Boston Scientific
Advancing science for life™

#1 Doctor Recommended LAAC Implant

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

A lifetime of stroke risk reduction without NOACs risks and complications

One Time. For a Lifetime.

For healthcare professional use.

Living with AFiB can be done safely without Oral Anticoagulation if needed.

Afib patients under NOAC might be exposed to increased likelihood of bleeding or stroke when living active lifestyles, having GI issues or NOAC intolerance.

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

The WATCHMAN™ Implant can be the solution.

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+

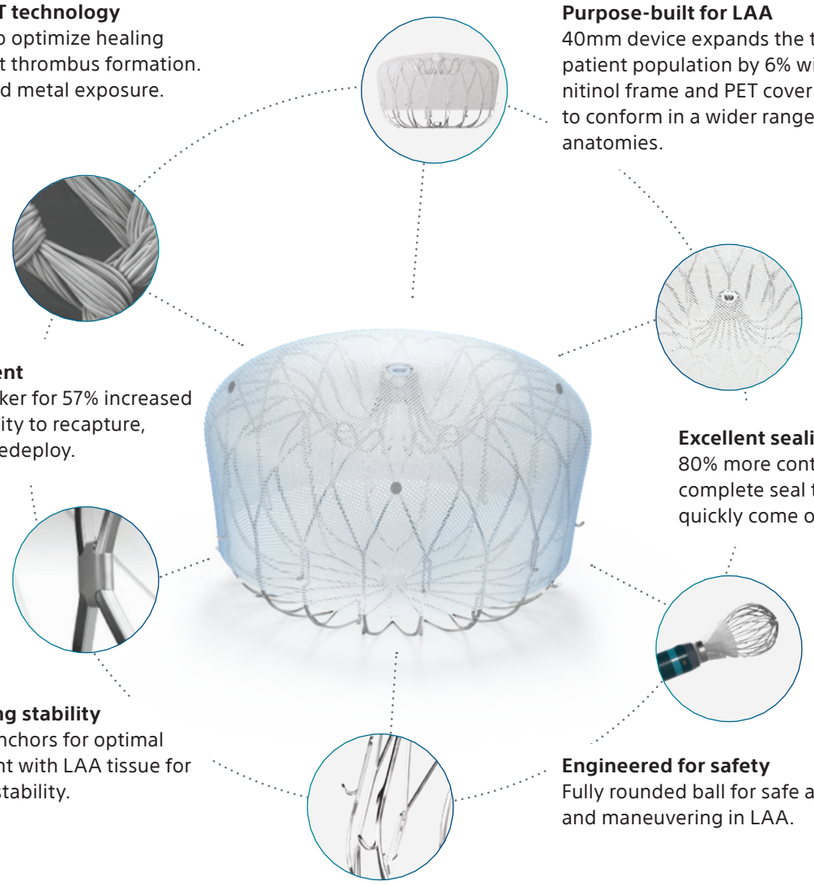
Lives Changed and Counting

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



HEMOCOAT technology
Designed to optimize healing and prevent thrombus formation. 77% reduced metal exposure.

Purpose-built for LAA
40mm device expands the treatable patient population by 6% with nitinol frame and PET cover design to conform in a wider range of anatomies.

Precise placement
Radiopaque Marker for 57% increased visibility and ability to recapture, reposition, and redeploy.

Excellent sealing
80% more contact points for faster complete seal to help patients quickly come off OACs.

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

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

*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.

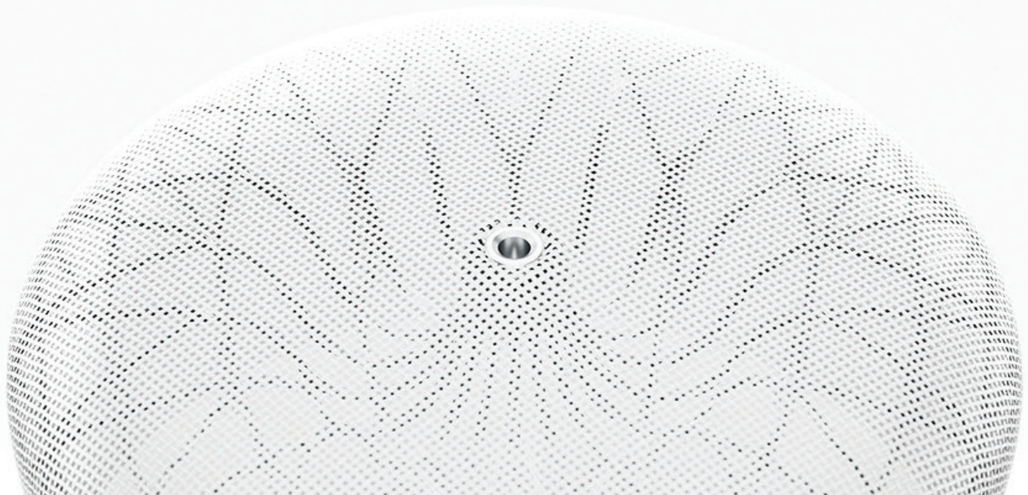
Broad range of anatomies.

