#1 Doctor Recommended LAAC Implant

WATCHMAN FLX™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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

One Time. For a Lifetime.

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 FLX™ Implant. For Life.

The WATCHMAN FLX LAAC device

Not actual size.

The WATCHMAN FLX 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.**

Most studied and implanted LAAC device in the world

Proven

99%

Patients Successfully Implanted (395/400)*[1]

Safe

0.5%

Major Adverse Event Rate†[1]

Effective

100%

Effective LAA Closure**[1]

PINNACLE FLX IDE Clinical Trial Results
*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

300,000+

Lives Changed and Counting

The Leader in LAAC.

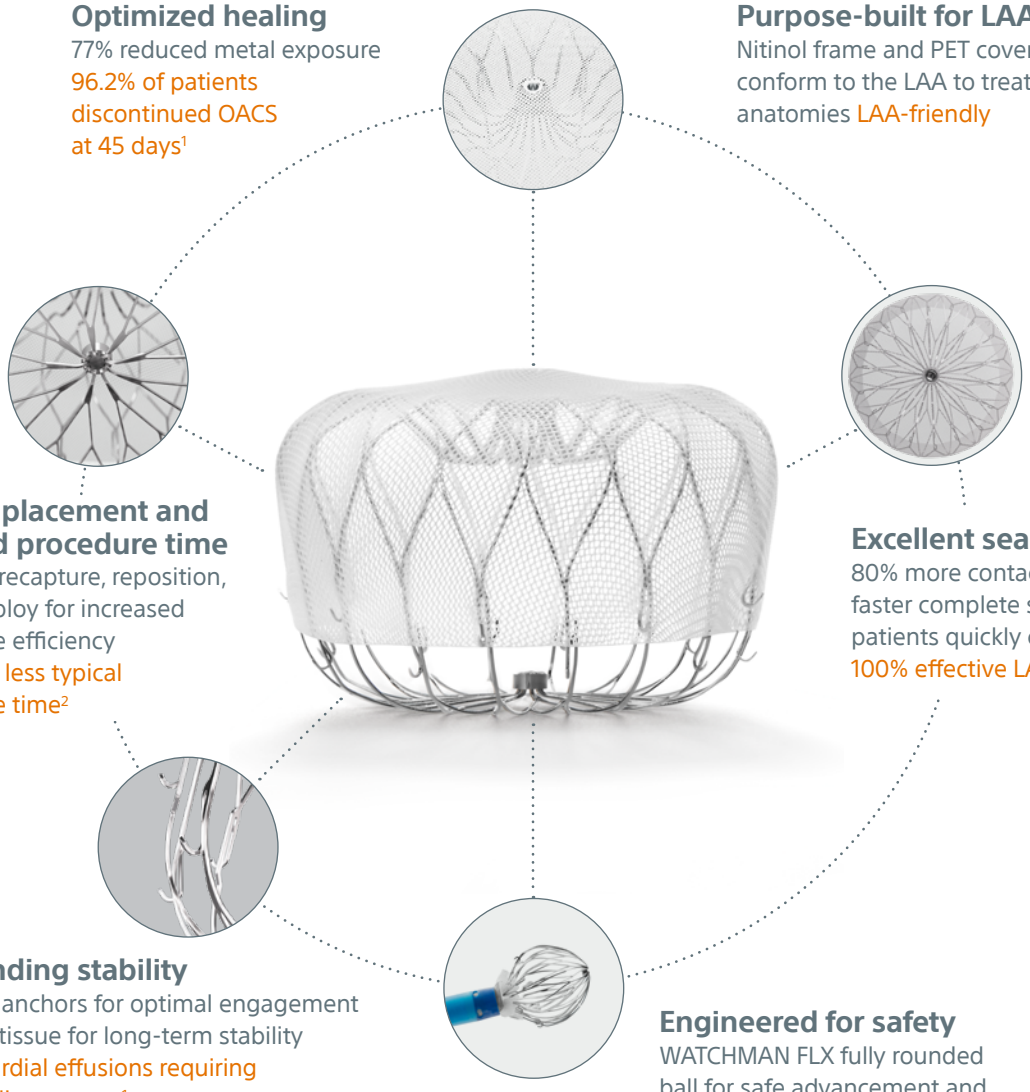
The world's most studied LAAC device safely treats more patients than ever.

