WATCHMAN™

Clinical Data
WHY WATCHMAN

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

A Necessary Alternative
Oral anticoagulants are not suitable for all patients due to the range of challenges associated with their use.

Suitable for a Broad Range of Patients
WATCHMAN is suitable for a broad range of patients looking for an alternative to blood thinners.

Clinically Proven Results
Long-term results demonstrated WATCHMAN reduced the risk of disabling stroke, bleeding post procedure, and mortality versus warfarin.¹, ², ³

An Affordable Alternative
WATCHMAN is less expensive by year two and half the cost by year five.⁶

Established Safety
WATCHMAN has a high 95% procedural success rate⁴* with a 1.5% major complication rate.⁵

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.

*Procedural success defined as deployment and release of the device into the left atrial appendage (LAA) with no leak greater than 5 mm.

“There are so many patients out there that can benefit from WATCHMAN. When you know that, you can’t give up.”

— Dr. Brad Mikaelian
Electrophysiologist
Memorial Hospital Center
University of Colorado Health
NEED FOR A SAFE ALTERNATIVE

The incidence of AF is growing. So is the need for an alternative to OACs.

<table>
<thead>
<tr>
<th>CHA2DS2-VAS2 Score in Men</th>
<th>CHA2DS2-VAS2 Score in Women</th>
<th>Guidelines Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>No anticoagulant</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>Aspirin (81-325 mg daily) or oral anticoagulants may be considered</td>
</tr>
<tr>
<td>≥ 2</td>
<td>≥ 3</td>
<td>Oral anticoagulants are recommended**</td>
</tr>
</tbody>
</table>

In the prevention of stroke for AF patients, it is important to balance stroke risk reduction vs. the bleeding risk that comes with long term oral anticoagulant therapy.

EXAMPLES OF RISK FACTORS

OACs are a popular therapy, but come with challenges:

**WARFARIN**
- Bleeding Risk
- Daily Regimen
- High Non-Adherence Rates
- Regular INR Monitoring
- Food and Drug Interaction Issues
- Complicates Surgical Procedures

**DOACs**
- Bleeding Risk
- Daily or 2x/Daily Regimen
- High Non-Adherence Rates
- Complicates Surgical Procedures
- High Cost

*LAAN – Left Atrial Appendage, NVAF – Non-Valvular Atrial Fibrillation, AF – Atrial Fibrillation.

**DOACs (dabigatran, rivaroxaban, apixaban, and edoxaban) recommended over warfarin in DOAC-eligible patients.
Bleeding Risk On Anticoagulants Compounds Over Time

The risk of bleeding associated with OACs compounds year over year.

![Bleeding Risk Graph](image)

<table>
<thead>
<tr>
<th>CHA2DS2-VASc Score</th>
<th>Annual % Stroke Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>1.3</td>
</tr>
<tr>
<td>2</td>
<td>2.2</td>
</tr>
<tr>
<td>3</td>
<td>3.2</td>
</tr>
<tr>
<td>4</td>
<td>4.0</td>
</tr>
<tr>
<td>5</td>
<td>6.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HAS-BLED Score</th>
<th>Annual % Bleed Risk</th>
<th>Estimated 10-Year Bleeding Risk (%) **</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.9</td>
<td>8.6</td>
</tr>
<tr>
<td>1</td>
<td>3.4</td>
<td>29.2</td>
</tr>
<tr>
<td>2</td>
<td>4.1</td>
<td>34.2</td>
</tr>
<tr>
<td>3</td>
<td>5.8</td>
<td>45.0</td>
</tr>
<tr>
<td>4</td>
<td>8.9</td>
<td>60.6</td>
</tr>
<tr>
<td>5</td>
<td>9.1</td>
<td>61.5</td>
</tr>
</tbody>
</table>

WITH OACS THE BLEEDING RISK IS REAL

~1/2 of patients with prior systemic thromboembolism/TIA on warfarin had a repeat bleed on a DOAC.