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

20 MM | 24 MM | 27 MM | 31 MM | 35 MM | 40 MM

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

> *WATCHMAN FLX Pro is a significant improvement for my LAAC everyday practice. With several new features we can now broaden the spectrum of patients which we can treat in our clinical practice.*
>
> **Prof. Marek Grygier, Poland**



How the WATCHMAN™ Implant works.

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

Permanent Solution

Minimally invasive

1 day average hospital stay

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.

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).

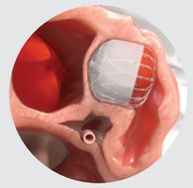
2 Cross

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]

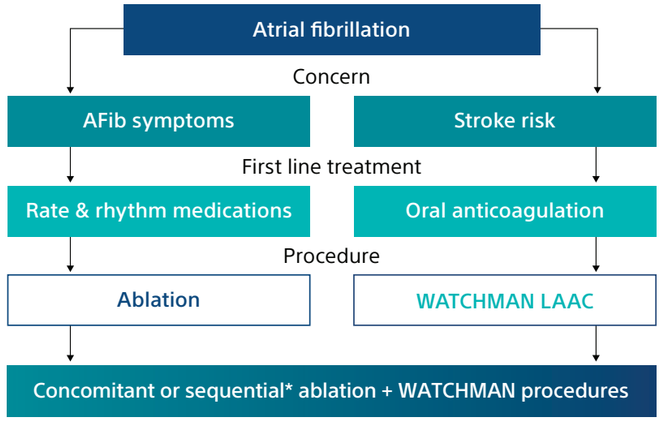
Combined procedure options for comprehensive AFib management

AFib adversely affects cardiac rhythm and elevates stroke risk.

90% of strokes originate in the left atrial appendage (LAA)[1,2]

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.

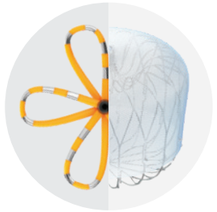
2.7%
Ablation (Only) + OAC
Procedural event rate (within 7 days)

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 Europe. 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 representative example for AFib ablation, though any modality may be used.
*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.

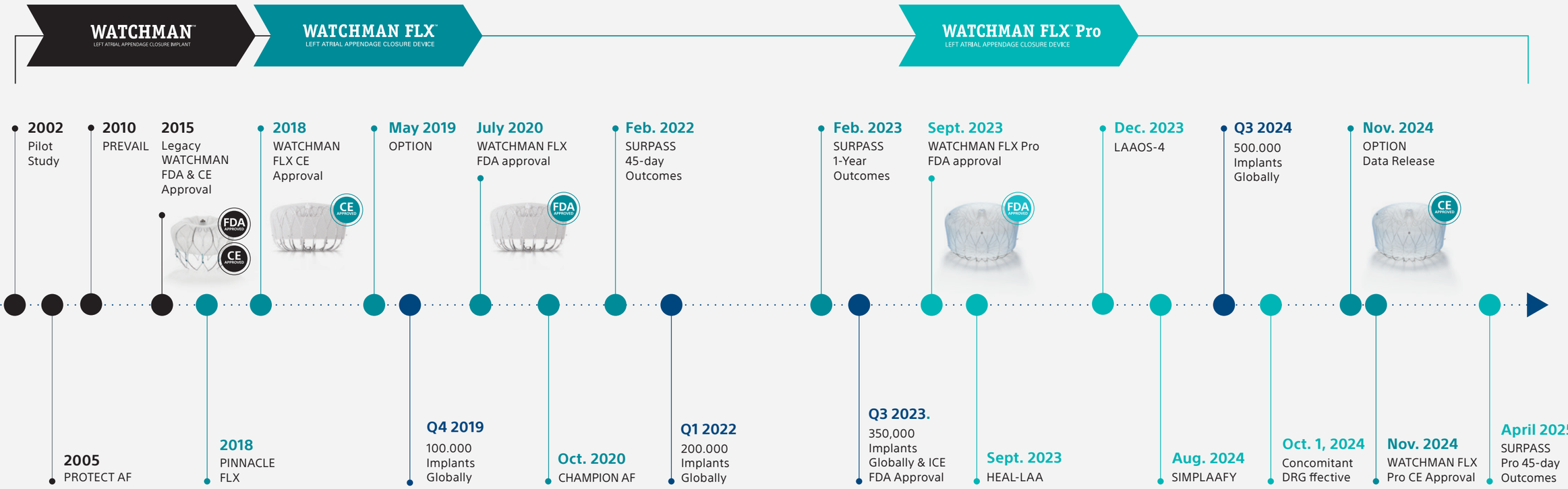
The WATCHMAN™ Implant is proven.

