

FOR YOUR NON-VALVULAR ATRIAL FIBRILLATION (NVAF) PATIENTS

**Boston  
Scientific**  
Advancing science for life™



**PROTECT  
AGAINST STROKE RISK.**

**PROTECT  
AGAINST OAC BLEED RISK.**

**FOR LIFE.**

**WATCHMAN™**  
INTEGRATED LAAC SOLUTIONS

**ONE TIME.  
FOR A LIFETIME.**







## A LIFETIME OF OAC THERAPY COMES WITH LIFELONG RISKS FOR PATIENTS WITH NON-VALVULAR AFIB.

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

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

**WATCHMAN™ CAN HELP.**

## PROTECT YOUR PATIENTS FOR LIFE WITH WATCHMAN™.

In patients with non-valvular atrial fibrillation (NVAF), over 90% of stroke-causing clots that come from the left atrium are formed in the left atrial appendage (LAA).<sup>1</sup>

WATCHMAN is a one-time procedure that permanently closes off the LAA, preventing blood clots from escaping.

The WATCHMAN FLX™ LAAC Device



**WATCHMAN. THE ONE-TIME PROCEDURE THAT DELIVERS A LIFETIME OF STROKE RISK REDUCTION, WITHOUT THE LIFELONG RISKS OF OACS.**

**98.8%**  
PATIENTS SUCCESSFULLY  
IMPLANTED\*<sup>2</sup>

**0.5%**  
EVENT RATE<sup>†2</sup>

**>96%**  
OF PATIENTS DISCONTINUED  
OAC AFTER 45 DAYS<sup>2</sup>

PINNACLE FLX IDE Clinical Trial Results

**150,000+** **LIVES CHANGED**  
**AND COUNTING**



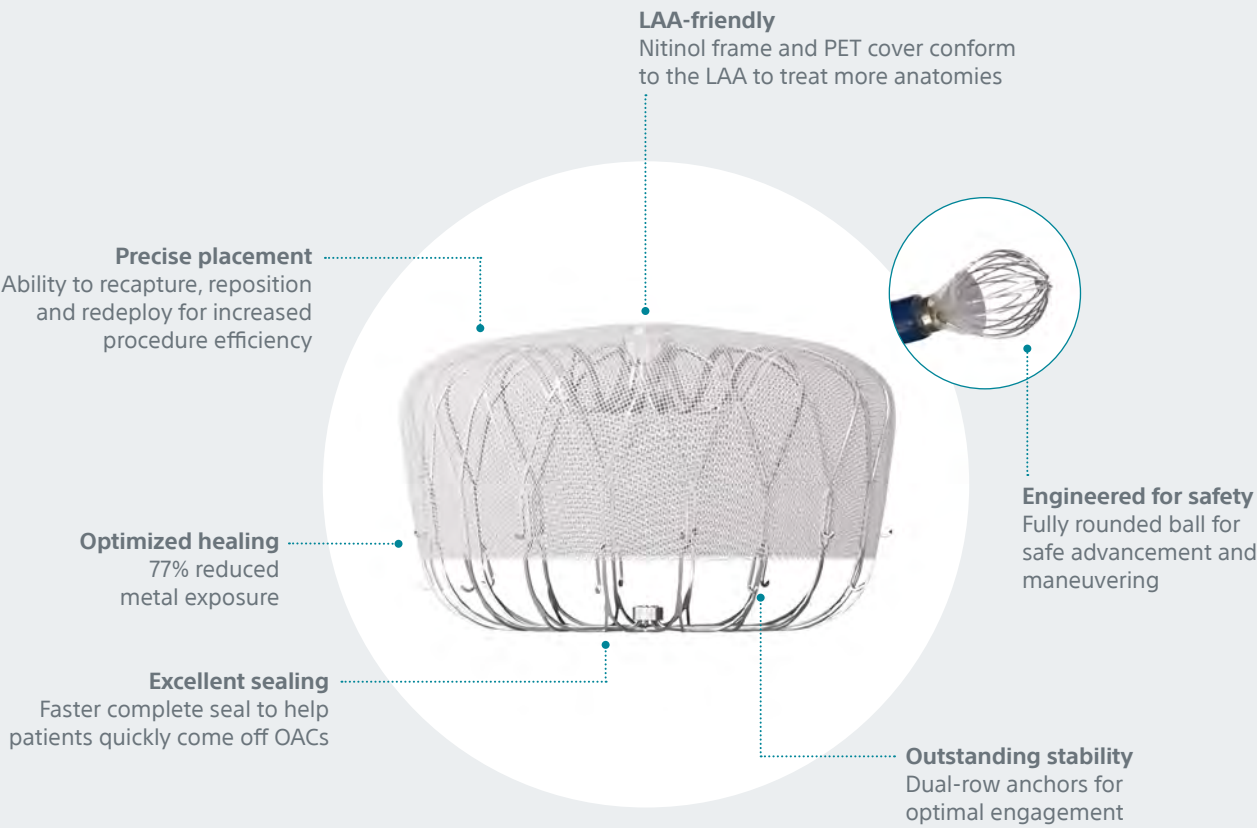
# THE LEADER IN LAAC.