The WATCHMAN FLX™ Implant is designed to advance procedural performance and safety while expanding the treatable patient population.

The WATCHMAN FLX Implant design differentiation.*

Optimized healing
77% reduced metal exposure
96.2% of patients discontinued OACS at 45 days[1]

Purpose-built for LAA
Nitinol frame and PET cover conform to the LAA to treat more anatomies LAA-friendly



Precise placement and reduced procedure time
Ability to recapture, reposition, and redeploy for increased procedure efficiency
30 min or less typical procedure time[2]

Excellent sealing
80% more contact points for faster complete seal to help patients quickly come off OACs
100% effective LAA closure[1]

Outstanding stability
Dual-row anchors for optimal engagement with LAA tissue for long-term stability
0% pericardial effusions requiring open cardiac surgery[1]

Engineered for safety
WATCHMAN FLX fully rounded ball for safe advancement and maneuvering in LAA
0.5% major adverse event rate[1]

*As compared to Legacy WATCHMAN Device (No Longer Sold in the US)

Broad range of anatomies.

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

99%

Implant Success Rate*[1]

20 MM ····· 24 MM ····· 27 MM ····· 31 MM ····· 35 MM

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

> *[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 FLX™ Implant works.

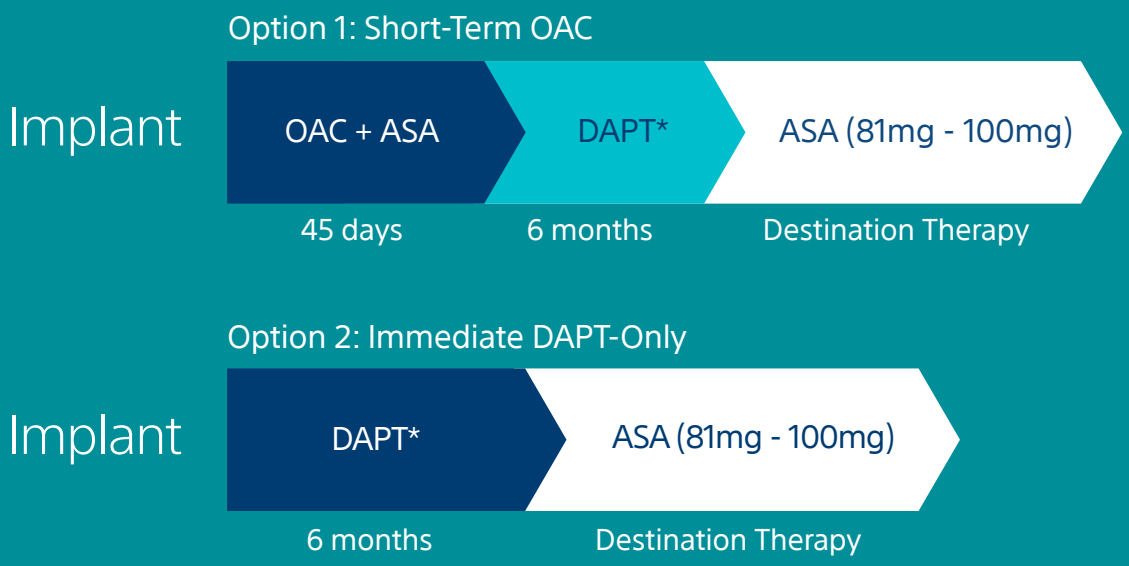
In non-valvular AFib, >90% of stroke-causing clots that come from the left atrium are formed in the left atrial appendage (LAA).[3] The WATCHMAN FLX Implant is a minimally invasive, one-time procedure designed to reduce the risk of strokes that originate in the LAA.

Permanent implant

Minimally invasive

1 day or less average hospital stay

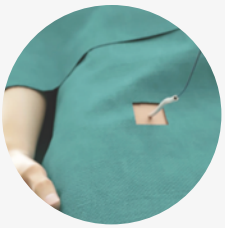
The only LAAC that offers choice between OAC and DAPT as a post drug regimen.



