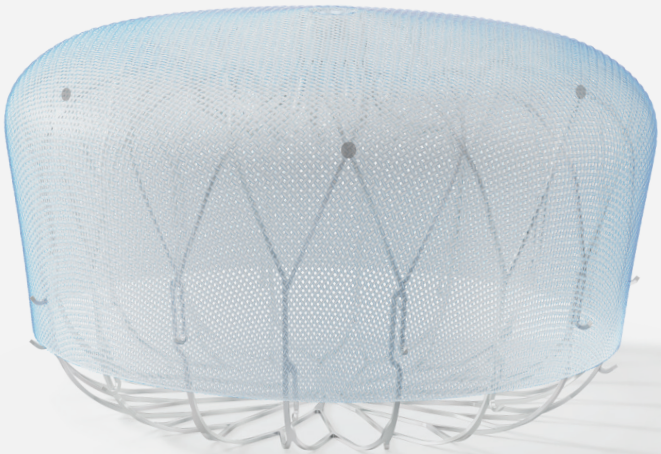


#1 Doctor Recommended LAAC Implant

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.

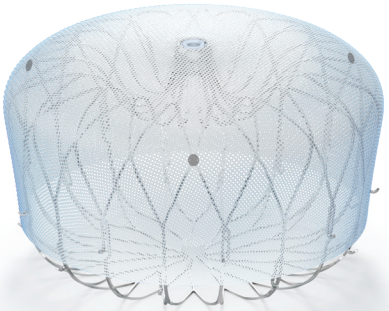
Afib doesn't have to mean a lifetime of oral anticoagulation therapy.

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.

WATCHMAN™ 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 ≤5mm per core laboratory-assessed TEE.

400,000+

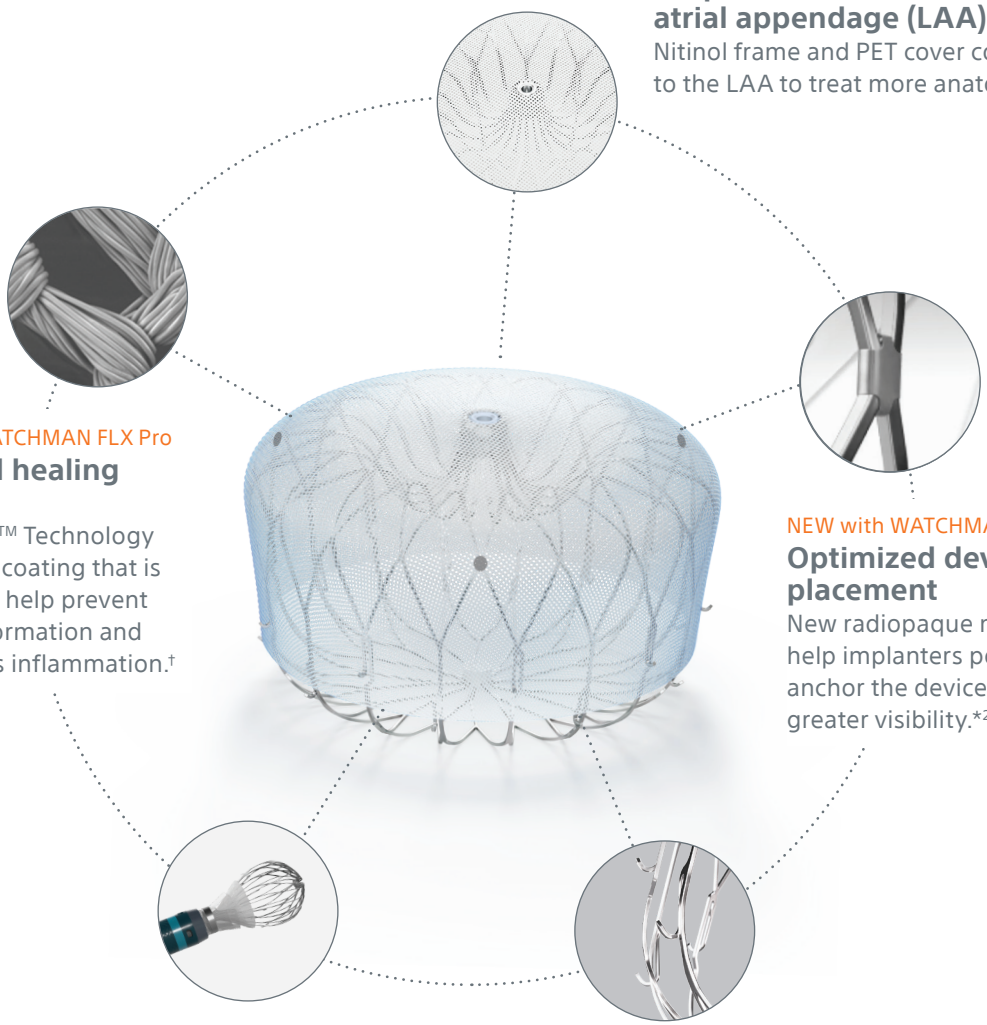
Lives Changed and Counting

The Leader in LAAC.

