



**#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+



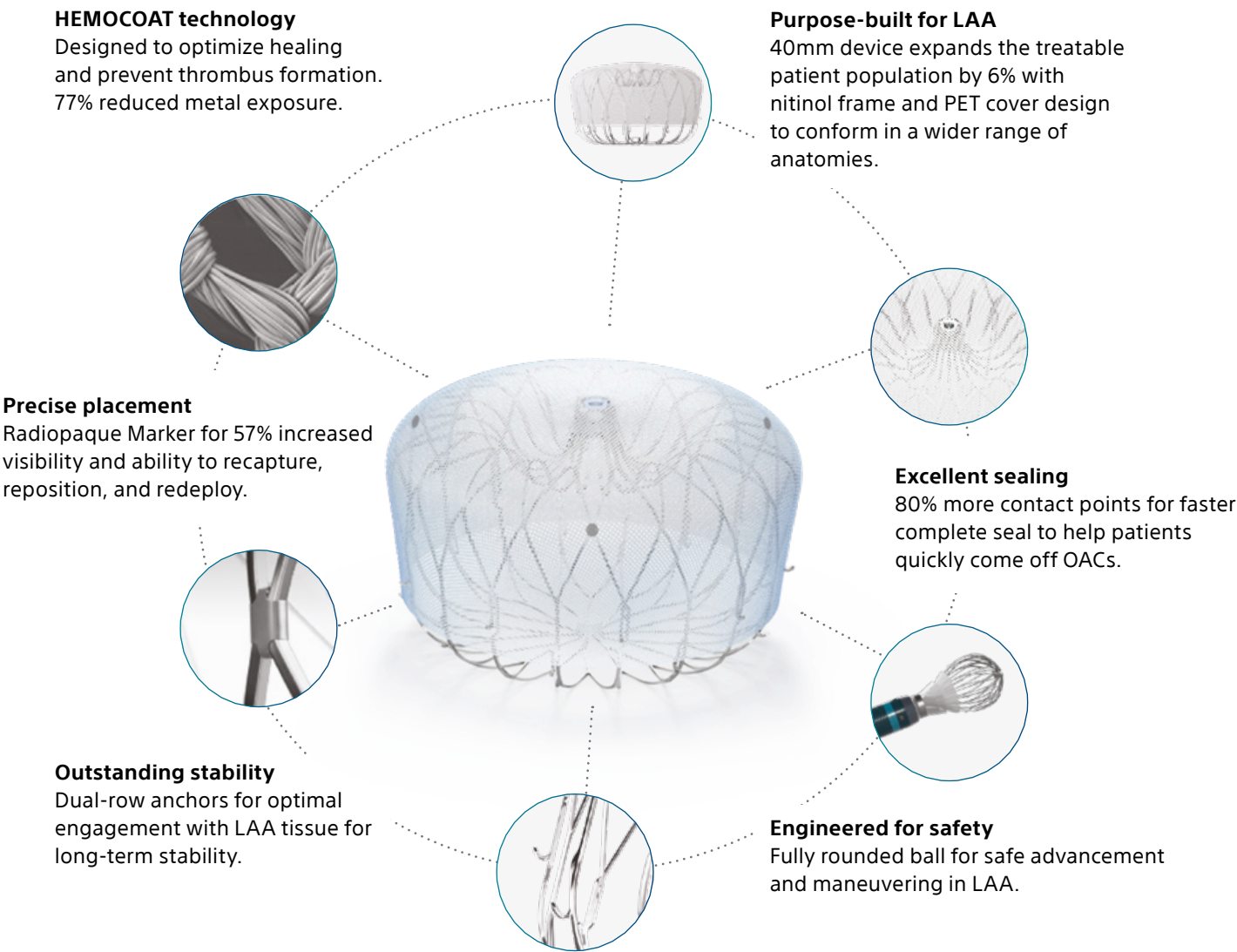
Lives Changed and Counting

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.*

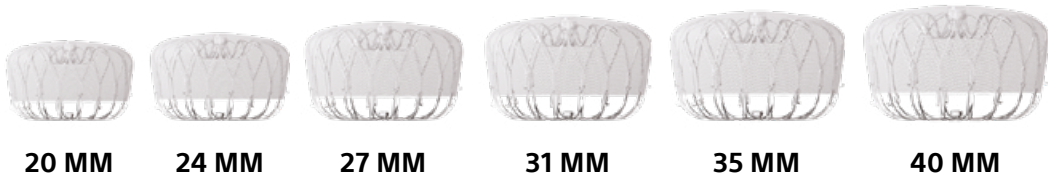