At TEE, if leak >5mm, patients remain on OAC + ASA until seal is documented (leak < 5mm)
*Any P2Y12 inhibitor and aspirin

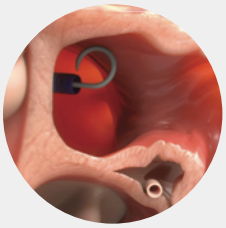
Implant procedure overview.

1



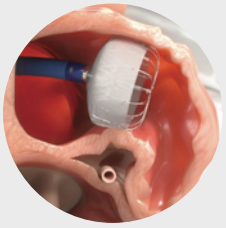
Using a standard percutaneous technique, a guidewire and vessel dilator are inserted into the femoral vein. The implant procedure is performed with fluoroscopy and transesophageal echocardiography (TEE).

2



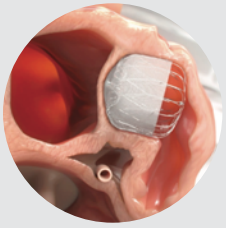
The interatrial septum is crossed using a standard transseptal access system. The access sheath is advanced over the guidewire into the left atrium and then navigated into the distal portion of the LAA over a pigtail catheter.

3



WATCHMAN FLX™ Device is deployed and released in LAA.

4



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

5

Fully endothelialized device.