63% of patients who experienced a bleeding event on a DOAC had a repeat bleeding event.

**NOTE: CHA2DS2-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. HAS-BLED score – Hypertension=1, Abnormal renal/liver function (1 pt each)=1 or 2, Hemorrhagic stroke=1, Bleeding history or disposition=1, Labile INRs=1, Elderly=1, Current drugs (medication) or alcohol use (1 pt each)=1 or 2.

**Assumes constant risk despite increasing age, and bleeding risk is independent from bleeding risk in previous years.

*The HAS-BLED scoring system predicts a patients risk of stroke while on warfarin.
Adherence To Anticoagulation Remains A Challenge

About half of patients with AF at high risk for stroke are not treated with OAC therapy. Of those treated, a significant number won’t continue long-term.

40% OF PATIENTS NOT TREATED\(^\text{12}\)

Bleeding Risks Are Comparable Across Oral Anticoagulant Therapies

For those that remain adherent, bleeding risks persist.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Study Drug Discontinuation Rate</th>
<th>Major Bleeding (rate/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rivaroxaban(^\text{14})</td>
<td>24%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Apixaban(^\text{15})</td>
<td>25%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Dabigatran(^\text{16}) (150 mg)</td>
<td>21%</td>
<td>3.1%</td>
</tr>
<tr>
<td>Edoxaban(^\text{17}) (60 mg / 30 mg)</td>
<td>34% / 33%</td>
<td>2.8% / 1.6%</td>
</tr>
<tr>
<td>Warfarin(^\text{14-17})</td>
<td>17-35%</td>
<td>3.1-3.4%</td>
</tr>
</tbody>
</table>

\textbf{NOTE:} Predicted probability of adherence; reported adherence rates adjusted for confounders. Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.
FOR YOUR NVAF PATIENTS TAKING OACS: IT’S TIME TO THINK OUTSIDE THE PILLBOX

“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, CA
WATCHMAN PROCEDURE

WATCHMAN LAAC
A one-time procedure designed to reduce the risk of strokes that originate in the LAA.

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

WATCHMAN IS AVAILABLE IN

5 SIZES

MINIMALLY INVASIVE
PERMANENT IMPLANT
TYPICAL PROCEDURE IS LESS THAN 1 HOUR
24-HOUR AVERAGE HOSPITAL STAY

21 mm 24 mm 27 mm 30 mm 33 mm
**WATCHMAN Post-Procedure Information**

**1 DAY PRIOR TO IMPLANT**  
Begin aspirin (81-100 mg)

**IMPLANT**  
Continue aspirin (81-100 mg) and add warfarin, adjusted to achieve INR of 2.0-3.0 until 45-day visit

**45 DAYS POST-IMPLANT**  
Is LAA seal ≤ 5mm?

- **YES**  
  Continue aspirin (81-100 mg) and warfarin, adjusted to achieve INR of 2.0-3.0
  
- **NO**  
  REASSESS SEAL*  
  Is LAA seal ≤ 5mm?

**CEASE WARFARIN and continue aspirin (300-325 mg). Add Clopidogrel (75 mg)**

**6-MONTH POST-IMPLANT**  
Cease Clopidogrel (75 mg) and maintain aspirin (300-325 mg) indefinitely

**FOLLOW-UP DURATION**  
Has the patient been followed for at least 6 months post-implant with adequate seal?

- **YES**  
  FOLLOW-UP DURATION  
  Cease warfarin and increase aspirin (300-325 mg)

- **NO**  
  REASSESS SEAL*  
  Is LAA seal ≤ 5mm?

*The performance and timing of TEE to re-evaluate the LAA seal is left to physician discretion.

---

**WATCHMAN Enables Patients To Discontinue Long-Term OAC**

9 out of 10 patients discontinue OAC’s 45 days after receiving the WATCHMAN implant.