600.000+
Patients implanted

20+ Years
Clinical trial and real-world experience

Included In
In ESC AFib Guidelines

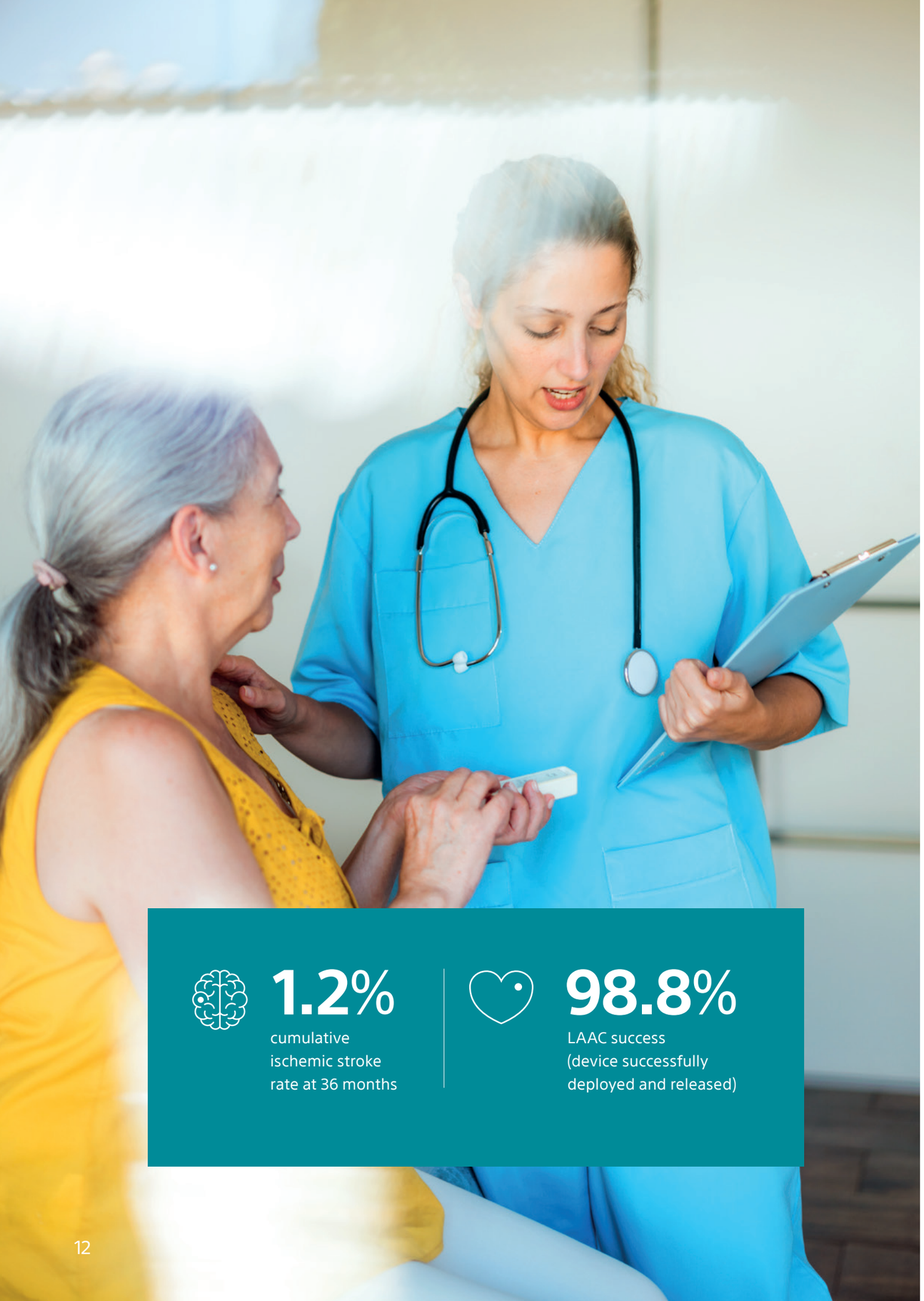
Clinical leadership in LAAC



- 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

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,*]

50%
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.)

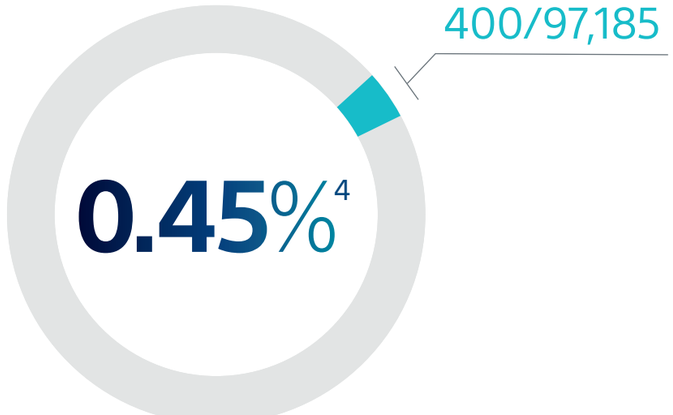
Real-world outcomes.

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

The SURPASS analysis reinforces the excellent safety profile the WATCHMAN FLX™ 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.



