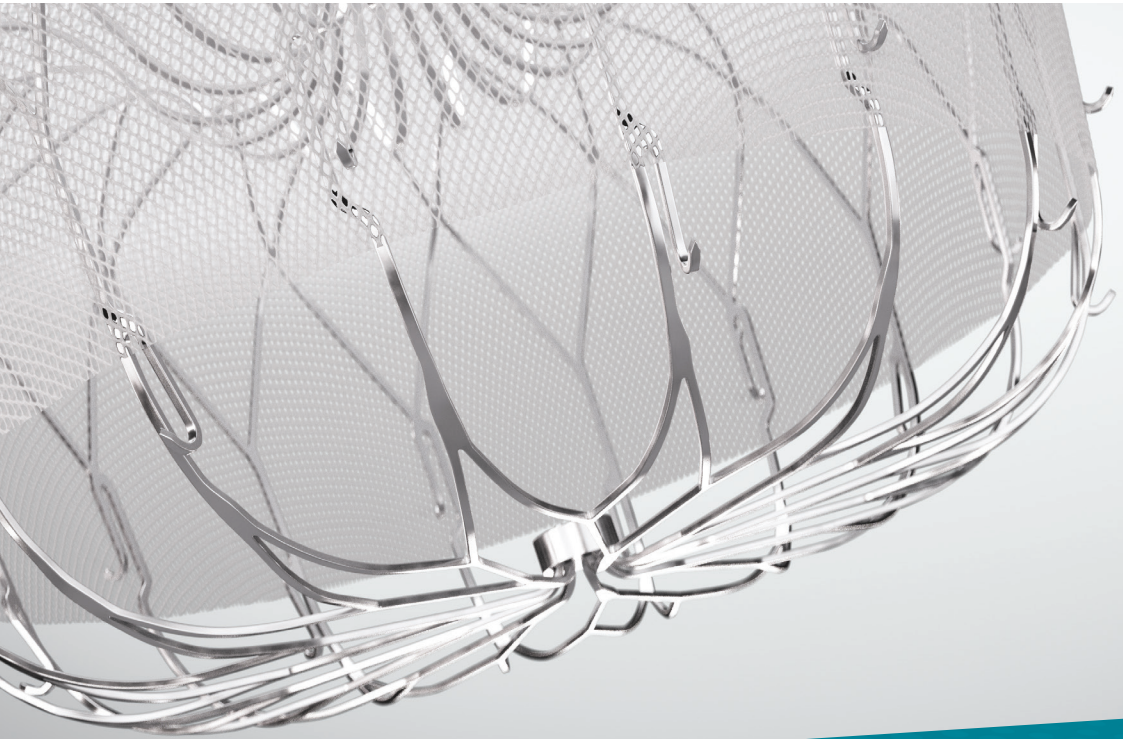
WATCHMAN FLX™

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Boston Scientific

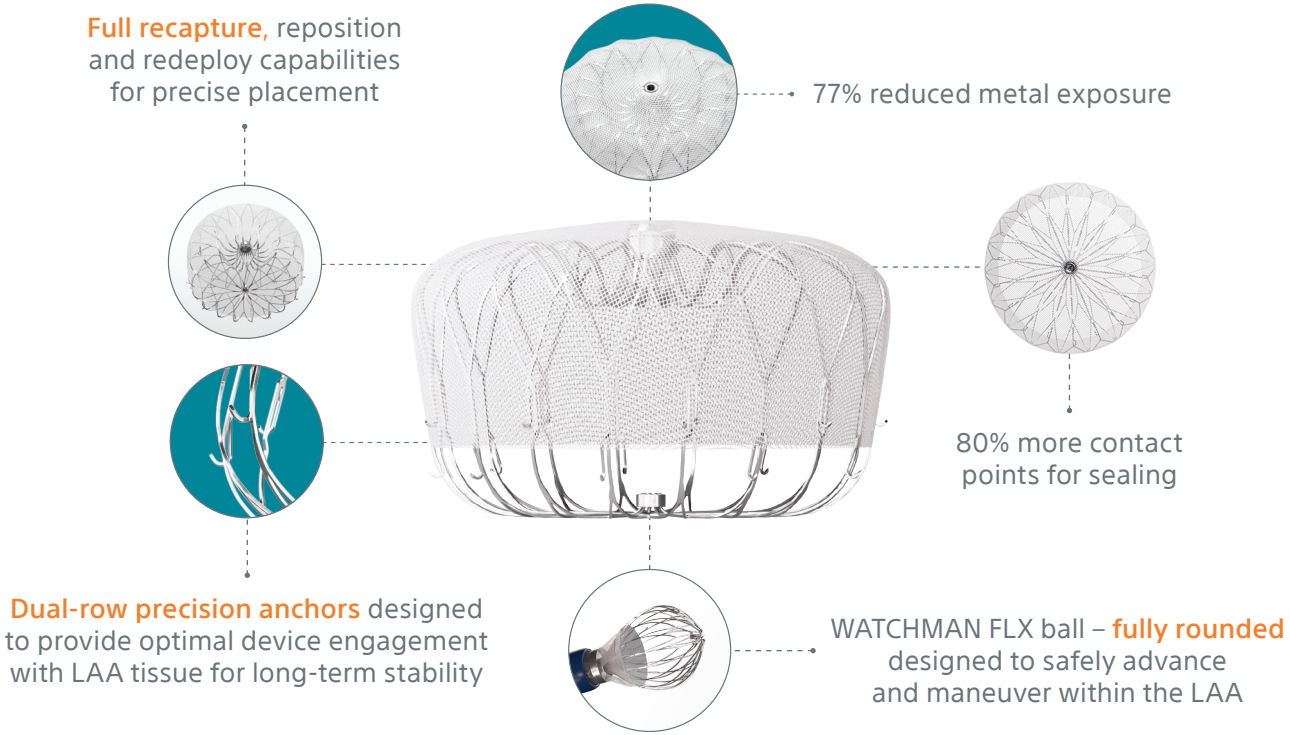
Advancing science for life™



# 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




ADVANCE SAFETY
ADVANCE PROCEDURAL PERFORMANCE
EXPAND THE TREATABLE PATIENT POPULATION

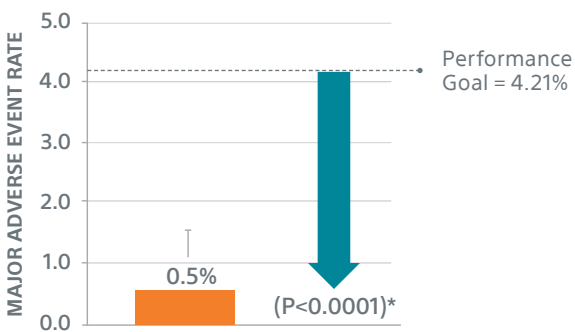
PINNACLE FLX
CLINICAL TRIAL

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

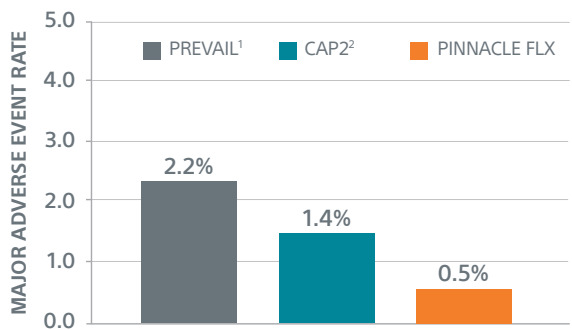
### Primary Safety Endpoint*

| 0.5% | 0% | 0% | 0% |
|---|---|---|---|
| Ischemic Stroke | All-cause Death | Pericardial Effusions Requiring Open Cardiac Surgery | Device Embolization |

**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.*



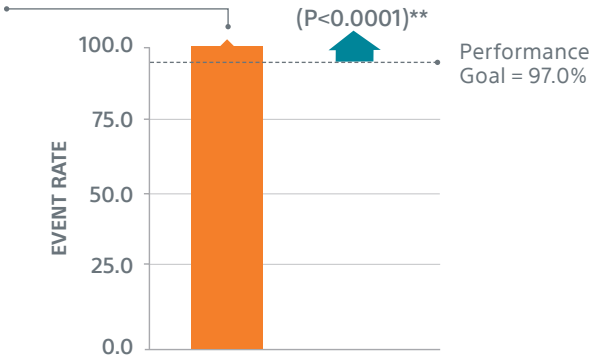

[1] Holmes, DR., et al. (2014). J Am Coll Cardiol 64(1): 1-12
[2] Holmes, DR., et al. JACC 2019

# 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 ≤ 5mm per core laboratory-assessed TEE*

***Performance goal based on the rates observed in PREVAIL[1] and CAP2[2], 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[1] | 92% |
| CAP2/warfarin[2] | 93% |