## THE WORLD’S MOST STUDIED LAAC DEVICE SAFELY TREATS MORE PATIENTS THAN EVER.

Boston Scientific is committed to making safe and effective treatments even better. WATCHMAN™ is no exception. The next-generation WATCHMAN FLX™ Device is designed to:

- **Advance Safety** with a high procedural success rate and low major complication rate
- **Enhance Procedural Performance** with a faster complete seal, helping patients quickly discontinue OACs and delivering best long-term outcomes
- **Expand Treatable Patient Population** with proprietary engineering that treats more anatomies

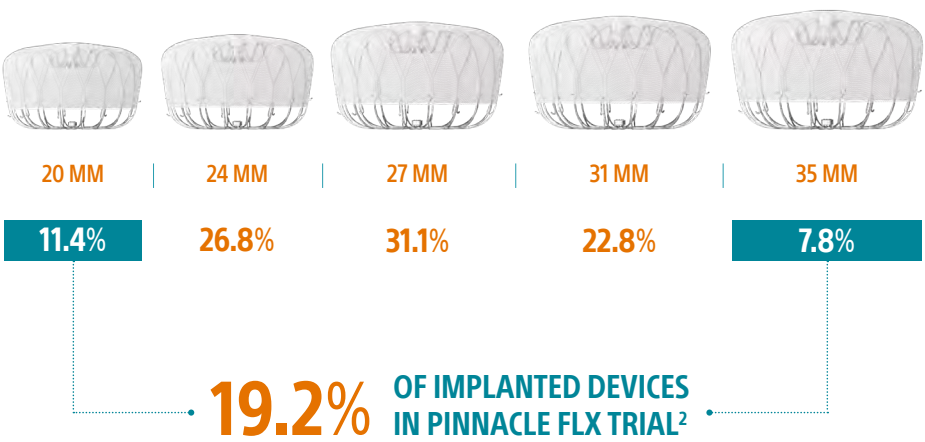
### THE WATCHMAN FLX LAAC DEVICE

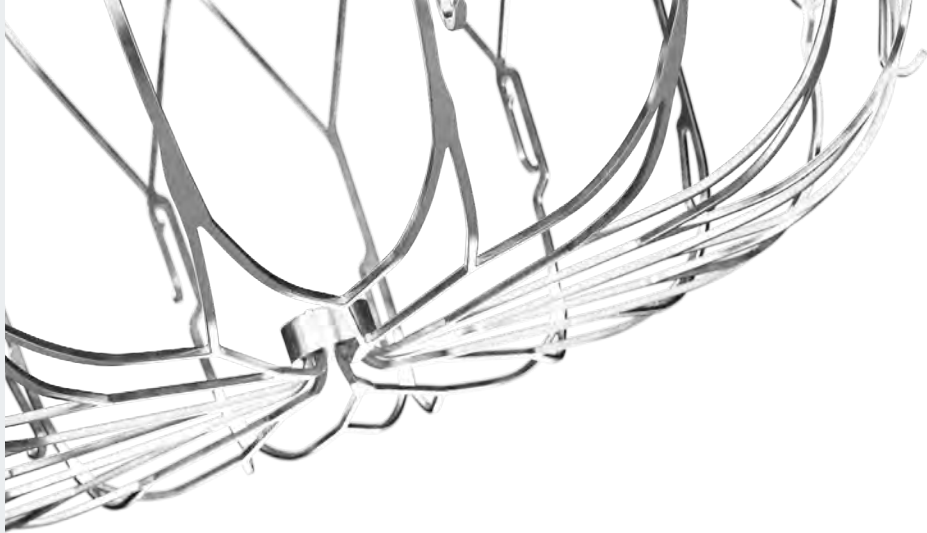


[WATCHMAN is] very easy to use. It’s flexible. It fits into a wide range of appendages... all of the nooks and crannies the different appendages present to us because that’s a very unique personal aspect of physiology and anatomy.

