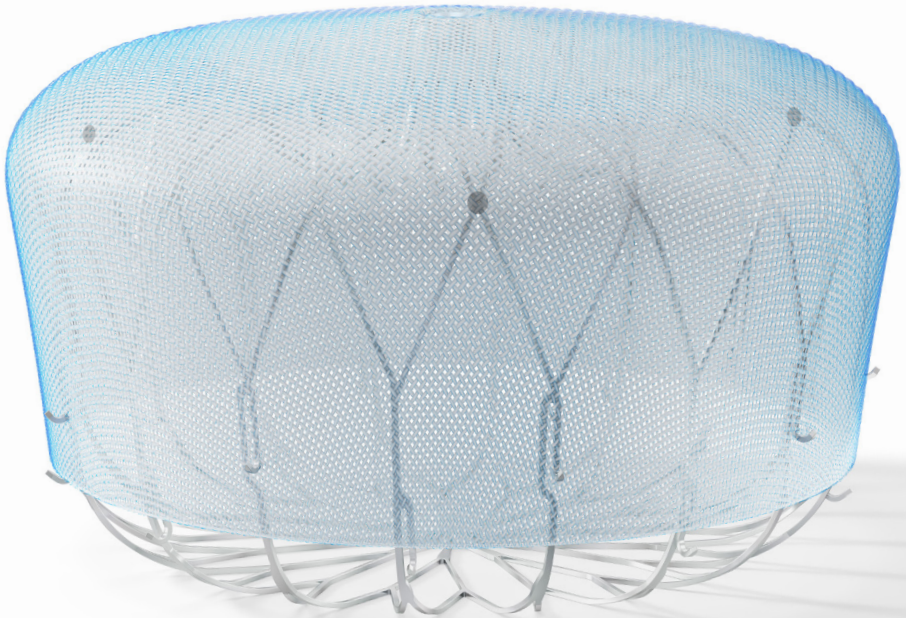
Boston Scientific
Advancing science for life™



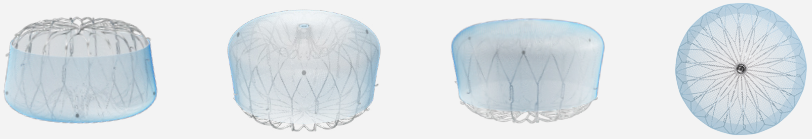
WATCHMAN FLX™ Pro

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Featuring HEMOCOAT™ Technology

Proven Performance.

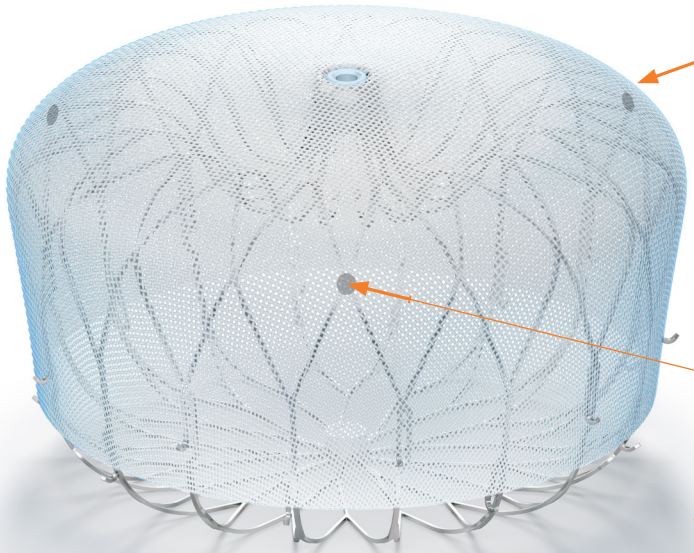
Optimized for Healing.



Built on the proven performance of the WATCHMAN FLX™ device, the WATCHMAN FLX™ Pro device featuring HEMOCOAT™ Technology helps promote faster, more complete endothelialization.

WATCHMAN FLX™ PRO DEVICE

WATCHMAN FLX™ Platform
with proven safety and procedural performance



HEMOCOAT™ Technology
to promote faster, more complete endotheliazation

Three New Radiopaque Markers
help position and anchor device with a new level of visual accuracy

New 40 mm Device
to treat the widest range of anatomies

The WATCHMAN FLX™ Pro Device takes the next step forward in LAAC with three first-ever features to advance performance and safety. The enhanced device features HEMOCOAT™ technology to improve the healing process, radiopaque markers for precise device placement, and a new 40 mm size for larger appendages.

