WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Boston Scientific
Advancing science for life™

Are your AF patients seeking an alternative to their warfarin medication?

WATCHMAN is a **safe alternative** to long term warfarin therapy which offers **comparable stroke risk reduction** and enables patients to **stop taking warfarin.**

watchmandevice.com

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 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.

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

Find the nearest WATCHMAN implanting center watchmandevice.com

1. Martinez, C., A. Katholing, et al. Thrombosis and Haemostasis 2016; 115(1): 31-39.
2. Holmes, DR et al. JACC 2014; 64(1):1-12.
3. Holmes, DR et al. JACC 2015; 65(24): 2614-2623.

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Despite warfarin and NOAC availability and adoption, the latest data still shows that **50% of patients won't or don't take warfarin long-term**, and **30% won't or don't take a NOAC long-term,** leaving patients at risk of stroke.[1]

Who Is the WATCHMAN Patient?

History of Bleeding

Gwen
Age: 65
Home Health Aide

Non-valvular AF, Hypertension, CHA_2DS_2-VASc: 3

Currently taking 100mg aspirin daily

Gwen experienced gastrointestinal bleeds on warfarin and on apixiban; She has been taking ASA alone since last GI bleed.

High Bleeding Risk

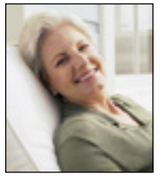
Frank
Age: 80
Involved Grandfather

Non-valvular AF, Congestive Heart Failure, Hypertension, Diabetes, CHA_2DS_2-VASc: 5

Although patient is suitable for warfarin, he is currently taking 15mg rivaroxaban daily

Frank has a history of falls, resulting in broken hip and cerebral contusion. His physician believes his medical conditions place him at high risk of major bleeding secondary to trauma.

Compliance/Adherence



Catherine
Age: 68
Retired Volunteer

Non-valvular AF, Hypertension, Vascular Disease, CHA_2DS_2-VASc: 4

Currently taking 5mg warfarin

Catherine is unable to comply with regular INR monitoring due to her proximity to the clinic and cannot afford NOAC medication.

Active Lifestyle

Andrew
Age: 55
Farmer

Non-valvular AF, Hypertension, Diabetes, CHA_2DS_2-VASc: 2

150mg dabigitran twice daily

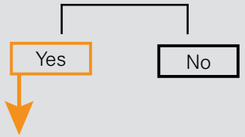
Andrew's physician determined his active lifestyle and desire to ride horses places him at risk of major bleeding secondary to trauma.

Case descriptions for educational purposes; not real patient cases.

The WATCHMAN™ Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation that meet the following criteria:

NVAF Patients

1. Increased Risk for Stroke & Recommended for Anticoagulation (CHA_2DS_2-VASc≥2)



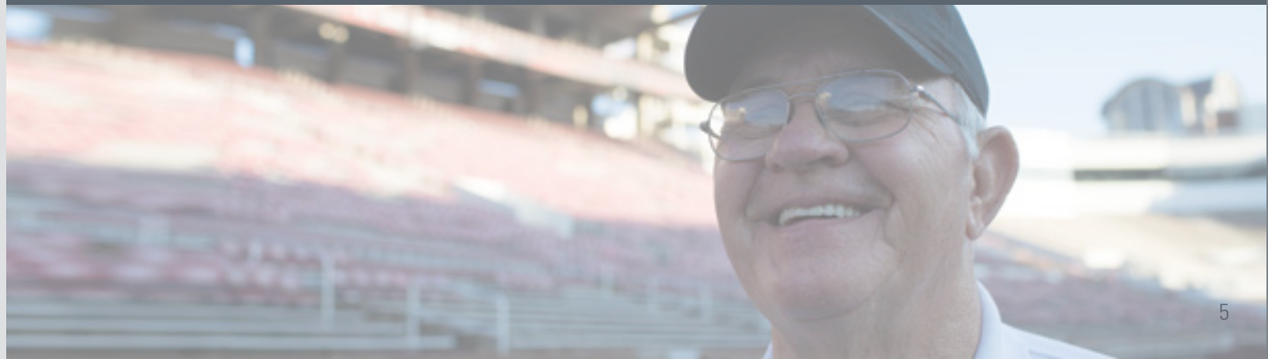
2. Suitable for warfarin

3. Patient Has Appropriate Rationale To Seek a Non-Pharmacologic Alternative to warfarin

Patient May Be a Candidate for the
WATCHMAN LAAC Device

Specific factors may include one or more of the following:

- History of major bleeding while taking anticoagulation therapy
- Patient's prior experience with OAC (if applicable):
  - inability to maintain stable INR
  - inability to comply with regular INR monitoring and unavailability of an approved alternative OAC
- Medical condition, occupation, or lifestyle placing patient at high risk of major bleeding secondary to trauma
- Presence of indication(s) for long-term warfarin use, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, hypercoagulable states, recurrent deep venous thrombosis)



The WATCHMAN™ LAAC Device is the most studied LAAC device in the world and is the **only device with long-term data from both randomized trials and multi-center registries.**

Safe alternative

The WATCHMAN Device is the only device FDA approved to **safely and effectively** reduce stroke risk in patients with non-valvular AF.

95% implant success rate with complication rate that is similar to ablation therapy[2]

Comparable stroke risk reduction

The WATCHMAN Device provided patients with ***comparable overall protection against all-cause stroke and statistically superior reductions in cardiovascular death and major bleeding*** compared to warfarin[3].

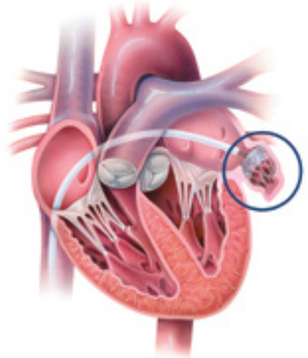
51% reduction in cardiovascular/ unexplained death[3]

49% reduction in non procedure-related major bleeding[3]

Enables Patients to Stop Taking warfarin

92% of patients stopped taking warfarin after 45 days[2]

99%+ discontinued warfarin at one year[2]



Get to know the procedure...

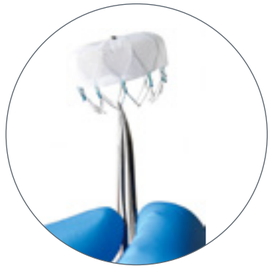
The WATCHMAN implant procedure is typically performed under general anesthesia in a catheterization laboratory setting using transfemoral access and a standard transseptal technique.

The WATCHMAN implant procedure usually lasts about an hour and the patient is typically in the hospital for 24 hours.

Patients remain on warfarin for at least 45 days post-procedure until the device endothelializes. Device endothelialization and the patient's ability to come off warfarin is confirmed using TEE.

By closing off the LAA, the risk of stroke may be reduced and, over time, patients may be able to stop taking anticoagulants.

VISIT the Patient Website
watchmanimplant.com
to access resources to educate your patient on the LAAC procedure



VISIT the HCP Website
watchmandevice.com
to learn more about the WATCHMAN Device and to find the nearest implanting center.