- **92%**  
  of patients were able to discontinue warfarin after 45 days

- **99%**  
  of patients were able to discontinue warfarin after 1 year

**Warfarin Cessation with WATCHMAN**

<table>
<thead>
<tr>
<th>Study</th>
<th>45-Day</th>
<th>12-Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROTECT AF</td>
<td>87%</td>
<td>&gt;93%</td>
</tr>
<tr>
<td>CAP</td>
<td>96%</td>
<td>&gt;96%</td>
</tr>
<tr>
<td>PREVAIL</td>
<td>92%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>CAP219</td>
<td>93%</td>
<td>&gt;96%</td>
</tr>
</tbody>
</table>

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**POST-IMPLANT**  
WATCHMAN therapy includes short-term adjunctive post-implant pharmacologic regimen.

**POST-PROCEDURE THERAPY**

- **IMPLANT**  
  warfarin + aspirin (81-100 mg) daily

- **45 DAYS**  
  clopidogrel (75 mg) + aspirin (300–325 mg) daily

**DESTINATION THERAPY**

- **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.
The only LAAC device proven with long-term data from randomized trials and multicenter registries

The U.S. Food and Drug Administration (FDA) approval of the WATCHMAN Implant is based on a robust body of evidence including long-term randomized data and perspective from numerous clinical studies and multicenter registries involving more than 6,000 patients and over 11,000 patient years of follow-up. This evidence also supports the approval and licensing of WATCHMAN Implant in over 75 countries.

HISTORY OF CLINICAL LEADERSHIP

**Pilot** 2002
ENDPOINTS: Safety and Efficacy
COMPARISON: Non-randomized
n = 66
mean CHADS₂ = 1.8
mean age = 68.5

**ProTECT AF** 2009
ENDPOINTS: Efficacy
COMPARISON: Warfarin
n = 666
mean CHADS₂-VASc = 3.9
mean age = 74

**ASAP** 2009
ENDPOINTS: Efficacy
COMPARISON: CHADS₂ score and expected stroke rate
n = 150
mean CHADS₂-VASc = 4.4
mean age = 72.5

**PREVAIL** 2010
ENDPOINTS: Safety and Efficacy
COMPARISON: Warfarin
n = 497
mean CHADS₂-VASc = 3.8
mean age = 74

**CAP REGISTRY** 2008
ENDPOINTS: Collect additional safety and efficacy data to be pooled with PROTECT AF
n = 566
mean CHADS₂-VASc = 3.9
mean age = 74

**CAP2 REGISTRY** 2012
ENDPOINTS: Collect additional safety and efficacy data
n = 578
mean CHADS₂-VASc = 4.5
mean age = 75

**EWOLUTION** 2013
ENDPOINTS: Registries in Europe and Asia

**NestEd** 2016
n = 2000
Post-approval statistical means:
CHA₂DS₂-VASc = 5
Age = 76.6

**U.S. FDA APPROVAL** 2015

**ASAP-TOO** 2016
ENDPOINTS: Safety and Efficacy
COMPARISON: Single Antiplatelet or No Therapy
n = Up to 888
Ongoing study in subjects with NVAF deemed not suitable for OAC therapy

**Pinnacle FLX** 2018
ENDPOINTS: Safety and Efficacy
COMPARISON: Non-randomized, FLX Device**, US IDE
n = 451

**Option** 2019
ENDPOINTS: Efficacy and Bleeding
COMPARISON: OAC, FLX Device**
n = 1600
Ongoing study in post-ablation patients

*The ASAP, ESC expanded guidelines and indication and Real World Registries in Europe and Asia studied the patient population contraindicated to the FDA-approved indications for use.

**The WATCHMAN FLX™ Left Atrial Appendage Closure Device is an investigational device and is not available for sale in the U.S.
NEED FOR AN ALTERNATIVE WATCHMAN PROCEDURE

CLINICALLY PROVEN SAFETY

Patent Indication

Affordable Alternative

Brief Summary

Watchman Has Clinically Proven Long-Term Outcomes

Long-term results demonstrated Watchman reduced risk of disabling stroke, post-procedure bleeding, and mortality vs. warfarin.

