Boston Scientific
Advancing science for life™

THINK OUTSIDE THE PILLBOX

WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

An innovative one-time procedure that reduces the risk of stroke in your non-valvular atrial fibrillation (NVAF) patients *and* the long-term risk of bleeding that comes with a lifetime of warfarin use.[1,2]

References can be found inside the back fold.

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

"When I was able to tell my patient that she could stop taking the blood thinner and she was still protected from stroke, she was ecstatic—it was a truly moving moment."

—Dr. Jonathan Hsu
ELECTROPHYSIOLOGIST, UNIVERSITY OF CALIFORNIA, SAN DIEGO

WHICH OF YOUR NVAF PATIENTS ARE RIGHT FOR WATCHMAN?
Read more on pages 8–9

A SAFE AND EFFECTIVE ALTERNATIVE TO OACs FOR YOUR NVAF PATIENTS

In patients with non-valvular atrial fibrillation (NVAF), more than 90% of stroke-causing clots that come from the left atrium form in the left atrial appendage (LAA).[3]

WATCHMAN closes off the LAA, preventing blood clots from migrating out of it. The procedure is performed under general anesthesia in a catheterization laboratory using a standard percutaneous technique.

This minimally invasive procedure usually lasts about an hour and patients typically stay in the hospital for a day. Following the procedure, patients typically take warfarin and aspirin for 45 days or until there is adequate seal. After discontinuing warfarin, patients take clopidogrel and an increased dose of aspirin, followed by ongoing aspirin therapy.

There are risks associated with the implantation and use of WATCHMAN. Please see inside back cover for a summary of the safety information and visit watchman.com/hcp to download the full Directions for Use.

95% IN A RANDOMIZED CONTROLLED TRIAL, WATCHMAN WAS SUCCESSFULLY IMPLANTED IN 95% OF PATIENTS (252/265)[4]*

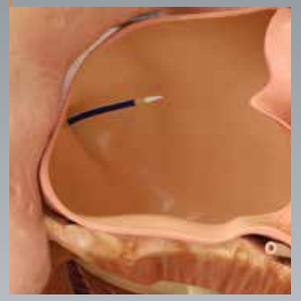
THE IMPLANT PROCEDURE

1

Using a standard percutaneous technique, a guidewire and vessel dilator are inserted into the femoral vein.

2

The implant procedure is performed with fluoroscopy and transesophageal echocardiography (TEE). The interatrial septum is crossed using a standard transseptal access system.

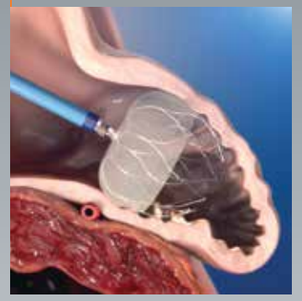


3

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.

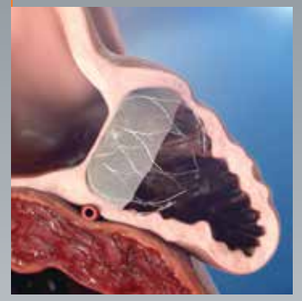
4

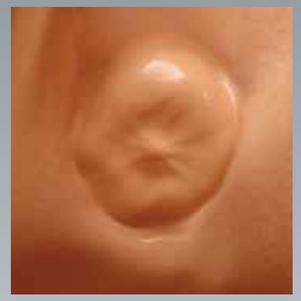
WATCHMAN is then deployed and released in the LAA.



5

Heart tissue grows over the WATCHMAN Implant and the LAA is permanently sealed. Patients remain on warfarin for at least 45 days post-procedure.





*Reasons for aborted implantation attempts: the patient did not stop anticoagulation before the procedure; pre-implant transesophageal echocardiography (TEE) revealed a new LAA thrombus; LAA size and shape were not optimal for the device; and the occurrence of an adverse event forced the procedure to stop.[4]

POST IMPLANT DRUG REGIMEN

Following the procedure, patients typically take warfarin and aspirin for 45 days or until there is adequate seal. After discontinuing warfarin, patients take clopidogrel and an increased dose of aspirin, followed by ongoing aspirin therapy.

POST-PROCEDURE THERAPY

IMPLANT	Warfarin + Aspirin (81–100 mg) daily	45 DAYS* TEE	Clopidogrel (75 mg) + Aspirin (300–325 mg) daily	6 MONTHS TEE	Aspirin (300–325 mg) daily

DESTINATION THERAPY

*If adequate seal is not demonstrated (leak > 5 mm) at 45-day follow-up, assess seal with TEE at 6 months.