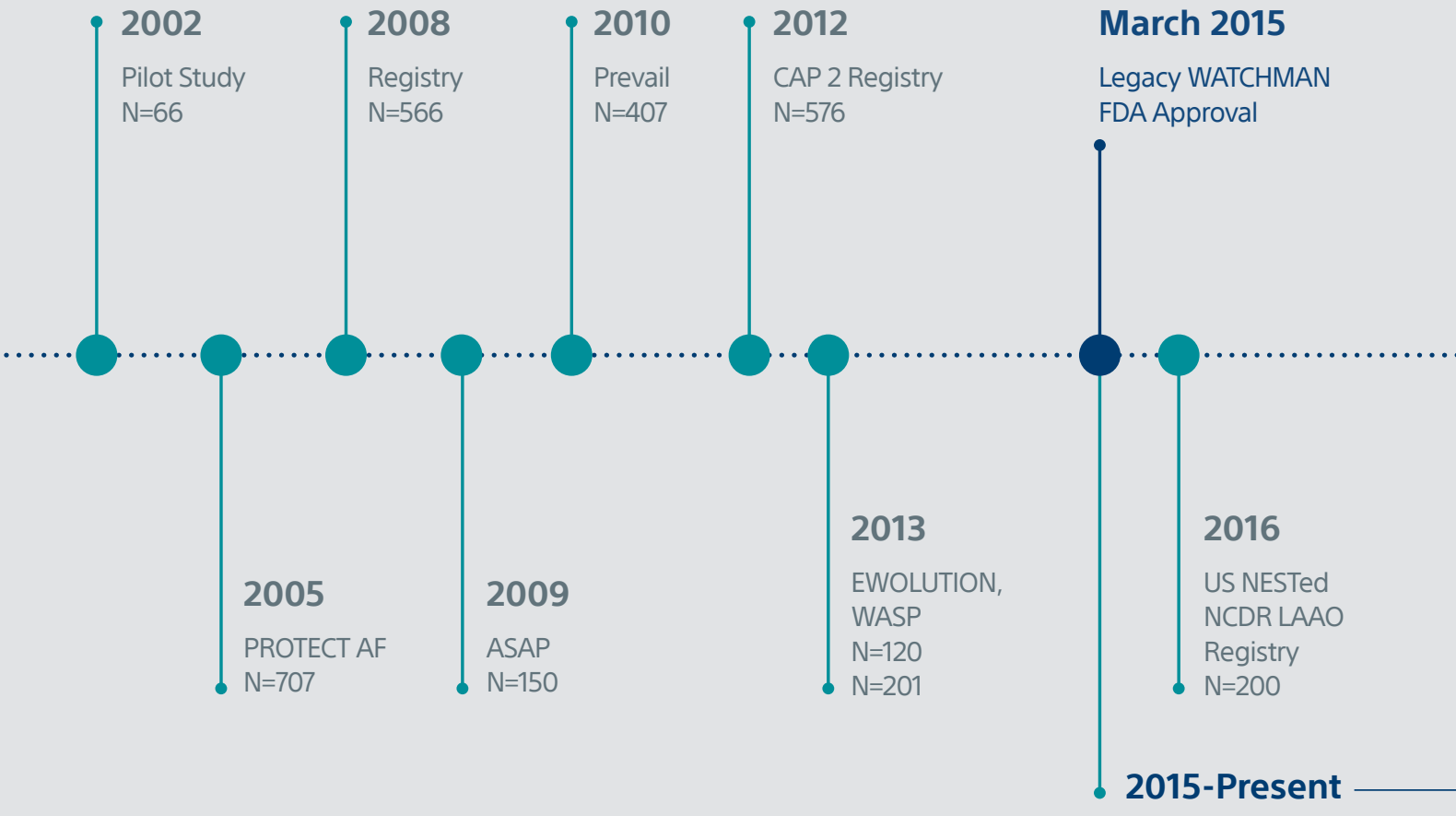
In the PINNACLE FLX clinical trial

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

The WATCHMAN FLX™ Implant is Proven.

Clinical leadership in LAAC

Legacy WATCHMAN™ LAAC Device



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.

300,000+
Patients implanted

20+ Years
Clinical trial and
real-world experience

Included In
ACC/AHA/HRS
AF Guidelines

WATCHMAN FLX™ LAAC Device

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

Clinically proven and safe outcomes.

In the PINNACLE FLX IDE Clinical Study, the WATCHMAN FLX™ Implant demonstrated a 99% implant success rate and low 0.5% major adverse event rate.[1]

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 cardiac 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 Study was designed to establish the procedural safety and closure efficacy of the WATCHMAN FLX Implant.

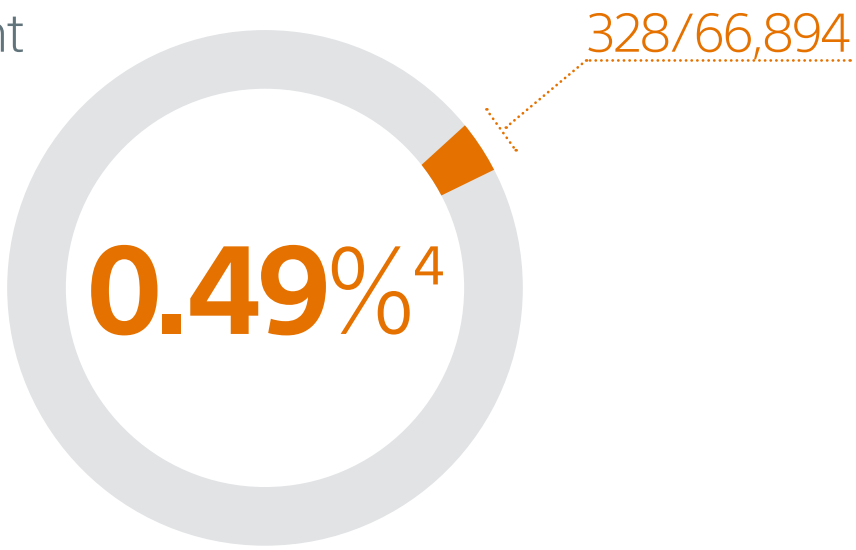
Real-world outcomes.

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 patients studied to date.

Key safety endpoint

SURPASS demonstrated 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 setting.

