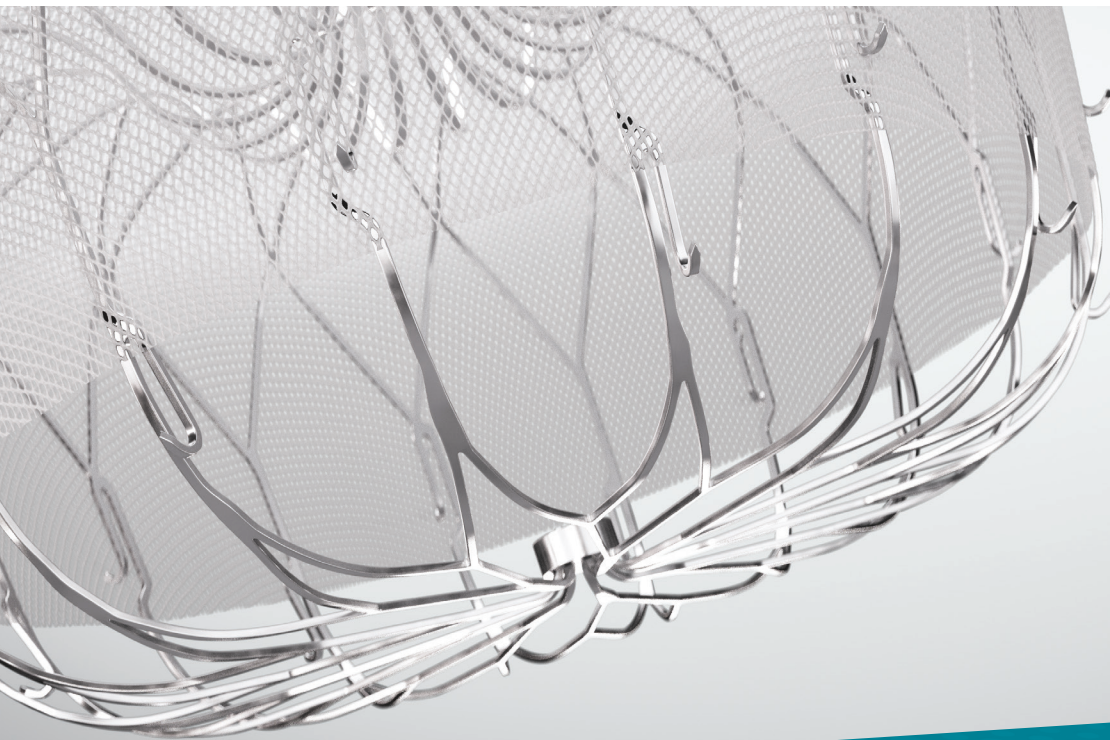


**WATCHMAN FLX™**  
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

**Boston  
Scientific**  
Advancing science for life™



—  
THE LEADER IN LAAC THERAPY

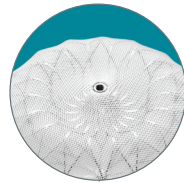
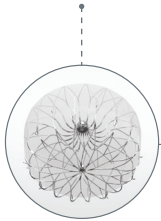


—  
BUILT ON THE MOST STUDIED AND IMPLANTED LAAC  
DEVICE IN THE WORLD — WATCHMAN FLX IS DESIGNED  
TO **ADVANCE PROCEDURAL PERFORMANCE** AND **SAFETY**  
WHILE **EXPANDING THE TREATABLE PATIENT POPULATION.**

