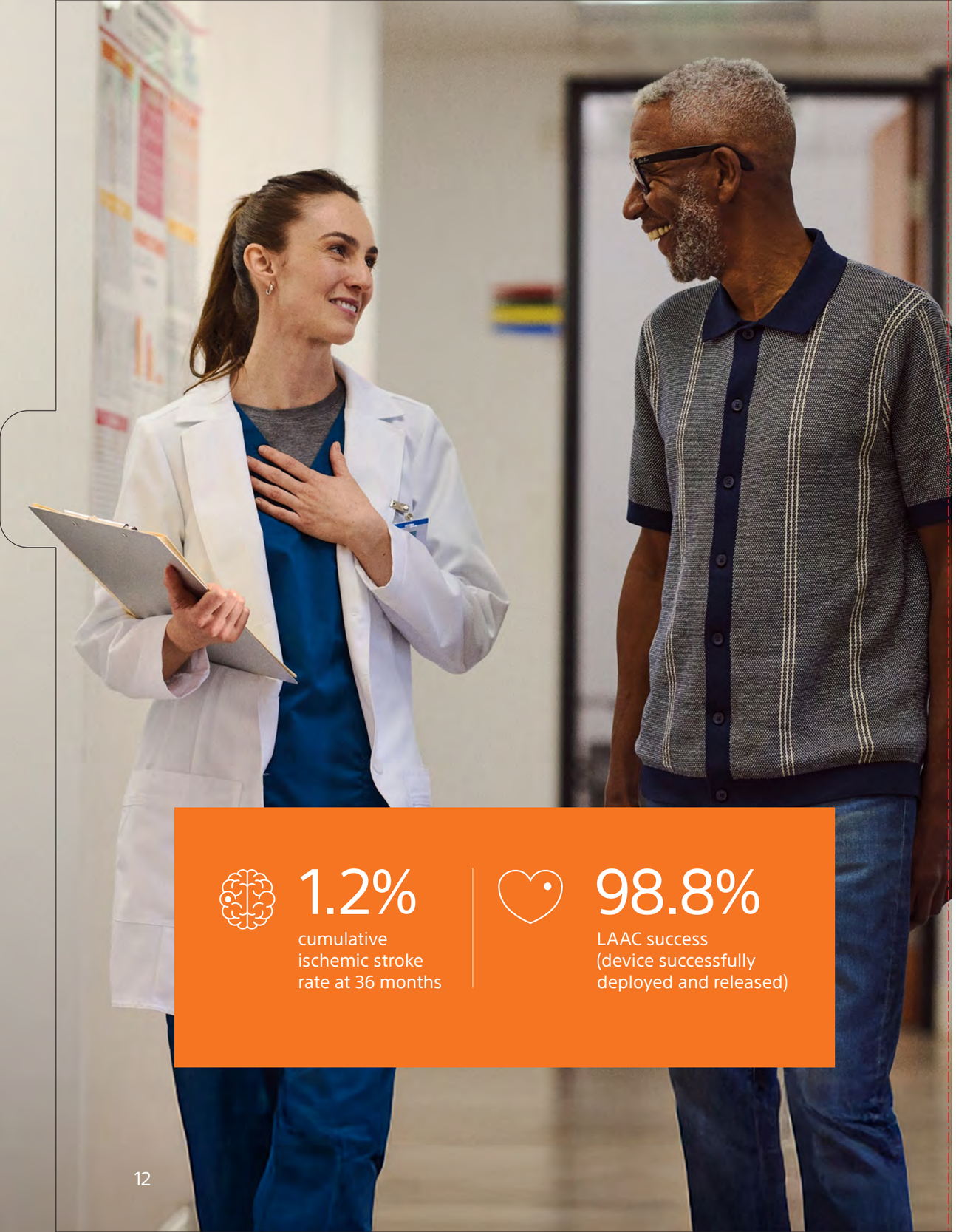
Clinical leadership in LAAC



- Milestones
- Legacy WATCHMAN
- WATCHMAN FLX
- WATCHMAN FLX Pro

Note: The ASAP, ESC expanded guidelines and indication and Real World Registries in Europe and Asia studied the patient population not in the scope of the FDA-approved indications for use.

*See Page 13 for more information about how OPTION trial reinforced the use of WATCHMAN after abalation



1.2%
cumulative ischemic stroke rate at 36 months

98.8%
LAAC success (device successfully deployed and released)

OPTION clinical trial

Primary endpoints show WATCHMAN is equally effective to OACs

The OPTION clinical trial, a breakthrough study in AFib treatment, is the **first randomized, head-to-head study comparing the WATCHMAN device to OAC (95% DOACs) after cardiac ablation**. The primary endpoints showed the WATCHMAN FLX™ device was **equally effective to OAC, with a superior safety profile**, which allowed patients to eliminate continuous medication use, and significantly reduce bleeding risk while maintaining stroke protection.