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

WATCHMAN FLX™ Pro is the next-generation WATCHMAN device with new 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.

NEW with WATCHMAN FLX Pro
Improved healing response
HEMOCOAT™ Technology is a durable coating that is designed to help prevent thrombus formation and result in less inflammation.†

NEW with WATCHMAN FLX Pro
Optimized device placement
New 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.

24 mm

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

WATCHMAN FLX Pro is available in a new 40 mm device size that accommodates additional patient anatomies and 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 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 choice between OAC and DAPT as a post-implant drug regimen.

Option 1: Short-Term OAC

Option 2: Immediate DAPT-Only

At TEE, if leak >5mm, patients remain on OAC + ASA until seal is documented (leak < 5mm)

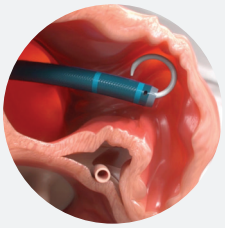
*Any P2Y12 inhibitor and aspirin

Implant procedure overview.

1

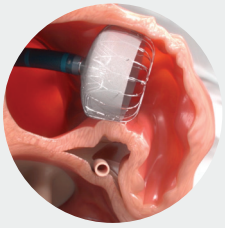
Using a standard percutaneous technique, a guidewire and vessel dilator are inserted into the femoral vein. The implant procedure is performed with fluoroscopy and transesophageal echocardiography (TEE).

2



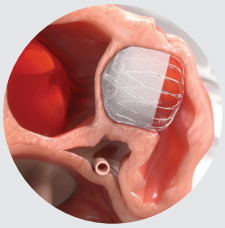
The interatrial septum is crossed using a standard transseptal access system. The access sheath is advanced over the guidewire into the left atrium and then navigated into the distal portion of the LAA over a pigtail catheter.

3



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

4



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

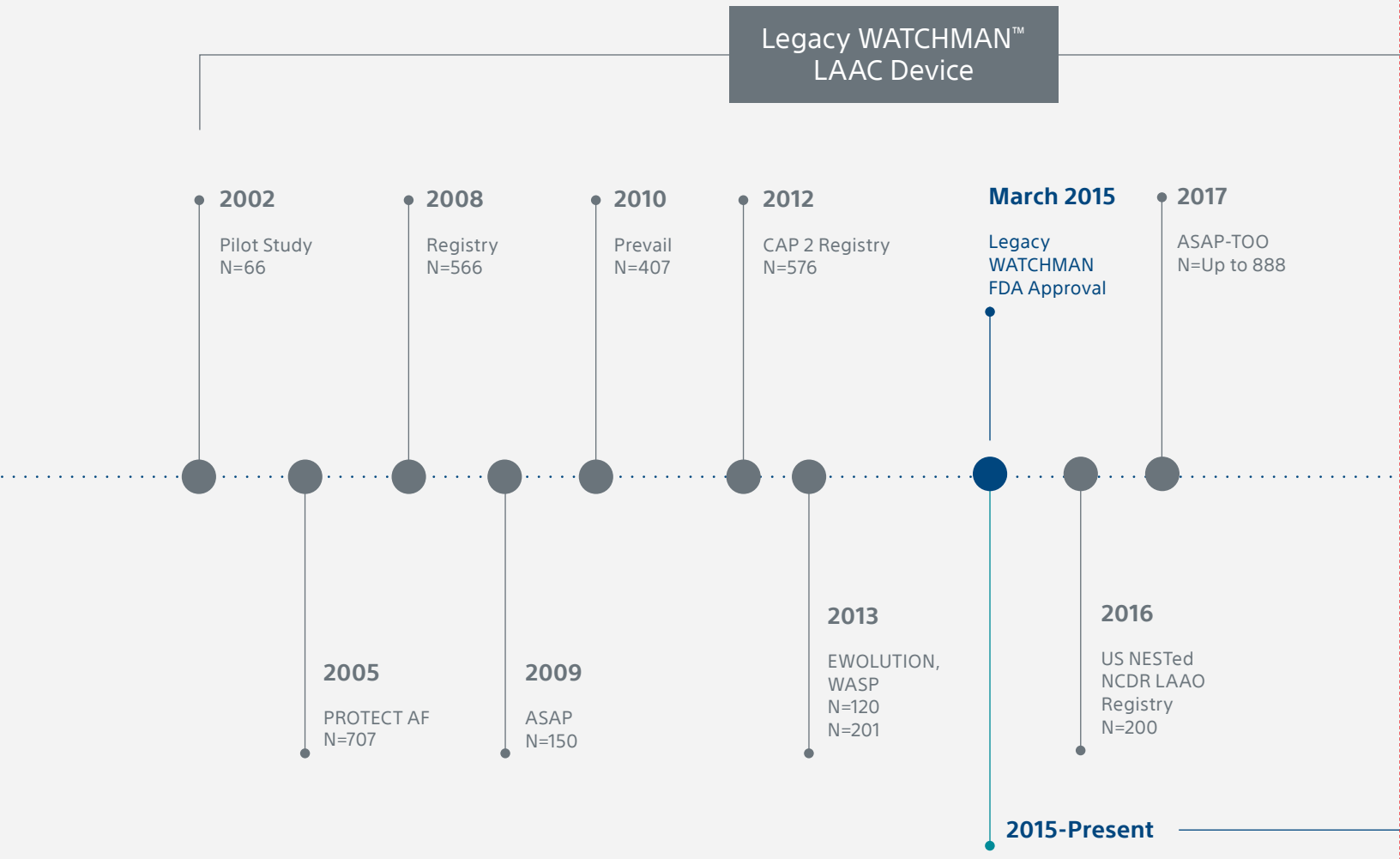
The implant is fully endothelialized.

