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.
77% reduced metal exposure

80% more contact points for sealing

**Full recapture,** reposition and redeploy capabilities for precise placement

**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

**WATCHMAN FLX DEVICE**
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**

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischemic Stroke</td>
<td>0.5%</td>
</tr>
<tr>
<td>All-cause Death</td>
<td>0%</td>
</tr>
<tr>
<td>Pericardial Effusions Requiring Open Cardiac Surgery</td>
<td>0%</td>
</tr>
<tr>
<td>Device Embolization</td>
<td>0%</td>
</tr>
</tbody>
</table>

*All-cause death, ischemic stroke, systemic embolism, or device- or procedure-related adverse events requiring surgery or major endovascular intervention within 7 days following the procedure or by hospital discharge, whichever is later.

*Based on the combined rate observed in PREVAIL\(^1\) and CAP2\(^2\), plus a clinically acceptable delta.

\(^1\) Holmes, DR., et al. (2014). J Am Coll Cardiol 64(1): 1-12

\(^2\) Holmes, DR., et al. JACC 2019
Primary Effectiveness Endpoint

100% of Subjects Demonstrated Effective LAA Closure at 12 Months*

* LAA closure at 12 months is defined as any peri-device flow with jet size ≤5mm per core laboratory-assessed TEE
** Performance goal based on the rates observed in PREVAIL¹ and CAP², minus a clinically relevant delta

Procedure Performance

Implant Success

99%

Implant success defined as successful delivery and release of a WATCHMAN FLX device into the LAA

NOAC Discontinuation

96.2% of Patients Discontinued NOAC at 45-day Follow-up

<table>
<thead>
<tr>
<th>Study/OAC</th>
<th>% Discontinuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PINNACLE FLX/NOAC</td>
<td>96.2%</td>
</tr>
<tr>
<td>PREVAIL/warfarin¹</td>
<td>92%</td>
</tr>
<tr>
<td>CAP2/warfarin²</td>
<td>93%</td>
</tr>
</tbody>
</table>

² Holmes DR et al, JACC 2019
EXPAND THE TREATABLE PATIENT POPULATION

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

*Devices not shown to scale

Greater Device Sizing Overlap

10-30% Compression
**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 FXD Curve Access System**
**HUB MATERIAL**
Pebax® with polycarbonate cap
**SHEATH MATERIAL**
Braided Pebax® with PTFE liner and platinum/iridium marker band
**DILATOR**
High density polyethylene (HDPE)/low density polyethylene (LDPE) 50:50 blend
# ORDERING INFORMATION

## 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>
</tr>
</thead>
<tbody>
<tr>
<td>M635WU50200</td>
<td>WATCHMAN FLX LAAC Device and Delivery Catheter</td>
<td>20 mm</td>
<td>08714729860488</td>
<td>–</td>
<td>12F</td>
<td></td>
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<tr>
<td>M635WU50240</td>
<td>WATCHMAN FLX LAAC Device and Delivery Catheter</td>
<td>24 mm</td>
<td>08714729860495</td>
<td>–</td>
<td>12F</td>
<td></td>
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<tr>
<td>M635WU50270</td>
<td>WATCHMAN FLX LAAC Device and Delivery Catheter</td>
<td>27 mm</td>
<td>08714729860501</td>
<td>–</td>
<td>12F</td>
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<tr>
<td>M635WU50310</td>
<td>WATCHMAN FLX LAAC Device and Delivery Catheter</td>
<td>31 mm</td>
<td>08714729860518</td>
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<tr>
<td>M635WU50350</td>
<td>WATCHMAN FLX LAAC Device and Delivery Catheter</td>
<td>35 mm</td>
<td>08714729860471</td>
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<td>12F</td>
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</tr>
</tbody>
</table>

## WATCHMAN FXD CURVE ACCESS SYSTEM ORDERING INFORMATION

<table>
<thead>
<tr>
<th>Reference Catalog No.</th>
<th>Description</th>
<th>Curve</th>
<th>Order Number (GTIN)</th>
<th>ID</th>
<th>OD</th>
<th>Barcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>M635TU800010</td>
<td>WATCHMAN FXD Access System SGL US</td>
<td>Single</td>
<td>00191506013806</td>
<td>12F</td>
<td>15F</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(4.2 mm)</td>
<td>(5.0 mm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>M635TU800020</td>
<td>WATCHMAN FXD Access System DBL US</td>
<td>Double</td>
<td>00191506013813</td>
<td>12F</td>
<td>15F</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(4.2 mm)</td>
<td>(5.0 mm)</td>
<td></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.
WATCHMAN FXD Curve™ Access System — eIFU 51254624

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 “Instructions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

INTENDED USE/INDICATIONS FOR USE
The WATCHMAN FXD Curve Access System is intended to provide vascular and transseptal access for WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System.

NOTE: Refer to WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System IFU for further information.

CONTRAINDICATIONS
Do not use the WATCHMAN FXD Curve Access System if:
• Intracardiac thrombus is present.
• An atrial septal defect repair or closure device is present.
• A patent foramen ovale repair or closure device is present.

Any of the customary contraindications for other percutaneous catheterization procedure (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 anticoagulation therapy, aspirin, or P2Y_{12} inhibitor.

For additional contraindications associated with the Closure Device, refer to WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System IFU.

WARNINGS
Use of the WATCHMAN FXD Curve Access System for implantation of the WATCHMAN FLX Closure Device should only be performed by interventional cardiologists and/or electrophysiologists who are educated in percutaneous and transseptal procedures and who have completed the WATCHMAN FLX Physician Training program.

• Careful consideration should be given to use of the Access Sheath in pregnant and/or breastfeeding women due to the risk of significant exposure to X-rays and the use of anticoagulation medication.

For additional warnings associated with the Closure Device, refer to WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System IFU.

PRECAUTIONS
The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying, recapturing, and repositioning the Closure Device.

• Use caution when introducing any WATCHMAN FXD Curve Access System to prevent damage to cardiac structures.
• Use caution when introducing Delivery System to prevent damage to cardiac structures.
• To prevent damage to the Delivery Catheter or Closure Device, do not allow the WATCHMAN FLX Closure Device to protrude beyond the Delivery Catheter when inserting the Delivery System into an Access Sheath.

BRIEF SUMMARY
If using a power injector, the maximum pressure should not exceed 100 psi.

For additional precautions associated with the Closure Device, refer to WATCHMAN FLX Left Atrial Appendage Closure Device with Delivery System IFU.

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, anesthetic, WATCHMAN FLX Implant material, or medications, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, Bruising, hematoma, or seroma near the catheter insertion site, Cardiac perforation, Chest pain/discomfort, Confusion post-procedure, Congestive heart failure, Contrast-related nephropathy, Cranial bleed, Death, Decreased hemoglobin, Deep vein thrombosis, Device embolism, Device fracture, Device thrombosis, Edema, Embolism, Excessive bleeding, Fever, Fistula, Groin pain, Groin puncture bleed, Hematuria, Hemoptyisis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection/pneumonia, Interatrial septum thrombus, Intra-tracheal bleeding, Major bleeding requiring transfusion, Misplacement of the device/improper seal of the appendage/movement of device from appendage wall, Myocardial erosion, Myocardial infarction, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Radiation injury, Renal failure, Respiratory insufficiency/failure, Stroke – Hemorrhagic, Stroke – Ischemic, Surgical removal of the device, TEE complications (e.g., throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular or vascular damage, Vasovagal reactions.

There may be other potential adverse events that are unforeseen at this time.

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