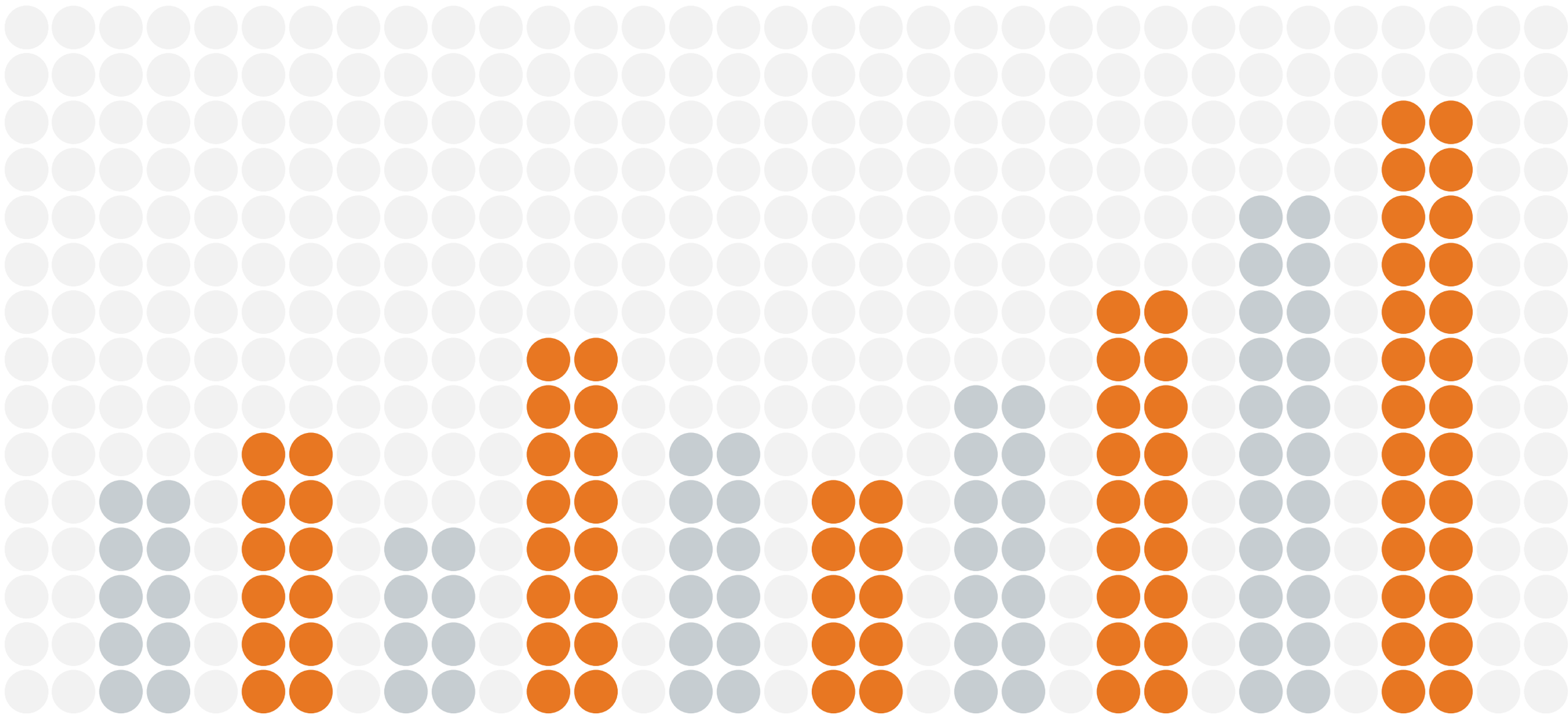
Boston Scientific
Advancing science for life™

WATCHMAN™

Clinical Data



watchman.com/hcp

WHY WATCHMAN

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

>10 CLINICAL STUDIES

FDA APPROVED

CMS NATIONAL COVERAGE

>20 YEARS OF CLINICAL PATIENT FOLLOW-UP

INCLUDED IN THE AF AND STROKE MANAGEMENT GUIDELINES

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 rate[4]* 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**.

"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

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

NEED FOR A SAFE ALTERNATIVE

~6M

6M

12M by 2030

PEOPLE IN THE U.S. WITH AF. THIS NUMBER IS ESTIMATED TO DOUBLE BY 2030[7]

5X

GREATER RISK OF STROKE FOR AF PATIENTS[8]

90%

OF STROKE-CAUSING CLOTS THAT COME FROM LEFT ATRIUM COME FROM THE LAA IN NVAF PATIENTS*[9]

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

CHA_2DS_2-VAS_C Score in Men	CHA_2DS_2-VAS_C Score in Women	Guidelines Recommendation[24]
0	0	No anticoagulant
1	2	Aspirin (81-325 mg daily) or oral anticoagulants may be considered
≥ 2	≥ 3	Oral anticoagulants are recommended**

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

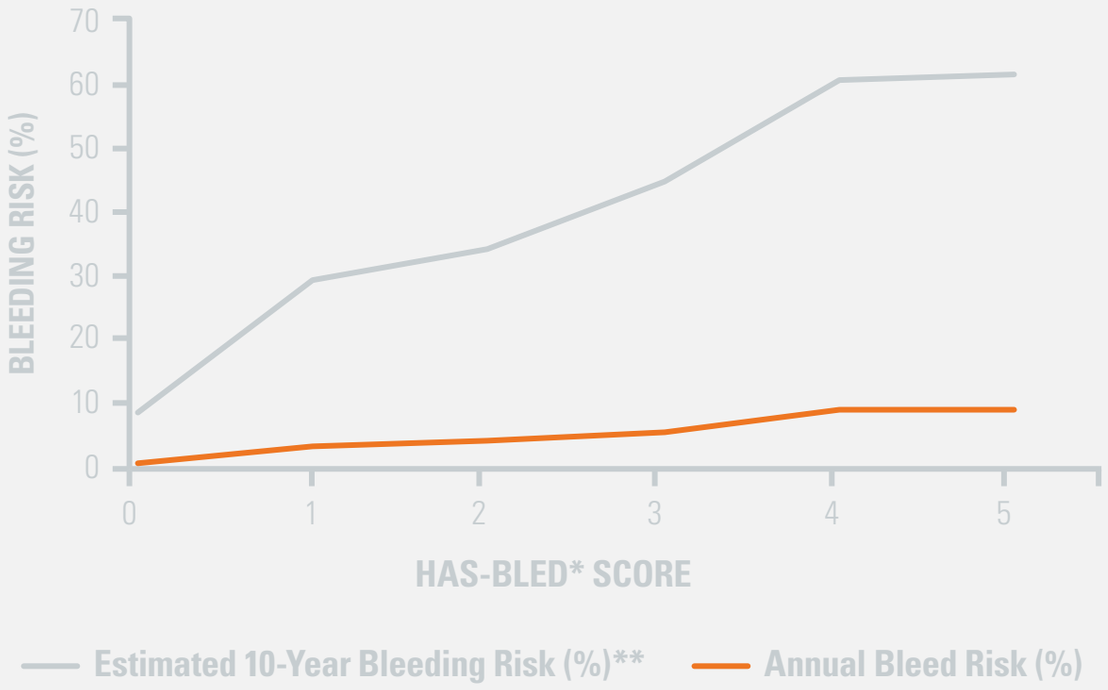
- Bleeding Risk
- Daily or 2x/Daily Regimen
- High Non-Adherence Rates
- Complicates Surgical Procedures
- High Cost

*__LAA__ – 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.



