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Introducing WATCHMAN™ LAAC Device

A first-of-its-kind, FDA-approved alternative to long-term warfarin therapy for stroke risk reduction in patients with non-valvular atrial fibrillation.

watchman.com/hcp

Patients with AF have a 5x increased risk of stroke.[1]

AF-related strokes are more frequently fatal and disabling. [2,3] Approximately half of acute stroke victims will die or live with a significant disability, which may result in institutional care.

While warfarin is effective for many patients, long-term warfarin therapy is not well tolerated by some patients, highlighting the need for additional treatment options.

Life-Changing Stroke Risk Treatment Option

Atrial fibrillation (AF) currently affects more than 5 million Americans.[4] *AF is projected to increase as population ages.*[5]

Patients with AF have a 5x greater risk of stroke.[1]
Strokes in patients with AF are the #1 cause of long-term disability and the #3 leading cause of death.[1]

In non-valvular AF, approximately ***90% of stroke-causing clots*** *that come from the left atrium* ***are formed in the left atrial appendage (LAA).***[6]

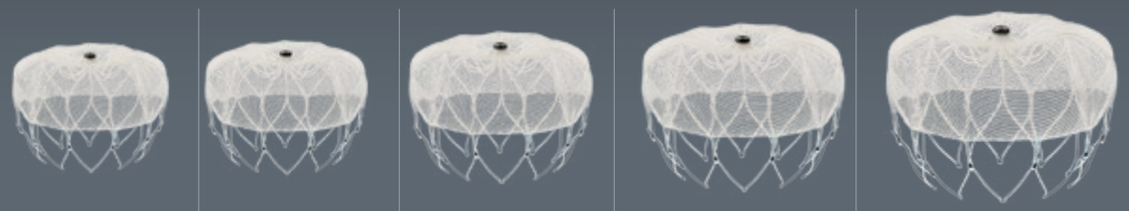
Approximately 45% of patients with AF who are eligible for warfarin are NOT being treated (tolerance/adherance).[7] Lifestyle limitations when taking warfarin include high risk of bleeding,[8] negative interactions with food and drugs,[9] serious side effects that are often difficult to tolerate,[10] and required frequent and ongoing monitoring.

Despite NOAC adoption and ability to switch NOACs, adherence remains a challenge. *50% of warfarin patients discontinue the therapy at 2 years, and 30% of NOAC patients stop taking any drug at 2 years.*[11]