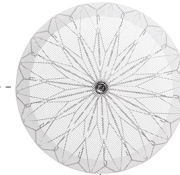
# WATCHMAN FLX DEVICE

---

**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



—  
ADVANCE SAFETY

ADVANCE PROCEDURAL PERFORMANCE

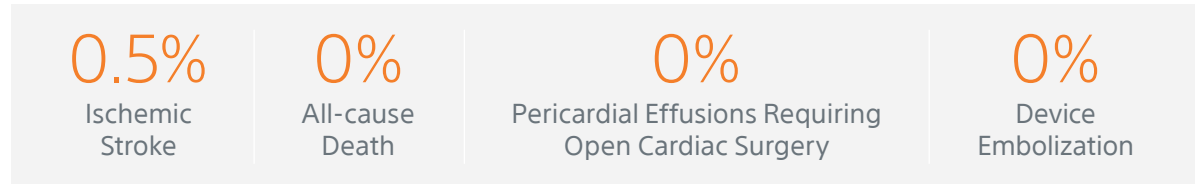
EXPAND THE TREATABLE PATIENT POPULATION

# ADVANCE SAFETY

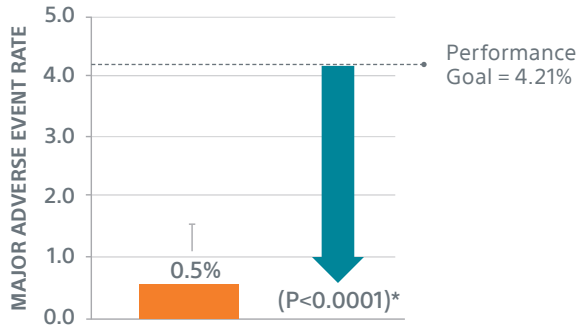


The PINNACLE FLX clinical trial demonstrated the procedural safety and closure efficacy of the WATCHMAN FLX device.

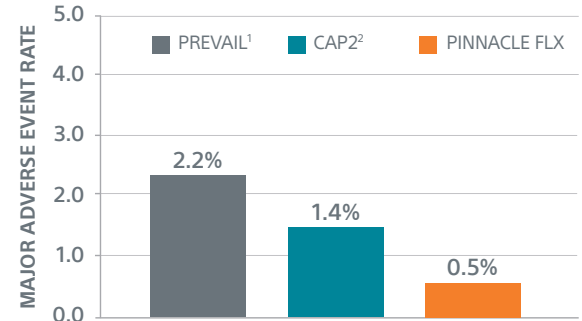
## Primary Safety Endpoint\*



\*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<sup>1</sup> and CAP2<sup>2</sup>, plus a clinically acceptable delta.



<sup>1</sup> Holmes, DR., et al. (2014). J Am Coll Cardiol 64(1): 1-12

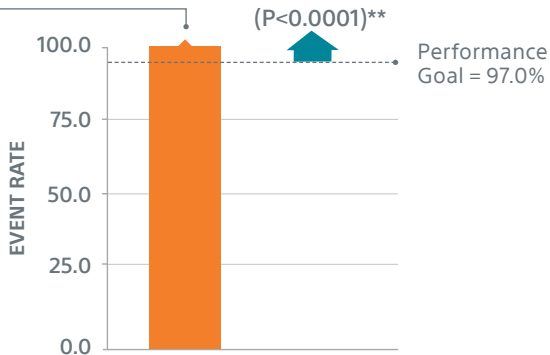
<sup>2</sup> Holmes, DR., et al. JACC 2019

# ADVANCE PROCEDURAL PERFORMANCE

## 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  $\leq 5$ mm per core laboratory-assessed TEE

\*\*Performance goal based on the rates observed in PREVAIL<sup>1</sup> and CAP2<sup>2</sup>, minus a clinically relevant delta

## Procedure Performance

### Procedure/Implant Success

99% Implant Success

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

Study/OAC	% Discontinuation
PINNACLE FLX/NOAC	96.2%
PREVAIL/warfarin <sup>1</sup>	92%
CAP2/warfarin <sup>2</sup>	93%