In the PINNACLE FLX clinical trial

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

The WATCHMAN™ Implant is proven.

Clinical leadership in LAAC



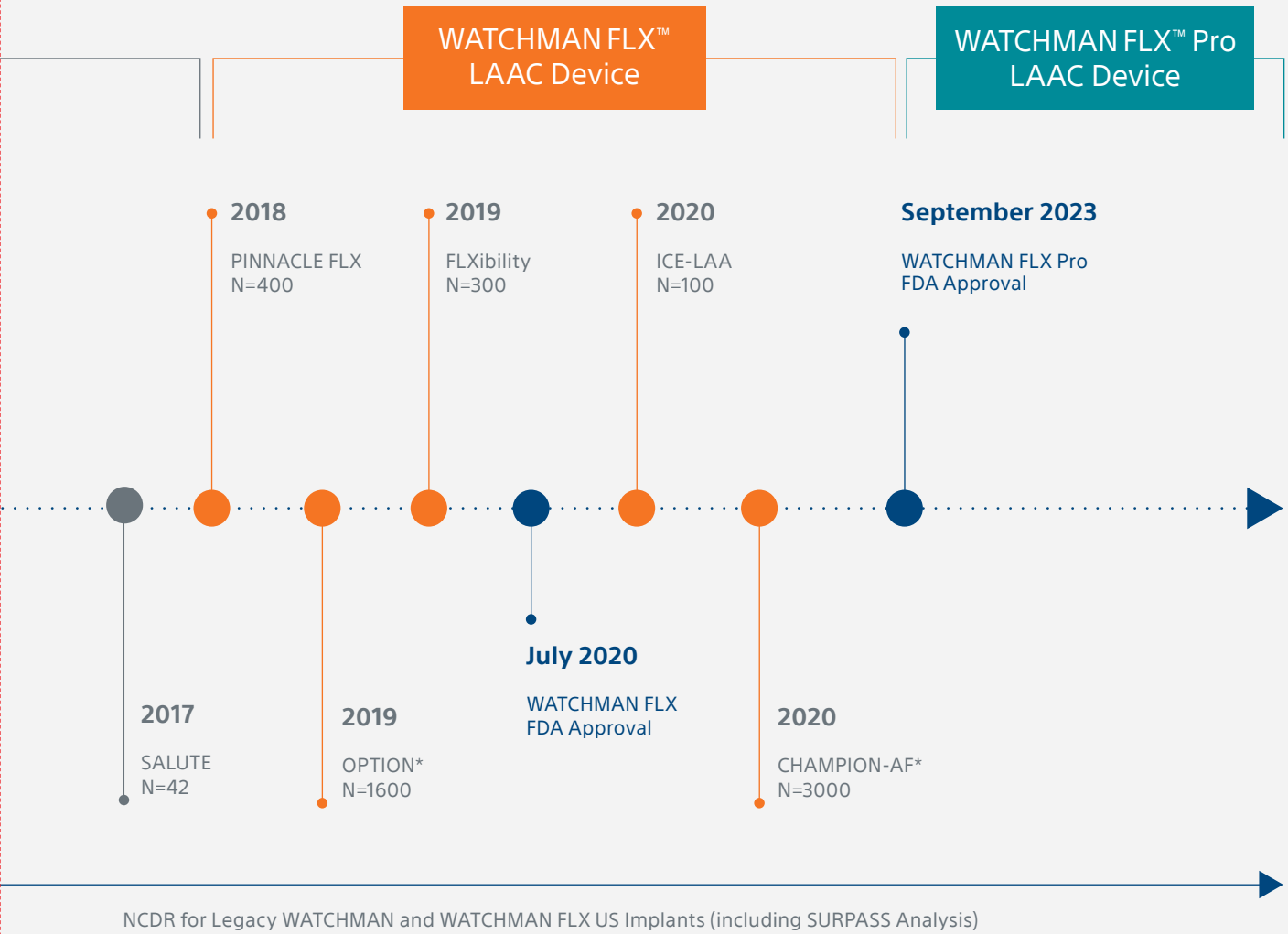
Note: The ASAP, ESC expanded guidelines and indication and Real World Registries in Europe and Asia studied the patient population not in the scope of the FDA-approved indications for use.