Designed for Implant Success

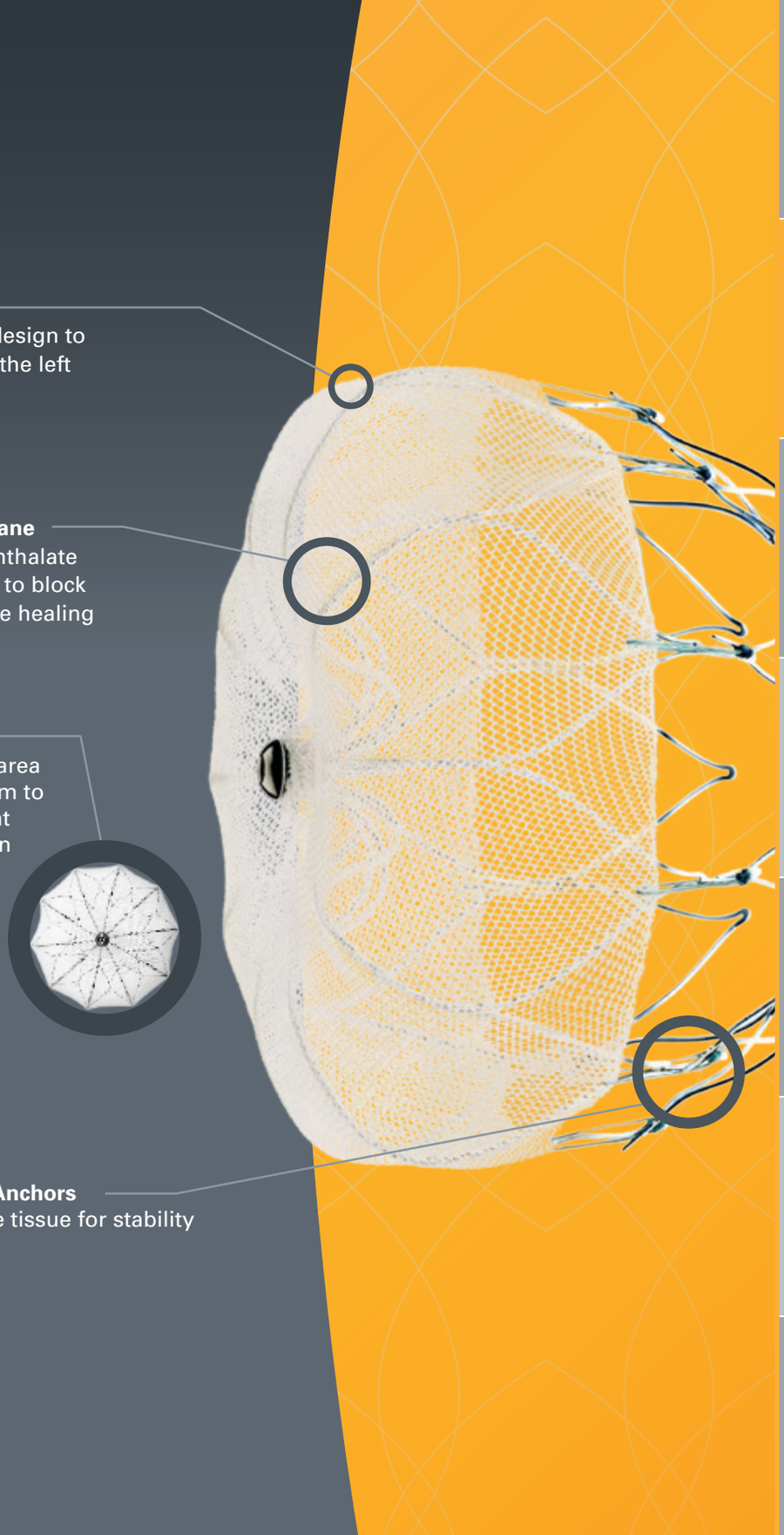
WATCHMAN™ is delivered via a transfemoral approach and is designed to close the left atrial appendage (LAA) to prevent migration of blood clots, thus reducing the risk of stroke and systemic embolism.

Minimally Invasive, Local Solution



21 mm	24 mm	27 mm	30 mm	33 mm

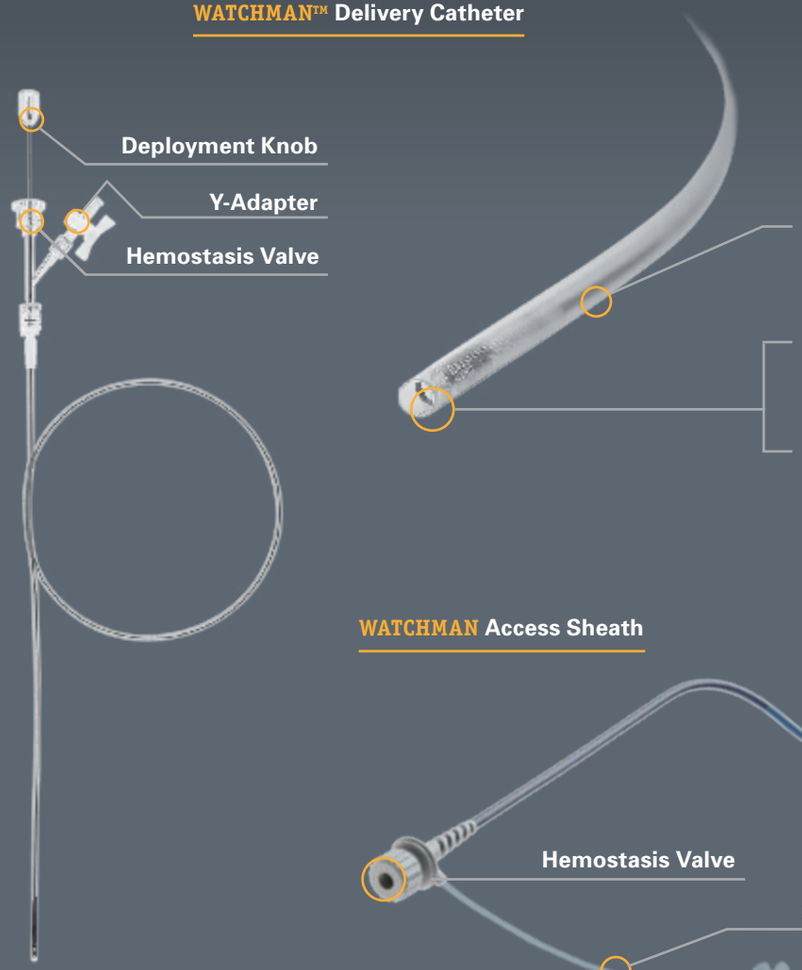
WATCHMAN is engineered to conform to the unique anatomy of the LAA to reduce embolization risk, as well as minimize the surface area facing the left atrium to reduce the risk of post-implant thrombus formation.