72% Relative Risk Reduction in Major Bleeding 6-Months Post Implant

80% Relative Risk Reduction in Hemorrhagic Stroke

55% Relative Risk Reduction in Disabling and Fatal Strokes

Meta Analysis Revealed That Watchman Reduced Hemorrhagic Strokes, Which Are Often Fatal and Disabling

27% Relative Risk Reduction in All-Cause Mortality

Watchman Is the Only FDA-Approved Device Proven To Reduce Stroke Risk In Patients With Non-Valvular Atrial Fibrillation

Five-year meta-analysis of Protect AF and Prevail data showed comparable primary efficacy results to warfarin.

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>HR</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All stroke or SE</td>
<td>0.82</td>
<td>0.30</td>
</tr>
<tr>
<td>Ischemic stroke or SE</td>
<td>0.96</td>
<td>0.90</td>
</tr>
<tr>
<td>Hemorrhagic stroke</td>
<td>1.70</td>
<td>0.08</td>
</tr>
<tr>
<td>Ischemic stroke or SE &gt;7 days</td>
<td>0.20</td>
<td>0.0022</td>
</tr>
<tr>
<td>Disabling/fatal stroke (MRS change of ≥2)**</td>
<td>1.40</td>
<td>0.30</td>
</tr>
<tr>
<td>Non-disabling stroke</td>
<td>0.46</td>
<td>0.003</td>
</tr>
<tr>
<td>CV/unexplained death*</td>
<td>1.37</td>
<td>0.35</td>
</tr>
<tr>
<td>All-cause death</td>
<td>0.59</td>
<td>0.03</td>
</tr>
<tr>
<td>Major bleed, all</td>
<td>0.73</td>
<td>0.04</td>
</tr>
<tr>
<td>Major bleeding, non-procedure-related</td>
<td>0.91</td>
<td>0.60</td>
</tr>
<tr>
<td>All-cause death</td>
<td>0.46</td>
<td>0.0003</td>
</tr>
</tbody>
</table>

Relative Risk Reduction in All-Cause Mortality

327%

Relative Risk Reduction in Major Bleeding 6-Months Post Implant

62%

Relative Risk Reduction in Hemorrhagic Stroke

72%

Relative Risk Reduction in Disabling and Fatal Strokes

55%

Relative Risk Reduction in All-Cause Mortality

27%

Note: Major bleeding defined as adverse event that was assigned one of several bleeding codes and was adjudicated by an independent Clinical Events Committee as significant (life-threatening or resulting in hospitalization, prolongation of hospitalization, substantial disability, or death).

*Cardiovascular death is defined as a death from a cardiovascular event including sudden death, MI, cardiac arrhythmia, and heart failure. In addition, any death caused by an undetermined etiology will be cardiovascular.

**Two strokes in PREVAIL are excluded because baseline MRS unavailable.
WATCHMAN Is Proven To Reduce Risk Of Disabling Strokes³

At five years, WATCHMAN patients had a 55% lower relative risk of disabling or fatal strokes compared to patients treated with warfarin.

WATCHMAN Significant Reduction in Disabling Strokes³

WATCHMAN Is Proven To Reduce Risk Of Disabling Strokes³

At five years, WATCHMAN patients had a 55% lower relative risk of disabling or fatal strokes compared to patients treated with warfarin.

WATCHMAN Comparable To Warfarin For Ischemic Stroke Risk Reduction²⁰

Across seven studies WATCHMAN consistently provides ischemic stroke risk reduction in line with warfarin and better than no therapy.

NOTE: Data from ASAP, WASP and EWOLUTION includes patients currently contraindicated for LAAC with WATCHMAN in the United States.
WATCHMAN Has Shown Significant Reduction In Major Bleeding*

Bleeding outcomes after WATCHMAN implant compared with long-term warfarin show significant reductions in the risk of stroke in your NVAF patients without the bleeding risks that come with a lifetime of anticoagulant use.

NOTE: Data are from five-year results from PROTECT AF and 2 year results from PREVAIL.