*Enrollment complete. Results pending.

400,000+
Patients implanted

20+ Years
Clinical trial and
real-world experience

Included In
ACC/AHA/HRS
AF Guidelines



NCDR for Legacy WATCHMAN and WATCHMAN FLX US Implants (including SURPASS Analysis)

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

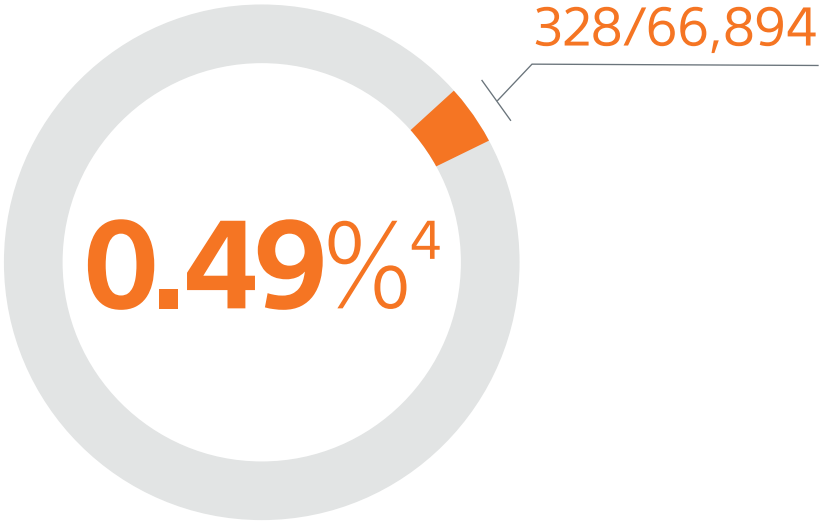
Real-world outcomes.

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.

Key safety endpoint

SURPASS demonstrated a 0.49% major procedural adverse event rate within 7 days or hospital discharge in 66,894 patients and confirmed the trusted safety profile of the WATCHMAN FLX Implant in real-world clinical practice settings.

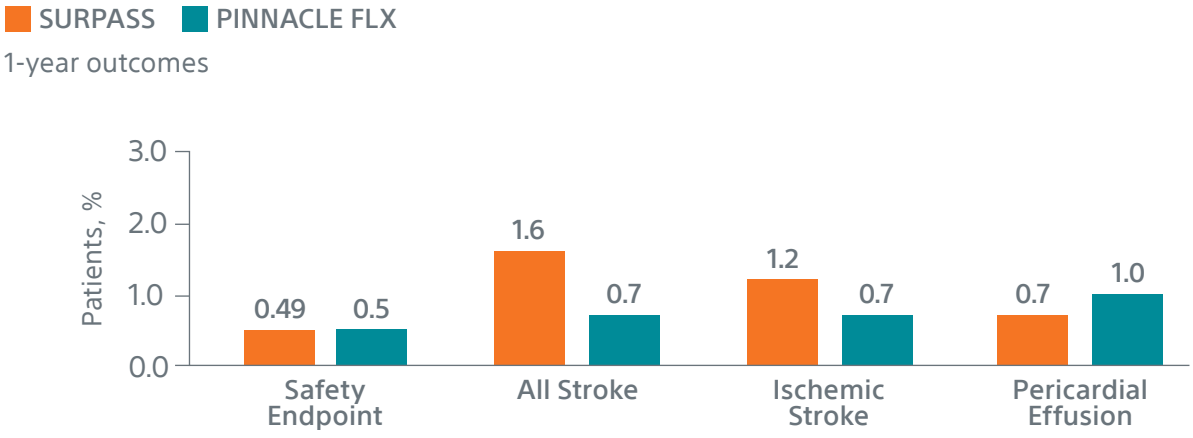


Procedural Success

98%

SURPASS data reinforces procedural success with 98% of patients implanted (N=66,894)[4] 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, 4*]



*Results from different clinical investigations are not directly comparable.

Proven efficacy outcomes.

Enhanced LAA closure.