Pre-loaded Delivery System

Dual-Catheter Delivery: One Access Sheath Fits All Device Sizes

WATCHMAN™ Delivery Catheter



Pre-Loaded Delivery System
Reduces procedure prep time

Flexible Core Wire
Provides for natural position post-deployment

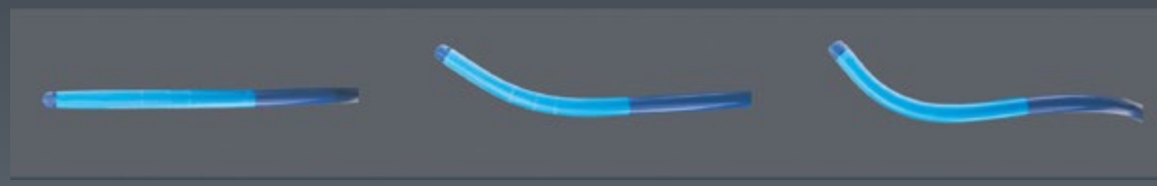
Visualization Aid
Radiopaque marker band guides placement

Tri-Cut Tip
Facilitates recapture and maintains sheath integrity

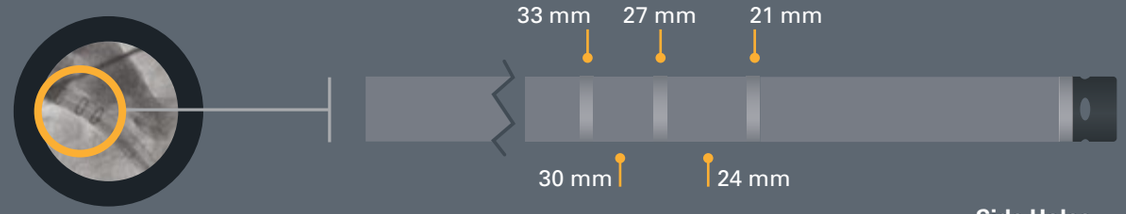
WATCHMAN Access Sheath

Sheath Options Facilitate Access to the LAA

Single Curve | Double Curve | Anterior Curve



12F inner, 14F outer diameter; 75 cm working length



Radiopaque Marker Bands
Help guide precise sheath placement

Side Holes
Allow multidirectional constrast for LAA visualization

One-Step Deployment: Recapturable and Repositionable

Distal Tip Pre-Deployment | Distal Tip Full Deployment

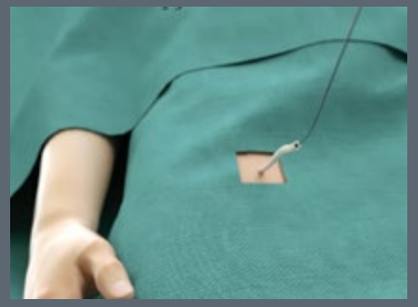
Designed to be repositioned if necessary

WATCHMAN™ is a one-time procedure and the only implant of its kind approved by the FDA.

