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THINK OUTSIDE THE PILLBOX

WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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

SEE WHICH OF YOUR NVAF PATIENTS ARE RIGHT FOR WATCHMAN

There are risks associated with the implantation and use of WATCHMAN. Please see pages 9 and 10 for a summary of the safety information and visit watchman.com/hcp to download the full Directions for Use.

HOW THE WATCHMAN IMPLANT WORKS

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

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

The procedure usually lasts about an hour and patients typically stay in the hospital for a day. Following the procedure, patients take aspirin and warfarin for about 45 days or until there is adequate seal. After stopping warfarin, patients take clopidogrel and an increased dose of aspirin for 6 months, followed by ongoing aspirin therapy.

*In a randomized controlled trial, WATCHMAN was successfully implanted in 95% of patients (252/265)[4]**

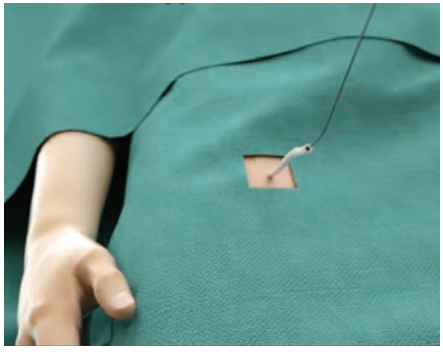
The Implant Procedure

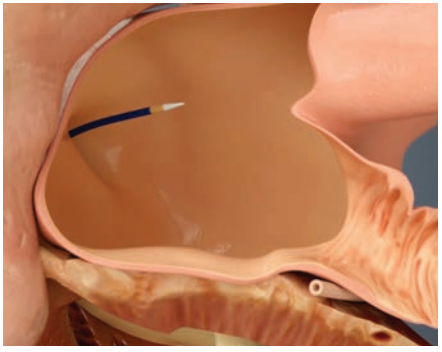
1

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

2

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





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

3

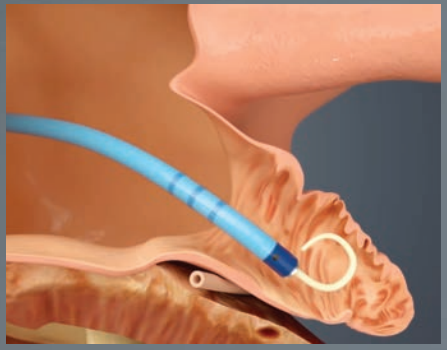
The access sheath is advanced over the guidewire into the left atrium and then navigated into the distal portion of the LAA over a pigtail catheter.

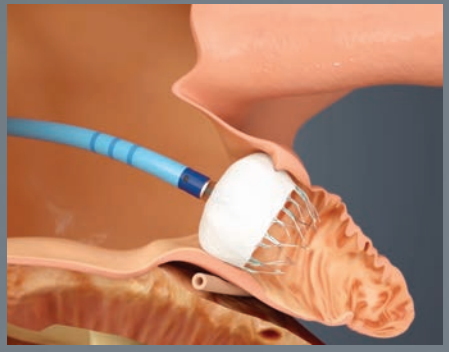
4

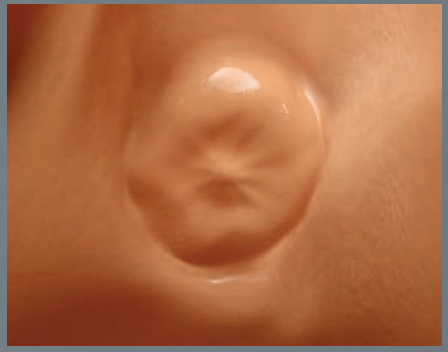
WATCHMAN is then deployed and released in the LAA.

5

Heart tissue grows over the WATCHMAN Implant and the LAA is permanently sealed. Patients remain on warfarin for at least 45 days post-procedure until the device endothelializes. TEE is used to confirm endothelialization.







