



WATCHMAN™ LAAC Device Hospital Messaging Guide

Congratulations on becoming one of the first institutions in the United States to implant the WATCHMAN Left Atrial Appendage Closure Device! This first-of-its kind implant from Boston Scientific offers indicated patients with non-valvular atrial fibrillation a potentially life-changing treatment option which could free them from the challenges of long-term warfarin therapy.

Product Naming: WATCHMAN™ Left Atrial Appendage Closure Device; WATCHMAN™ LAAC Device; WATCHMAN™ Device

Product Description: A catheter-delivered heart implant intended to reduce the risk of AF-related stroke by closing the left atrial appendage.

Primary Product Message:

- The WATCHMAN™ Left Atrial Appendage Closure Device is a first-of-its-kind, proven alternative to long-term warfarin therapy for stroke risk reduction in patients with non-valvular atrial fibrillation.

Product Category Message:

- The WATCHMAN™ LAAC Device offers a new stroke risk reduction option for patients with non-valvular atrial fibrillation who are seeking an alternative to long-term warfarin therapy.

Therapeutic Benefit Message:

- The WATCHMAN™ LAAC Device offers a potentially life-changing stroke risk treatment option which could free indicated patients from the challenges of long-term warfarin therapy.

Clinical Messages/Proof Points:

- The WATCHMAN™ LAAC Device is the most studied LAAC device, and the only one proven with long-term data from randomized or multi-center registries.
- The robust WATCHMAN™ clinical program consists of five studies, more than 2400 patients and nearly 6000 patient-years of follow-up.
- The WATCHMAN™ LAAC Device demonstrated comparable stroke risk reduction, and statistically superior reductions in hemorrhagic stroke, disabling stroke and cardiovascular death compared to warfarin over long-term follow-up*:
 - 85% in hemorrhagic stroke
 - 63% in disabling stroke
 - 56% in cardiovascular death

*PROTECT AF. Relative risk reductions in hemorrhagic stroke and CV death at 5 yrs, disabling stroke at 4 yrs

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- After 45 days, most patients were able to stop taking warfarin, and over 99% were off of warfarin at 1 year.*
*PREVAIL trial
- Patients treated with the WATCHMAN™ therapy had a 71% relative reduction in major bleeding after six months compared to patients treated with warfarin.*
*After per-protocol cessation of anti-thrombotics by WATCHMAN patients. Source: Price MJ. Avoidance of Major Bleeding with WATCHMAN LAA Closure Compared with Long-Term Anticoagulation: A Pooled analysis of PROTECT AF and PREVAIL trials. TCT 2014

About Atrial Fibrillation and Stroke

Non-valvular atrial fibrillation (AF) is an irregular heartbeat that can lead to blood clots, stroke, heart failure and other heart-related complications. AF is the most common cardiac arrhythmia, currently affecting more than five million Americans.¹ Patients with AF have a five-fold increased risk of stroke due to blood stagnating in the improperly beating atrium and the resulting blood clot formation.² Twenty percent of all strokes occur in patients with AF, and AF-related strokes are more frequently fatal and disabling.^{3,4}

The most common treatment for stroke risk reduction in patients with AF is blood-thinning warfarin therapy. Despite its proven efficacy, long-term warfarin therapy is not well-tolerated by some patients and carries a significant risk for bleeding complications.

1 Colilla et al., Am J Cardiol. 2013; 112:1142-1147

2 Holmes DR, Seminars in Neurology 2010; 30:528-536

3 Hart RG, Halperin JL., Ann Intern Med. 1999; 131:688-695

4 McGrath ER, Neurology 2013; 81:825-832

About the WATCHMAN™ LAAC Device

- The WATCHMAN™ LAAC Device is a catheter-delivered heart implant designed to close the left atrial appendage (LAA) without interfering with the left atrium. The WATCHMAN Device is intended to prevent the migration of blood clots from the LAA, and thus, reduce the risk of stroke and systemic embolism for higher risk patients with non-valvular atrial fibrillation (AF). The LAA is a thin, sack-like appendix attached to the heart and is believed to be the source of the majority of stroke-causing blood clots in people with non-valvular AF.¹ The WATCHMAN Device was approved for sale in Europe in 2005 and some countries in Asia in 2009. It is commercially available in > 55 countries, registered in >70 countries, with > 10,000 implants performed worldwide.

1 Blackshear J. and Odell J., Annals of Thoracic Surgery. 1996; 61:755-759

Additional information can be found at:

<http://www.watchmandevice.com/>



ABBREVIATED STATEMENT

WATCHMAN™ Left Atrial Appendage Closure Device with Delivery System and WATCHMAN Access System

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.

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LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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.

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