*Major bleeding defined as adverse event that was assigned one of several bleeding codes and was adjudicated by an independent Clinical Events Committee as significant (life-threatening or resulting in hospitalization, prolongation of hospitalization, substantial disability, or death).

>7 DAYS POST-PROCEDURE
>6 MONTHS POST-PROCEDURE

<table>
<thead>
<tr>
<th>TIME (MONTHS)</th>
<th>EVENT-FREE PROBABILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
</tr>
<tr>
<td>0</td>
<td>0.50</td>
</tr>
<tr>
<td>6</td>
<td>0.60</td>
</tr>
<tr>
<td>12</td>
<td>0.70</td>
</tr>
<tr>
<td>18</td>
<td>0.72</td>
</tr>
<tr>
<td>24</td>
<td>0.74</td>
</tr>
<tr>
<td>30</td>
<td>0.75</td>
</tr>
<tr>
<td>36</td>
<td>0.75</td>
</tr>
<tr>
<td>42</td>
<td>0.75</td>
</tr>
<tr>
<td>48</td>
<td>0.75</td>
</tr>
<tr>
<td>54</td>
<td>0.75</td>
</tr>
<tr>
<td>60</td>
<td>0.75</td>
</tr>
</tbody>
</table>

MAJOR BLEEDING
(95% CI: 0.32-0.75, p=0.001)

MAJOR BLEEDING
(95% CI: 0.16-0.49, p<0.001)

WATCHMAN Demonstrated A Reduction In Mortality Vs. Warfarin

In clinical studies, WATCHMAN reported a reduction in all-cause mortality by 27% compared to warfarin, at five years.³

<table>
<thead>
<tr>
<th></th>
<th>WARFARIN</th>
<th>WATCHMAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL-CAUSE MORTALITY</td>
<td>4.9%</td>
<td>3.6%</td>
</tr>
</tbody>
</table>

P= 0.04
ESTABLISHED SAFETY

In a real-world, post-approval analysis, the WATCHMAN implant has demonstrated high rates of procedural success and low rates of complication for patients with NVAF who are seeking an alternative to long-term warfarin therapy.

95% Procedural Success*4

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

1.5% Major Complication Rate5

Primary composite safety endpoint: death, ischemic stroke, systemic embolism, or device/procedure-related events necessitating cardiac surgery or major endovascular intervention within either 7-days post-implant or hospital discharge, whichever occurred later

IMPLANT SUCCESS RATES IN CLINICAL STUDIES AND INITIAL US COMMERCIAL EXPERIENCE

“Eventually what I want my patient to have is a good quality of life and this device [WATCHMAN] provides a good quality of life.”

—Dr. Devi Nair
Electrophysiologist
St. Bernard’s Medical Center
Jonesboro, AR

U.S. Commercial Implant Success Rate

WATCHMAN U.S. NESTed Post Approval Study

PROTECT AF
N = 449
90.9%

CAP
N = 566
94.4%

PREVAIL
N = 265
95.1%

CAP2
N = 578
94.8%

EWOLUTION31
N = 1019
98.5%

WASP21
N = 201
98.5%

ASAP22
N = 150
94.7%

US COMMERCIAL4
N = 3822
95.6%

NEED FOR AN ALTERNATIVE WATCHMAN PROCEDURE CLINICALLY PROVEN ESTABLISHED SAFETY PATIENT INDICATION AFFORDABLE ALTERNATIVE BRIEF SUMMARY
WATCHMAN Demonstrates Low Complication Rate In Real-World Setting

The WATCHMAN procedure has proven safety, with a 1.5% major complication rate in the highest-risk patients studied to date.3

SAFETY PRIMARY ENDPOINT

Primary composite safety endpoint: death, ischemic stroke, systemic embolism, or device/procedure-related events necessitating cardiac surgery or major endovascular intervention within either 7-days post-implant or hospital discharge, whichever occurred later.