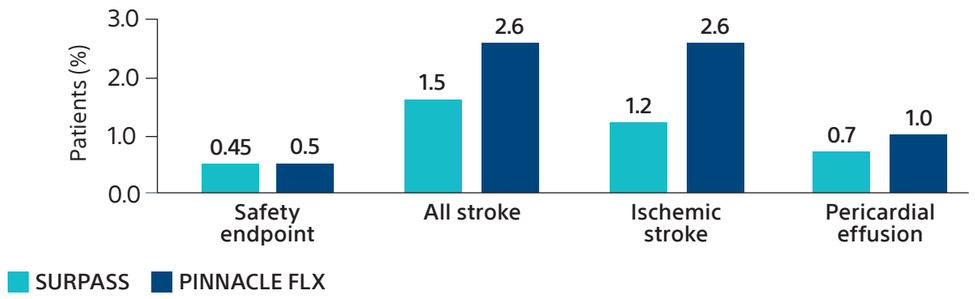
Procedural success

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*]

1-year outcomes



*Results from different clinical investigations are not directly comparable.

Proven efficacy outcomes.

Enhanced LAA closure.

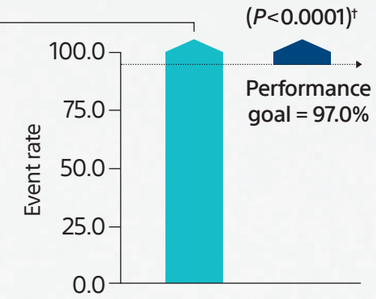
The WATCHMAN FLX™ Implant is designed for enhanced LAA closure, which was demonstrated with 100% rate of effective LAA closure at 12 months.[1]

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.

