Introducing **WATCHMAN™** LAAC Device

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.

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**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/adherence). \(^7\) 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

<table>
<thead>
<tr>
<th>Size (mm)</th>
<th>Image</th>
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<td>21</td>
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**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.

- **Intra-LAA Design**: Unique intra-LAA design to avoid contact with the left atrial wall.
- **160 Micron Membrane**: Polyethylene terephthalate (PET) cap designed to block emboli and promote healing.
- **Proximal Face**: Minimizes surface area facing the left atrium to reduce post-implant thrombus formation.
- **Nitinol Frame**: Conforms to the unique anatomy of the LAA to reduce embolization risk.
- **10 Active Fixation Anchors**: Designed to engage tissue for stability.
Pre-loaded Delivery System

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

**WATCHMAN™ Delivery Catheter**
- Deployment Knob
- Y-Adapter
- Hemostasis Valve
- 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**
- Hemostasis Valve
- Sideport

**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

**One-Step Deployment: Recapturable and Repositionable**
- Distal Tip
  - Pre-Deployment
- Distal Tip
  - Full Deployment

Designed to be repositioned if necessary

**Sheath Options**
- 33 mm
- 27 mm
- 21 mm
- 30 mm
- 24 mm

**Side Holes**
Allow multidirectional contrast for LAA visualization

**WATCHMAN IMPACT™ Delivery System**
- **WATCHMAN DEVICE**
- **NEED FOR ALTERNATIVE MEDICATIONS**
- **WATCHMAN CLINICAL LEADERSHIP**
- **STROKE RISK REDUCTION**
- **PATIENT SELECTION**
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.

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. 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.

<table>
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<tr>
<th>Implant</th>
<th>45 Days</th>
<th>6 Months</th>
<th>1 Year</th>
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<tbody>
<tr>
<td>Warfarin + Aspirin</td>
<td>TEE</td>
<td>Plavix + Aspirin</td>
<td>TEE*</td>
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</tbody>
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* If adequate seal is not demonstrated (leak >5 mm) at 45-day follow-up, assess seal with TEE at 6 months.
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 CHADS₂ = 1.8, mean age = 68.5

**2005**
**PROTECT AF**
Endpoints: Safety and Efficacy
Comparison: Warfarin
n = 707 pts, mean CHA₂DS₂-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 CHA₂DS₂-VASc = 3.9, mean age = 74

**2009**
**ASAP**
Endpoints: Efficacy
Comparison: CHADS₂ score expected stroke rate
n = 150, mean CHA₂DS₂-VASc = 4.4, mean age = 72.5

**2010**
**PREVAIL**
Endpoints: Safety and Efficacy
Comparison: Warfarin
n = 407 pts, mean CHA₂DS₂-VASc = 4.0, mean age = 74

**2012**
**CAP2 Registry**
Endpoints: Collect additional safety and efficacy data
n = 379, mean CHA₂DS₂-VASc = 4.3, 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

>2,400 patients studied
~6,000 patient-years of follow-up
>20,000 patients implanted worldwide
92% of patients successfully implanted with WATCHMAN discontinued warfarin at 45 days\(^2\)
99% of patients successfully implanted with WATCHMAN are off warfarin at 1 year\(^2\)

* 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.
**WATCHMAN™: Proven Stroke Risk Reduction Alternative**

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

**Efficacy**

- **All stroke or SE**
  - HR: 0.79, P value: 0.22
- **Ischemic stroke or SE**
  - HR: 1.95, P value: 0.05
- **Hemorrhagic stroke**
  - HR: 0.22, P value: 0.004
- **Ischemic stroke or SE > 7 days**
  - HR: 1.56, P value: 0.21
- **CV/unexplained death**
  - HR: 0.48, P value: 0.006

**Procedural Safety**

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

**Results**

- **Reduction: Cardiovascular/Unexplained Death**
  - 52% (p=0.006)
- **Reduction: Major Bleeding > 6 months post-procedure**
  - 72% (p=0.001)
- **Reduction: Hemorrhagic Stroke**
  - 78% (p=0.004)

**Imputation**

- **WATCHMAN™ Reduces Ischemic Stroke Over No Therapy**
  - Imputation based on published rate with adjustment for score (2.0).

**Procedure/Device-Related Safety Adverse Events Within 7 Days**

- **PROTECT AF**
  - 9.9%
- **PREVAIL Only**
  - 4.8%
- **CAP**
  - 3.8%

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$_2$DS$_2$-VASc$\geq$2)$^{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$_2$DS$_2$-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 cerebrovascular accident. 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?**

**CATHARINE, 68**, struggles with compliance

**Occupation:** Retired, volunteer
**Medical conditions:** NVAF, hypertension, vascular disease
**CHA$_2$DS$_2$-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$_2$DS$_2$-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?**
Indications for Use

The WATCHMAN Device is intended 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 patient facing need repair or closure device is present. • This 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 a TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorders) 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 fluoroscopy and ultrasound guidance (TEE recommended) to 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 cardiovascular 30 days following device implantation. Verify device position post-cardioversion during this period. • Administer appropriate endocarditis prophylaxis for 8 months following device implantation. The decision to continue endocarditis prophylaxis beyond 8 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 study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin for 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, Amputated mean status, Ascites requiring transfusion, Anemia requiring transfusion, Anesthesia risks, Arrhythmias, Atrial septal defect, AV fistula, Bruising, hematoma or seroma, Cardiac perforation, Chest pain/discomfort, Confusion post procedure, Congestive heart failure, Contrast related nephropathy, Cerebral bleed, Decreased hemoglobin, Deep vein thrombosis, Death, Device embolism, Device fracture, Device thrombosis, Edema, Excessive bleeding, Fever, Gastroin test, Gastroin test pain, Heart failure, Hemopneumothorax, Hypotension, Hypoxia, Improper wound handling, Injury to reposition, occlusion, or reposition the device; Injury to pneumonia, Interalarial septum, Infrastrachopharyngeal 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, Right atrial erosion, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic, Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thromboplastinaemia, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasoactive 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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