Primary Safety (N=1000) | 1.5% (15 pts, 17 events)

EVENT RATE (95% CI) N=1000

Real World Data: NESTed SAP (LAAO Registry Major Procedural Complications within 7 Days)

Highest risk population of any study to date
Mean Age: 76.6
Mean CHA₂DS₂-VASc: 5.0
Mean HAS-BLED: 2.7

PERFORMANCE GOAL: <3.36

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 not optimal.

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

“"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

BROAD RANGE OF PATIENTS

The WATCHMAN implant may be an appropriate option for your NVAF patients who meet these criteria. Eligible patients must:

1. Have an increased risk for stroke and be recommended for anticoagulation (CHA₂DS₂-VASc ≥ 2 for men, ≥ 3 for women)*
2. Be suitable for short-term warfarin
3. Have an appropriate reason to seek a non-pharmacologic alternative to warfarin

*CHA₂DS₂-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 2019 ACC/AHA/HRS Guidelines Recommend WATCHMAN As An Option For Patients Who Are Contraindicated To Long-Term Anticoagulation Use

This recommendation comes as a result of years of clinical and real-world evidence demonstrating the safety and effectiveness of the WATCHMAN device.

**Recommendation for percutaneous approaches to occlude the LAA**

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIB</td>
<td>B-NR</td>
<td>Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation (S4.4.1.1-S4.4.1.5). NEW Clinical trial data and FDA approval of the WATCHMAN device necessitated this recommendation.</td>
</tr>
</tbody>
</table>

The guidelines state that percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation. Examples include:

- Patients with a history or risk of bleeding (including those with an active lifestyle or occupation)
- Patients who are not adherent or compliant with their medication
- Patients taking medications not compatible with anticoagulation

WHICH NVAF PATIENTS ARE RIGHT FOR WATCHMAN?

**BOB, 67**
**Drug Interaction Issues**

*Occupation:* Psychologist  
*Medical conditions:* NVAF, osteoarthritis  
*CHA\(_2\)DS\(_2\)-VASc score:* 5

Bob has osteoarthritis as well as NVAF. He had frequent non-major bleeding incidents due to combining his OAC with NSAIDs to manage his osteoarthritis pain, eventually leading to OAC non-compliance.

**What approach do you take with your NVAF patients experiencing drug interaction issues?**

**FRANK, 80**
**High Risk for Bleeding**

*Occupation:* Active, involved grandfather  
*Medical conditions:* NVAF, congestive heart failure, hypertension, diabetes  
*CHA\(_2\)DS\(_2\)-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\(_2\)DS\(_2\)-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\(_2\)DS\(_2\)-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.
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.

CMS WILL COVER PERCUTANEOUS LAAC IMPLANTS WHEN SPECIFIC CRITERIA ARE MET.28

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

- **LAA REGISTRY:** Patients must be enrolled in a prospective national registry such as the Left Atrial Appendage Occlusion (LAAO) Registry (NCT02699957)
- **OPERATOR REQUIREMENTS:** IC or EP or cardiovascular surgeon must have performed at least 25 transseptal punctures (TSP) through intact septum – Must maintain at least 25 TSP over a two-year period (at least 12 are LAAC)
- **FACILITY REQUIREMENTS:** The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program

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**WATCHMAN IS AN AFFORDABLE CHOICE**6

Total out-of-pocket (OOP) spending for WATCHMAN is lower than warfarin by year two and half the cost by year five.

A budget impact analysis of Medicare beneficiaries found the following expenses associated with treatment and complication for patients taking warfarin or dabigatran to reduce strokes in AF.

<table>
<thead>
<tr>
<th></th>
<th>WARFARIN</th>
<th>DABIGATRAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average cumulative OOP over 5 years</td>
<td>$10,827</td>
<td>$9,296</td>
</tr>
<tr>
<td>Average OOP cost per year over 5 years</td>
<td>$2,165</td>
<td>$1,859</td>
</tr>
<tr>
<td>Average OOP cost per month over 5 years</td>
<td>$180</td>
<td>$155</td>
</tr>
</tbody>
</table>

Dabigatran is a product of Boehringer Ingelheim pharmaceuticals, Germany.