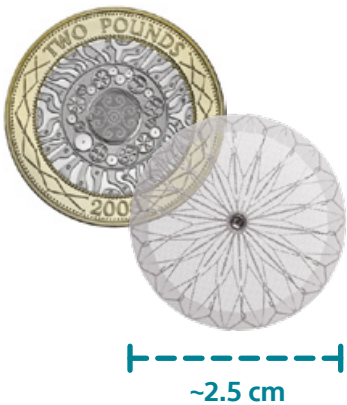
WATCHMAN FLX Pro Implant design



*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.

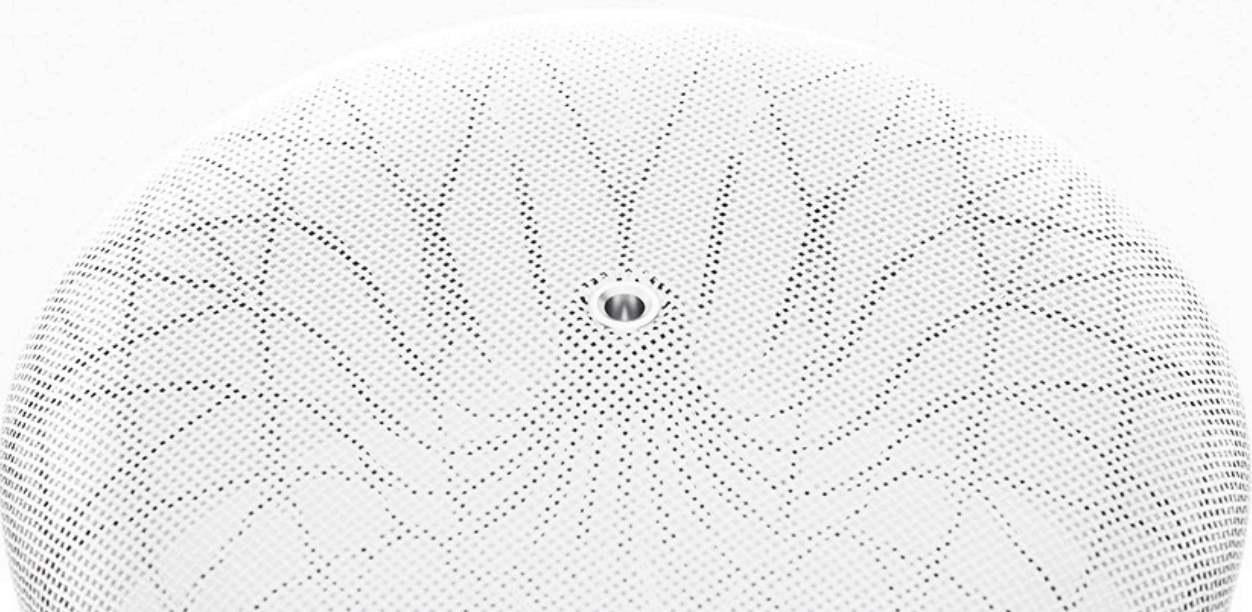
Broad range of anatomies.