CHA_2DS_2-VASc Score	Annual % Stroke Risk
0	0
1	1.3
2	2.2
3	3.2
4	4.0
5	6.7

HAS-BLED* Score[8]	Annual % Bleed Risk[10]	Estimated 10-Year Bleeding Risk (%)**
0	0.9	8.6
1	3.4	29.2
2	4.1	34.2
3	5.8	45.0
4	8.9	60.6
5	9.1	61.5

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[11]

63%

of patients who experienced a bleeding event on a DOAC had a repeat bleeding event[11]

*The HAS-BLED scoring system predicts a patients risk of stroke while on warfarin.

NOTE: CHA_2DS_2-VASc score – Congestive heart failure=1, Hypertension (SBP >160)=1, Age > 75 yrs=2, Diabetes mellitus=1, Prior stroke, TIA, or thromboembolism=2, Vascular disease (PAD, MI)=1, Age 65-74 yrs=1, Sex category (female)=1.
HAS-BLED score – Hypertension=1, Abnormal renal/liver function (1pt 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.

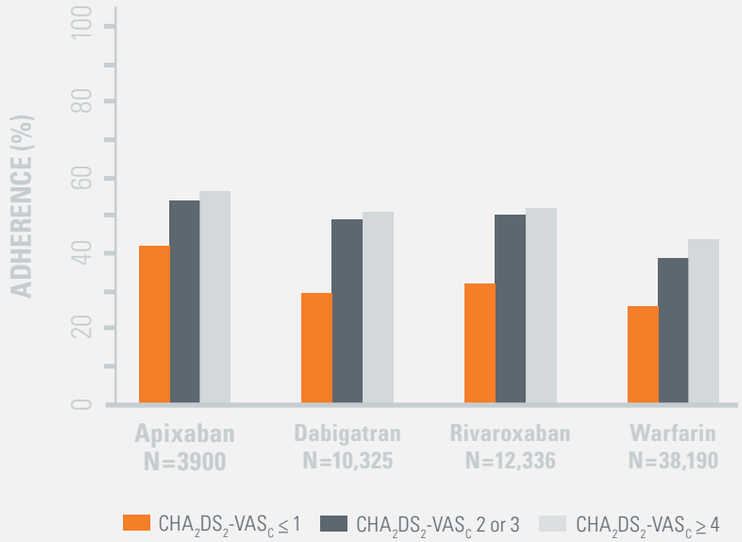
**Assumes constant risk despite increasing age, and bleeding risk is independent from bleeding risk in previous years.

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%

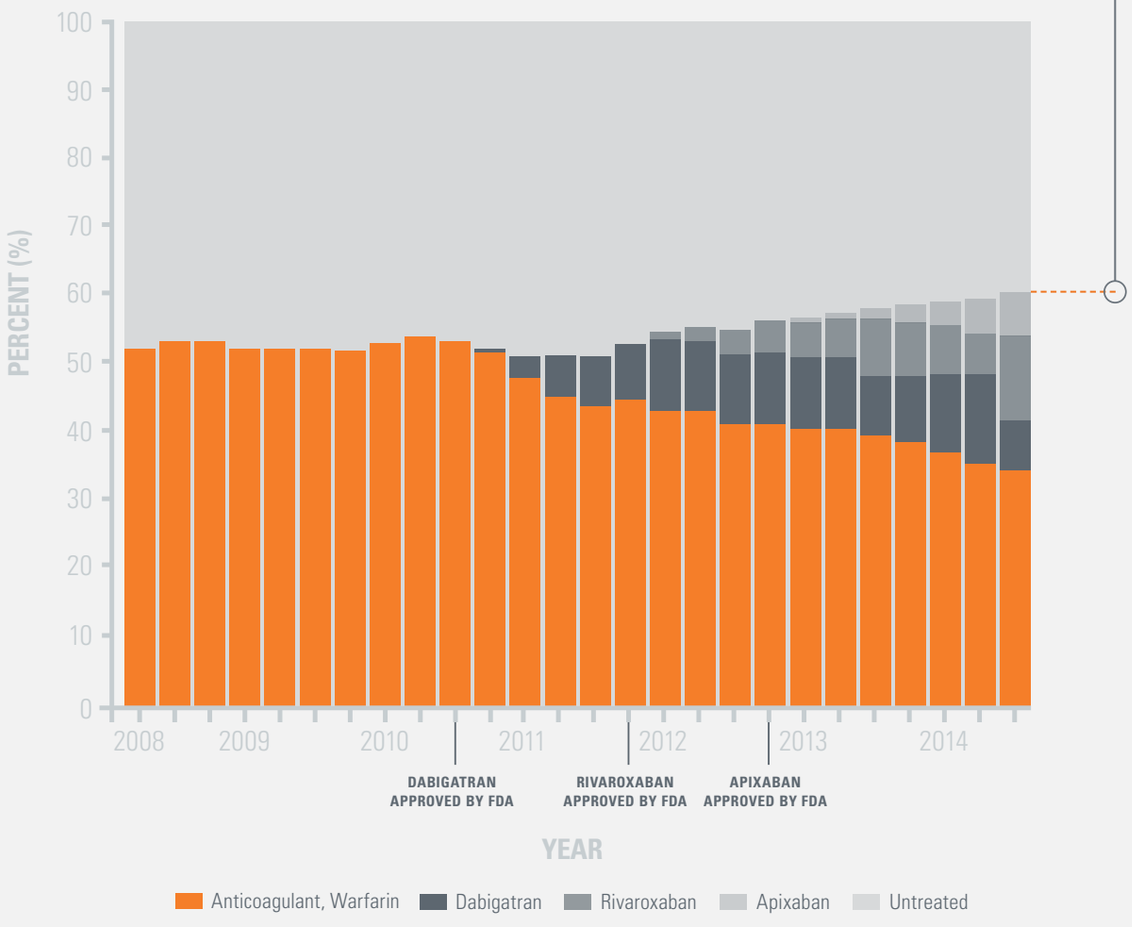
OF PATIENTS NOT TREATED[12]