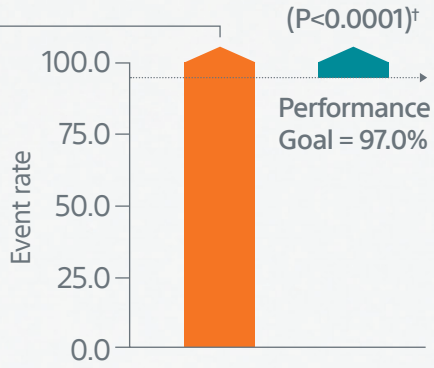
The WATCHMAN FLX™ Implant is designed for enhanced LAA closure, which was demonstrated with 100% rate of effective LAA closure at 12 months.[1]

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 ≤5mm per core laboratory-assessed TEE

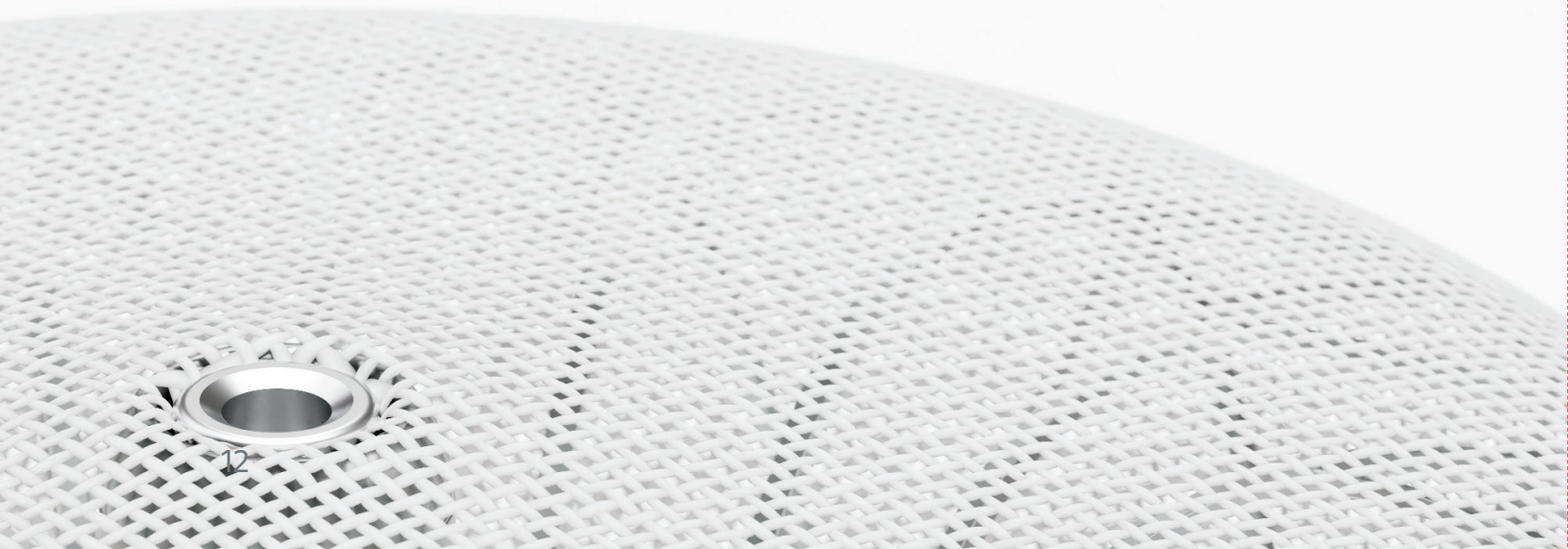
†Performance goal based on the rates observed in PREVAIL(2) and CAP2(3), minus a clinically relevant delta

Enabling more patients to leave OACs behind.

NOAC discontinuation

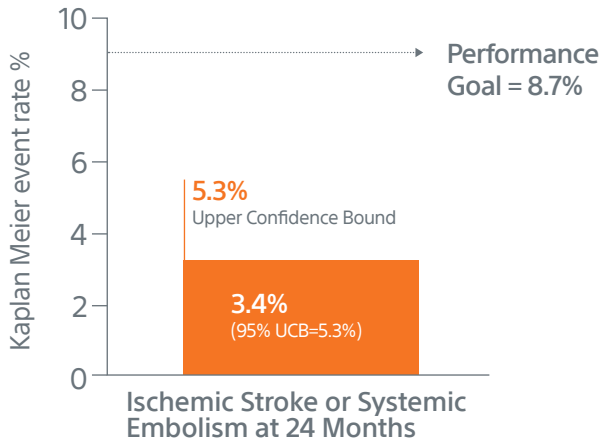
96.2%

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.[5]

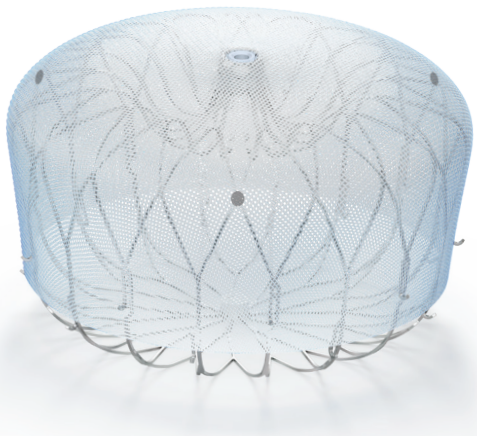


1.7%

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:

1. Have an increased risk for stroke and be recommended for anticoagulation (CHA_2DS_2-VASc ≥ 2 for men, ≥ 3 for women)*†
2. Are suitable for short-term oral anticoagulation
3. Have an appropriate reason to seek a non-pharmacologic alternative to OACs

*CHA_2DS_2-VASc score – Congestive heart failure = 1, Hypertension (SBP >160) = 1, Age > 75 yrs = 2, Diabetes mellitus = 1, Prior stroke, TIA, or thromboembolism = 2, Vascular disease (PAD, MI) = 1, Age 65-74 yrs = 1, Sex category (female) = 1.