The road to concomitant

October 2024

CMS expands procedure reimbursement

The Centers for Medicare and Medicaid Services (CMS) introduced a new MS-DRG allowing cost coverage for concomitant AFib ablation and WATCHMAN procedures.[4]

November 2024

Positive OPTION results announced

Data from the OPTION clinical trial demonstrated that the WATCHMAN FLX™ device offers superior safety with comparable efficacy to OACs in stroke risk reduction for post-ablation patients.[5]

April 2025

OPTION sub-analysis published

A sub-analysis of the OPTION trial showed LAAC has similar efficacy compared with OAC, and a significantly lower risk of post-procedure bleeding in high-risk patients following AFib ablation regardless of whether it is implanted in concomitant or sequential procedures.[6,*]

Reduction in ISTH bleeding (including procedural bleeding) at 36 months†

Primary safety endpoint

Superiority met. The WATCHMAN FLX device demonstrated a statistically significant **56% risk reduction in International Society on Thrombosis and Haemostasis (ISTH) non-procedural bleeding at 36 months.****

Primary efficacy endpoint

Non-inferiority met. WATCHMAN FLX was non-inferior for the primary efficacy endpoint of stroke, all-cause death, and systemic embolism at 36 months.

View full clinical trial 36-month results here

*In the OPTION trial, sequential LAAC was a minimum of 90 days (as a protocol-driven blanking period) and less than 6 months post-AF ablation.
** Statistic inclusive of non-procedural bleeding (HR 0.44 [0.33, 0.59]; P<0.0001.)
† Reaffirming the primary safety endpoint, WATCHMAN FLX demonstrated a statistically significant 50% risk reduction in ISTH bleeding at 36 months, inclusive of procedural bleeding (HR 0.50 [0.38, 0.66]; P<0.0001.)

Clinically proven and safe outcomes

The next-generation WATCHMAN™ Implant, WATCHMAN FLX™ Pro, is built on the safety and procedural success of the WATCHMAN FLX™ Implant.

Procedure performance

99%

Patients successfully implanted (395/400)[1,*]

Proven safety

0.5%

Major adverse event rate[1,†]

*Procedure success defined as successful delivery and release of a WATCHMAN FLX Device into the LAA

Setting a new standard for safety.

The low 0.5% event rate demonstrates the enhanced safety profile of the WATCHMAN FLX LAAC device, showing a statistically significant difference to the performance goal set for similar safety endpoints in the PREVAIL trial and CAP2 registry.[1]

0.5%
Major adverse event rate[1,†]

- **0.5%** Ischemic stroke (2/400)[1,†]
- **0%** All-cause death
- **0%** Pericardial effusions requiring open cardicac surgery
- **0%** Device embolization

†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.

The PINNACLE FLX US IDE clinical trial was designed to establish the procedural safety and closure efficacy of the WATCHMAN FLX Implant.

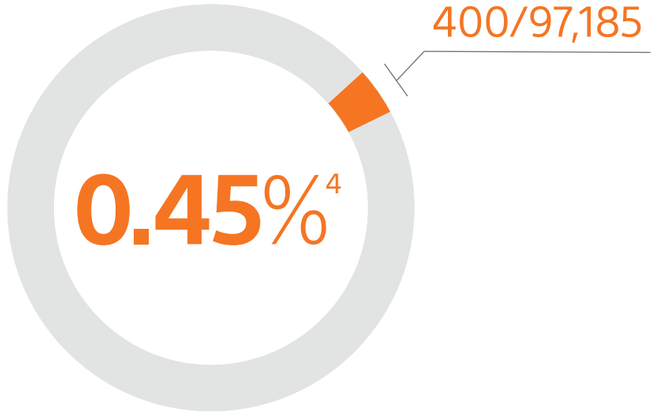
Real-world outcomes

SURPASS 1-Year Outcomes Analysis of the NCDR-LAAO Registry.™

The SURPASS analysis reinforces the excellent safety profile the WATCHMAN FLX™ Implant demonstrated in the PINNACLE FLX Trial, with the largest real-world WATCHMAN FLX patient population studied to date (97,185 patients implanted between August 2020-September 2022).

Key safety endpoint

SURPASS demonstrated a 0.45% major procedural adverse event rate within 7 days or hospital discharge in >97,000 patients and confirmed the trusted safety profile of the WATCHMAN FLX Implant in real-world clinical practice settings.