ANTHONY MAGNANO, MD, ELECTROPHYSIOLOGIST




## DESIGNED TO TREAT THE WIDEST RANGE OF PATIENT ANATOMIES





# HOW WATCHMAN™ WORKS.

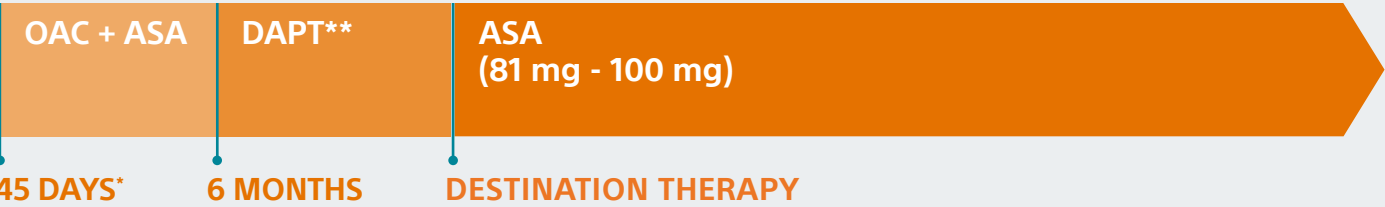
WATCHMAN is designed to permanently close the left atrial appendage (LAA) and reduce the risk of thromboembolism.

-  Minimally invasive, permanent implant
-  Procedure time typically 1 hour or less
-  Patients usually stay in the hospital overnight and return home next day

“The thing patients are happiest about is getting off their blood thinner...not having fear [of a] spontaneous bleed again.”  
RAGU MURTHY, MD, CARDIOLOGIST

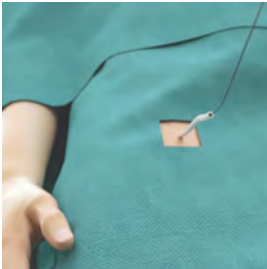
## POST-IMPLANT DRUG REGIMEN

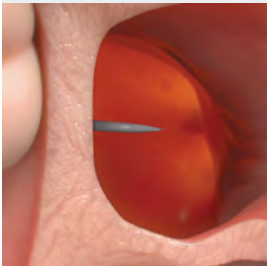
### POST-PROCEDURE THERAPY

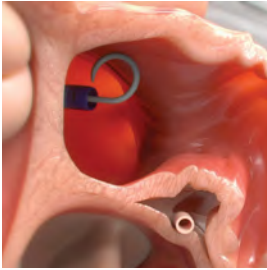


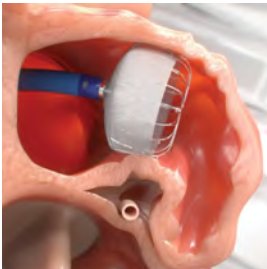
\*At TEE, if leak >5mm, patients remain on OAC + ASA until seal is documented (leak < 5mm), skipping the P2Y12 inhibitor + ASA pharmacotherapy  
\*\*Any P2Y12 Inhibitor and Aspirin

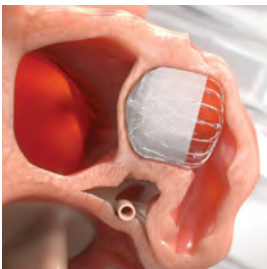
## THE WATCHMAN™ PROCEDURE


- 

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). 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.
- 

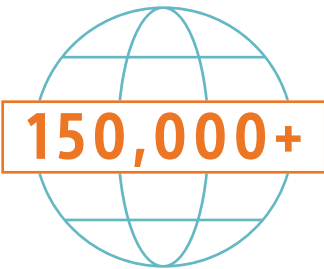
WATCHMAN is deployed and released in LAA.
- 

Heart tissue grows over implant and LAA is permanently sealed; patients remain on OAC for at least 45 days post-procedure.
- 

Fully endothelialized device.

>96%  
OF PATIENTS  
DISCONTINUED  
OACS AT 45 DAYS²

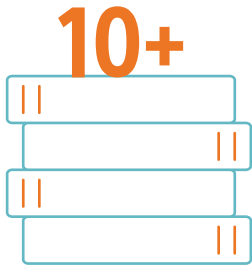
# WATCHMAN™ IS PROVEN.