ONLY

~1/2

OF PATIENTS REMAIN ADHERENT[13]

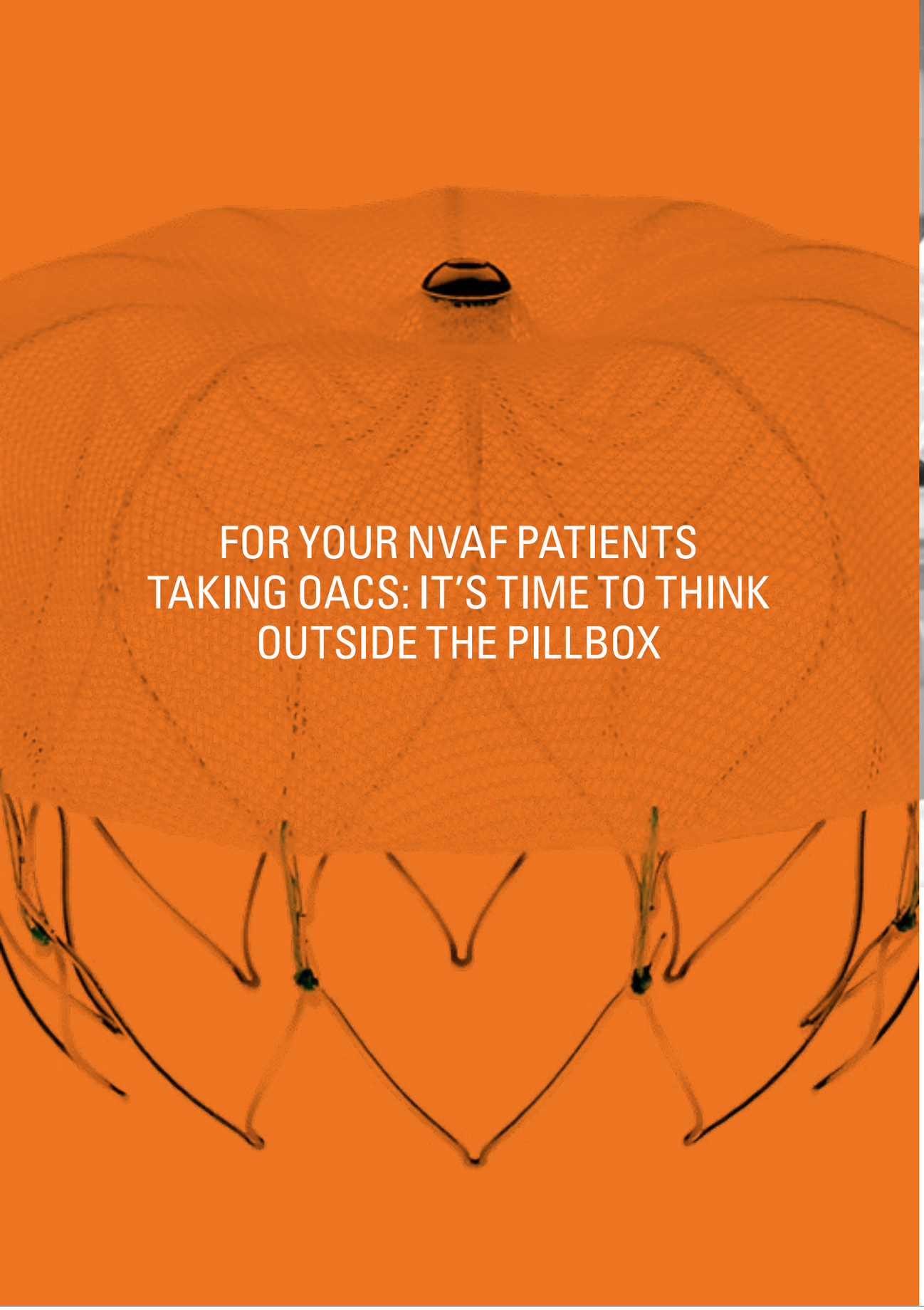


Bleeding Risks Are Comparable Across Oral Anticoagulant Therapies

For those that remain adherent, bleeding risks persist.

Treatment	Study Drug Discontinuation Rate	Major Bleeding (rate/year)
Rivaroxaban[14]	24%	3.6%
Apxiaban[15]	25%	2.1%
Dabigatran[16] (150 mg)	21%	3.1%
Edoxaban[17] (60 mg / 30 mg)	34% / 33%	2.8% / 1.6%
Warfarin[14-17]	17-35%	3.1-3.4%

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.

