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.
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)
Shelf life: 3 years
Sterilization: Ethylene Oxide

WATCHMAN Delivery System with Device

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
<th>Size</th>
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<tbody>
<tr>
<td>M635WU21060</td>
<td>WATCHMAN LAA Closure US 21 mm</td>
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<tr>
<td>M635WU24060</td>
<td>WATCHMAN LAA Closure US 24 mm</td>
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<tr>
<td>M635WU27060</td>
<td>WATCHMAN LAA Closure US 27 mm</td>
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<tr>
<td>M635WU30060</td>
<td>WATCHMAN LAA Closure US 30 mm</td>
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<tr>
<td>M635WU33060</td>
<td>WATCHMAN LAA Closure US 33 mm</td>
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WATCHMAN Access System

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Description</th>
<th>Size</th>
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<tbody>
<tr>
<td>M635TU10060</td>
<td>WATCHMAN Single Curve 14F</td>
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<tr>
<td>M635TU30060</td>
<td>WATCHMAN Double Curve 14F</td>
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<tr>
<td>M635TU40060</td>
<td>WATCHMAN Anterior Curve 14F</td>
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**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.

**Contraindications**
Do not use the WATCHMAN Device if:
- Intra-cardiac thrombus is visualized by echocardiographic imaging.
- 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**
- The WATCHMAN Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.
- 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.
- In view of the concerns that were raised by the RE-ALIGN 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.

**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.
- Use caution when introducing the Delivery System to prevent damage to cardiac structures.
- If a power injector is used, the maximum pressure should not exceed 100 psi.
- Do not use the WATCHMAN Device if:
  - 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.
  - Are deemed by their physicians to be suitable for warfarin; and
  - Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy.

**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, Anemia, Aortic dissection, Atrial septal defect, AV fistula, Bruising, Stroke – Hemorrhagic, Systemic embolism, TEE complications (thrombus, bleeding, subacute thrombus), Thrombocytopenia, Thrombus, Transient ischemic attack (TIA), Valvular damage, Vasovagal reactions.

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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.