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



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

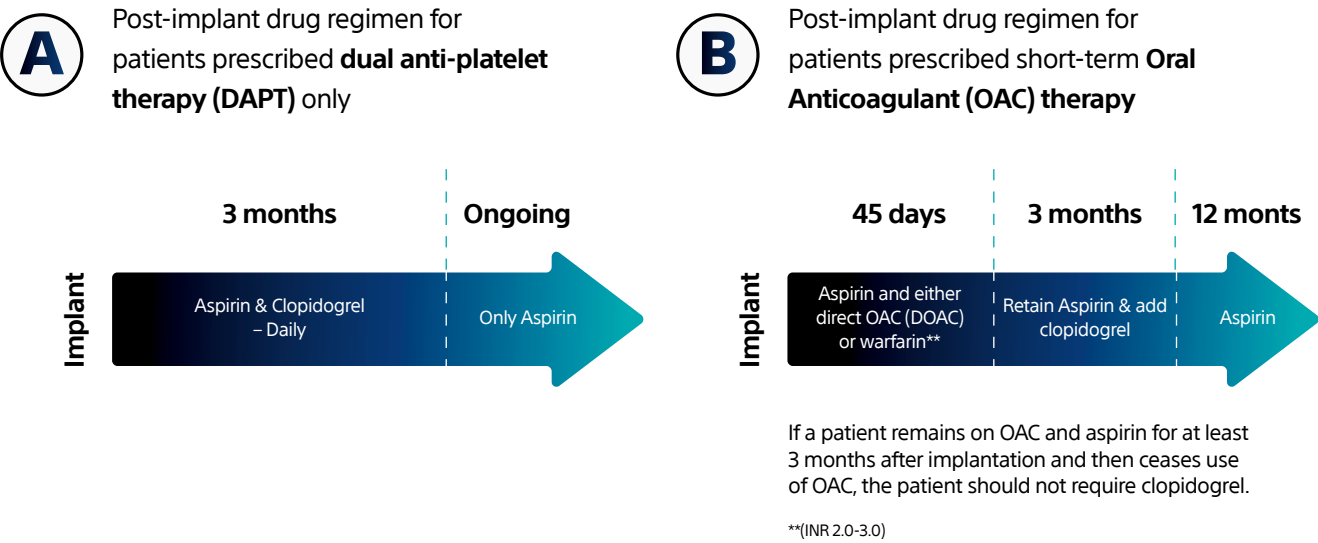


Minimally invasive



1 day average hospital stay

Post-implant drug regimen options

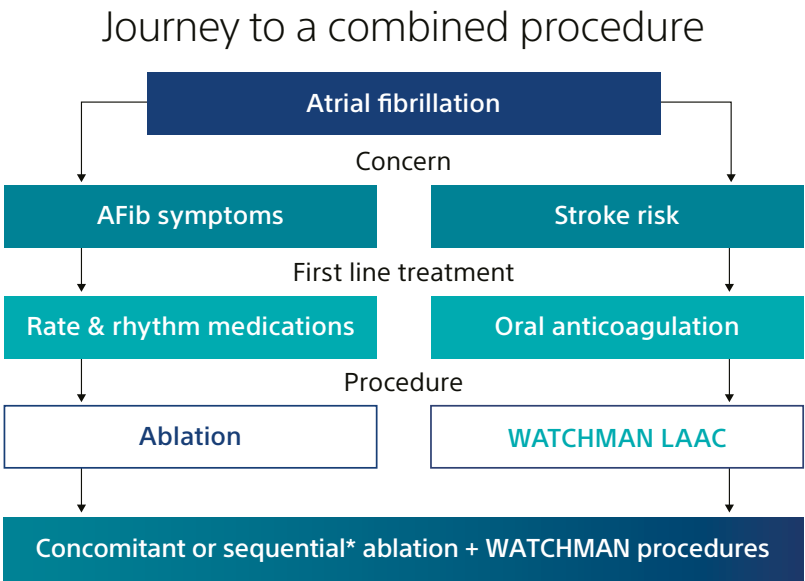


Combined procedure options for comprehensive AFib management

AFib adversely affects cardiac rhythm and elevates stroke risk.

90% of strokes originate in the left atrial appendage (LAA)¹²

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.