MINIMALLY INVASIVE

PERMANENT IMPLANT

TYPICAL PROCEDURE IS LESS THAN 1 HOUR

24-HOUR AVERAGE HOSPITAL STAY

WATCHMAN IS AVAILABLE IN

5 SIZES

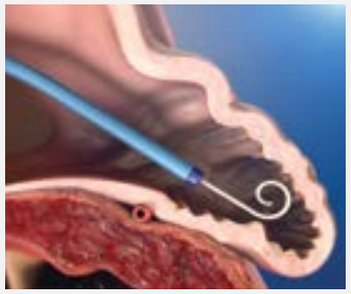
21 mm | 24 mm | 27 mm | 30 mm | 33 mm

1

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

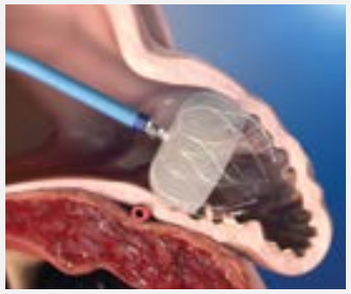
2

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



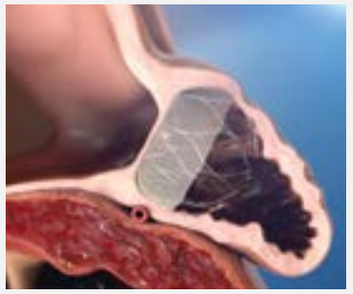
3

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

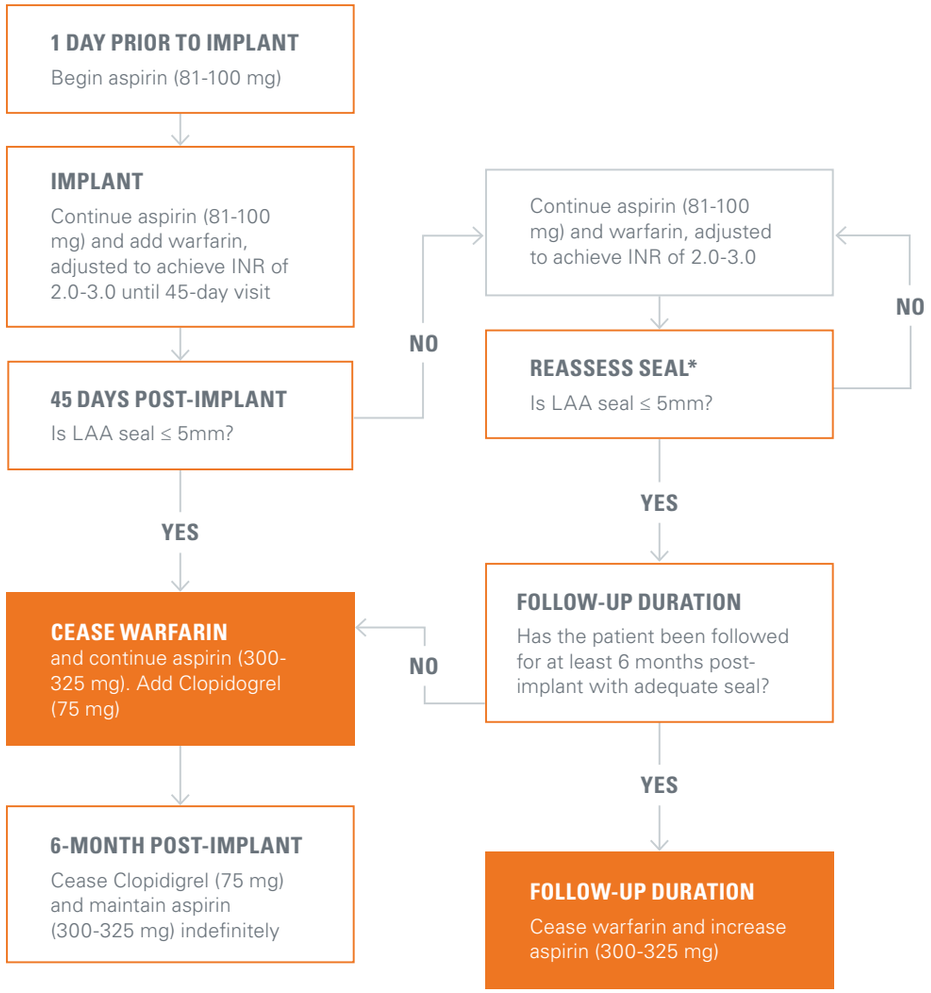
WATCHMAN is then deployed and released in the LAA.



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.

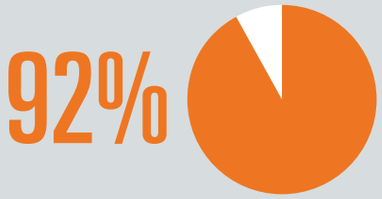
WATCHMAN Post-Procedure Information



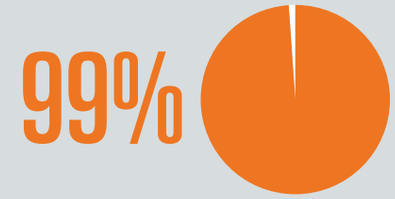
*The performance and timing of TEE to re-evaluate the LAA seal is left to physician discretion.

WATCHMAN Enables Patients To Discontinue Long-Term OAC[18]

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



of patients were able to discontinue warfarin **after 45 days**



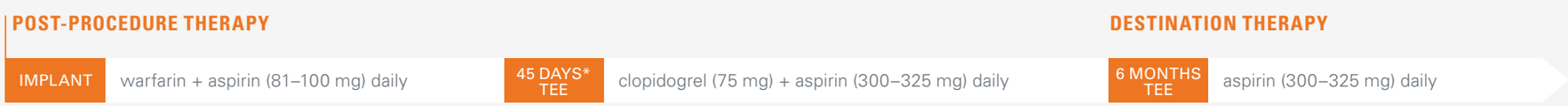
of patients were able to discontinue warfarin **after 1 year**

Warfarin Cessation with WATCHMAN

Study	45-Day	12-Month
PROTECT AF	87%	>93%
CAP	96%	>96%
PREVAIL	92%	>99%
CAP2[19]	93%	>96%

POST-IMPLANT

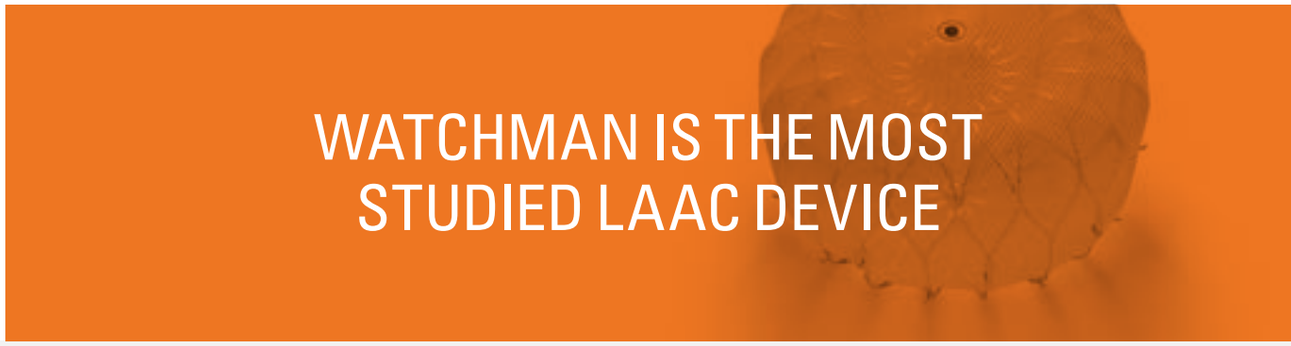
WATCHMAN therapy includes short-term adjunctive post-implant pharmacologic regimen.



*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: Feasibility and Safety

COMPARISON: Non-randomized

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

PROTECT AF
2005

ENDPOINTS: Safety and Efficacy

COMPARISON: Warfarin

n = 707, mean CHA_2DS_2-VASc = 3.4
mean age = 72

CAP REGISTRY
2008

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

ASAP*
2009

ENDPOINTS: Efficacy

COMPARISON: $CHADS_2$ score and expected stroke rate

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

PREVAIL
2010

ENDPOINTS: Safety and Efficacy

COMPARISON: Warfarin

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

ESC GUIDELINES
2012

Expanded guidelines and indication

CAP2 REGISTRY
2012

ENDPOINTS: Collect additional safety and efficacy data

n = 578
mean CHA_2DS_2-VASc = 4.5
mean age = 75

EWOLUTION, WASP
2013

Registries in Europe and Asia*

ENDPOINTS: Additional information in a real-world setting

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

NESTED
2016

n = 2000

Post-approval statistical means:
CHA_2DS_2-VASc = 5
Age = 76.6

PINNACLE FLX
2018

ENDPOINTS: Safety and Efficacy

COMPARISON: Non-randomized, FLX Device**, US IDE

n = 451

INCLUDED IN AHA/ACC/HRS GUIDELINES
2019

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.