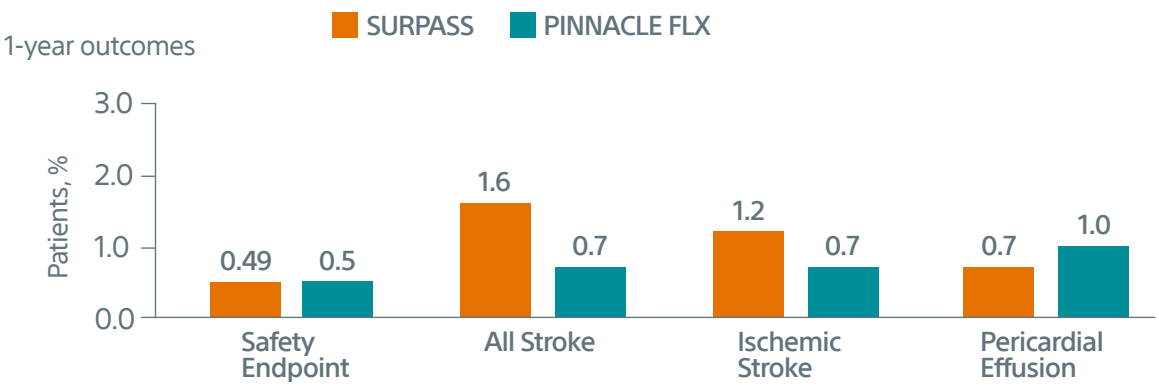


Procedural Success

98%

SURPASS data reinforce 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

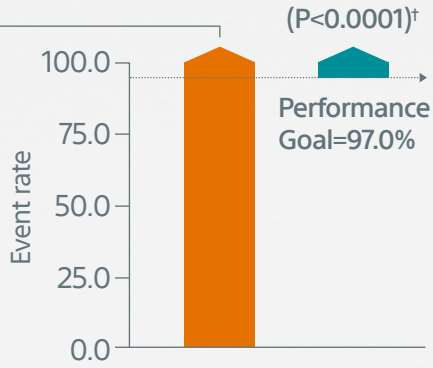
The WATCHMAN FLX™ Implant is designed for enhanced LAA closure, which was demonstrated with 100% rate of effective LAA closure at 12 months.[1]

Primary efficacy endpoint.

Effective LAA closure at 12 months*[1]

100%

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



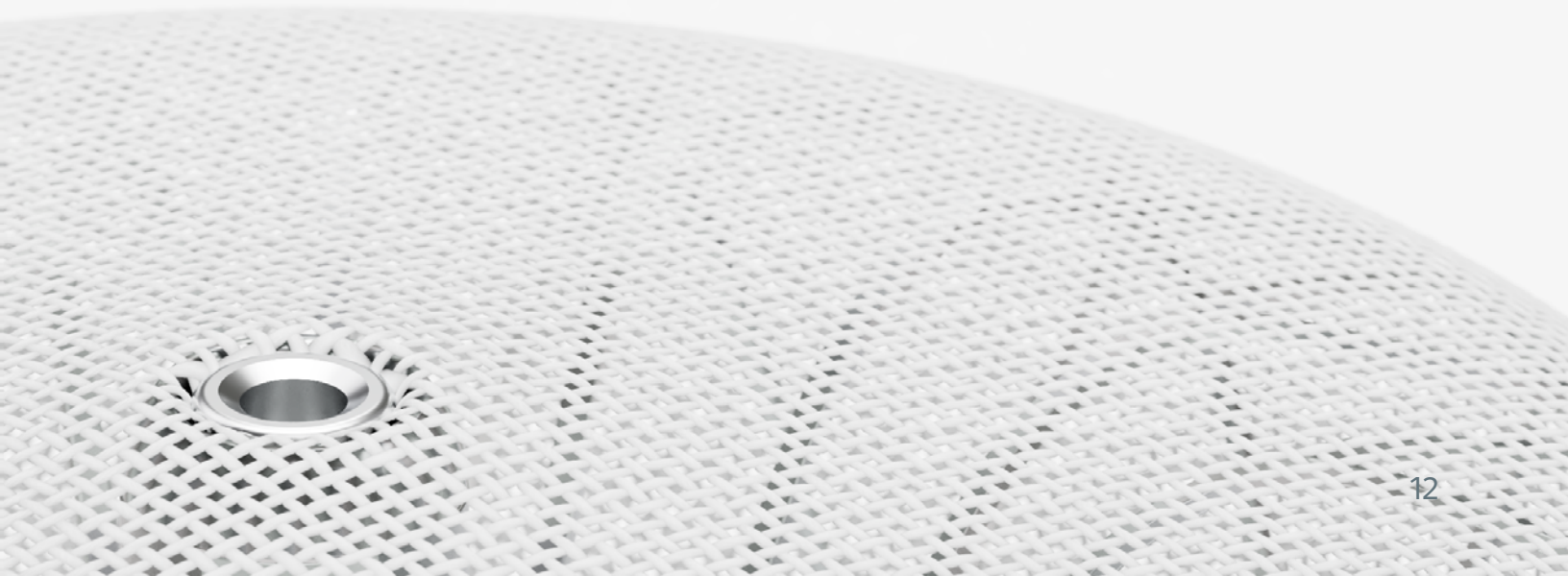
*LAA closure at 12 months is defined as any peri-device flow with jet size ≤5mm per core laboratory-assessed TEE
†Performance goal based on the rates observed in PREVAIL(2) and CAP2(3), minus a clinically relevant delta