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% vs. 2.7%

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

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.

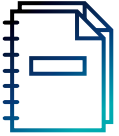
Together, FARAPULSE and WATCHMAN offer a vital solution for AFib management.

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.

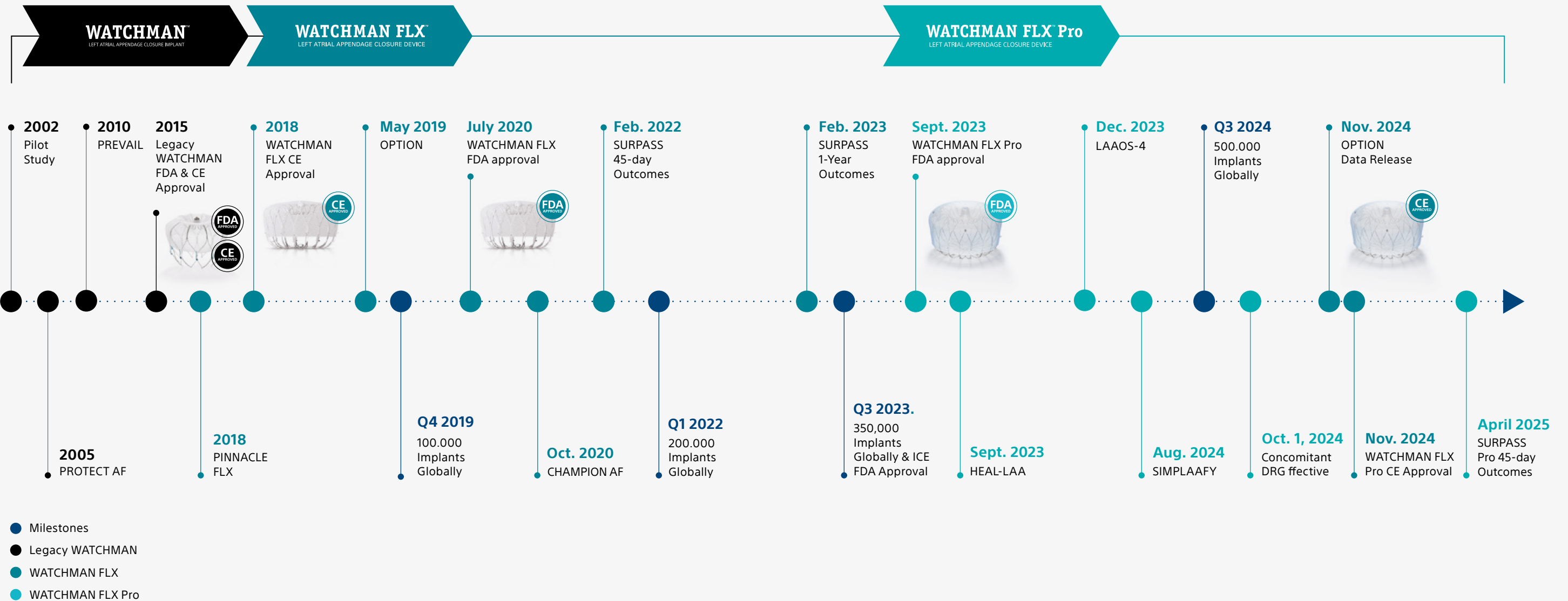
The WATCHMAN™ Implant is proven.


600.000+
Patients implanted


20+ Years
Clinical trial and
real-world experience


Included In
In ESC AFib Guidelines

Clinical leadership in LAAC



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.

