WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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; or
• 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 is a patent foramen ovale repair or closure device is present. See Section 12.0 of the DFU. • The LAA anatomy will not accommodate a device. See Table 46 in the DFU.

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

Possible side effects, including death, may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to:

• Ischemic, stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasovagal reactions.

Adverse Events
Financial all-cause events for patients other than those associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to:

• 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, Gift pain, Groin puncture bleed, Hematuria, Hemorrhagic, Hypersensitivity, Hypotension, Implant wound healing failure (leading to reposition, escape, or retrieval of the WATCHMAN Device), Intracranial hemorrhage, Intracranial septal thrombus, Intracranial hemorrhage, Major bleeding requiring transfusion, Migration of the appliance, Post-operative nausea and vomiting, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic; Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, washout, esophageal trauma, Thrombocytopenia, Transient ischemic attack (TIA), Valve 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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Find the nearest WATCHMAN implanting center watchmandevice.com

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, CHA2DS2-VASC: 3
- Currently taking 100mg aspirin daily

Gwen experienced gastrointestinal bleeds on warfarin and on apixaban; 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, CHA2DS2-VASC: 5

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, CHA2DS2-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, CHA2DS2-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.
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:

1. Increased Risk for Stroke & Recommended for Anticoagulation (CHA₂DS₂-VASc ≥ 2)
   - Yes
   - No

2. Suitable for warfarin
   - Yes
   - No

3. Patient Has Appropriate Rationale To Seek a Non-Pharmacologic Alternative to warfarin
   - Yes
   - No

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.

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.