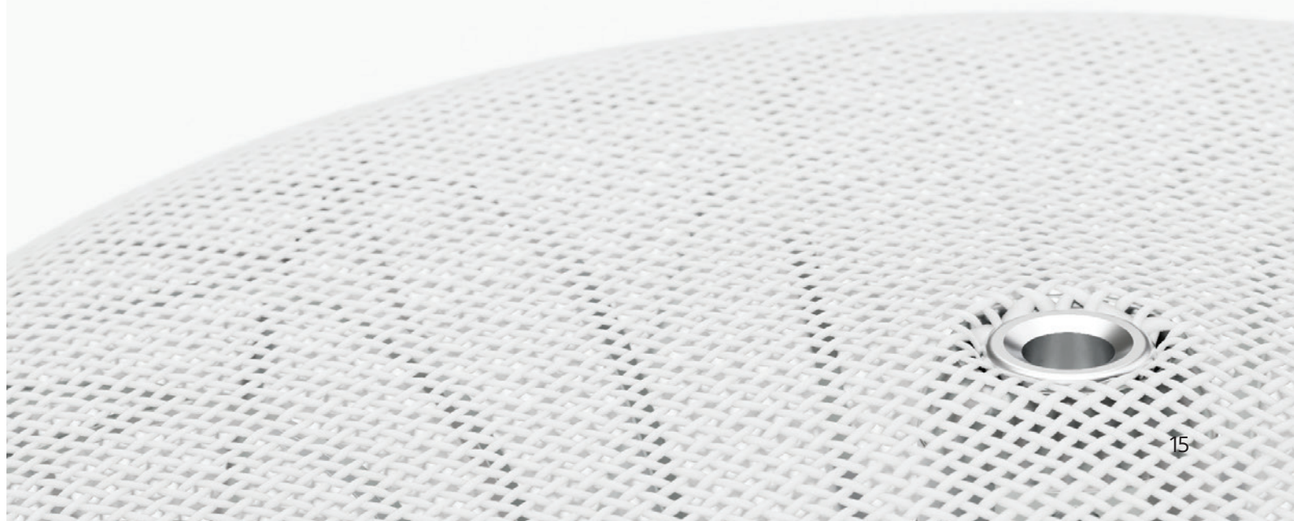
†Performance goal based on the rates observed in PREVAIL(2) and CAP2(3), minus a clinically relevant delta.

Enabling more patients to leave OACs behind.

NOAC discontinuation

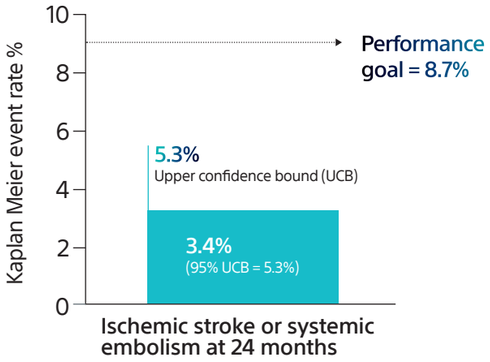
96.2%

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 NVAF patients.

Indicated for a broad range of patient types.

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

Patient has Non-Valvular Atrial Fibrillation (NVAF) and:

1. Contraindication to oral anticoagulation[1]
2. Intolerance to oral anticoagulation[2]
3. Elevated bleeding risk (HAS-BLED>=3; Elevated bleeding risk outside HAS-BLED-Score; Need for prolonged or repetitive triple therapy; Renal failure (severe) as contraindication to NOAC)[1]
4. Individual and specific anticoagulation risk constellation for stroke (Inefficient OAC; Electrically isolated LAA post ablation (indication for LAA occlusion controversial)[1]

[1] Increased Risk = CHA2DS2-VASc ≥ 2 in men, ≥ 3 in women. Providers are encouraged to read the decision memo in its entirety for additional detail Commercial Policies' medical criteria may vary.
[2] Option for immediate DAPT-only post-implant drug regimen for standalone WATCHMAN procedures

From the 2024 international consensus on Left Atrial Appendage Closure (LAAC); for patients with high AF-related stroke risk who cannot be treated with anticoagulants due to continued risks of bleeding events or ischemic strokes, LAAC is the only option.[10]

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.[11]

Patient education

Resources to help your patients along their WATCHMAN journey.

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

Tell your patients to visit WATCHMAN.com/hcp 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**

References

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11. ACC, HRS, SCAI LAAC NCD consensus memo to CMS. https://www.cms.gov/medicare-coverage-database/staticpages/public-comment.aspx?commentID=29406&ReportType=nca.
12. Johnson W.D., et al. The left atrial appendage: our most lethal human attachment! Surgical implications. Eur J Cardiothorac Surg. 2000 Jun;17(6):718-22.

WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

Protected by the WATCHMAN Implant. For Life.

Proven[7]

500,000+ 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.

Boston Scientific

Advancing science for life™

* 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. All trademarks are the property of their respective owners.

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