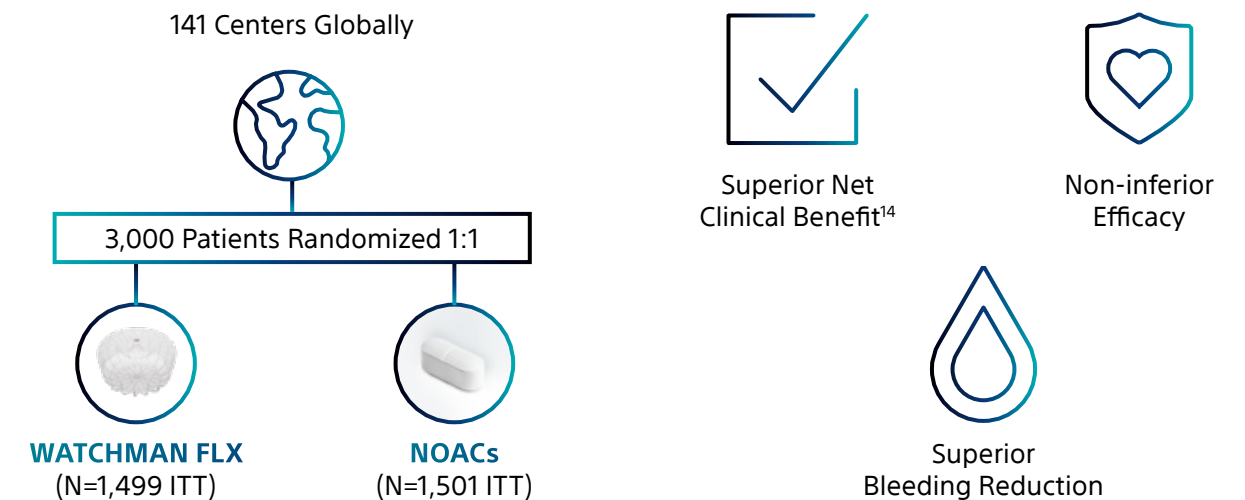
*See Page 13 for more information about how OPTION trial reinforced the use of WATCHMAN after ablation



CHAMPION AF Clinical Trial¹⁴

WATCHMAN FLX™ met all trial endpoints as a first-line option vs. NOACs in a broad AFib patient population

CHAMPION-AF is the first and largest randomized controlled trial comparing the WATCHMAN FLX™ LAAC Device to NOACs as a first-line option for stroke risk reduction in a broad population of patients with non-valvular atrial fibrillation (NVAF), including those who are at low-to-moderate risk of bleeding from the use of anticoagulation.



Primary Endpoint Met

WATCHMAN FLX demonstrated statistical non-inferiority to NOACs for the occurrence of cardiovascular (CV) death (hemorrhagic and/or unexplained death), stroke (ischemic and/or hemorrhagic), and systemic embolism (5.7% vs. 4.8%; P_{non-inferiority} <0.0001)

Primary Safe Endpoint Met

WATCHMAN FLX demonstrated statistical superiority to NOACs for the occurrence of ISTH non-procedural major bleeding and modified* clinically relevant non-major bleeding (10.9% vs. 19.0%; P_{superiority} <0.0001)

34%

Reaffirming superiority of the primary safety endpoint, WATCHMAN FLX demonstrated a statistically significant 34% risk reduction in ISTH bleeding (including procedural) at 36 months (12.8% vs. 19.0% (HR 0.66 [0.54, 0.80]); P<0.0001).



