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.
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 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.

**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 polybutylate 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)

**Sterilization**

- Ethylene Oxide

**Shelf life**

- 3 years

**Sterilization**

- Ethylene Oxide

**WATCHMAN Delivery System**

**WATCHMAN Access System**
**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 CHA2DS2-VASC or CHADS2-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.

**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 fluoroscopic 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.

**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.
- Do not release the WATCHMAN Device from the core wire if the device does not meet all release criteria.

**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, 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, Gastrointestinal bleed, Hematuria, Hemoptysis, Hypoglycemia, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection / pneumonia, Interal atrial septum thrombus, Intracranial bleeding, Major bleeding requiring transfusion, Misplacement of the device / improper seal of the appendage / movement of device from appendage wall, Myocardial infarction, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pneumonia, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic, Stroke – Hemorrhagic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thromboembolism, 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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