**WATCHMAN FLX DEVICE**

Full recapture, reposition and redeploy capabilities for precise placement

77% reduced metal exposure

80% more contact points for sealing

Dual-row precision anchors designed to provide optimal device engagement with LAA tissue for long-term stability

WATCHMAN FLX ball – fully rounded designed to safely advance and maneuver within the LAA

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**BUILT ON THE MOST STUDIED AND IMPLANTED LAAC DEVICE IN THE WORLD — WATCHMAN FLX IS DESIGNED TO ADVANCE PROCEDURAL PERFORMANCE AND SAFETY WHILE EXPANDING THE TREATABLE PATIENT POPULATION.**
ADVANCE SAFETY
ADVANCE PROCEDURAL PERFORMANCE
EXPAND THE TREATABLE PATIENT POPULATION
The Pinnacle FLX clinical trial demonstrated the procedural safety and closure efficacy of the WATCHMAN FLX device.

### Primary Safety Endpoint
- **Ischemic Stroke**: 0.5%
- **All-cause Death**: 0%
- **Pericardial Fluid or Requiring Open Cardiac Surgery**: 0%
- **Device Embolization**: 0%

**Primary Effectiveness Endpoint**
- **LAA Closure at 12 months**: 100%
- **Device Success Rate**: >98%

### Procedure Performance
- **Implant Success**: 98.8% (95% CI: 95.4–99.9%
- **Study/OAC**
  - **PINNACLE FLX/NOAC**: 96.2%
  - **PREVAIL/warfarin**: 92%
  - **CAP2/warfarin**: 93%

### Greater Device Sizing Overlap
- **Ostium Diameter (mm)**
  - **20 mm**: 20 mm
  - **24 mm**: 24 mm
  - **27 mm**: 27 mm
  - **31 mm**: 31 mm

**WATCHMAN FLX is designed to treat the widest range of patient anatomies, with five device sizes treating ostia from 14mm to 31.5mm.**
WATCHMAN FLX SYSTEM

WATCHMAN FLX Device
Nitinol frame with Polyethylene Terephthalate (PET) fabric cover

WATCHMAN FLX Delivery Catheter
SHEATH MATERIAL
Braided Pebax® with PTFE liner and platinum/iridium marker band

WATCHMAN TruSeal Access System
HUB MATERIAL
Pebax® with polycarbonate
SHEATH MATERIAL
Pebax® with PTFE liner and platinum/iridium marker band
DILATOR
HDPE/LDPE high density polyethylene/low density polyethylene (50:50 blend)

WATCHMAN FLX LAAC DEVICE ORDERING INFORMATION

<table>
<thead>
<tr>
<th>Reference Catalog No.</th>
<th>Description</th>
<th>Size</th>
<th>Order Number (GTIN)</th>
<th>ID</th>
<th>OD</th>
<th>Barcode</th>
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<tr>
<td>M635WUS0200</td>
<td>WATCHMAN FLX LAAC Device and Delivery Catheter</td>
<td>20 mm</td>
<td>08714729860488</td>
<td>12F</td>
<td>4.0 mm</td>
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<tr>
<td>M635WUS0240</td>
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<td>08714729860495</td>
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<tr>
<td>M635WUS0310</td>
<td>WATCHMAN FLX LAAC Device and Delivery Catheter</td>
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<td>08714729860518</td>
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<td>M635WUS0350</td>
<td>WATCHMAN FLX LAAC Device and Delivery Catheter</td>
<td>35 mm</td>
<td>08714729860471</td>
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WATCHMAN TRUSEAL ACCESS SYSTEM ORDERING INFORMATION

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<th>Reference Catalog No.</th>
<th>Description</th>
<th>Curve</th>
<th>Order Number (GTIN)</th>
<th>ID</th>
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<tr>
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<td>WATCHMAN TruSeal Access System</td>
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<td>08714729965701</td>
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<td>M635TU70020</td>
<td>WATCHMAN TruSeal Access System</td>
<td>Double</td>
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<td>M635TU70040</td>
<td>WATCHMAN TruSeal Access System</td>
<td>Anterior</td>
<td>08714729965725</td>
<td>12F</td>
<td>4.2 mm</td>
<td></td>
</tr>
</tbody>
</table>

Please contact your Boston Scientific sales representative for ordering information.

WATCHMAN FLX is preloaded into the delivery catheter thus reducing the preparation time.
INTENDED USE/INDICATIONS FOR USE

Are at increased risk for stroke and systemic embolism who:

• Suitability for percutaneous, transseptal procedures and who have completed the WATCHMAN FLX Physician Training program.

• The LAA anatomy will not accommodate a Closure Device (see Table 45).

• Intracardiac thrombus is present.

• The presence of indication(s) for long-term anticoagulation therapy, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, prostatic hypertrophy, stable, recurrent deep-vein thrombosis).

• Any of the customary contraindications for percutaneous cardiac 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.

• The patient has a known hypersensitivity to any component of the device material or the individual components (see Device Description section of the eIFU) such that the use of the WATCHMAN FLX Device is contraindicated.

• Are at increased risk for stroke or systemic embolism (e.g. due to atrial septal defect or patent foramen ovale) or evidence of device embolism, Airway trauma, Allergic reaction to the contrast media or closure device material, or medications, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Aneurysm, Anisocoria, encephalopathy, Arthrits, Atherosclerotic disease, Aspiration pneumonitis, Aspiration, Attack (TIA), Valvular or vascular damage, Bahner reaction.

• Potential for Closure Device embolization exists with the WATCHMAN FLX Device implantation; verify Closure Device position after cardioversion during this period.

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• Use caution when introducing a WATCHMAN FLX Access System into the Access Sheath.

• The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX 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, repositioning, and removing the Closure Device.

• Use caution when introducing a WATCHMAN Access System to prevent damage to cardiac structures.

• Use caution when introducing the WATCHMAN FLX Device and implantation procedure; verify Closure Device position before cardioversion during this period.

• Willingness to comply with the recommended post-WATCHMAN FLX Device implantation pharmaco- logical regimen (see Post-Procedural Information for oral anticoagulation therapy, aspirin, or P2Y12 inhibitor. Rx Statement: product, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, prostatic hypertrophy, stable, recurrent deep-vein thrombosis).

• To prevent damage to the Delivery Catheter during, and repositioning the Closure Device.

• Use caution during introducing a WATCHMAN FLX Access System into the Access Sheath. And the continued risk of partial or complete thrombus.

• The safety and effectiveness of the WATCHMAN FLX Device compared to anticoagulation therapy should be followed. See Post-Procedural Information for oral anticoagulation therapy, aspirin, or P2Y12 inhibitor. Rx Statement: product, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, prostatic hypertrophy, stable, recurrent deep-vein thrombosis).

• The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.

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