Newsletter

Boston Scientific
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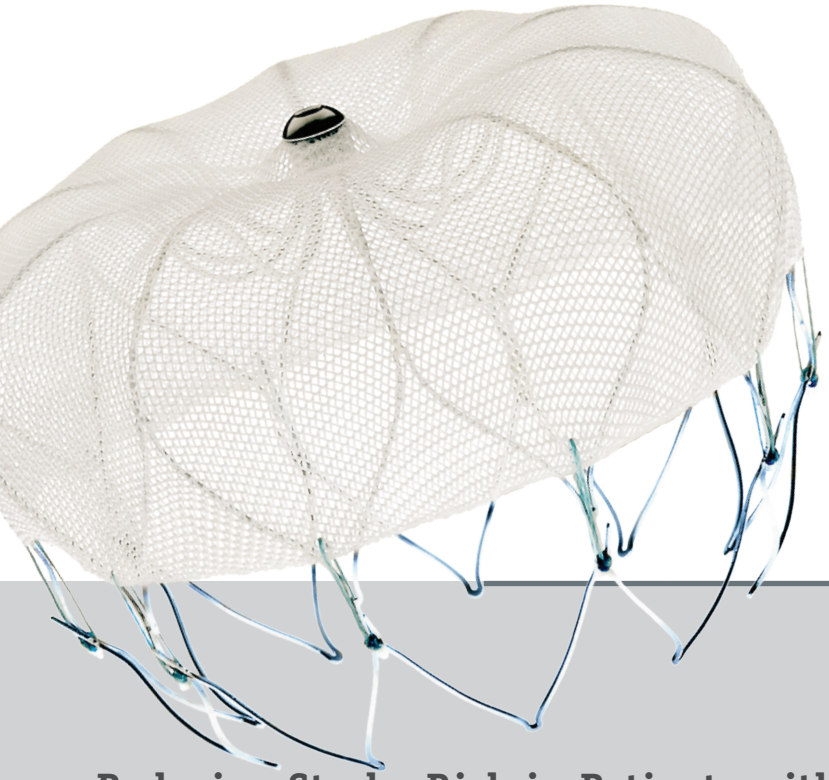
<INSERT DATE>

WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE



Reducing Stroke Risk in Patients with Non-Valvular Atrial Fibrillation

<INSERT FACILITY NAME> Among first hospitals to offer an alternative to long-term warfarin therapy with the newly-approved WATCHMAN LAAC Device

<INSERT FACILITY NAME> is among the first hospitals in <INSERT STATE, REGION OR CITY NAME> to implant the new Boston Scientific WATCHMAN Left Atrial Appendage Closure (LAAC) Device, a first-of-its-kind, proven alternative to long-term warfarin therapy for stroke risk reduction in patients with non-valvular atrial fibrillation (AF).

The WATCHMAN Device is intended for percutaneous, transcatheter closure of the left atrial appendage (LAA). Patients with non-valvular atrial fibrillation who are at increased risk for stroke and systemic embolism, are suitable for warfarin and seek a non-pharmacologic alternative to warfarin may be eligible for a WATCHMAN Device. By closing off the LAA, a thin, sack-like appendix arising from the left side of the heart that is believed to be the source of a majority of stroke-causing blood clots in people with non-valvular AF[1], the risk of stroke may be reduced and, over time, patients may be able to stop taking warfarin.

<INSERT FACILITY NAME> Among first hospitals to offer an alternative to long-term warfarin therapy with the newly-approved WATCHMAN™ LAAC Device

Fulfilling A Need

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.[2] Patients with AF have a five-fold increased risk of stroke due to blood stagnating from the improperly beating atrium and the resulting blood clot formation.[3] Stroke is more severe for patients with AF, as they have a 70% chance of death or permanent disability.[3] 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. Nearly half of patients eligible for warfarin are currently untreated due to tolerance and adherence issues.[4]

Clinical Study Results

The WATCHMAN Device can be implanted safely[5], enables patients to discontinue warfarin[6] and reduces AF stroke risk comparably to warfarin[7]. In addition, the WATCHMAN Device demonstrated statistically superior reductions in hemorrhagic stroke, disabling stroke and cardiovascular death compared to warfarin over long-term follow-up[8]:

- 85% in hemorrhagic stroke
- 63% in disabling stroke
- 56% in cardiovascular death

Implant Procedure

Implanting the WATCHMAN Device is a one-time procedure that usually lasts about an hour and is typically conducted with general anesthesia. The WATCHMAN Device is implanted through a femoral access via a trans-septal approach by using a catheter-based delivery system. The device is designed to permanently close off the LAA, believed to be the source of a majority of stroke-causing blood clots,[1] and thereby avoid the migration of emboli to the brain. Following the procedure, patients typically need to stay in the hospital for 24 hours.

The WATCHMAN LAAC Device is approved in more than 70 countries and over 10,000 implants have been performed worldwide.

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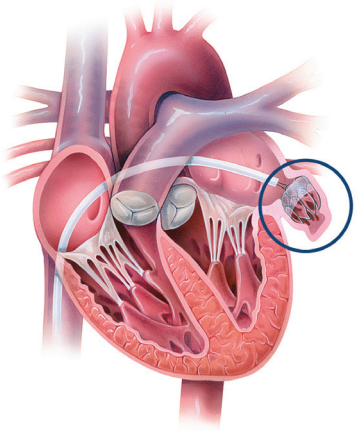

CONTACT US

<INSERT IMPLANTING PHYSICIAN(S) NAME(S), CONTACT INFORMATION & PHOTOGRAPH(S)>

1. Blackshear J. and Odell J., Annals of Thoracic Surgery. 1996;61:755-759
2. Colilla et al., Am J Cardiol. 2013; 112:1142-1147
3. Holmes DR, Seminars in Neurology 2010; 30:528–536
4. Waldo, AL. JACC 2005; 46:1729-1736
5. PROTECT AF, CAP, PREVAIL and CAP2
6. PROTECT AF, CAP, PREVAIL
7. PROTECT AF
8. PROTECT AF. Relative risk reductions in hemorrhagic stroke and CV death at 5 yrs, disabling stroke at 4 yrs

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., 0º, 45º, 90º, 135º).
- 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.

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