The Implant Procedure

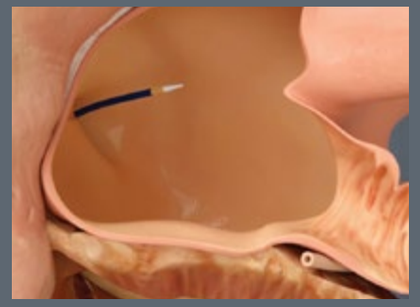
1

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



2

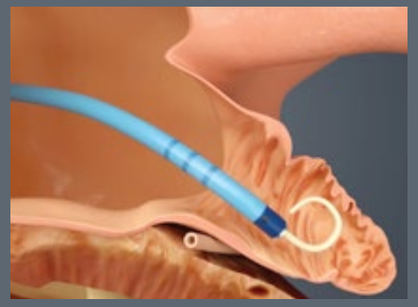
The implant procedure is performed with fluoroscopy and transesophageal echocardiography (TEE). The interatrial septum is crossed using a standard transseptal access system.



60 Minutes
Typical Implant Procedure Time

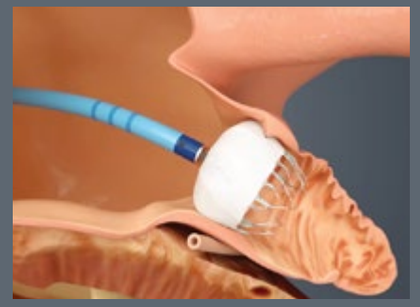
3

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

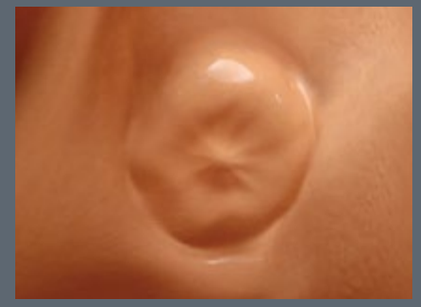
WATCHMAN is then deployed and released in the LAA.



24 Hours
Average Hospital Stay

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. TEE is used to confirm seal.



Post-Procedure

Following the procedure, patients take warfarin and aspirin for 45 (±15) days or until there is adequate seal. After discontinuing warfarin, patients take clopidogrel and an increased dose of aspirin, followed by ongoing aspirin therapy.

Implant		45 Days		6 Months		1 Year
Warfarin + Aspirin	TEE	Plavix + Aspirin	TEE*	Aspirin daily	TEE	Aspirin daily

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

History of Clinical Leadership

WATCHMAN™ is the most-studied LAAC device and the only one proven with long-term data from randomized trials.

2002
PILOT
Endpoints: Feasibility and Safety
Comparison: Non-randomized
n = 66, mean $CHADS_2$ = 1.8, mean age = 68.5

2005
PROTECT AF
Endpoints: Safety and Efficacy
Comparison: Warfarin
n = 707 pts, mean CHA_2DS_2-VASc = 3.5, mean age = 72

2008
CAP Registry
Endpoints: Collect additional safety and efficacy data to be pooled with PROTECT AF
n = 566, mean CHA_2DS_2-VASc = 3.9, mean age = 74

2009
ASAP*
Endpoints: Efficacy
Comparison: $CHADS_2$ score expected stroke rate
n = 150, mean CHA_2DS_2-VASc = 4.4, mean age = 72.5

2010
PREVAIL
Endpoints: Safety and Efficacy
Comparison: Warfarin
n = 407 pts, mean CHA_2DS_2-VASc = 4.0, mean age = 74

2012
CAP2 Registry
Endpoints: Collect additional safety and efficacy data
n = 579, mean CHA_2DS_2-VASc = 4.5, mean age = 75

2013
Real-World Registries in Europe and Asia*
Endpoints: Additional information in a real-world setting

2016
ASAP-TOO
Endpoints: Safety and Efficacy
Comparison: Single Antiplatelet or No Therapy
Ongoing study in subjects with NVAF deemed not suitable for OAC therapy