Enabling more patients to leave OACs behind

NOAC discontinuation

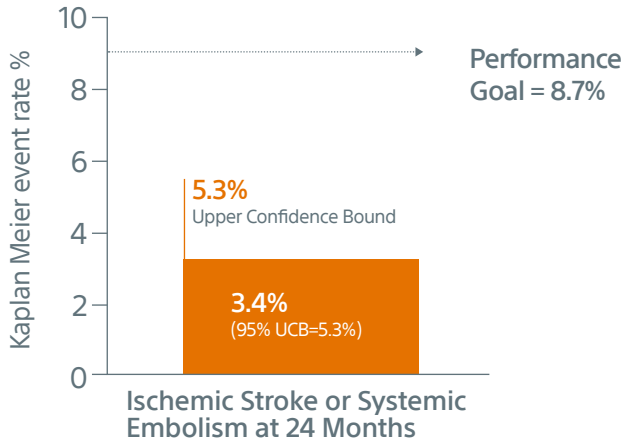
96.2%

of patients discontinued OAC after 45 days.[1]



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

PINNACLE FLX 24-month data demonstrate 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 continue to differentiate WATCHMAN FLX LAAC 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 FLX™ 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

WATCHMAN included in Atrial Fibrillation Guidelines.

Oral anticoagulation remains the preferred therapy for stroke prevention for most patients with AF and elevated stroke risk. However, for patients who are poor candidates for long-term oral anticoagulation (because of the propensity for bleeding or poor drug tolerance or adherence), the WATCHMAN FLX Implant provides an alternative.

- 2019 AHA/ACC/HRS Guideline Update for the Management of Patients with Atrial Fibrillation.

Most common reasons cardiologists recommend WATCHMAN for their patients include:

- History of major or non-major bleeding
- At high risk of bleeding, includes mobility issues or fall risk
- Hobby, activity, or occupation where long-term OAC is not ideal
- Prior inability to comply with OAC treatment regimen
- Co-morbidities requiring treatments that may not be compatible with OACs

The three leading cardiology and cardiovascular societies in the U.S. recognize 12 appropriate contraindications to anticoagulation.[6]

Patient screening, education, and support.

From identifying appropriate patient candidates to guiding them along the WATCHMAN journey, these tools and resources can help streamline the process, saving you time and effort.

WATCHMAN screening and referral form

Screen potential candidates and connect them with an implanter for a consultation.

Patient education specialists (call center)

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

Patient education

Brochures, guides, and animations address patient questions and facilitate your conversation.

Patient Ambassador program

People who have received WATCHMAN LAAC Devices[1] volunteer to answer questions and share their personal experiences with potential patients.

Looking for resources? Talk to your Boston Scientific representative or 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[7]

A typical Medicare patient in 2023 is estimated to pay no more than

$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.