PATIENTS IMPLANTED



CLINICAL AND  
REAL-WORLD EXPERIENCE



CLINICAL STUDIES

“  
There’s a lot of evidence now that shows the long-term outcome of WATCHMAN is very positive... the farther out we go the better the data looks because you get the procedure out of the way and you’re off anticoagulation so those complications go away.  
SAUMIL OZA, MD, ELECTROPHYSIOLOGIST

## CLINICAL LEADERSHIP IN LAAC

2002

PILOT

ENDPOINTS:  
Feasibility and Safety  
COMPARISON:  
Non-randomized  
n=66,  
mean CHADS<sub>2</sub>=1.8,  
mean age=68.5

2005

PROTECT AF

ENDPOINTS:  
Safety and Efficacy  
COMPARISON:  
Warfarin  
n=707, mean  
CHA<sub>2</sub>DS<sub>2</sub>-VASC=3.4,  
mean age=72

2008

CAP REGISTRY

ENDPOINTS:  
Collect additional  
safety and efficacy  
data to be pooled  
with PROTECT AF  
n=566, mean  
CHA<sub>2</sub>DS<sub>2</sub>-VASC=3.9,  
mean age=74

2009

ASAP\*

ENDPOINTS:  
Efficacy  
COMPARISON:  
CHADS<sub>2</sub> score and  
expected stroke rate  
n=150, mean  
CHA<sub>2</sub>DS<sub>2</sub>-VASC=4.4,  
mean age=72.5

2010

PREVAIL

ENDPOINTS:  
Safety and Efficacy  
COMPARISON:  
Warfarin  
n=407, mean  
CHA<sub>2</sub>DS<sub>2</sub>-VASC=3.8,  
mean age=74

2012

CAP2  
REGISTRY

ENDPOINTS:  
Collect additional  
safety and efficacy data  
n=579, mean  
CHA<sub>2</sub>DS<sub>2</sub>-VASC=4.5,  
mean age=75  
ESC\*  
Expanded guidelines  
and indication

2013

EWOLUTION,  
WASP

Registries in Europe  
and Asia\*  
ENDPOINTS: Additional  
information in a real-  
world setting

2016

ASAP-TOO

ENDPOINTS: Safety  
and efficacy  
COMPARISON:  
Single Antiplatelet  
or No Therapy  
Ongoing study in  
subjects with NVAF  
deemed not suitable  
for OAC therapy

2018

PINNACLE FLX

ENDPOINTS: Safety  
and Efficacy  
n=451,  
Non-randomized,  
WATCHMAN FLX™  
Device, US IDE

2019

OPTION

COMPARISON: OAC\*  
n=1600, Randomized  
\*Trial design in  
development

2020

CHAMPION AF

ENDPOINTS: Safety and  
Efficacy (WATCHMAN FLX)  
COMPARISON: NOACS  
n=3000  
Studied a broader NVAF  
population, inclusive of  
lower risk patients

NCDR-LAAO

n=38,000  
Registry analysis:  
review of the first 3 years  
of real-world data in  
high-risk patient population;  
confirms low acute adverse  
event rates

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.



# WATCHMAN™ IS SAFE.

## SAFETY PROFILE CONTINUES TO ADVANCE WITH WATCHMAN FLX™

In the PINNACLE FLX IDE Clinical Study, WATCHMAN FLX demonstrated high procedural success and a low major complication rate.<sup>2</sup>