[1] *Holmes, DR., et al. (2014). J Am Coll Cardiol 64(1): 1-12*
[2] *Holmes DR et al, JACC 2019*

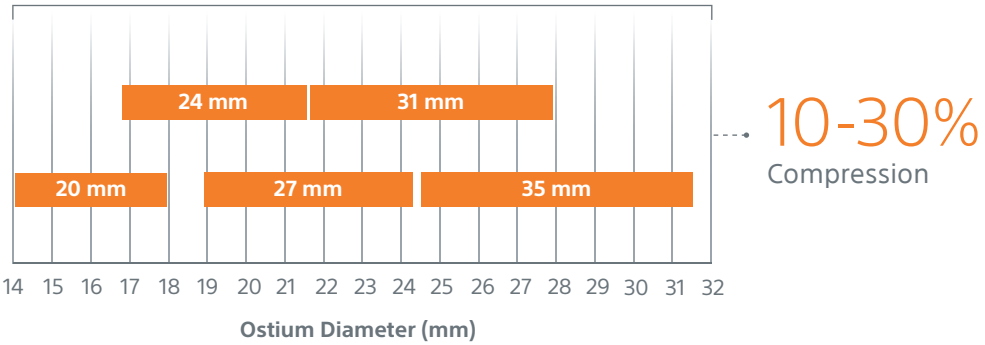
# EXPAND THE TREATABLE PATIENT POPULATION

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.

20 mm | 24 mm | 27 mm | 31 mm | 35 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

| 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

**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 FLX™ 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 $CHA_2DS_2$-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy;
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

## CONTRAINDICATIONS

Do not use the WATCHMAN FLX Device if:

- Intracardiac thrombus is present.
- 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 Closure Device (see Table 62 of the eIFU).
- The patient has a known hypersensitivity to any portion 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.
- 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 anti-coagulation therapy, aspirin, or P2Y12 inhibitor.

## WARNINGS

Implantation of the WATCHMAN FLX Device should only be performed by interventional cardiologists and/or electrophysiologists who are proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized and who have completed the WATCHMAN FLX Physician Training program.

- This device has not been studied in pregnant or breastfeeding women. Careful consideration should be given to use of the Closure Device in pregnant and/or breastfeeding women due to the risk of significant exposure to x-rays and the use of anticoagulation medication.
- Device selection should be based on accurate LAA measurements obtained using transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]); For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium.
- Do not release (i.e., unscrew) the WATCHMAN FLX Device from the core wire unless all release criteria are satisfied to avoid suboptimal results.
- Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section (of the eIFU) for further detail.

## PRECAUTIONS

- 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, recapturing, and repositioning the Closure Device.
- Use caution when introducing a 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 Closure Device, do not allow the WATCHMAN FLX 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 690 kPa (100 psi).

## PATIENT SELECTION FOR TREATMENT

In considering the use of the WATCHMAN FLX Device, the rationale for seeking an alternative to long-term anticoagulation therapy and the safety and effectiveness of the device compared to anticoagulation should be taken into account.

- The presence of indication(s) for long-term anticoagulation therapy, other than non-valvular atrial fibrillation (e.g., mechanical heart valve, hypercoagulable states, recurrent deep venous thrombosis). Details regarding the indications, contraindications, warnings, and precautions for oral anticoagulants approved for patients with non-valvular atrial fibrillation are provided in their respective Instructions for Use.

Of note:

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Device has not been established in patients for whom long-term anti-coagulation is determined to be contraindicated. Factors that need to be considered for the WATCHMAN FLX Device and implantation procedure include the following:
- Overall medical status, including conditions which might preclude the safety of a percutaneous, transcatheter procedure.
- Suitability for percutaneous, transseptal procedures, including considerations of:
  - Cardiac anatomy relating to the LAA size and shape.
  - Vascular access anatomy (e.g., femoral vein size, thrombus, or tortuosity).
  - Ability of the patient to tolerate general or local anesthesia.
  - Ability of the patient to undergo required imaging.
- Ability to comply with the recommended post-WATCHMAN FLX Device implant pharmacologic regimen (see Post-Procedure Information section) especially for patients at high risk for bleeding.

## 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 the contrast media, anesthetic, WATCHMAN Implant material, or medication, 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, Intratracheal 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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**Interventional Cardiology**
300 Boston Scientific Way
Marlborough, MA 01752-1234
**www.bostonscientific.com**
*Medical Professionals:*
*1.800.CARDIAC (227.3422)*
*Patients and Families:*
*1.866.484.3268*



SH-1152208-AA