For Medicare patients seeking an alternative to long-term warfarin therapy, the same analysis revealed the following regarding cumulative OOP patient costs:

**ANNUAL CUMULATIVE PATIENT OOP COSTS**

<table>
<thead>
<tr>
<th>Year</th>
<th>Warfarin</th>
<th>LAAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yr 1</td>
<td>$10,827</td>
<td>$9,406</td>
</tr>
<tr>
<td>Yr 2</td>
<td>$9,406</td>
<td>$3,514</td>
</tr>
<tr>
<td>Yr 3</td>
<td>$3,514</td>
<td>$1,570</td>
</tr>
<tr>
<td>Yr 4</td>
<td>$1,570</td>
<td>$1,421</td>
</tr>
<tr>
<td>Yr 5</td>
<td>$1,421</td>
<td>$5,084</td>
</tr>
</tbody>
</table>

**AVERAGE TOTAL OOP COSTS AT YEAR FIVE**

<table>
<thead>
<tr>
<th></th>
<th>WATCHMAN</th>
<th>WARFARIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATCHMAN had lower patient OOP costs than warfarin by year two</td>
<td>$10,827</td>
<td>$9,406</td>
</tr>
<tr>
<td>WATCHMAN was 53% LESS EXPENSIVE than warfarin by year five</td>
<td>$9,406</td>
<td>$5,084</td>
</tr>
</tbody>
</table>

For Medicare patients seeking an alternative to long-term warfarin therapy, the same analysis revealed the following regarding cumulative OOP patient costs:

**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

**INCREASED RISK FOR STROKE**

- CHADS2 score ≥ 2 or a CHA2DS2-VASc score ≥ 3

**SUITE FOR SHORT-TERM WARFARIN**

- But deemed unable to take long-term oral anticoagulation

**DOCUMENTED IN MEDICAL RECORD**

- **LAA REGISTRY:** Patients must be enrolled in a prospective national registry such as the Left Atrial Appendage Occlusion (LAAO) Registry (NCT02699957)
- **OPERATOR REQUIREMENTS:** IC or EP or cardiovascular surgeon must have performed at least 25 transseptal punctures (TSP) through intact septum – Must maintain at least 25 TSP over a two-year period (at least 12 are LAAC)
- **FACILITY REQUIREMENTS:** The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program

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**NEED FOR AN ALTERNATIVE WATCHMAN PROCEDURE**

**CLINICALLY PROVEN**

**ESTABLISHED SAFETY**

**PATIENT INDICATION**

**AFFORDABLE ALTERNATIVE**

**BRIEF SUMMARY**
A Typical Medicare Patient Will Pay No More Than $2,219 In Out-Of-Pocket Costs To Receive WATCHMAN

Estimated Medicare Patient OOP Costs for WATCHMAN Implant.

<table>
<thead>
<tr>
<th>PREPARING FOR WATCHMAN</th>
<th>WATCHMAN IMPLANT</th>
<th>POST-WATCHMAN THERAPY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-screening TEE*</td>
<td>$90</td>
<td></td>
</tr>
<tr>
<td>Inpatient deductible</td>
<td>$1,364</td>
<td>Warfarin/clopidogrel/ASA** through one year[^20, 30]</td>
</tr>
<tr>
<td>(Medicare Part A)</td>
<td></td>
<td>$67</td>
</tr>
<tr>
<td>Medical Services</td>
<td>$185</td>
<td>45-day follow-up TEE</td>
</tr>
<tr>
<td>Deductible</td>
<td></td>
<td>$96</td>
</tr>
<tr>
<td>(Medicare Part B)</td>
<td></td>
<td>1-year follow-up TEE</td>
</tr>
</tbody>
</table>