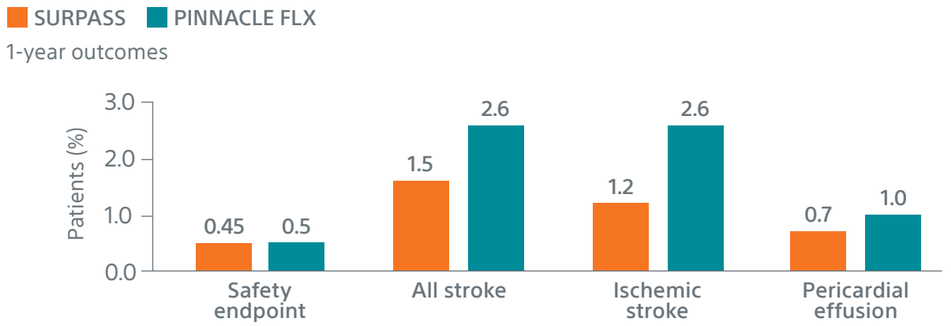


Procedural success

98%

SURPASS data reinforces procedural success with 98% of patients implanted (*N*=97,185)[7] across nearly all anatomies in a real-world setting, confirming that the WATCHMAN FLX Implant real-world experience replicates clinical trial outcomes.

Comparison with PINNACLE FLX[1,8*]



*Results from different clinical investigations are not directly comparable.

Proven efficacy outcomes

Enhanced LAA closure

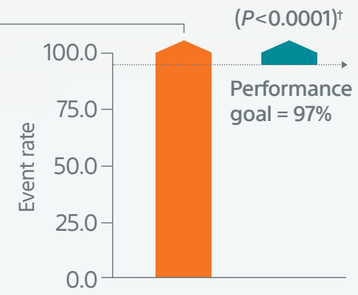
The WATCHMAN FLX™ Implant is designed for enhanced LAA closure, which was demonstrated with 100% rate of effective LAA closure at 12 months.[1]

Primary efficacy endpoint

Effective LAA closure at 12 months[1,*]

100%

of patients demonstrated effective LAA closure at 12 months[1,*]



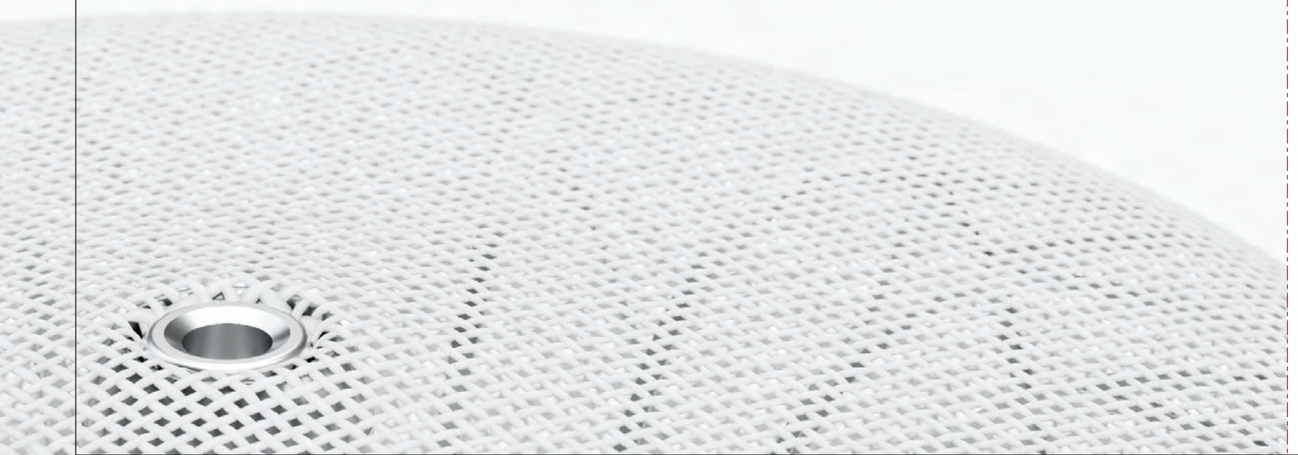
*LAA closure at 12 months is defined as any peri-device flow with jet size ≤5 mm per core laboratory-assessed TEE.

†Performance goal based on the rates observed in PREVAIL(2) and CAP2(3), minus a clinically relevant delta.

Enabling more patients to leave OACs behind

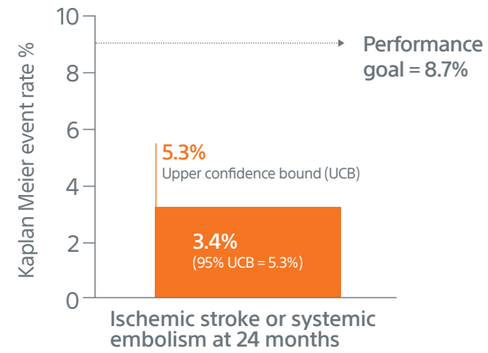
NOAC discontinuation

96.2% of patients discontinued OAC after 45 days.[1]



PINNACLE FLX 24-month outcomes reinforce proven long-term efficacy

PINNACLE FLX 24-month data demonstrates proven efficacy with a low annualized stroke rate.[9]



1.7%

per 100 patient-years/ annualized stroke or systemic embolism rate.