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[2]

80%
Relative Risk Reduction
IN **HEMORRHAGIC STROKE**[3]

55%
Relative Risk Reduction
IN **DISABLING AND FATAL STROKES**[3]

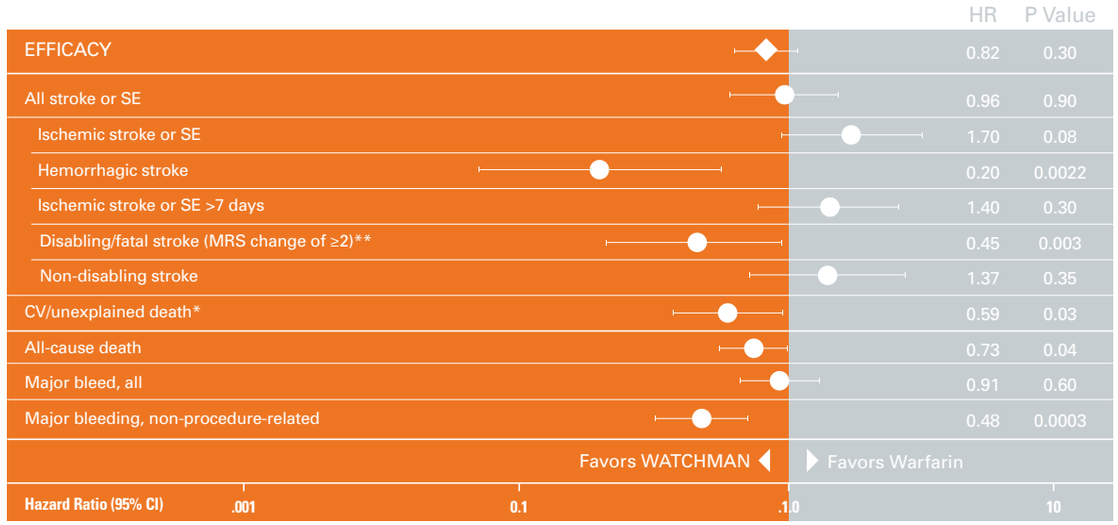
META ANALYSIS REVEALED THAT WATCHMAN REDUCED HEMORRHAGIC STROKES, WHICH ARE OFTEN FATAL AND DISABLING

27%
Relative Risk Reduction
IN **ALL-CAUSE MORTALITY**[3]

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).

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 wafarin[3]



These trials randomized patients with NVAF who were suitable for long-term warfarin treatment to receive either the WATCHMAN implant or warfarin. Both studies used the composite primary endpoint of all-cause stroke, systemic embolism (SE), and cardiovascular (CV)/unexplained death. Because both trials used the same primary endpoint, the data were pooled in a patient-level meta-analysis.

Individual endpoints were measured for all-cause stroke or SE and CV/unexplained death; all stroke was also subdivided into ischemic stroke and hemorrhagic stroke. In addition, analyses were done for all-cause death and major bleeding events.

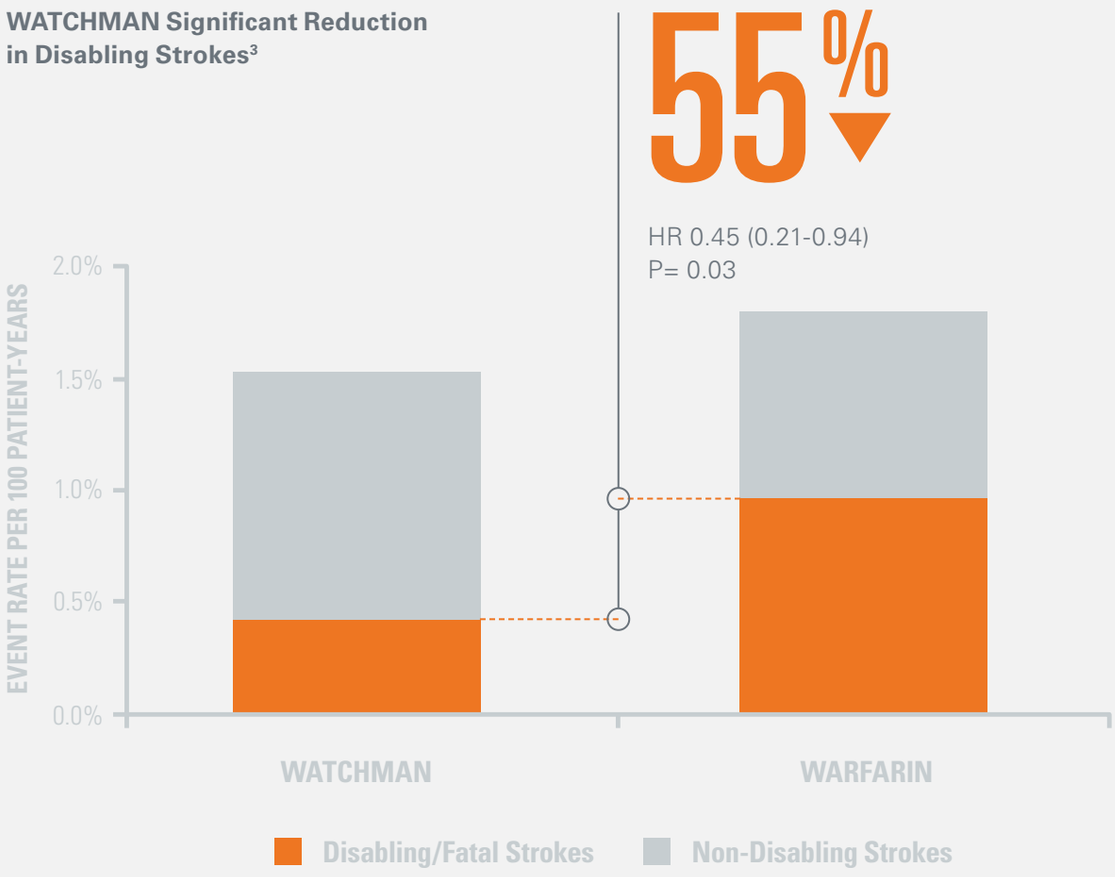
*Cardiovascular death is defined as a death from a cardiovascular event including sudden death, MI, cardiac arrhythmia, and heart failure. In addition, any death caused by an undetermined etiology will be cardiovascular.