<sup>1</sup> Holmes, DR., et al. (2014). J Am Coll Cardiol 64(1): 1-12

<sup>2</sup> Holmes DR et al, JACC 2019

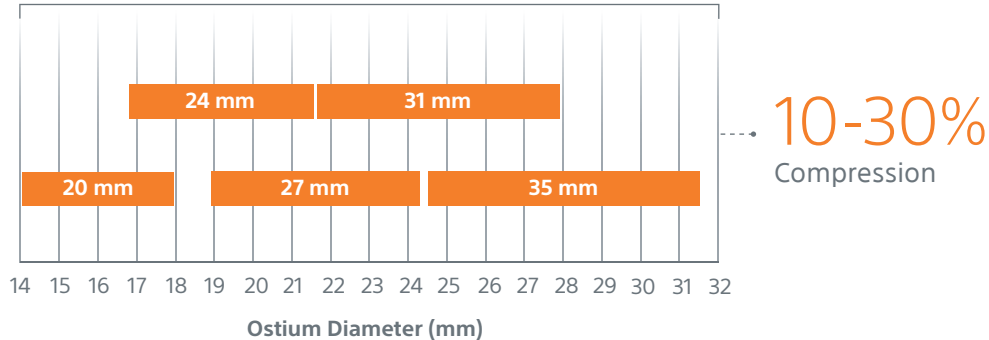
# EXPAND THE TREATABLE PATIENT POPULATION

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





# WATCHMAN FLX SYSTEM

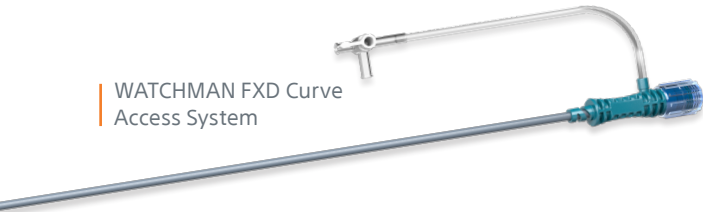
WATCHMAN FLX  
Device



Delivery  
Catheter



WATCHMAN FXD Curve  
Access 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

Reference Catalog No.	Description	Size	Order Number (GTIN)	ID	OD	Barcode
M635WU50200	WATCHMAN FLX LAAC Device and Delivery Catheter	20 mm	08714729860488	-	12F (4.0 mm)	
M635WU50240	WATCHMAN FLX LAAC Device and Delivery Catheter	24 mm	08714729860495	-	12F (4.0 mm)	
M635WU50270	WATCHMAN FLX LAAC Device and Delivery Catheter	27 mm	08714729860501	-	12F (4.0 mm)	
M635WU50310	WATCHMAN FLX LAAC Device and Delivery Catheter	31 mm	08714729860518	-	12F (4.0 mm)	
M635WU50350	WATCHMAN FLX LAAC Device and Delivery Catheter	35 mm	08714729860471	-	12F (4.0 mm)	

### WATCHMAN FXD CURVE ACCESS SYSTEM ORDERING INFORMATION

Reference Catalog No.	Description	Curve	Order Number (GTIN)	ID	OD	Barcode
M635TU80010	WATCHMAN FXD Access System SGL US	Single	00191506013806	12F (4.2 mm)	15F (5.0 mm)	
M635TU80020	WATCHMAN FXD Access System DBL US	Double	00191506013813	12F (4.2 mm)	15F (5.0 mm)	

Please contact your Boston Scientific sales representative for ordering information.

WATCHMAN FLX is preloaded into the delivery catheter thus reducing the preparation time.

## BRIEF SUMMARY

---

### **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<sub>12</sub> 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.

- The WATCHMAN FXD Curve Access Sheath should not be used with any WATCHMAN Device that requires the use of a proximal marker band placed at, or just distal to LAA ostium prior to deployment.

- 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.

- 
- 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, Hemoptysis, 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.

©2021 Boston Scientific Corporation or its affiliates. All rights reserved. All trademarks are property of their respective owners. 92773949 A.1.



#### **Interventional Cardiology**

300 Boston Scientific Way  
Marlborough, MA 01752-1234

**[www.bostonscientific.com](http://www.bostonscientific.com)**

*Medical Professionals:*

*1.800.CARDIAC (227.3422)*

*Patients and Families:*

*1.866.484.3268*

©2020 Boston Scientific Corporation  
or its affiliates. All rights reserved.

SH-1152208-AA