1.1%

Annualized ischemic stroke rate



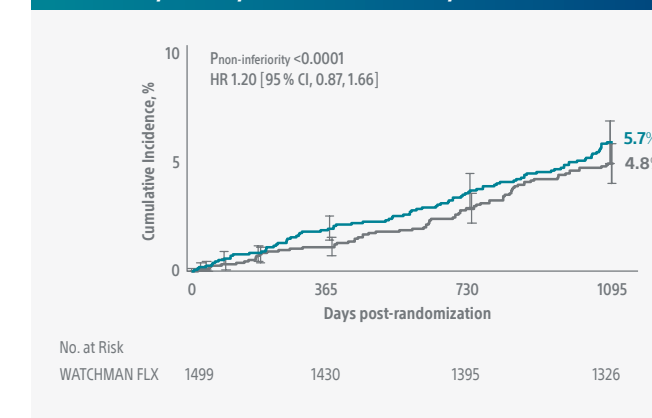
98.8%

Procedural Success

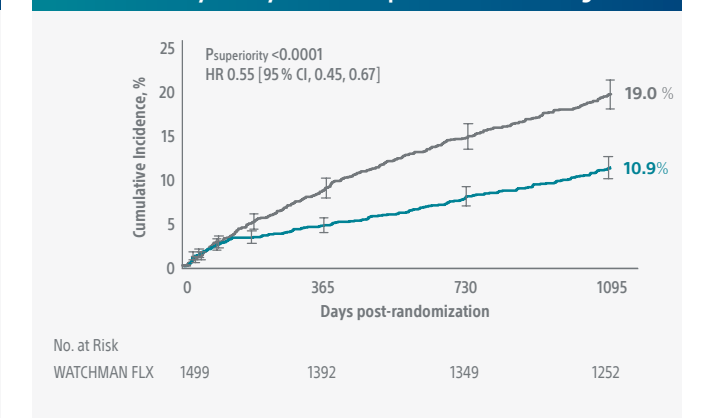
View the full clinical trial results and all the related resources here

Placeholder for QR-Code

Primary Efficacy: CV Death, Stroke, Systemic Embolism



Primary Safety: ISTH Non-procedural Bleeding



* Modified ISTH clinically relevant non-major bleeding was defined as any sign or symptom of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for the ISTH definition of major bleeding but does meet at least one of the following criteria.

- Requiring medical intervention by a healthcare professional
- Leading to hospitalization or increased level of care (e.g., ER visit, diagnostic procedures, medication change)



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,*}



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]; $P < 0.0001$.)

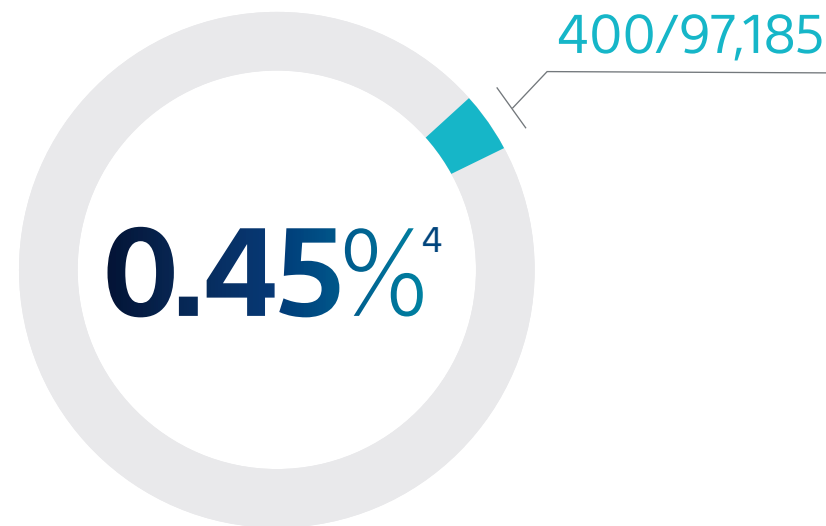
Real-world outcomes.

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

The SURPASS analysis reinforces the excellent safety profile the WATCHMAN FLXTM 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.