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)[5]*
2. Be suitable for warfarin
3. Have an appropriate reason to seek a non-pharmacologic alternative to warfarin

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

CONSIDER WATCHMAN FOR YOUR 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 description for educational purposes; not a real patient case.

THE WATCHMAN DIFFERENCE

The WATCHMAN Implant **reduces the risk of stroke as effectively as warfarin** and the long-term risk of bleeding associated with warfarin use.[1,2]

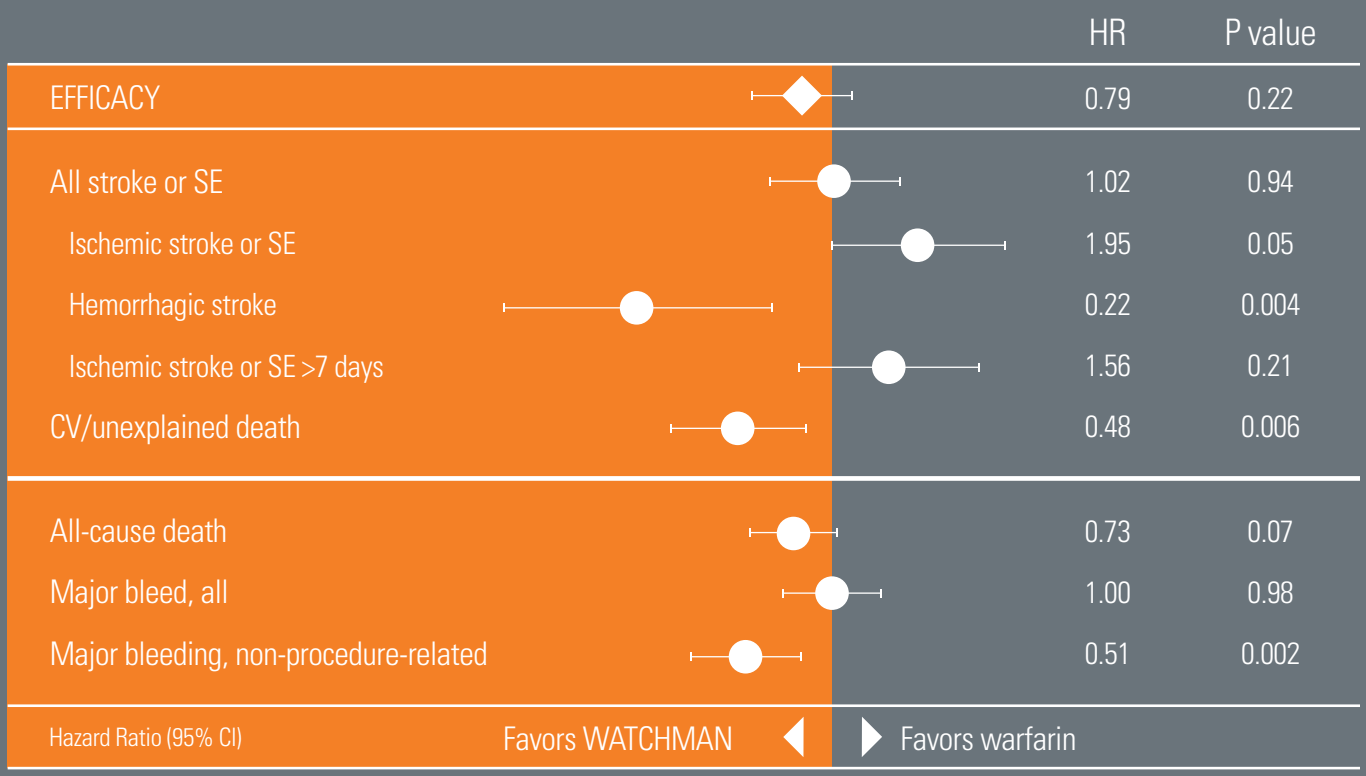
In a patient-level meta-analysis of 2 randomized controlled trials (N=1114), the WATCHMAN Implant was compared with warfarin.[2]