**Two strokes in PREVAIL are excluded because baseline MRS unavailable.

WATCHMAN Is Proven To Reduce Risk Of Disabling Strokes[3]

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

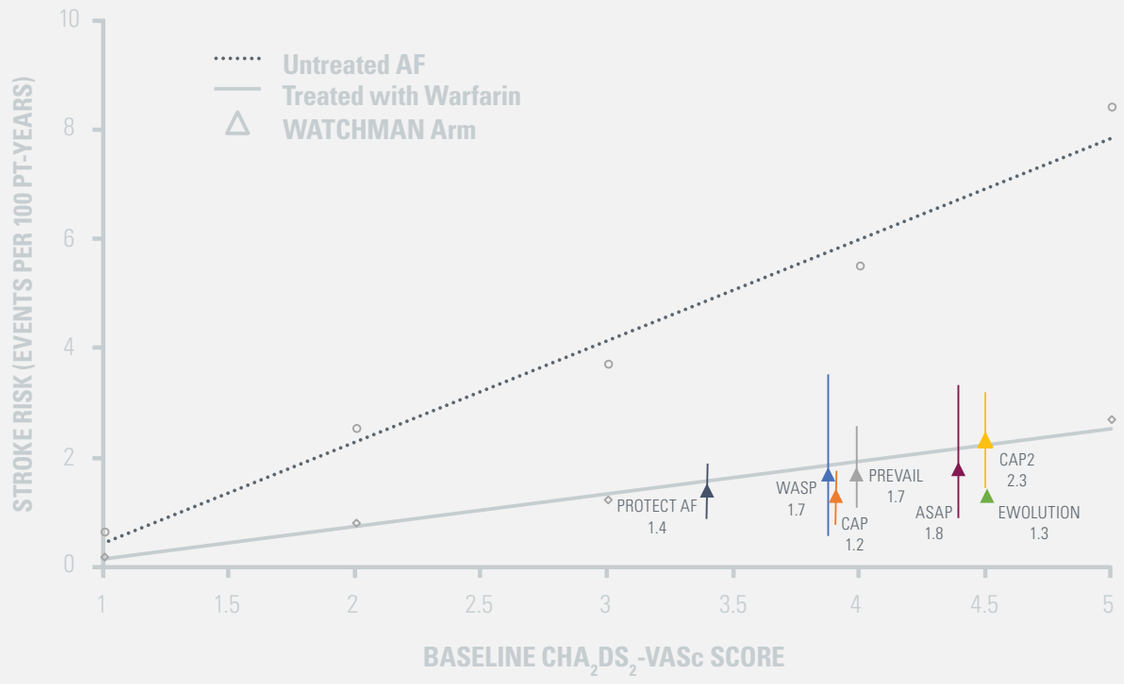
WATCHMAN Significant Reduction in Disabling Strokes[3]



WATCHMAN Comparable To Warfarin For Ischemic Stroke Risk Reduction[20]

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

Ischemic Stroke Risk (Events per 100 PT-Years)[3, 20-24]

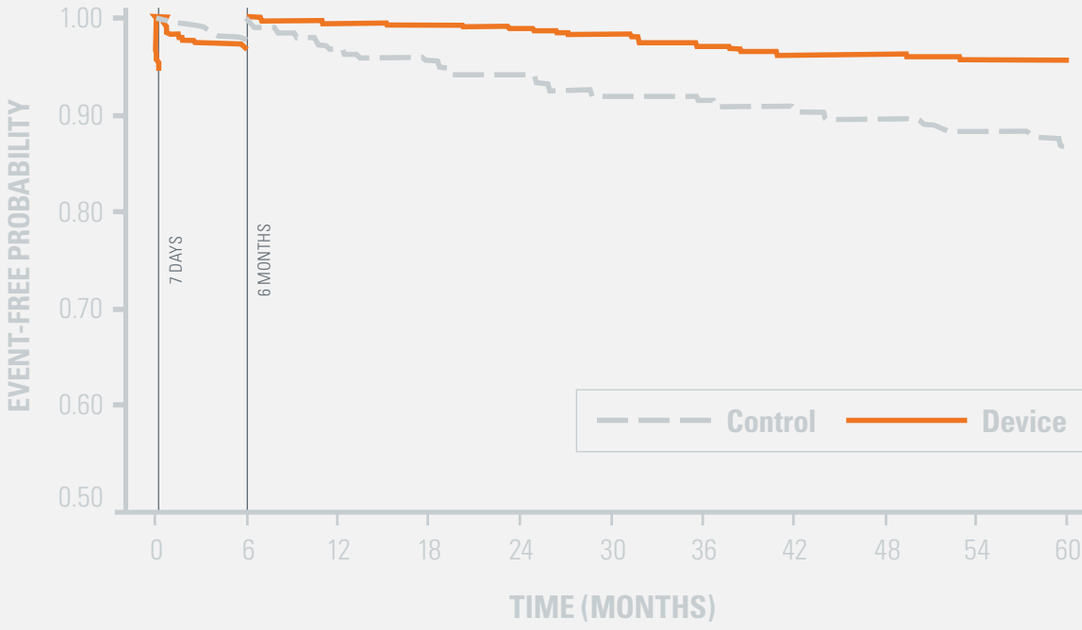


NOTE: Data from ASAP, WASP and EWOLUTION includes patients currently contraindicated for LAAC with WATCHMAN in the United States.

WATCHMAN Has Shown Significant Reduction In Major Bleeding*

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

Freedom of Major Bleeding Over Three Adjunctive Pharmacotherapy Intervals[2]



>7 DAYS POST-PROCEDURE

51%

MAJOR BLEEDING
(95% CI: 0.32-0.75, p=0.001)[3]

>6 MONTHS POST-PROCEDURE

after discontinuation of concomitant antithrombotic therapy

72%

MAJOR BLEEDING
(95% CI: 0.16-0.49, p<0.001)[2]

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]

WARFARIN 4.9%

WATCHMAN 3.6%

27%

ALL-CAUSE MORTALITY[3]
P= 0.04

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).

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.

