WATCHMAN™ LEFT ATRIAL APPENDAGE CLOSURE (LAAC) IMPLANT

The Most Studied LAAC Device with Long-Term Clinical Data Demonstrates Safety and Efficacy

A robust body of evidence, including long-term data from **numerous clinical studies (PROTECT AF, CAP Registry, PREVAIL, CAP 2 Registry),** supports the WATCHMAN implant U.S. Food and Drug Administration (FDA) approval and the subsequent Centers for Medicare and Medicaid Services (CMS) national coverage decision for the therapy in the U.S., as well as approval and licensing of the WATCHMAN implant in **75 countries.**

In a real-world, post-approval analysis, the WATCHMAN implant has **demonstrated high rates of procedural success and low rates of complication** for patients with non-valvular atrial fibrillation who are seeking an alternative to long-term warfarin therapy.

WATCHMAN

SAFETY
Procedure is Safe
- **95%** implant success;
- **~4%** complication rates[1]

PRIMARY EFFICACY
All-cause stroke, systemic embolism and cardiovascular/unexplained mortality
Comparable to Warfarin
- **18%** reduction in events (p=0.27)[2] Non-Inferior

WARFARIN CESSATION
Allows 9 out of 10 Patients to Discontinue Warfarin
- **92%** of patients discontinue **after 45-days**
- **99%** of patients discontinue **after 1 year**[3]

STROKE
Comparable to Warfarin with Statistically Significant Reductions in
- **55%** reduction in disabling/fatal stroke (p=0.03)*, largely driven by[2]
- **80%** reduction in hemorrhagic strokes (p=0.002)[2]

MORTALITY
Statistically Significant Reductions in
- **27%** reduction in all-cause mortality (p=0.04)[2]
- **41%** reduction in CV/unexplained mortality (p=0.03)[2]

MAJOR BLEEDING
Statistically Significant Reduction vs. Warfarin Post-Procedure
- **72%** reduction vs. warfarin after 6-months (p=0.001)[4]

1. WATCHMAN FDA Panel Sponsor Presentation. Oct. 2014. • 2. Reddy VY, Doshi SK, Kar S, et al. 5-Year Outcomes After Left Atrial Appendage Closure: From the PREVAIL and PROTECT AF Trials. J. Am Coll Cardiol. 2017; In Press • 3. Holmes, DR et al. JACC 2014; 64(1): 1-12. • 4. Price, M. J., V. Y. Reddy, et al., JACC: CV Interventions 2015; 8(15): 1925-1932
*Two strokes in PREVAIL are excluded because the baseline MRS score was unavailable

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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^{o}, 45^{o}, 90^{o}, 135^{o}).
- 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.