The WATCHMAN Implant

- Significantly reduced major bleeding events >7 days post-procedure[2]
- Significantly reduced hemorrhagic stroke[2]
- Significantly reduced cardiovascular/ unexplained death[2]

See more pivotal trial data at ***watchman.com/hcp***

WATCHMAN showed comparable efficacy to warfarin[2]



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

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.[2]

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.[2]

WATCHMAN REDUCED LONG-TERM BLEEDING EVENTS VS WARFARIN*

The patient-level meta-analysis of the PROTECT-AF and PREVAIL trials found that the longer a patient has a WATCHMAN Implant, the greater the reduction in bleeding events.[1]

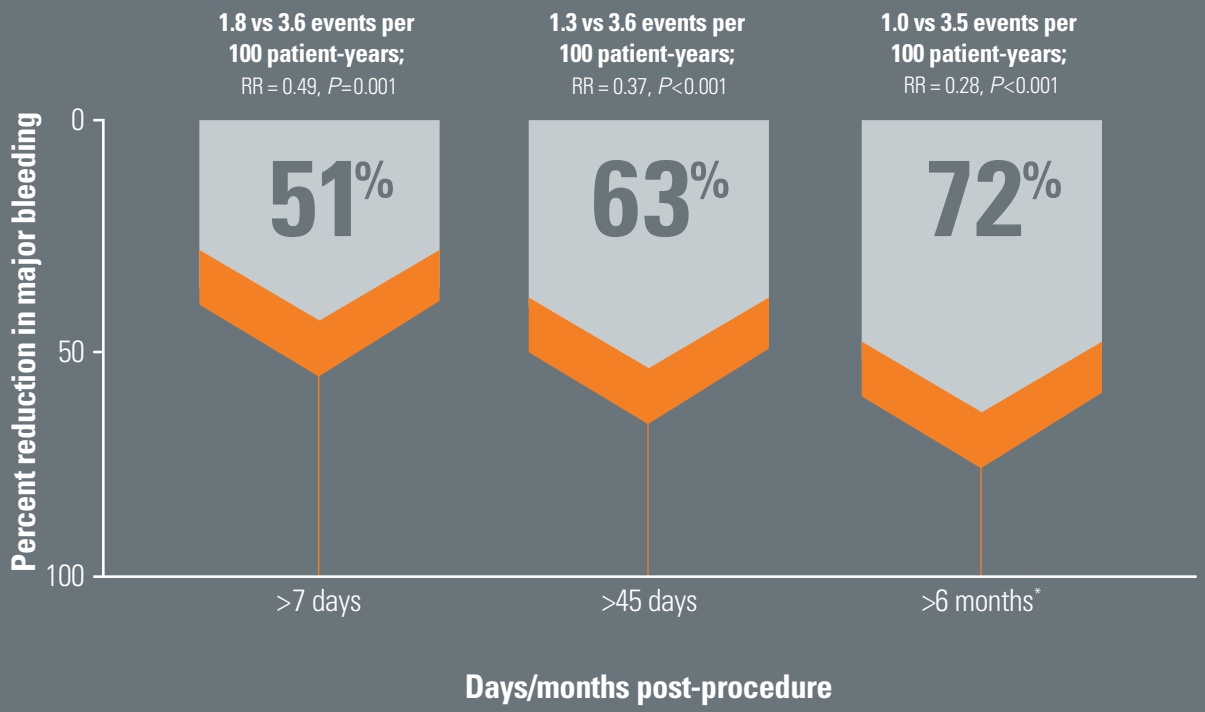
At 6 months post-procedure, WATCHMAN reduced major bleeding events vs warfarin by 72% (1.0 vs 3.5; $P<0.001$).[1]

In the PREVAIL trial:

- 92% of patients were able to stop taking warfarin 45 days after WATCHMAN implantation[4]
- More than 99% of patients were able to stop taking warfarin 1 year after implantation[4]

*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).