†CMS coverage criteria requires a shared decision-making interaction and 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.

The 2023 ACC/AHA/ACCP/HRS Guidelines for the Diagnosis and Management of Atrial Fribrillation have upgraded left atrial appendage occlusion devices to a 2a Class of Recommendation for patients with a contraindication to long-term oral anticoagulants (OACs).

Consider WATCHMAN for patients who can't, won't, or shouldn't take 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 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.[6]

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.

Education specialists (call center)

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

Ambassadors

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

Tell your patients to visit WATCHMAN.COM 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.[7]

A typical Medicare patient in 2024 is estimated to pay approximately

$2,600

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 2023 Medicare rates set by the CY2023 CMS Physician Fee Schedule and CY2023 CMS Hospital Outpatient Prospective Payment System Annual Rules. CF=$33.8872. Payments from Optum, Inc. Accessed 01/04/2023.

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.

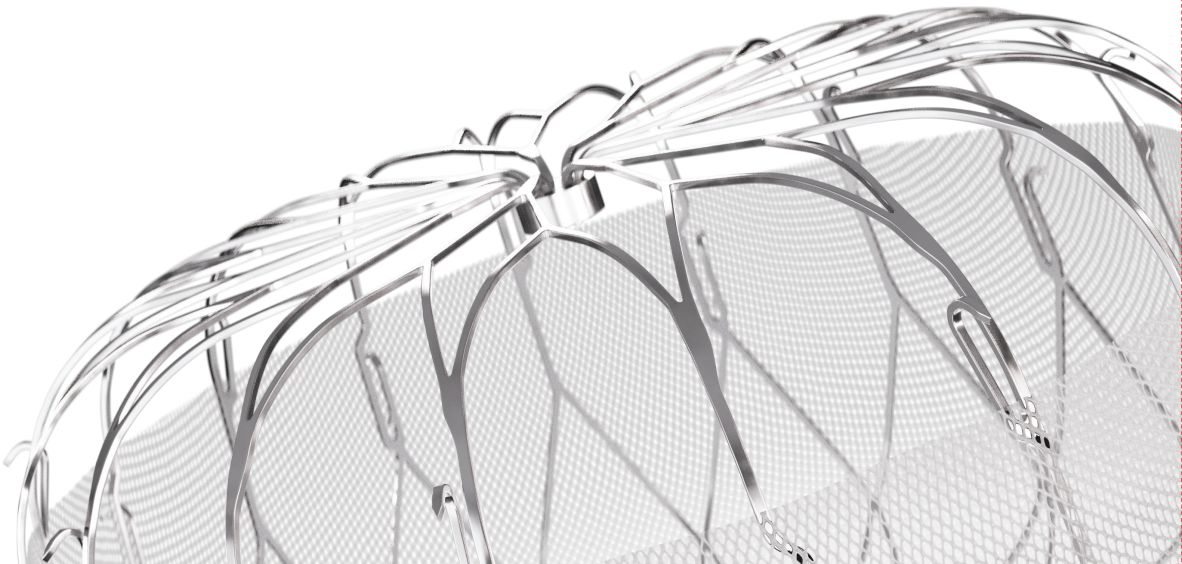
This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice.

Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, 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.



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.