PROCEDURE PERFORMANCE

98.8%

PATIENTS SUCCESSFULLY  
IMPLANTED (395/400)\*<sup>2</sup>

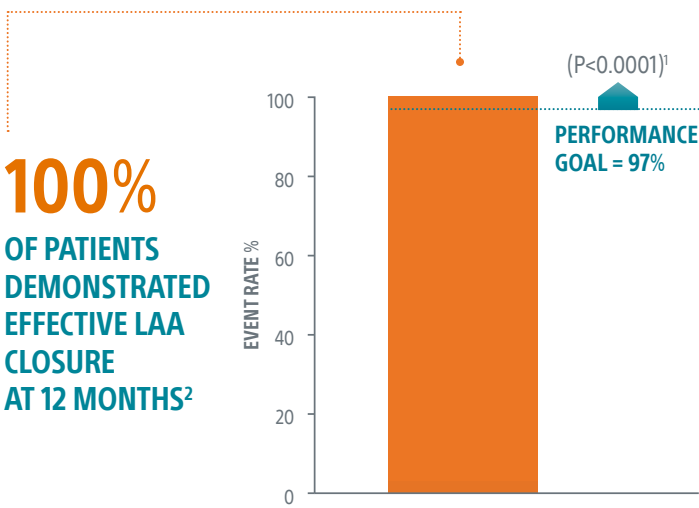


PROVEN SAFETY

0.5%

EVENT RATE<sup>†2</sup>

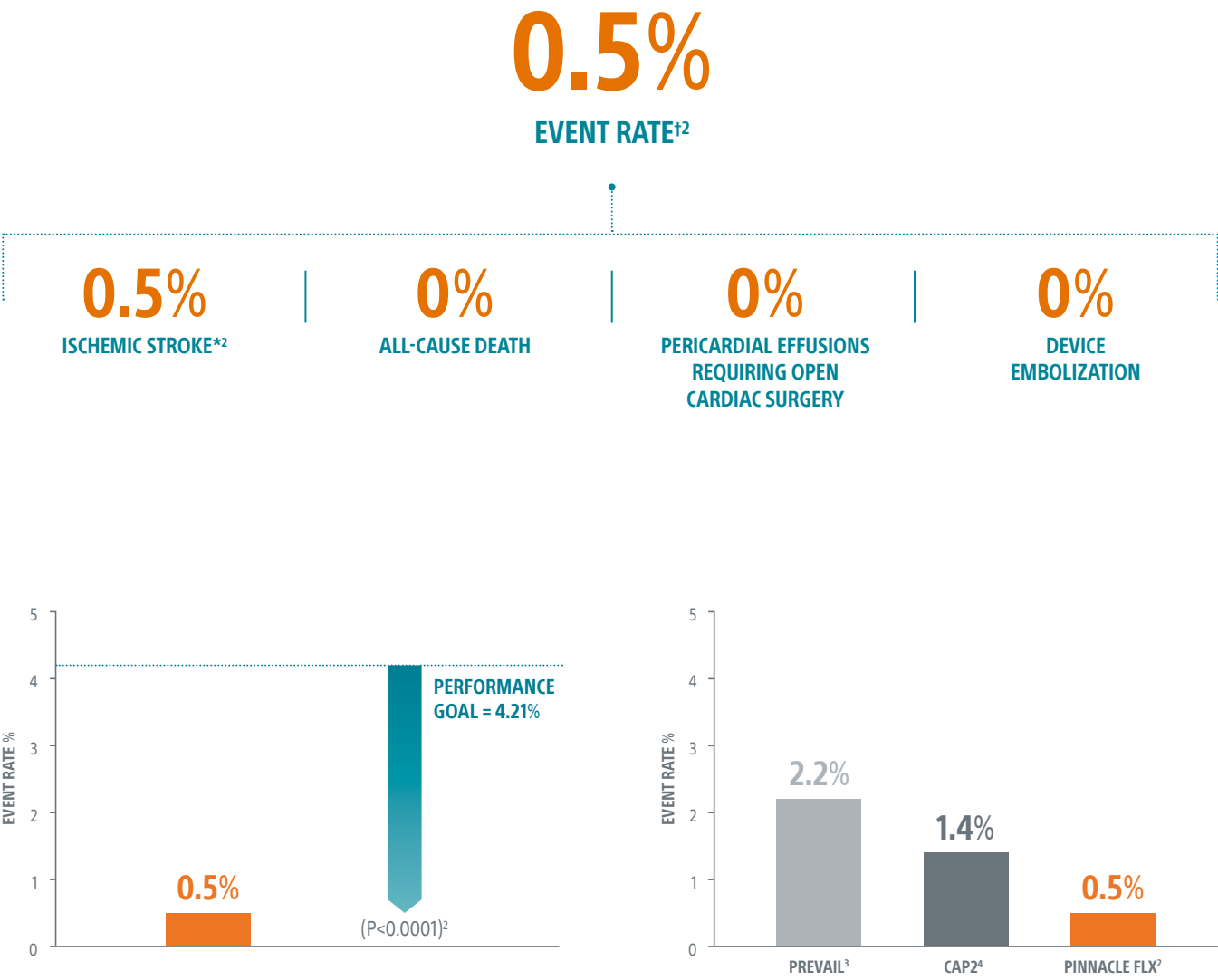
## 100% LAA CLOSURE AT 12 MONTHS



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<sup>3</sup> and CAP2<sup>4</sup>, minus a clinically relevant delta.