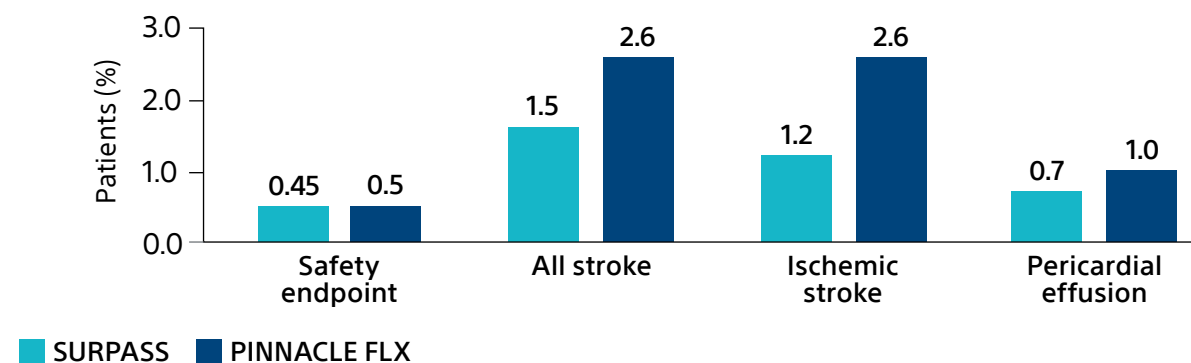
Procedural success

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.

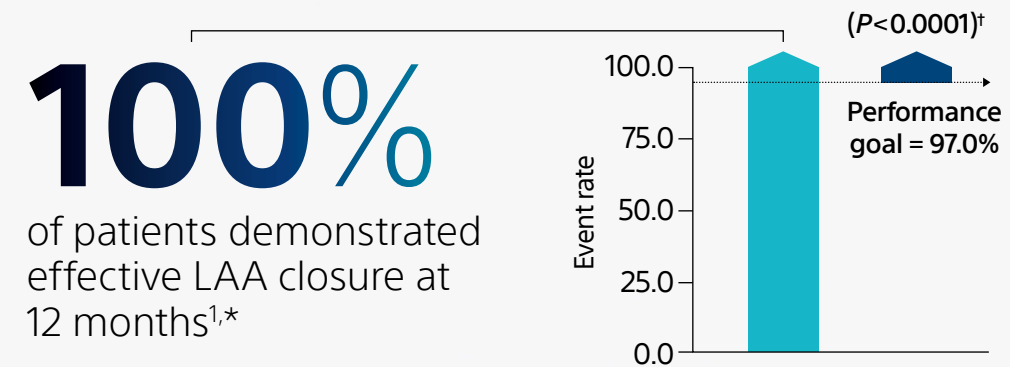
Proven efficacy outcomes.

Enhanced LAA closure.

The WATCHMAN FLXTM 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,*}



*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.

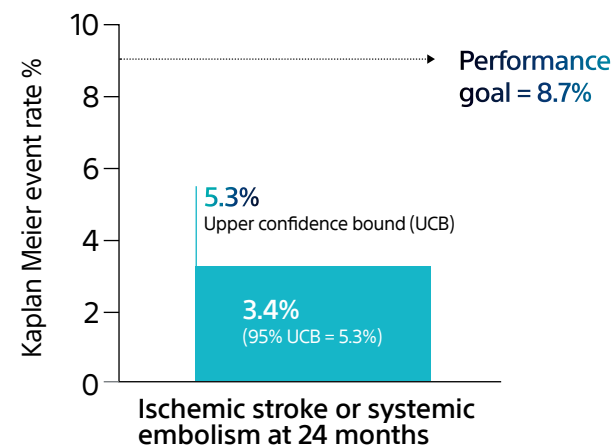
Enabling more patients to leave OACs behind.

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 anticoagulation¹
- 2 Intolerance to oral anticoagulation²
- 3 Elevated bleeding risk (HAS-BLED $\geq$ 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 $\geq$ 2 in men, $\geq$ 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](https://www.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](https://www.watchman.com/hcp)



References

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Notes

Notes

Protected by the WATCHMAN Implant. For Life.

Proven

600K+
patients successfully
implanted²

20+
years clinical
experience²

Safe

-34%
reduction vs NOAC
in ISTH bleeding
(incl. procedural) at 3yrs
(12.8% vs. 19.0%; P<0.0001)¹⁴

99%
implant success rate
(395/400)¹

0.5%
major adverse event rate¹

Effective

1.1%
Annualized ischemic
stroke rate¹

100%
effective LAA closure
at 12 months¹

>96%
discontinued OAC at
45 days in clinical trial¹

One Time. For a Lifetime.

**Boston
Scientific**
Advancing science for life™

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