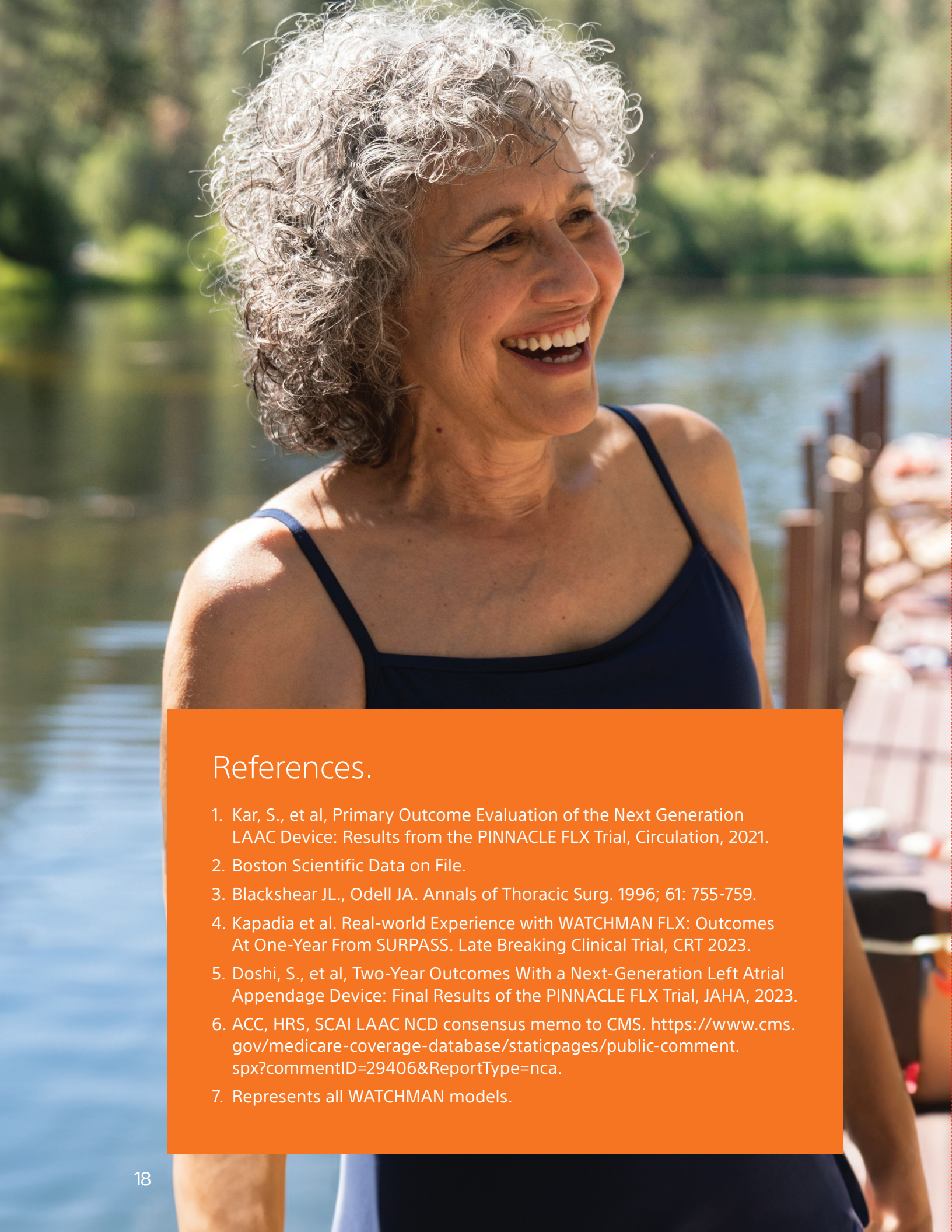
— Referring Cardiologist

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†

*Criteria are highlighted above. 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.



References.

1. Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.
2. Boston Scientific Data on File.
3. Blackshear JL., Odell JA. Annals of Thoracic Surg. 1996; 61: 755-759.
4. Kapadia et al. Real-world Experience with WATCHMAN FLX: Outcomes At One-Year From SURPASS. Late Breaking Clinical Trial, CRT 2023.
5. Doshi, S., et al, Two-Year Outcomes With a Next-Generation Left Atrial Appendage Device: Final Results of the PINNACLE FLX Trial, JAHA, 2023.
6. ACC, HRS, SCAI LAAC NCD consensus memo to CMS. https://www.cms.gov/medicare-coverage-database/staticpages/public-comment.spx?commentID=29406&ReportType=nca.
7. Represents all WATCHMAN models.

Brief summary.

WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE

The WATCHMAN FLX Pro Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy;
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

CONTRAINDICATIONS

Do not use the WATCHMAN FLX Pro Device if:

- Intracardiac thrombus is present.
- An atrial septal defect repair or closure device is present.
- A patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a Closure Device *(see Step 7 in the IFU).*
- The patient has a known hypersensitivity to any portion of the device material or the individual components *(see Device Description section in the IFU)* such that the use of the WATCHMAN FLX Pro Device is contraindicated.
- Any of the customary contraindications for other percutaneous catheterization procedure (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.
- There are contraindications to the use of anti-coagulation therapy, aspirin, or P2Y12 inhibitor.

WARNINGS

Implantation of the WATCHMAN FLX Pro Device should only be performed by interventional cardiologists and/or electrophysiologists who are proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized and who have completed the WATCHMAN FLX Pro Physician Training program.

- For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the Closure Device and/or lead to Closure Device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the Closure Device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Closure Device may lead to injury, illness, or death of the patient.
- This device has not been studied in pregnant or breastfeeding women. Careful consideration should be given to use of the Closure Device in pregnant and/ or breastfeeding women due to the risk of significant exposure to x-rays and the use of anticoagulation medication.
- Device selection should be based on accurate LAA measurements obtained using transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]; For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium.
- Do not release (i.e., unscrew) the WATCHMAN FLX Pro Device from the core wire unless all release criteria *(Step 15 in the IFU)* are satisfied to avoid suboptimal results.
- Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period.
- If thrombus is observed on the device, anticoagulation therapy is recommended until resolution of thrombus is demonstrated by TEE.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section for further detail.
- Do not use if the temperature exposure indicator dot on the pouch label is red or missing, indicating Closure Device performance may have been compromised.