** 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.*

>2,400
patients studied

~6,000
patient-years of follow-up

>20,000
patients implanted worldwide

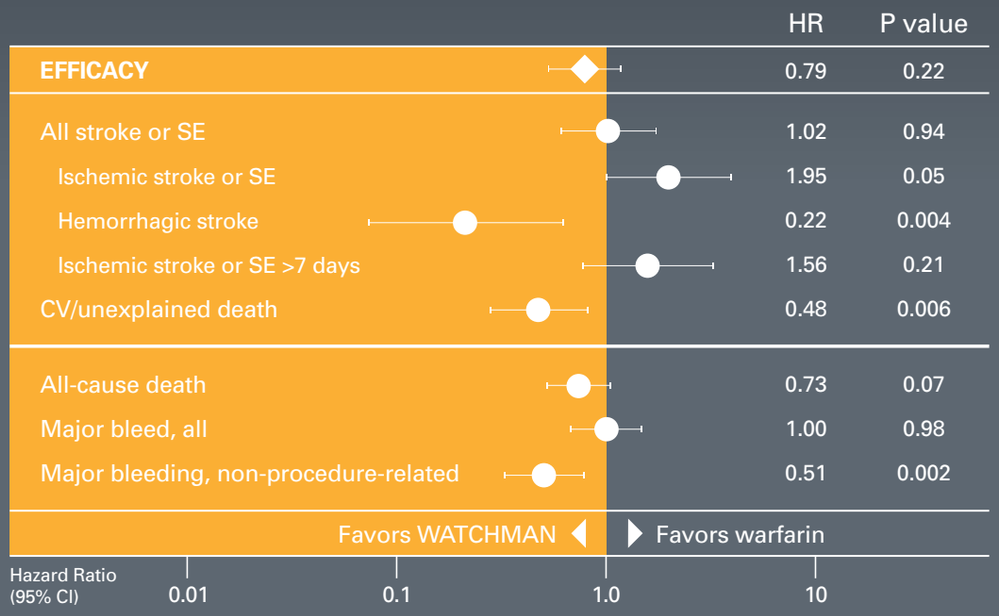
of patients successfully implanted with **WATCHMAN** discontinued warfarin at **45 days**[12]

of patients successfully implanted with **WATCHMAN** are off warfarin at **1 year**[12]

WATCHMAN™: Proven Stroke Risk Reduction Alternative

WATCHMAN Showed Comparable Efficacy to Warfarin[13]

WATCHMAN is a safe alternative to warfarin therapy. It offers comparable stroke risk and enables patients to stop taking warfarin.



Adapted from Holmes 2015. Copyright © 2015, JACC Online by American College of Cardiology Foundation.

REDUCTION:
Cardiovascular/ Unexplained Death[13]

52% (p=0.006)

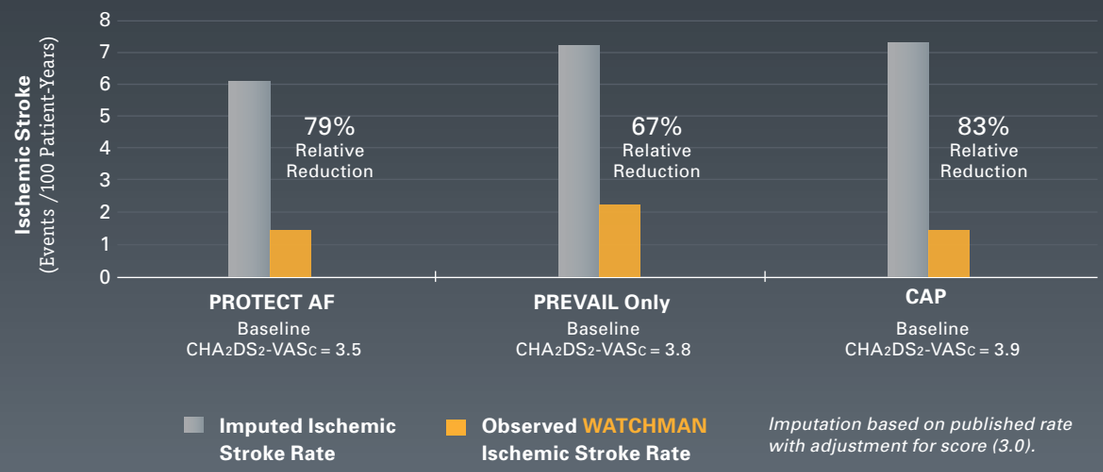
REDUCTION:
Major Bleeding > 6 months post-procedure[14]