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 5mm

WATCHMAN U.S. NESTed Post Approval Study

1.5%

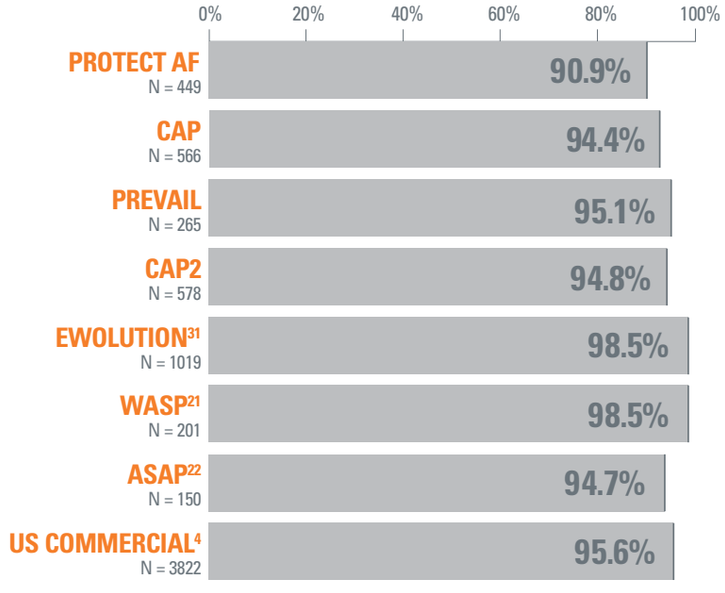
Major Complication Rate[5]

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

"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

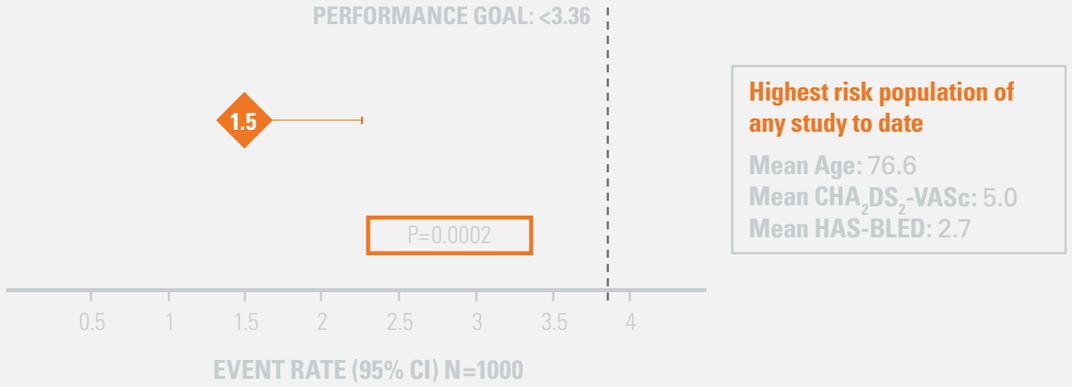
IMPLANT SUCCESS RATES IN CLINICAL STUDIES AND INITIAL US COMMERCIAL EXPERIENCE



WATCHMAN Demonstrates Low Complication Rate In Real-World Setting[5]

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



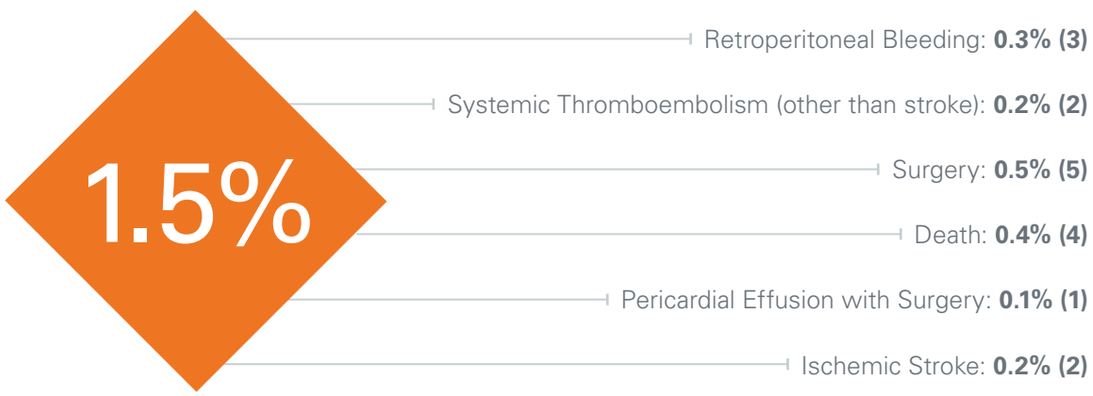
Highest risk population of any study to date

Mean Age: 76.6
Mean CHA_2DS_2-VASc: 5.0
Mean HAS-BLED: 2.7

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

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)



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 (CHA_2DS_2-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

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 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

*CHA_2DS_2-VASc score – Congestive heart failure=1, Hypertension (SBP >160)=1, Age > 75 yrs=2, Diabetes mellitus=1, Prior stroke, TIA, or thromboembolism=2, Vascular disease (PAD, MI)=1, Age 65-74 yrs=1, Sex category (female)=1.

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[24]

COR	LOE	RECOMMENDATION
IIB	B-NR	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.

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.[24] 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_2DS_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_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.

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]

DOCUMENTED IN MEDICAL RECORD

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

- **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

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.

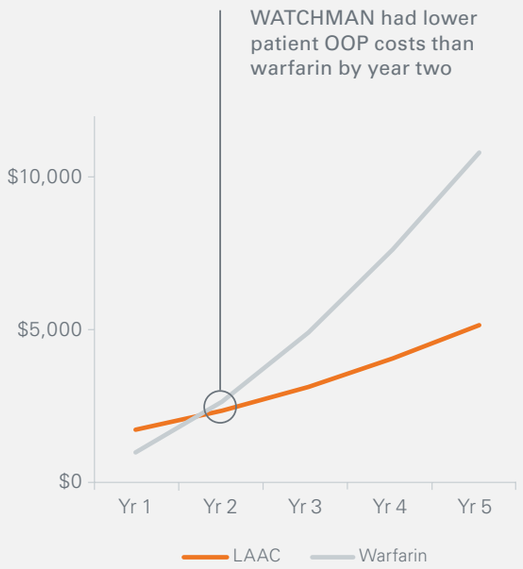
A budget impact analysis of Medicare beneficiaries found the following expenses associated with treatment and complication for patients taking warfarin or dabigatran to reduce strokes in AF.

	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

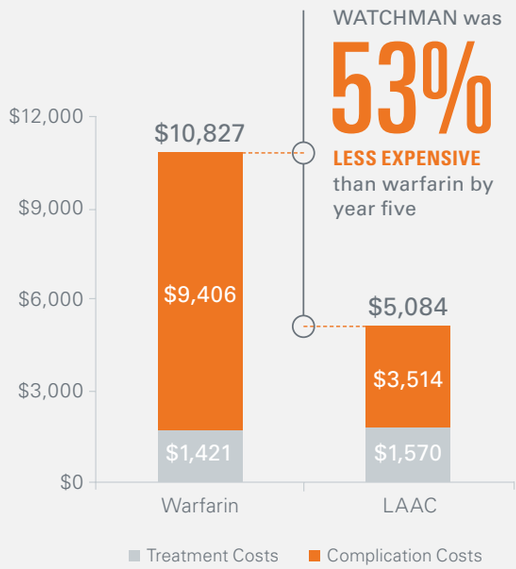
Dabigatran is a product of Boehringer Ingelheim pharmaceuticals, Germany.