PRECAUTIONS

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Pro Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.
- The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying, recapturing, and repositioning the Closure Device.
- Use caution when introducing a WATCHMAN Access System to prevent damage to cardiac structures.
- Use caution when introducing the Delivery System to prevent damage to cardiac structures.
- To prevent damage to the Delivery Catheter or Closure Device, do not allow the WATCHMAN FLX Pro Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath.
- If using a power injector, the maximum pressure should not exceed 690 kPa (100 psi).
- Use caution when manipulating the Delivery System. Excessive counterclockwise rotation of the deployment knob or Delivery System hub independent from the rest of the Delivery System can cause premature implant detachment.

ADVERSE EVENTS

Potential adverse events which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are

- Air embolism
- Airway trauma
- Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medication
- Altered mental status
- Anemia requiring transfusion
- Anesthesia risks
- Angina
- Anoxic encephalopathy
- Arrhythmias
- Atrial septal defect
- Bruising, hematoma, or seroma near the catheter insertion site
- Cardiac perforation
- Chest pain/discomfort
- Confusion post procedure
- Congestive heart failure
- Contrast-related nephropathy
- Cranial bleed
- Death
- Decreased hemoglobin
- Deep vein thrombosis
- Device embolism
- Device fracture
- Device thrombosis
- Edema
- Embolism
- Excessive bleeding
- Fever
- Fistula
- Groin pain
- Groin puncture bleed
- Hematuria
- Hemoptysis
- Hypotension
- Hypoxia
- Improper wound healing
- Inability to reposition, recapture, or retrieve the device
- Infection/pneumonia
- Interatrial septum thrombus
- Intratracheal bleeding
- Major bleeding requiring transfusion
- Misplacement of the device/improper seal of the appendage/movement of device from appendage wall
- Myocardial erosion
- Myocardial infarction
- Nausea
- Oral bleeding
- Pericardial effusion/tamponade
- Pleural effusion
- Prolonged bleeding from a laceration
- Pseudoaneurysm
- Pulmonary edema
- Radiation injury
- Renal failure
- Respiratory insufficiency/failure
- Stroke – Hemorrhagic
- Stroke – Ischemic
- Surgical removal of the device
- TEE complications (e.g., throat pain, bleeding, esophageal trauma)
- Thrombocytopenia
- Thrombosis
- Transient ischemic attack (TIA)
- Valvular or vascular damage
- Vasovagal reactions

There may be other potential adverse events that are unforeseen at this time.

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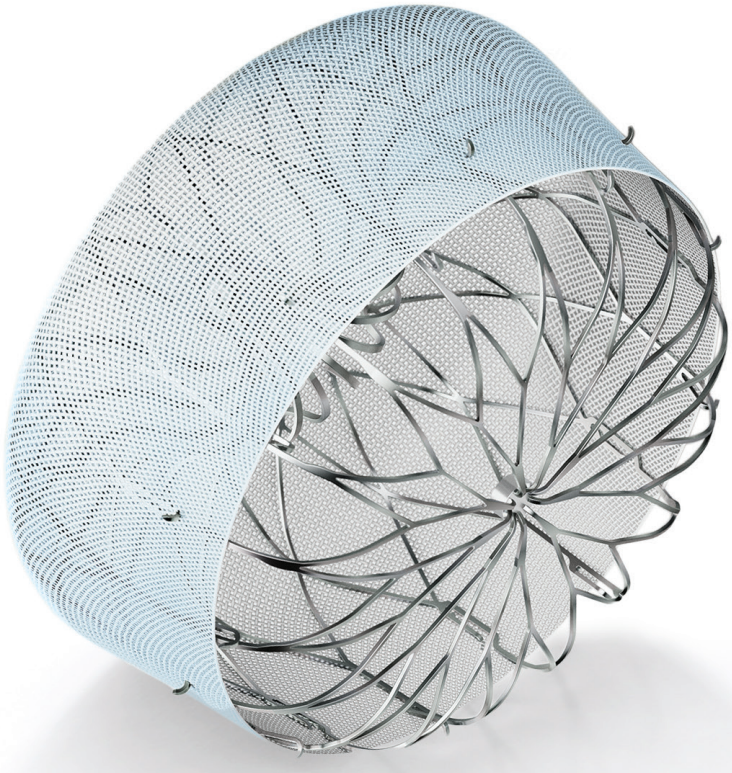

#1 Doctor Recommended LAAC Implant

Protected by the WATCHMAN Implant. For Life.

Proven[7]

400,000+ 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

*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

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

One Time. For a Lifetime.

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

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Marlborough, MA 01752-1234
www.bostonscientific.com

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