This rate is consistent with expectations in this high stroke risk patient population.

Expected rate of 4.0% (derived from the combined PROTECT-AF, CAP, PREVAIL, and CAP-2 studies) plus a clinically relevant delta.

Long-term data continues to differentiate WATCHMAN and provide ongoing clinical support for LAAC to reduce the risk of ischemic stroke and systemic embolism in AFib patients.

Indicated for a broad range of patient types

The WATCHMAN™ Implant may be an appropriate solution for your patients who meet these criteria:

1. Have an increased risk for stroke and are recommended for anticoagulation (OAC)*
2. Are suitable for short-term OAC.†
3. Have 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.

* Increased 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.
† 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-AFib ablation.

The 2023 ACC/AHA/ACCP/HRS Guidelines for the Diagnosis and Management of Atrial Fibrillation consider left atrial appendage occlusion (LAAO) devices a **2a Class of Recommendation** for patients with a contraindication to long-term OACs.

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

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
History of stroke due to:
- Non-compliance
- Inability to maintain international normalized ratio (INR)

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.[10]

Patient education and support

Resources to help your patients along their WATCHMAN journey.

Patient education

Brochures and educational videos address patient questions and help facilitate your conversation.

Ambassadors

People who have received WATCHMAN LAAC Devices volunteer to answer questions and share their personal experiences with potential patients.

Education specialists (call center)

Trained healthcare professionals answer patient questions before, during, and/or after receiving a WATCHMAN™ Implant.

Tell your patients to visit WATCHMAN.com/hcp to learn more.

An affordable option

Covered nationally for a broad range of patients by Centers for Medicare and Medicaid Services (CMS) and an ever-increasing number of commercial insurers.

Estimated Medicare patient out-of-pocket costs for implant procedures with one of the WATCHMAN LAAC devices.[11]

A typical Medicare patient who has not met their annual deductibles in 2025 will pay no more than $3,286.

≤ $3,286

Cost includes

Pre-screen TEE,* implant procedure, professional physician fees, and post-implant OAC therapy and TEE.

*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.

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.

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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, 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.

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Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements.
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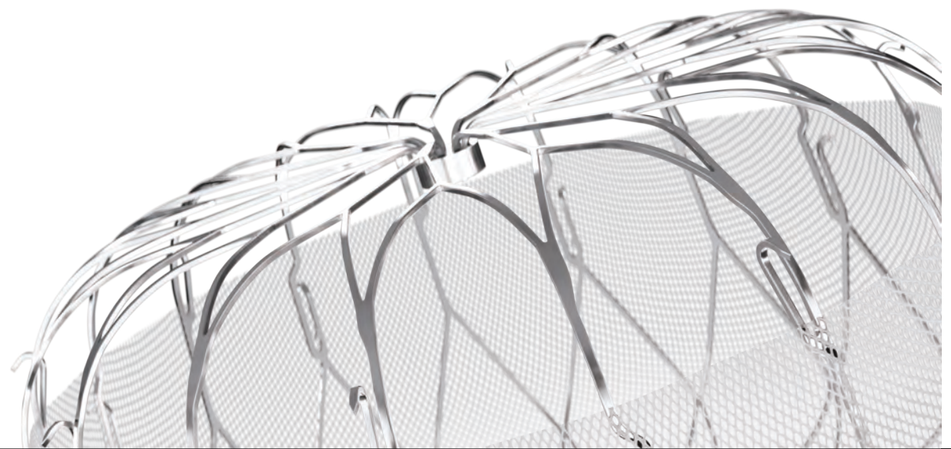

I consider WATCHMAN as an alternative to anticoagulation anytime patients are at an elevated stroke risk and have an elevated bleeding risk, be it based on their comorbidities, their lifestyle, their frailty, or risk of falling.

— Referring Cardiologist

CMS will cover LAAC 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 tool†

*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.

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11. Represents all WATCHMAN models

WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

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

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

Protected by the WATCHMAN Implant. For Life.

Proven[7]

600,000+ successful implants
20+ years patient experience

Safe[1]

99% implant success rate*
0.5% major adverse event rate†

Effective[1]

>96% of patients discontinued their OAC at 45 days

100% effective LAA closure at 12 months

One Time. For a Lifetime.

#1 Doctor Recommended LAAC 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.

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