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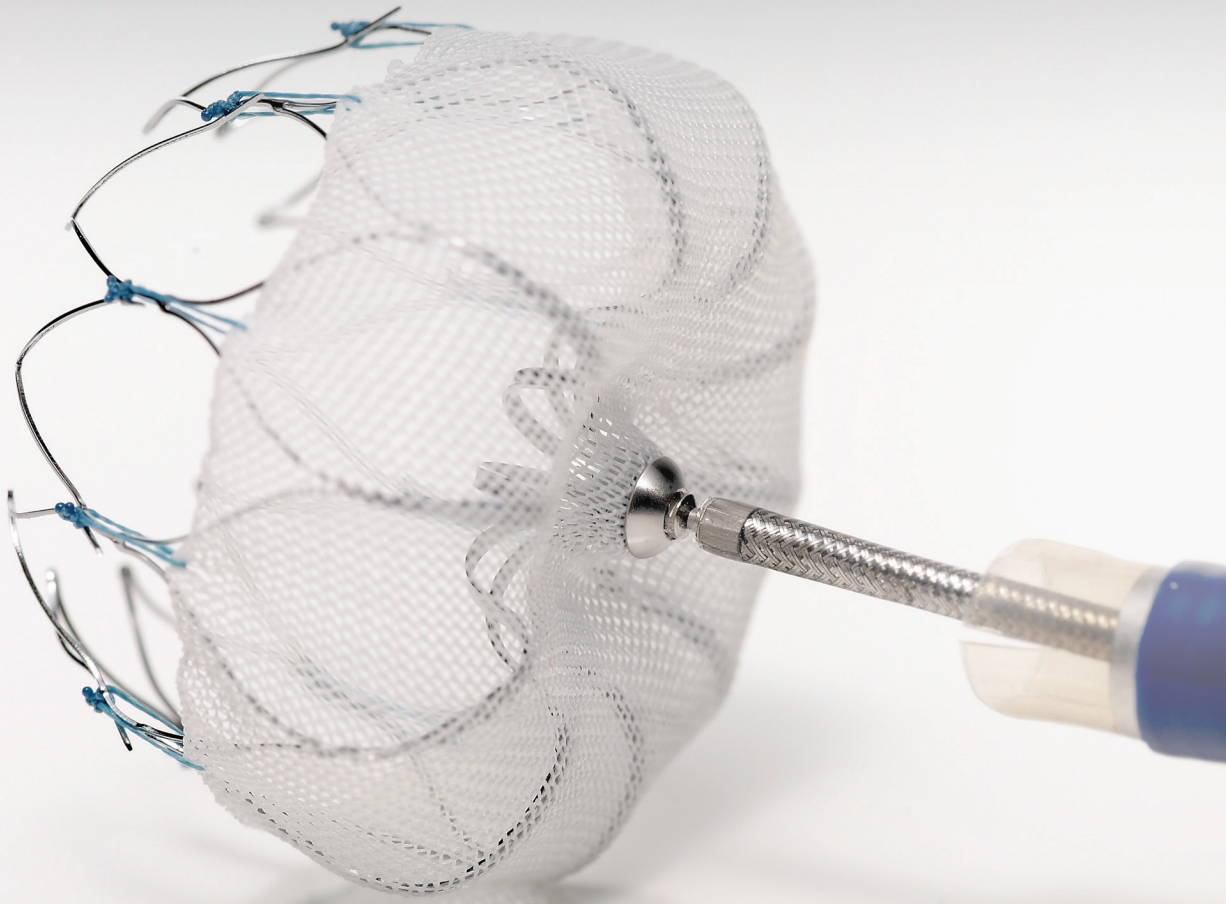
WATCHMAN™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

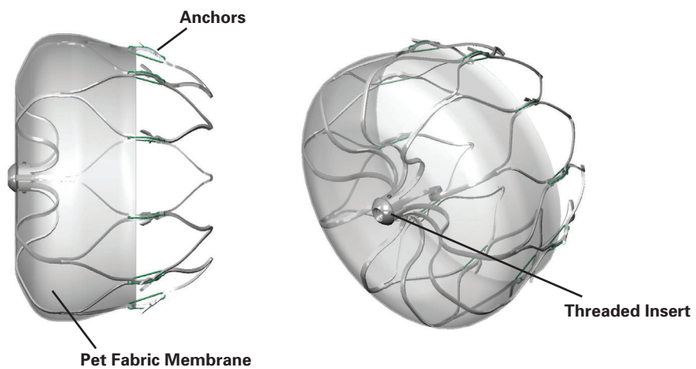


Left Atrial Appendage Closure Technology

The WATCHMAN Left Atrial Appendage Closure (LAAC) Technology consists of the Access System (Access Sheath and Dilator) and Delivery System (Delivery Catheter and WATCHMAN Device). The Access System and Delivery System permit Device placement in the left atrial appendage (LAA) via femoral venous access and inter-atrial septum crossing into the left atrium.

WATCHMAN™ LAAC Device

- The WATCHMAN Device is a self-expanding nitinol structure with a porous covering on the proximal face.
- The Device is constrained within the Delivery System until deployment in the LAA.
- The Device is available in 5 sizes from 21 to 33 mm.
- The WATCHMAN LAAC Device is designed to be permanently implanted at or slightly distal to the ostium of the LAA to trap potential emboli before they exit the LAA.

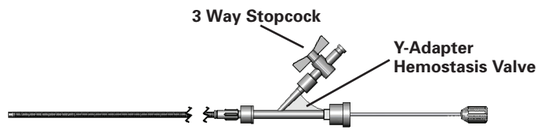


General Specifications and Materials List

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 $CHADS_2$ or CHA_2DS_2-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.
Available device sizes	21 mm, 24 mm, 27 mm, 30 mm, 33 mm
Access system sheath length	75 cm
Access system outer diameter	14 Fr
Delivery system outer diameter	12 Fr
Available access system configurations	Single Curve, Double Curve, Anterior Curve
Device frame material	Nitinol alloy
PET fabric membrane material	Polyethylene Terephthalate (PET) knit fabric, 160 µm mesh
Suture (attaches fabric to frame) material	Polyester surgical suture with a polybutilate coating
Threaded insert material	Titanium
Access and delivery sheath marker band material	Platinum Iridium
Access and delivery sheath tubing material	PEBAX™
Access sheath liner material	Polytetrafluoroethylene (PTFE)
Shelf life	3 years
Sterilization	Ethylene Oxide

WATCHMAN™ LAAC Device

WATCHMAN Delivery System



WATCHMAN Access System

WATCHMAN Product Ordering Information

WATCHMAN Delivery System with Device		
M635WU21060	WATCHMAN LAA Closure US	21 mm
M635WU24060	WATCHMAN LAA Closure US	24 mm
M635WU27060	WATCHMAN LAA Closure US	27 mm
M635WU30060	WATCHMAN LAA Closure US	30 mm
M635WU33060	WATCHMAN LAA Closure US	33 mm

WATCHMAN Access System		
M635TU10060	WATCHMAN Single Curve	14F
M635TU20060	WATCHMAN Double Curve	14F
M635TU40060	WATCHMAN Anterior Curve	14F

WATCHMAN™ LAAC 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;
- 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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SH-230105-AA MAR2015