## ENHANCED SAFETY PROFILE: A CLOSER LOOK

- The PINNACLE FLX US IDE Clinical Study established procedural safety and closure efficacy<sup>2</sup>
- Safety outcomes were statistically significant vs. similar endpoints met in previous WATCHMAN device trials (PREVAIL Trial, CAP2 Registry)<sup>2</sup>



Based on the combined rate observed in PREVAIL<sup>3</sup> and CAP2<sup>4</sup>, plus a clinically acceptable delta. PREVAIL<sup>3</sup> & CAP2<sup>4</sup> studied the WATCHMAN LAAC Device.

# WATCHMAN™ IS EFFECTIVE.

## LONG-TERM SAFETY AND EFFICACY IN CONTINUED ACCESS LAAC REGISTRIES<sup>5</sup>

- Largest number and longest follow-up of patients implanted with the only FDA-approved LAAC device.

## CAP REGISTRY (5-YEAR RESULTS)

ENDPOINTS: Collect additional safety and efficacy data (n=566)

- Continued access registry to the 2005 PROTECT-AF Randomized Controlled Trial (RCT)
- Inclusion/exclusion criteria identical to PROTECT-AF

## CAP2 REGISTRY (4-YEAR RESULTS)

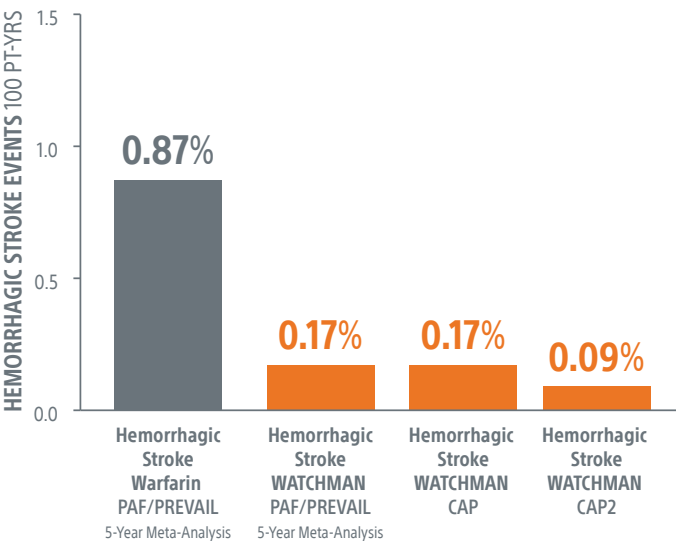
ENDPOINTS: Collect additional safety and efficacy data (n=578)

- Continued access registry to the 2010 PREVAIL RCT
- Inclusion/exclusion criteria identical to PREVAIL

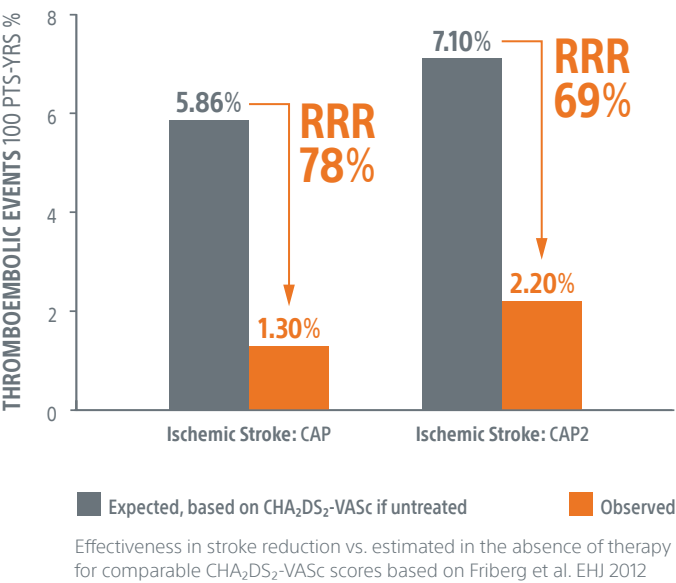
Patients in CAP2 registry (n=578) had a higher risk profile than those in CAP registry (n=566)

IN CLINICAL STUDIES AND REAL-WORLD EXPERIENCE, WATCHMAN DEMONSTRATES SIGNIFICANT REDUCTIONS IN STROKE RISK AND BLEEDING RISK ASSOCIATED WITH LIFELONG OAC THERAPY. <sup>5,6,7</sup>