The longer a patient has a WATCHMAN Implant, the greater the reduction in bleeding events[1]



STUDY DESIGN

The patient-level meta-analysis of the PROTECT-AF and PREVAIL trials also compared the relative risk of major bleeding with WATCHMAN and long-term warfarin therapy. In both trials, patients who were randomly assigned to WATCHMAN continued to take warfarin and aspirin 45 days after the procedure. Transesophageal echocardiography was then performed to confirm adequate left atrial appendage (LAA) sealing (peridevice leak <5 mm in diameter). If the LAA adequately sealed, patients discontinued warfarin and were treated with aspirin and clopidogrel for 6 months after the procedure, followed by ongoing aspirin therapy. If LAA sealing was inadequate, patients remained on warfarin and aspirin and did not receive clopidogrel. Post-hoc analyses were performed at 3 intervals (7 days, 45 days, and 6 months post-procedure) to assess the procedural complications and relative risk to events like major bleeding.[1]

*The study followed patients for five years.

SAFETY

Indications for use
The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

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

Contraindications
Do not use the WATCHMAN Device if: • Intracardiac thrombus is visualized by echocardiographic imaging. • An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present. • The LAA anatomy will not accommodate a device. See **Table 46** in the DFU. • Any of the customary contraindications for other percutaneous catheterization procedures (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present. • There are contraindications to the use of warfarin, aspirin, or clopidogrel. • The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN Device is contraindicated.

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

Precautions
• The safety and effectiveness (and benefit-risk profile) of the WATCHMAN Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated. • The LAA is a thin-walled structure. • Use caution when accessing the LAA and deploying the device. • Use caution when introducing the WATCHMAN Access System to prevent damage to cardiac structures. • Use caution when introducing the Delivery System to prevent damage to cardiac structures. • To prevent damage to the Delivery Catheter or device, do not allow the WATCHMAN Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath. • If using a power injector, the maximum pressure **should not** exceed 100 psi. • In view of the concerns that were raised by the RE-ALIGN[1] study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.

Adverse Events
Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to: Air embolism, Airway trauma, Allergic reaction to contrast media/medications or device materials, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, AV fistula, Bruising, hematoma or seroma, Cardiac perforation, Chest pain/discomfort, Confusion post procedure, Congestive heart failure, Contrast related nephropathy, Cranial bleed, Decreased hemoglobin, Deep vein thrombosis, Death, Device embolism, Device fracture, Device thrombosis, Edema, Excessive bleeding, Fever, Groin pain, Groin puncture bleed, Hematuria, Hemoptysis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection / pneumonia, Interatrial septum thrombus, Intratracheal bleeding, Major bleeding requiring transfusion, Misplacement of the device / improper seal of the appendage / movement of device from appendage wall, Myocardia erosion, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic, Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasovagal reactions.

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

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

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

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1. Price MJ, Reddy VY, Valderrábano M, et al. Bleeding outcomes after left atrial appendage closure compared with long-term warfarin. *JACC Cardiovasc Interv.* 2015;8(15):1925-1932.
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5. January CT, Wann JS, Alpert JS, et al. 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation. *J Am Coll Cardiol.* 2014;64(21):e1-e76.

WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

AN INNOVATIVE ALTERNATIVE TO OACs FOR YOUR NVAF PATIENTS

1. WATCHMAN reduced the risk of stroke in NVAF patients as effectively as warfarin[2]
2. WATCHMAN *also* reduces the long-term risk of bleeding associated with warfarin[1]
3. WATCHMAN is a one-time procedure and the only implant of its kind approved by the FDA
4. WATCHMAN is covered by Medicare and Medicaid Services for patients meeting coverage criteria

There are risks associated with the implantation and use of WATCHMAN. Please see pages 9 and 10 for a summary of the safety information and visit watchman.com/hcp to download the full Directions for Use.

HAVE A WATCHMAN PATIENT IN MIND?

Refer your patient to one of the more than 150 medical centers across the United States that are certified to implant WATCHMAN.

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

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