WATCHMAN IS THE MOST STUDIED LAAC DEVICE

Globally, WATCHMAN has been implanted in more than 70,000 patients and studied in more than 10 clinical studies. WATCHMAN is a safe and effective alternative to warfarin for stroke risk reduction and enables patients to discontinue OAC therapy.

A PROVEN ALTERNATIVE:

- >10 CLINICAL STUDIES
- FDA APPROVED
- CMS NATIONAL COVERAGE
- >20 YEARS OF CLINICAL PATIENT FOLLOW-UP
- INCLUDED IN AF MANAGEMENT GUIDELINES

HISTORY OF CLINICAL LEADERSHIP:

2002 PILOT

ENDPOINTS: Feasibility and Safety

COMPARISON: Non-randomized

n = 66, mean $CHADS_2$ = 1.8, mean age = 68.5

2005 PROTECT AF

ENDPOINTS: Safety and Efficacy

COMPARISON: Warfarin

n = 707, mean CHA_2DS_2-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_2DS_2-VASc = 3.9, mean age = 74

2009 ASAP*

ENDPOINTS: Efficacy

COMPARISON: $CHADS_2$ score and expected stroke rate

n = 150, mean CHA_2DS_2-VASc = 4.4, mean age = 72.5

2010 PREVAIL

ENDPOINTS: Safety and Efficacy

COMPARISON: Warfarin

n = 407, mean CHA_2DS_2-VASc = 3.8, mean age = 74

2012 CAP2 REGISTRY

ENDPOINTS: Collect additional safety and efficacy data

n = 579, mean CHA_2DS_2-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, FLX Device, US IDE

2019 OPTION

COMPARISON: OAC*

n = TBD, Randomized

*Trial design in development

*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.

THE WATCHMAN DIFFERENCE

Five-year results have confirmed that WATCHMAN is safe, effective, and enables patients to discontinue OAC medications.

WATCHMAN IS EFFECTIVE:

Long-term results demonstrated WATCHMAN reduced risk of disabling stroke, post-procedure bleeding, and mortality vs. warfarin.[1]

PROTECT AF AND PREVAIL META-ANALYSIS (5 YEAR)

55%

REDUCTION IN
DISABLING AND FATAL STROKES[1]

72%

REDUCTION IN
MAJOR BLEEDING
6 MONTHS POST IMPLANT[2]

PREVAIL findings (3 Years vs. 5)

27%

REDUCTION IN
ALL CAUSE MORTALITY[1]

WATCHMAN DEMONSTRATES LOW COMPLICATION RATE IN REAL-WORLD SETTING:

The WATCHMAN procedure has proven safety, with only a 1.5% major complication rate in the highest-risk patients studied to date.[5]

U.S. COMMERCIAL IMPLANT SUCCESS RATE

95%

Procedural Success*[4]

*Procedural Success defined as deployment and release of the device into the LAA with no leak greater than or equal to 5mm

WATCHMAN U.S. NESTED POST APPROVAL STUDY

1.5%

Major Complication Rate[5]

WATCHMAN ENABLES PATIENTS TO DISCONTINUE LONG-TERM OAC:

9 out of 10 patients discontinue OACs 45 days after receiving the WATCHMAN implant.

PROTECT AF, CAP AND PREVAIL CLINICAL TRIALS

92%

OF PATIENTS WERE ABLE TO DISCONTINUE WARFARIN **AFTER 45 DAYS**[4]

99%

OF PATIENTS WERE ABLE TO DISCONTINUE WARFARIN **AFTER 1 YEAR**[4]

CONSIDER WATCHMAN FOR YOUR PATIENTS THAT NEED AN ALTERNATIVE

The WATCHMAN Implant may be an appropriate option for your non-valvular atrial fibrillation patients who meet these criteria. Patients must:

1. Have an increased risk for stroke and be recommended for anticoagulation (CHA_2DS_2-VASc ≥ 2)*
2. Be suitable for warfarin
3. Have an appropriate reason to seek a non-pharmacologic alternative to warfarin

*__C__=congestive heart failure; __H__=hypertension; __A_2__=Age≥75 years; __D__=diabetes mellitus; __S_2__=prior stroke or transient ischemic attack or thromboembolism; __V__=vascular disease; __A__=Age 65–74 years; __Sc__=sex category

Payer coverage policies may not be consistent with BSC device labeling.

A BROAD RANGE OF PATIENTS MAY HAVE A REASON TO SEEK AN ALTERNATIVE TO BLOOD THINNERS.

SOME EXAMPLES INCLUDE:

BLEEDER
History of major and/or non-major bleeding.

FUTURE BLEEDER
No prior bleeds but high-risk HAS-BLED > CHA_2DS_2-VASc; includes fall risk.

