THINK OUTSIDE THE PILLBOX

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.
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.

WHICH OF YOUR NVAF PATIENTS ARE RIGHT FOR WATCHMAN?

Read more on pages 8–9

“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

A SAFE AND EFFECTIVE ALTERNATIVE TO OACs FOR YOUR NVAF PATIENTS

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.
HOW IT WORKS

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.

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

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

DESTINATION THERAPY

*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.

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

*In a randomized controlled trial, Watchman was successfully implanted in 95% of patients (252/265).
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.

HISTORY OF CLINICAL LEADERSHIP:

2005 PROTECT AF
ENDPOINTS: Safety and Efficacy
COMPARISON: Warfarin
n = 337, mean CHA2DS2-VASc = 3.4, mean age = 73

2008 CAP REGISTRY
ENDPOINTS: Collect additional safety and efficacy data
COMPARISON: PROTECT AF
n = 566, mean CHA2DS2-VASc = 3.8, mean age = 74

2009 ASAP*
ENDPOINTS: Efficacy
COMPARISON: CHA2DS2 score and expected stroke rate
n = 100, mean CHA2DS2-VASc = 4.4, mean age = 72.5

2010 PREVAIL
ENDPOINTS: Safety and Efficacy
COMPARISON: Warfarin
n = 407, mean CHA2DS2-VASc = 3.8, mean age = 74

2012 CAP2 REGISTRY
ENDPOINTS: Collect additional safety and efficacy data
COMPARISON: Warfarin
n = 566, mean CHA2DS2-VASc = 4.5, mean age = 74

2013 EVOOLUTION, WASP
ENDPOINTS: Registries in Europe and Asia*
COMPARISON: Additional information in a real-world setting

2018 PINNACLE FLX
ENDPOINTS: Safety and Efficacy
COMPARISON: Single Antiplatelet or No Therapy
Ongoing registry in patients with NVAF deemed not suitable for OAC therapy

2019 OPTION
COMPARISON: OAC*
Edition TBD, Randomized
Protocol in development

REFERENCES:
- ESC expanded guidelines and indication
- Real World Registries in Europe and Asia

* 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

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.²

WATCHMAN ENABLES PATIENTS TO DISCONTINUE LONG-TERM OAC:
9 out of 10 patients discontinue OACs 45 days after receiving the WATCHMAN implant.

PROVEN RESULTS

55% REDUCTION IN DISABLING AND FATAL STROKES³

72% REDUCTION IN MAJOR BLEEDING 6 MONTHS POST IMPLANT²

27% REDUCTION IN ALL CAUSE MORTALITY¹

95% U.S. COMMERCIAL IMPLANT SUCCESS RATE

1.5% WATCHMAN U.S. NESTED POST APPROVAL STUDY

92% PROTECT AF, CAP AND PREVAIL CLINICAL TRIALS

99% OF PATIENTS WERE ABLE TO DISCONTINUE WARFARIN AFTER 45 DAYS⁴

99% OF PATIENTS WERE ABLE TO DISCONTINUE WARFARIN AFTER 1 YEAR⁴

¹Procedural Success defined as deployment and release of the device into the LAA with no leak greater than or equal to 5mm

²Procedural Success defined as deployment and release of the device into the LAA with no leak greater than or equal to 5mm

³PREVAIL findings (3 Years vs. 5)

⁴PREVAIL findings (5 Years vs. 5)

99% REDUCTION IN DISABLING AND FATAL STROKES¹

64% REDUCTION IN MAJOR BLEEDING 6 MONTHS POST IMPLANT²

27% REDUCTION IN ALL CAUSE MORTALITY¹

95% U.S. COMMERCIAL IMPLANT SUCCESS RATE

1.5% WATCHMAN U.S. NESTED POST APPROVAL STUDY

92% PROTECT AF, CAP AND PREVAIL CLINICAL TRIALS

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²Procedural Success defined as deployment and release of the device into the LAA with no leak greater than or equal to 5mm

³PREVAIL findings (3 Years vs. 5)

⁴PREVAIL findings (5 Years vs. 5)
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 (CHA2DS2-VASc ≥ 2)*
2. Be suitable for warfarin
3. Have an appropriate reason to seek a non-pharmacologic alternative to warfarin

PATIENT ELIGIBILITY

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 > CHA2DS2-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.

*CH = congestive heart failure; H = hypertension; A17 = Age ≥ 75 years; D = diabetes mellitus; S = 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.

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
CMS-SPECIFIC PATIENT CRITERIA FOR LAAC ELIGIBILITY:

1. INCREASED RISK FOR STROKE
   CHADS2 SCORE ≥ 2 OR A CHA2DS2-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 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
53% LESS THAN WARFARIN

ANNUAL CUMULATIVE PATIENT OUT-OF-POCKET COSTS

- WATCHMAN had lower patient out-of-pocket costs than warfarin by year 2.
- WATCHMAN was 53% less expensive than warfarin by year 5.

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.

NATIONAL COVERAGE

INCREASED RISK FOR STROKE
CHADS2 SCORE ≥ 2 OR A CHA2DS2-VASC SCORE ≥ 3

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

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.

AVERAGE TOTAL OUT-OF-POCKET COSTS AT YEAR 5

- WATCHMAN had lower patient out-of-pocket costs than warfarin by year 2.
- WATCHMAN was 53% less expensive than warfarin by year 5.

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  
CHA₂DS₂-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  
CHA₂DS₂-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  
CHA₂DS₂-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.

“The moment I realized I no longer depended on blood thinners, I had peace of mind.”  
—WATCHMAN patient
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$_2$S$_{hs}$ or CHA$_2$DS$_2$-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 therapy; • Are deemed by their physicians to be suitable for warfarin; and
- Are deemed by their physicians to be suitable for warfarin.

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 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 fluoroscopy 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 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 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 release 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 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 or device materials, 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, recurrence, or retrieval of the device, Infection / pneumonia, Interatrial septum thrombosis, Intracranial bleeding, Major bleeding requiring transfusion, Misplacement of the device / improper seal of the device / movement of device from appendage wall, Myocardia anssion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoneuropathy, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic, Stroke – Hemorrhagic, Systemic embolism, TEE related complications (thromboembolism, 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.
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

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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