**PHYSICIAN PROFESSIONAL FEE CO-PAYS**

- Implanter: $166
- Anesthesiologist: $102
- Intraoperative TEE Operator: $47

**TOTALES**

PREPARING FOR WATCHMAN: $96
WATCHMAN IMPLANT: $1,865
POST-WATCHMAN THERAPY: $259

Total Estimated Patient OOP Costs: $2,219

**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.

**WATCHMAN, warfarin, and dabigatran costs include treatment costs and complication costs based on 2015 Medicare patient costs.**

**WATCHMAN TREATMENT COSTS:** procedure costs as taken from the 2015 Medicare Part A deductible for admission; costs for procedural complications were not included as they do not impact patient out-of-pocket costs.

**OAC TREATMENT COSTS:** drug costs were taken from Medicare Part D costs and averaged across the four states with the largest percentage of Medicare beneficiaries.

**COMPLICATION COSTS:** includes costs associated with an inpatient admission related to ischemic stroke, hemorrhagic stroke, systemic embolism, major bleeding, and all-cause mortality; inpatient and/or outpatient rehabilitation costs following inpatient admission of stroke.


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

**ASA:** Acetylsalicylic acid (aspirin).
ABBREVIATED STATEMENT WATCHMAN™ LEFT ATRIAL APPENDAGE CLOSURE DEVICE WITH DELIVERY SYSTEM AND WATCHMAN™ ACCESS SYSTEM

18. Boston Scientific WATCHMAN Left Atrial Appendage Closure Device with Delivery System DFU, 2015; 9076221-01C.
20. Frierb. Eur Heart J (2012);

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 CHADS2 or CHA2DS2-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 catheteral or conditions (e.g., acute 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 fluoros 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 within 30 days following device implantation. Verify device position post-implantation.
• Administer appropriate anticoagulants prophylaxis for 6 months following device implantation. The decision to continue anticoagulants 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-ALIGN1 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, Aortic endocarditis, Arhythmias, Atrial septal defect, AV fistula, Bruising, Cranial bleed, Decreased hemoglobin, Deep vein thrombosis, Death, Device embolism, Device fracture, Device thrombosis, Edema, Excessive bleeding, Fever, Gastro-intestinal bleed, Hematuria, Hemoptysis, Hypotension, Hypoxia, Impaired wound healing, Inability to reposition, recapture, or retrieve the device, Infection / pneumonia, Intracardiac thrombus, Intracranial bleeding, Major bleeding requiring transfusion, Misplacement of the device / improper seal of the appendage / movement of device from appendage wall, Myocardial ischemia, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pseudotumor, Renal failure, Respiratory insufficiency / failure, Surgical removal of device, Systemic embolism, 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. ©2017 Boston Scientific Corporation or its affiliates. All rights reserved.
Watchman is a necessary alternative. Oral anticoagulants are not suitable for all patients due to the range of challenges associated with their use. Suitable for a broad range of patients, Watchman is suitable for a broad range of patients looking for an alternative to blood thinners. Clinically proven results, Watchman reduced the risk of stroke, bleeding post procedure, and mortality versus warfarin.1, 2, 3 An affordable alternative, Watchman is less expensive by year two and half the cost by year five.6 Established safety, Watchman has a high 95% procedural success rate4* with a 1.5% major complication rate.5

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.

Interested in learning more about Watchman?

Visit us at watchman.com/hcp

WATCHMAN IS SAFE, EFFECTIVE, AND ENABLES PATIENTS TO DISCONTINUE OAC MEDICATIONS

A Necessary Alternative
Oral anticoagulants are not suitable for all patients due to the range of challenges associated with their use.

Suitable for a Broad Range of Patients
Watchman is suitable for a broad range of patients looking for an alternative to blood thinners.

Clinically Proven Results
Long-term results demonstrated Watchman reduced the risk of stroke, bleeding post procedure, and mortality versus warfarin.1, 2, 3

An Affordable Alternative
Watchman is less expensive by year two and half the cost by year five.6

Established Safety
Watchman has a high 95% procedural success rate4* with a 1.5% major complication rate.5

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