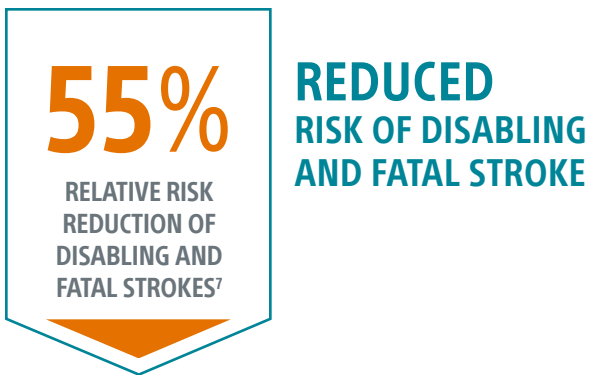
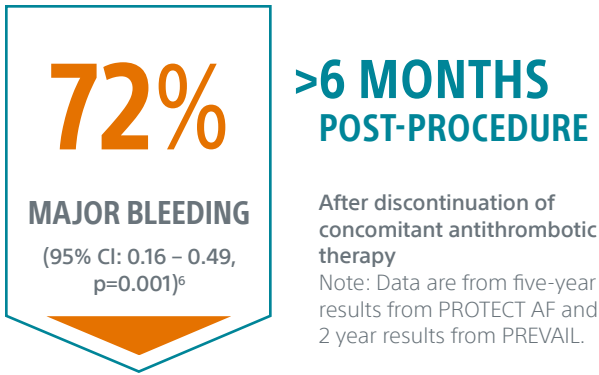
### LOWEST REPORTED RATE OF HEMORRHAGIC STROKE TO DATE<sup>5</sup>



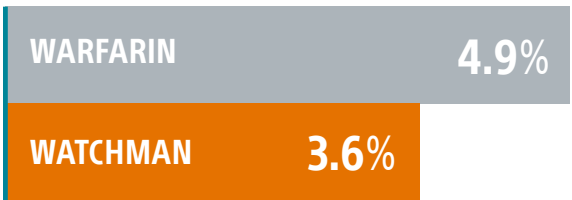
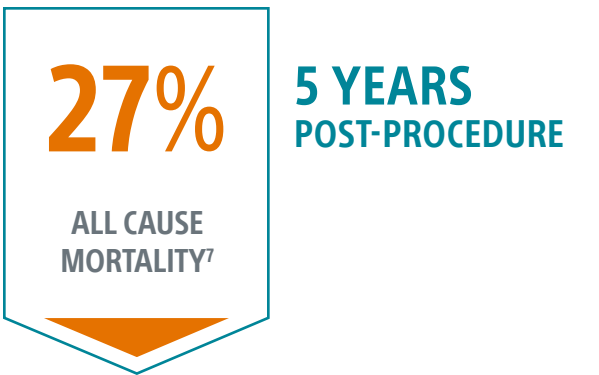
### SIGNIFICANT RELATIVE REDUCTIONS IN ISCHEMIC STROKE, WHEN COMPARED TO EXPECTED RATES<sup>5</sup>



## REDUCED RISK OF MAJOR BLEEDING VS. WARFARIN<sup>6</sup>



## REDUCED MORTALITY VS. WARFARIN



# WATCHMAN™ IS DESIGNED TO PROTECT A BROAD RANGE OF PATIENT TYPES. FOR LIFE.

The WATCHMAN implant may be suitable for a broad range of NVAF patients and may be an appropriate option for your NVAF patients who meet these criteria.

- 1

Have an increased risk for stroke and be recommended for anticoagulation (CHA<sub>2</sub>DS<sub>2</sub>-VASc ≥ 2 for men, ≥ 3 for women)\*
- 2

Be suitable for short-term oral anticoagulation
- 3

Have an appropriate reason to seek a non-pharmacologic alternative to OACs

\*CHA<sub>2</sub>DS<sub>2</sub>-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.

The three leading cardiology and cardiovascular societies in the U.S. recognize 12 appropriate contraindications to anticoagulation.<sup>8</sup>



PREVIOUS BLEED RISK



FUTURE BLEED RISK



LIFESTYLE RISK



NON-COMPLIANT



DRUG INTERACTION

“I generally categorize three groups of patients. One is my G.I. bleeders. The other is my older patients that fall. The third category of patients... they’re more at risk for actually having bleeding issues based upon their professions or what they like doing.”  
RAGU MURTHY, MD, CARDIOLOGIST



## SCREENING, EDUCATION AND SUPPORT.

From identifying patients to helping them along the WATCHMAN journey, these tools and resources streamline the process, saving you time and effort.

### PATIENT SCREENING & REFERRAL TOOL

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 WATCHMAN.