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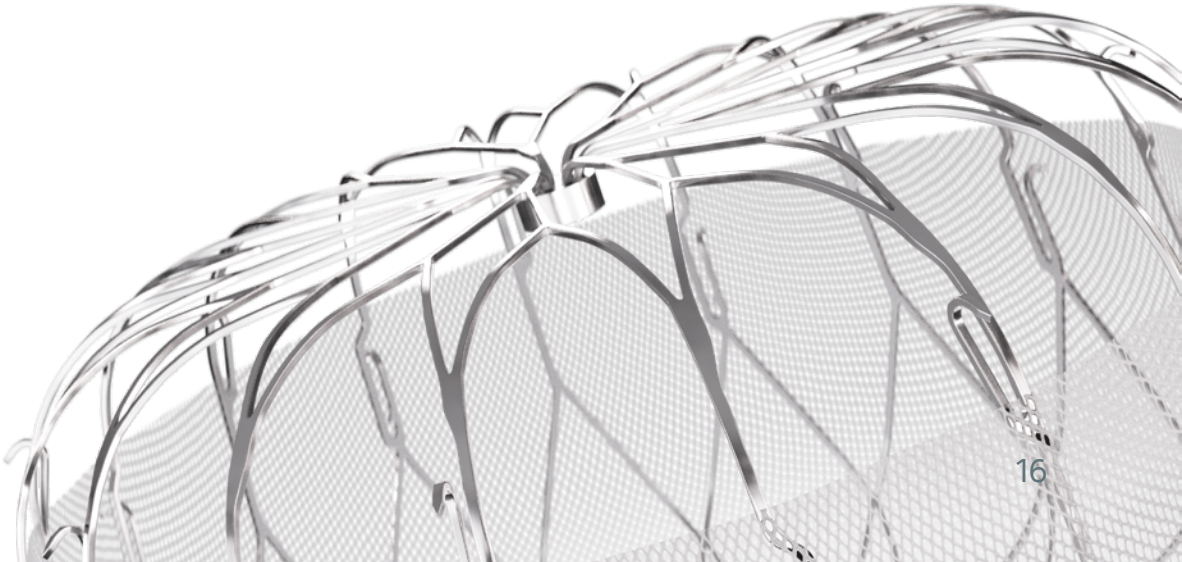


If they have issues with the affordability of the medication, consistently taking [it], people at risk of fall... who are very active in their lifestyle... those people would be candidates, in my opinion, for a WATCHMAN Implant.

— Interventional 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

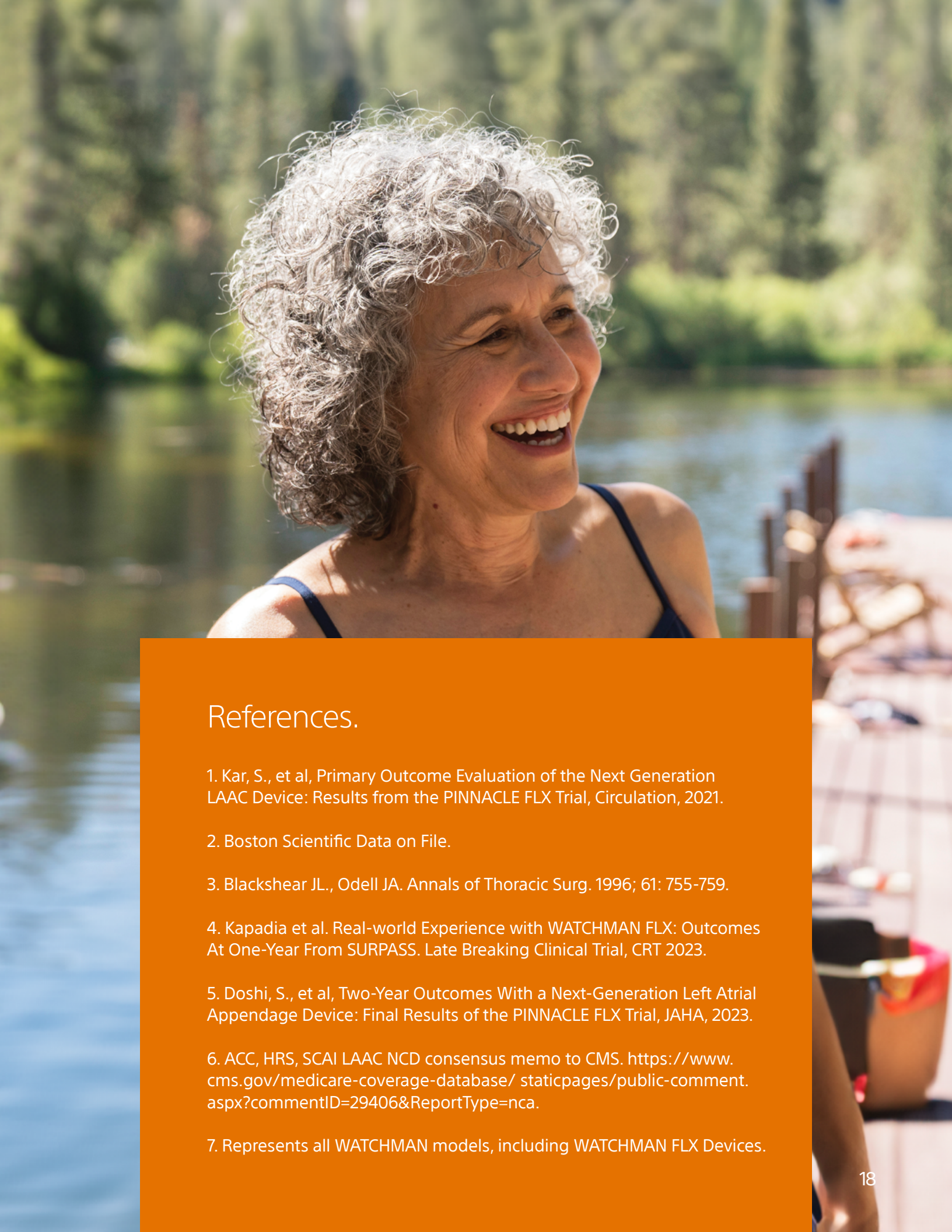
But deemed unable to take long-term oral anticoagulation