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



AVERAGE TOTAL OOP COSTS AT YEAR FIVE



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.

PREPARING FOR WATCHMAN		WATCHMAN IMPLANT		POST-WATCHMAN THERAPY	
Pre-screening TEE*	$90	Inpatient deductible (Medicare Part A)	$1,364	Warfarin/clopidogrel/ ASA** through one year[29, 30]	$67
		Medical Services Deductible (Medicare Part B)	$185		
		PHYSICIAN PROFESSIONAL FEE CO-PAYS		45-day follow-up TEE	$96
		Implanter	$166	1-year follow-up TEE	$96
		Anesthesiologist	$102		
		Intraoperative TEE Operator	$47		
Totals	**$96**		**$1,865**		**$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.

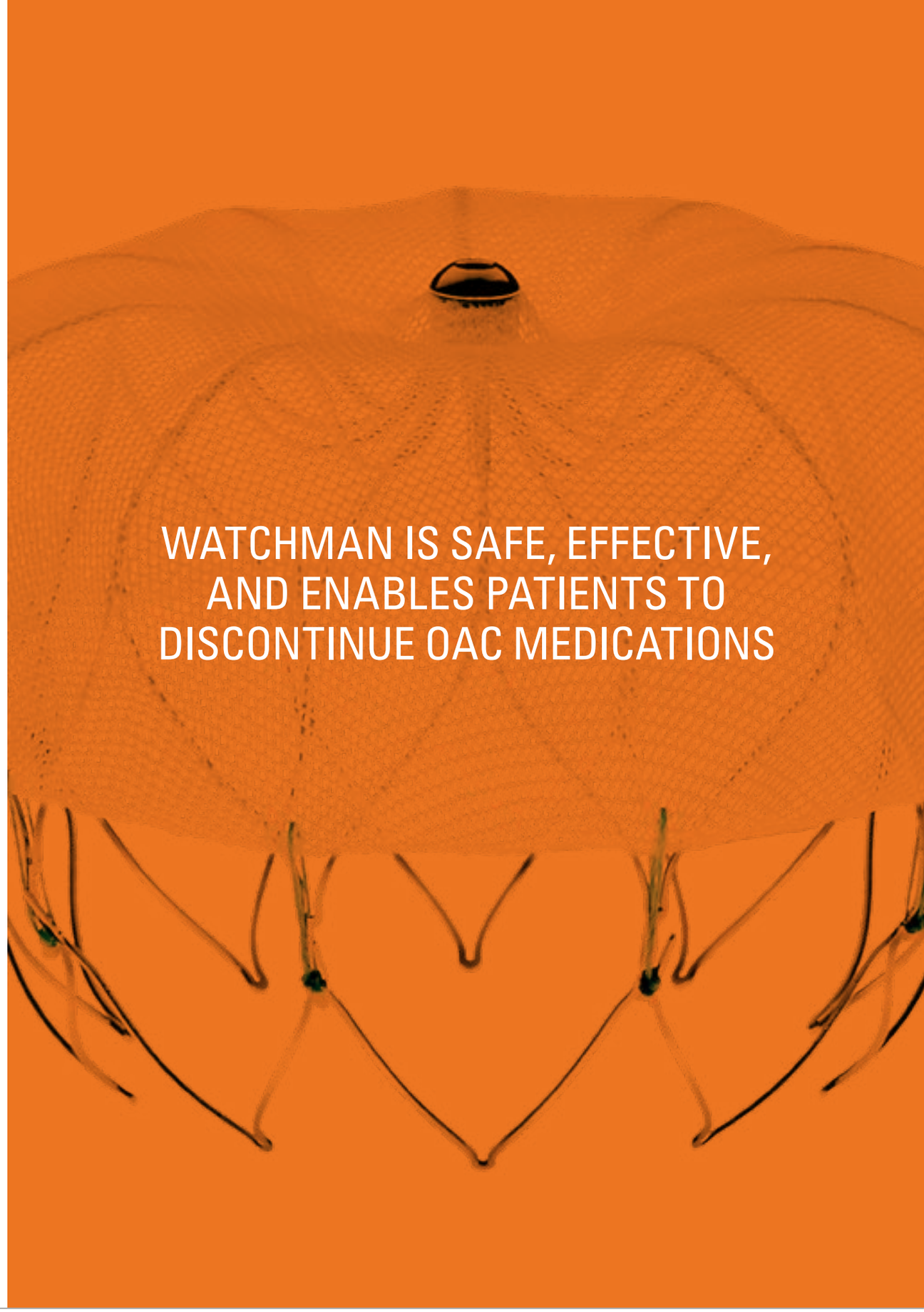
OAC TREATMENT COSTS: drug costs were taken from Medicare Part D costs and averaged across the four states with the largest percentage of Medicare beneficiaries.

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

Further cost sourcing detail is available in the abstract Armstrong S, Amorosi SL, et al. Medicare Beneficiary Out-of-Pocket Spending for Strke Prevention in Non-valvular Atrial Fibrillation: A Budget Analysis. Poster presentation, PMD15, ISPOR 2015. Available online – http://www.ispor.org/research_pdfs/49/pdffiles/PMD15.pdf.

*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

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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-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, 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.

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.

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

Established Safety
WATCHMAN has a high 95% procedural success rate[4]* with a 1.5% major complication rate.[5]

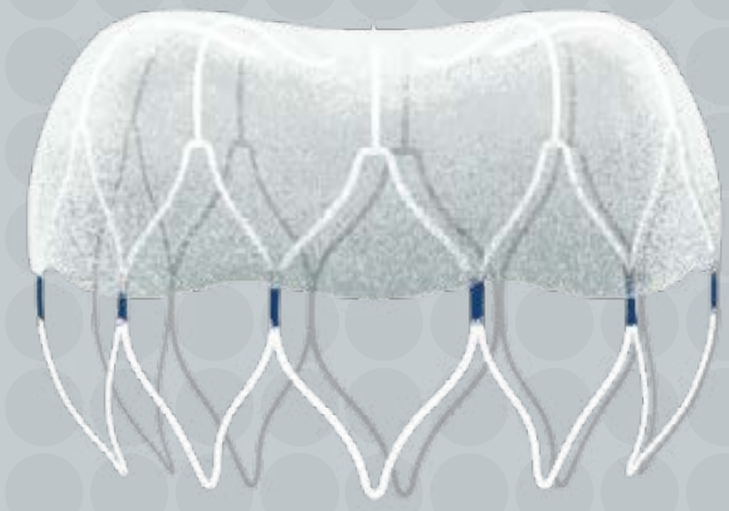
Suitable for a Broad Range of Patients
WATCHMAN is suitable for a broad range of patients looking for an alternative to blood thinners.

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

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



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