NON-COMPLIANT
Struggles with maintaining a therapeutic INR, skips doses or discontinues OAC medication.

LIFESTYLE & OCCUPATION
Lifestyle or profession for which anticoagulation is inappropriate.

DRUG INTERACTIONS
Not suitable for long-term warfarin use due to other medical treatment needs.

Which of your NVAF patients are right for WATCHMAN?

"If I think back at some of my most grateful patients, it's those patients that had a positive impact on their quality of life after the WATCHMAN by being able to come off their anticoagulation."

—**Dr. Jamie Kim**
ELECTROPHYSIOLOGIST, CATHOLIC MEDICAL CENTER

WATCHMAN IS COVERED NATIONALLY BY CMS AND A GROWING NUMBER OF COMMERCIAL INSURERS

WATCHMAN is covered for a broad range of patients who want to avoid the long-term risk of bleeding with OACs, including those with an active lifestyle, a physical occupation, trouble maintaining a stable INR, or problems with treatment compliance.

AVERAGE TOTAL OUT-OF-POCKET COSTS AT YEAR 5[6]

53% LESS THAN WARFARIN

CMS-SPECIFIC PATIENT CRITERIA FOR LAAC ELIGIBILITY:

1 INCREASED RISK FOR STROKE
$CHADS_2$ SCORE ≥ 2 OR
A CHA_2DS_2-VASC SCORE ≥ 3

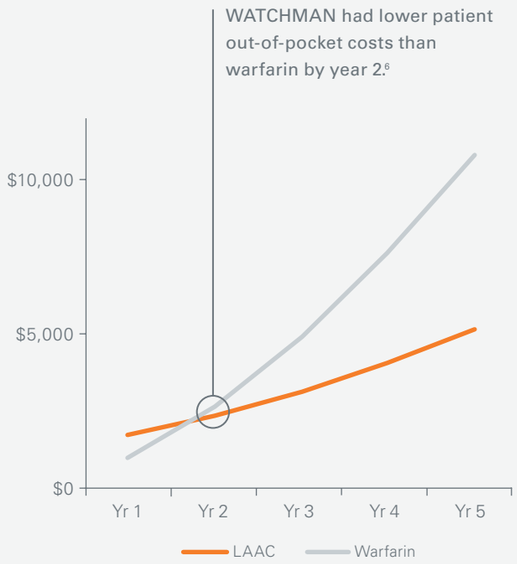
2 SUITABLE FOR SHORT-TERM WARFARIN
BUT DEEMED UNABLE TO TAKE LONG-TERM ORAL ANTICOAGULATION

3 FORMAL SHARED DECISION MAKING INTERACTION
DOCUMENTED EVIDENCE OF A FORMAL INTERACTION BETWEEN THE PATIENT AND AN INDEPENDENT NON-INTERVENTIONAL PHYSICIAN USING AN OAC EVIDENCE-BASED DECISION TOOL

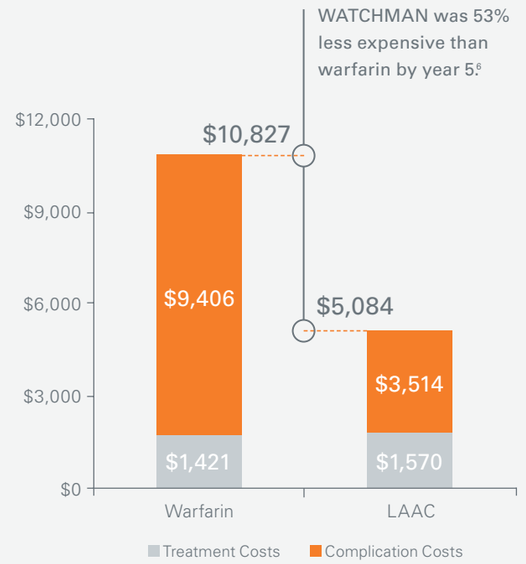
WATCHMAN IS APPROXIMATELY HALF THE COST OF WARFARIN FOR PATIENTS:

A budget impact analysis of Medicare beneficiaries revealed the total out-of-pocket spending for WATCHMAN is lower than warfarin by year 2 and half the cost by year 5.

ANNUAL CUMULATIVE PATIENT OUT-OF-POCKET COSTS[6]



AVERAGE TOTAL OUT-OF-POCKET COSTS AT YEAR 5[6]



Note Estimated costs are based on national averages of 2019 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.

WHICH OF YOUR NVAF PATIENTS ARE RIGHT FOR WATCHMAN?