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.aspx?commentID=29406&ReportType=nca.

7. Represents all WATCHMAN models, including WATCHMAN FLX Devices.

Brief summary.

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The WATCHMAN FLX™ 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 CHA2DS2-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.

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CONTRAINDICATIONS

Do not use the WATCHMAN FLX Device if:

- Intracardiac thrombus is present.
- An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a Closure Device (see Table 62 of the eIFU).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section of the eIFU) such that the use of the WATCHMAN FLX 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 anticoagulation therapy, aspirin, or P2Y12 inhibitor.

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WARNINGS

Implantation of the WATCHMAN FLX 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 Physician Training program.

- 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 Device from the core wire unless all release criteria 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.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section (of the eIFU) for further detail.

PRECAUTIONS

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX 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 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)..

PATIENT SELECTION FOR TREATMENT

In considering the use of the WATCHMAN FLX Device, the rationale for seeking an alternative to long-term anticoagulation therapy and the safety and effectiveness of the device compared to anticoagulation should be taken into account.

- The presence of indication(s) for long-term anticoagulation therapy, other than non-valvular atrial fibrillation (e.g., mechanical heart valve, hypercoagulable states, recurrent deep venous thrombosis). Details regarding the indications, contraindications, warnings, and precautions for oral anticoagulants approved for patients with non-valvular atrial fibrillation are provided in their respective Instructions for Use. Of note:
- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated. Factors that need to be considered for the WATCHMAN FLX Device and implantation procedure include the following:
- Overall medical status, including conditions which might preclude the safety of a percutaneous, transcatheter procedure.
- Suitability for percutaneous, transseptal procedures, including considerations of:
  - Cardiac anatomy relating to the LAA size and shape.
  - Vascular access anatomy (e.g., femoral vein size, thrombus, or tortuosity).
  - Ability of the patient to tolerate general or local anesthesia.
  - Ability of the patient to undergo required imaging.
- Ability to comply with the recommended post-WATCHMAN FLX Device implant pharmacologic regimen (see Post-Procedure Information section) especially for patients at high risk for bleeding.

ADVERSE EVENTS

Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to:

- Air embolism
- Airway trauma
- Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medications
- 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 FLX Implant. For Life.

Proven[7]

300,000+ 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 FLX™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

One Time. For a Lifetime.

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

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Advancing science for life™

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