72% (p<0.001)

REDUCTION:
Hemorrhagic Stroke[13]

78% (p=0.004)

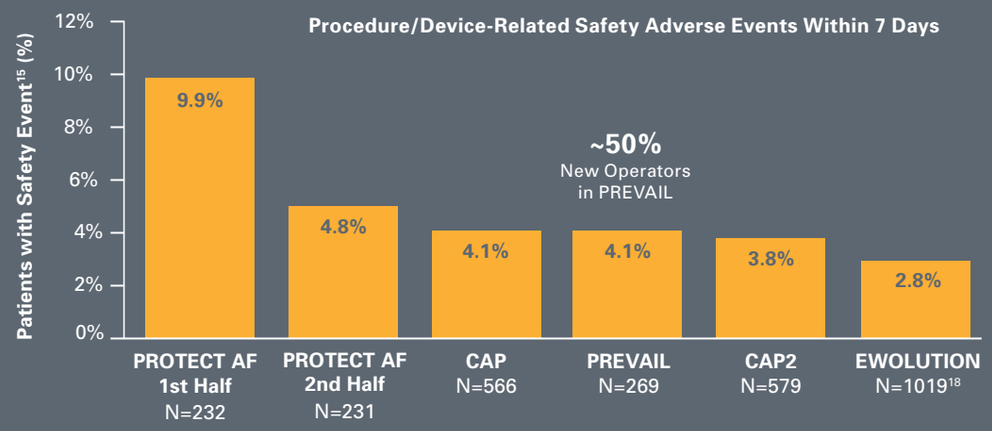
WATCHMAN™ Reduces Ischemic Stroke Over No Therapy[15,16]



Imputation based on published rate with adjustment for score (3.0).

Procedural Safety

WATCHMAN has a 95% implant success rate in the hands of both new and experienced operators.[12] Procedural complication rate similar to other left-sided procedures (e.g., AF ablation).[17]



The EWOLUTION Registry is a European prospective registry which reflects CE Mark indications for use, which differ from the FDA indications for use, but the procedure and device are similar around the world.

Which of Your NVAF Patients Are Right for WATCHMAN™?

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

1. Have an increased risk for stroke and be recommended for anticoagulation (CHA_2DS_2-VASc≥2)[19]*
2. Be suitable for warfarin
3. Have an appropriate reason to seek a non-pharmacologic alternative to warfarin

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

Consider WATCHMAN for NVAF Patients Who Have:

- A history of major bleeding while taking oral anticoagulants (OACs)
- A career or lifestyle that increases the risk of major bleeding (secondary to trauma)
- Prior experience of being inadequately controlled on OACs
  - Inability to maintain stable INR
  - Inability to comply with regular INR monitoring and unavailability of an approved alternative OAC

FRANK, 80, high risk for bleeding

Occupation: 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, 68, 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 novel oral anticoagulants (NOACs).

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

ABIGAIL, 72, 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 descriptions for educational purposes; not real patient cases

ABBREVIATED STATEMENT WATCHMAN™ Left Atrial Appendance Closure Device with Delivery System and WATCHMAN Access System

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.

Download WATCHMAN Resources at: watchmandownloadcenter.com

Educate patients on NVAF stroke risk and the WATCHMAN Implant at WATCHMAN.com

Sourcing

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Meta-Analysis Study Design

The efficacy and safety of WATCHMAN was assessed in both the PROTECT AF (N=707) and PREVAIL (N=407) trials. These trials randomized patients with NVAF who were suitable for long-term warfarin treatment to receive either the WATCHMAN Implant or warfarin.[12]

Both studies used the composite primary endpoint of prevention of 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 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.[12]

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