### PATIENT EDUCATION

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

### PATIENT AMBASSADOR PROGRAM

Volunteers living with WATCHMAN share their experiences with prospective patients and answer their questions.

TALK TO YOUR BOSTON SCIENTIFIC REPRESENTATIVE OR VISIT [WATCHMAN.COM/HCP](http://WATCHMAN.COM/HCP) FOR MORE RESOURCES.



# WATCHMAN™ IS AN AFFORDABLE OPTION.

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

CMS Will Cover LAAC When the Following Criteria are Met:

- 1

**Increased Risk for Stroke**  
CHADS<sub>2</sub> score ≥ 2 or a CHA<sub>2</sub>DS<sub>2</sub>-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**  
Non-interventional physician using an OAC evidence-based decision tool\*

\*Documented in medical record



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.

VAQAR ALI, MD, INTERVENTIONAL CARDIOLOGIST

## ESTIMATED MEDICARE PATIENT OUT-OF-POCKET (OOP) COSTS FOR WATCHMAN IMPLANT<sup>9</sup>

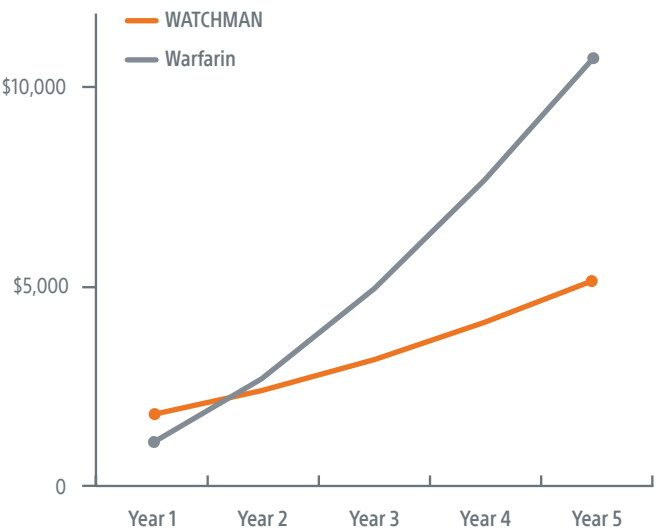
A TYPICAL MEDICARE PATIENT IN 2021 IS ESTIMATED TO PAY NO MORE THAN

\$2,200

INCLUDES PRE-SCREEN TEE\*, IMPLANT, PROFESSIONAL PHYSICIAN FEES, AND POST-WATCHMAN OAC THERAPY

\*The pre-screen TEE will not be covered within a 72-hour window of implant due to the global period

### ANNUAL CUMULATIVE PATIENT OOP COSTS<sup>9</sup>



WATCHMAN HAD LOWER PATIENT OUT-OF-POCKET COSTS THAN WARFARIN BY YEAR 2

Note: This budget impact analysis modeled Medicare patient OOP expenses for three stroke prevention strategies: warfarin, dabigatran 150mg twice daily and LAAC with WATCHMAN, based on the PROTECT AF 4-year data and the RE-LY 2-year data. All costs were based on 2015 Medicare patient costs and are subject to change annually.

|   | WARFARIN | DABIGATRAN |
|---|----------|------------|
| Average cumulative OOP over 5 years     | \$10,827 | \$9,296    |
| Average OOP cost per year over 5 years  | \$2,165  | \$1,859    |
| Average OOP cost per month over 5 years | \$180    | \$155      |

Note: Estimated costs are based on national averages of 2020 U.S. Medicare rates, and assume a 20% copay for Medicare Part B. These estimates will vary depending upon the patient's individual healthcare policy. Insurance coverage can vary significantly from one plan to another, even within the same insurance company. We therefore recommend that patients contact their insurance provider directly with questions regarding estimated patient-specific out-of-pocket costs.



# SAFETY

*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 CHADS<sub>2</sub> or CHA<sub>2</sub>DS<sub>2</sub>-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- 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 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 45 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 P2Y<sub>12</sub> inhibitor.

## WARNINGS

Implantation of the WATCHMAN FLX Device should only be performed by interventional cardiologists and/or electrophysiologists who are trained in percutaneous and transseptal procedures 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 echocardiographic imaging guidance in multiple views (TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]) to avoid improper Closure Device sizing.

- 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 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, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, 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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## REFERENCES

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\* 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.

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

‡ LAA closure at 12 months is defined as any per-device flow with jet flow < 5mm per core laboratory-assessed TEE.

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