FRANK, 80
HIGH RISK FOR BLEEDING

Occupation: Active, involved grandfather

Medical conditions: NVAF, congestive heart failure, hypertension, diabetes

CHA_2DS_2-VASc score: 5

Frank is suitable for warfarin, but he is currently taking 15 mg of rivaroxaban daily. He has a history of falls, resulting in a broken hip and cerebral contusion. His physician believes his medical conditions place him at a high risk of major bleeding secondary to trauma.

What approach do you take with your NVAF patients at high risk for bleeding?

CATHERINE, 72
STRUGGLES WITH COMPLIANCE

Occupation: Retired, volunteer

Medical conditions: NVAF, hypertension, vascular disease

CHA_2DS_2-VASc score: 4

Catherine takes 5 mg of warfarin but is unable to comply with regular INR monitoring because she lives far from the clinic and cannot afford direct oral anticoagulants (DOACs).

What approach do you take with your NVAF patients who struggle with compliance?

ABIGAIL, 65
LEADS AN ACTIVE LIFE

Occupation: Retired, frequent flyer

Medical conditions: NVAF, hypertension, diabetes

CHA_2DS_2-VASc score: 4

Abigail is currently taking 5 mg of warfarin, but her physician feels that her active lifestyle and frequent travel place her at high risk of bleeding should trauma occur.

What approach do you take with your NVAF patients with active lives?

Case description for educational purposes; not a real patient case.

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"The moment I realized I no longer depended on blood thinners, I had peace of mind."

—WATCHMAN patient

REFERENCES

1. Reddy VY, et al. *JACC* 2017; 70(24): 2964–2975.
2. Price, MJ, et al. *JACC: CV Interv* 2015; 8(15): 1925–1932.
3. Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg.* 1996;61:755–759.
4. Holmes DR Jr, Kar S, Price MJ, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. *J Am Coll Cardiol.* 2014;64(1):1–12.
5. Varosy P et al. *JACC* 2018; 71(11): A320.
6. Armstrong S, Amorosi SL, Patel P, Erickson GC, Stein K. Medicare Beneficiary Out-of-pocket Spending for Stroke Prevention in Non-valvular Atrial Fibrillation: A Budget Analysis. *ISPOR* 2015.

SAFETY

Indications for use
The WATCHMAN 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 $CHADS_2$ or CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy; • Are deemed by their physicians to be suitable for warfarin; and • Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin. The WATCHMAN Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.

Contraindications
Do not use the WATCHMAN Device if: • Intracardiac thrombus is visualized by echocardiographic imaging. • 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 device. **See Table 46** in the DFU. • Any of the customary contraindications for other percutaneous catheterization procedures (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 warfarin, aspirin, or clopidogrel. • The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN Device is contraindicated.

Warnings
• Device selection should be based on accurate LAA measurements obtained using fluoro and ultrasound guidance (TEE recommended) in multiple angles (e.g., 0°, 45°, 90°, 135°). • Do not release the WATCHMAN Device from the core wire if the device does not meet all release criteria. • If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE. • The potential for device embolization exists with cardioversion <30 days following device implantation. Verify device position post-cardioversion during this period. • Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion. • For single use only. Do not reuse, reprocess, or resterilize.

Precautions
• The safety and effectiveness (and benefit-risk profile) of the WATCHMAN 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 the device. • Use caution when introducing the 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 device, do not allow the WATCHMAN 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. • In view of the concerns that were raised by the RE-ALIGN[1] study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.

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 contrast media/ medications or device materials, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, AV fistula, Bruising, hematoma or seroma, Cardiac perforation, Chest pain/ discomfort, Confusion post procedure, Congestive heart failure, Contrast related nephropathy, Cranial bleed, Decreased hemoglobin, Deep vein thrombosis, Death, Device embolism, Device fracture, Device thrombosis, Edema, Excessive bleeding, Fever, 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, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic, Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasovagal reactions.

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

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.*

1 Eikelboom JW, Connolly SJ, Brueckmann M, et al. *N Engl J Med* 2013;369:1206-14.

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

A SAFE AND EFFECTIVE ALTERNATIVE TO OACs FOR YOUR NVAF PATIENTS

1. WATCHMAN has clinically proven long-term outcomes
2. WATCHMAN procedure has proven safety
3. WATCHMAN is suitable for a broad range of patients seeking an alternative
4. WATCHMAN is an affordable choice

There are risks associated with the implantation and use of WATCHMAN. Please see inside back cover for a summary of the safety information and visit watchman.com/hcp to download the full Directions for Use.

HAVE A WATCHMAN PATIENT IN MIND?

Refer your patient to one of the more than 550 medical centers across the United States that are now implanting WATCHMAN.

Find a center near you at:
WATCHMAN.COM/HCP

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