COATED FOR CONTROLLED HEALING

HEMOCOAT™ Technology is a durable, thromboresistant coating that results in less inflammation and leads to faster, more complete endothelialization.[1]

Established

PVDF-HFP has a long history of safe use on permanently implanted, blood-contacting medical devices[2]

Stable

Durable, thin coating encapsulates healing surface of device, maintains pore size and mechanical performance of WATCHMAN FLX platform (<1µm)[3]

Demonstrated

Impressive performance in challenging preclinical model[1]

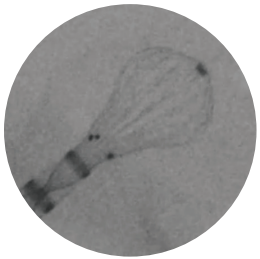
Testing in pre-clinical model has shown remarkable results for faster, more controlled healing.[1]

1. Saliba et al. JACC: Clinical Electrophysiology, May 2023. Bench testing or pre-clinical study results may not necessarily be indicative of clinical performance. N=12 in a pre-clinical canine study.
2. Wagner et al., Biomaterials Science: An Introduction to Materials in Medicine, 4th Edition, 2020.
3. Boston Scientific Data on File.

NEXT LEVEL VISIBILITY

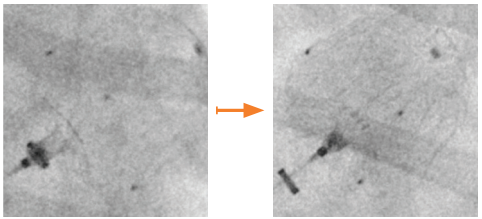
Three new radiopaque markers help position and anchor the device with a new level of visual accuracy.

Enhance Deployment Precision



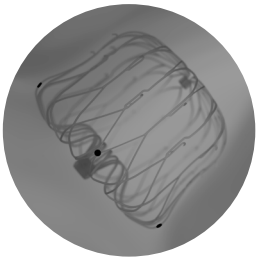
57% increased visibility for more accurate device positioning[4]

Ensure Device Stability



Improved assessment of device anchoring when performing tug test

Enable Confident Release



Improved visualization of device

4. Bench study performed under CT by Boston Scientific. Data on file.

New 40 mm Device
to treat the widest range of anatomies

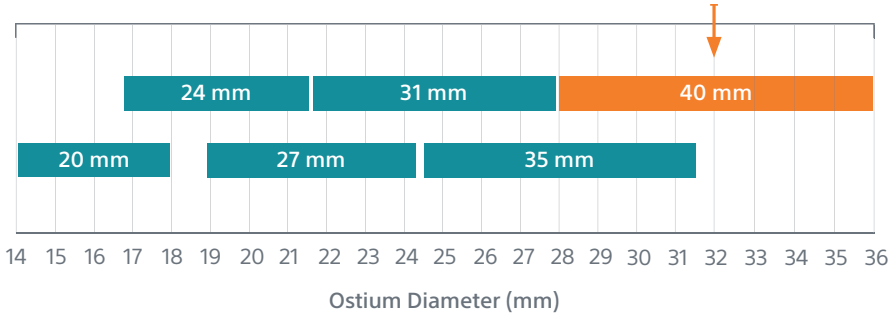
- Same Performance
- Same Compression Range (10-30%)
- Same Depth Requirement

A new 40 mm size to treat larger appendages.

6 models: 20 mm – 40 mm Ostium

**Devices not shown to scale.*

25%
Larger Size Range



ORDERING INFORMATION

WATCHMAN FLX™ Pro LAAC Device Ordering Information

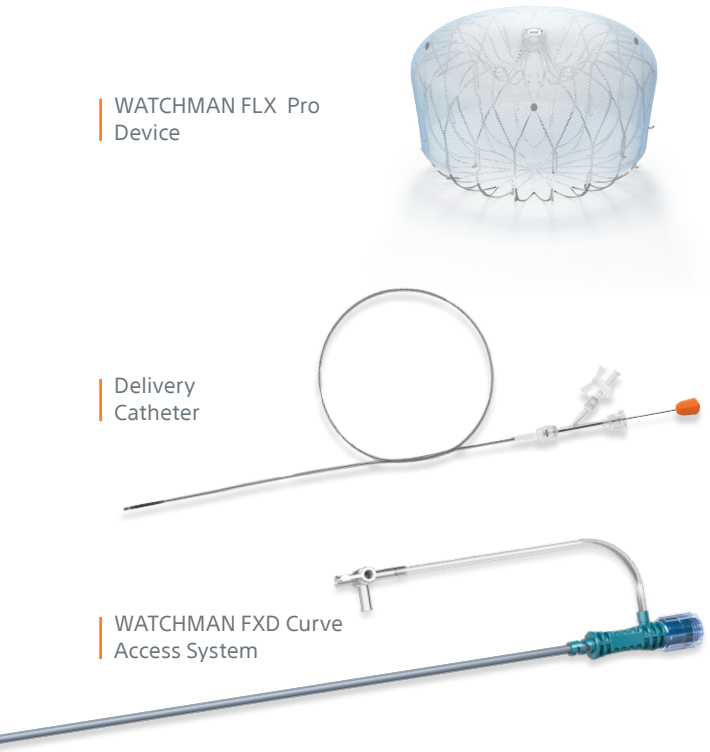
Reference Catalog No.	Description	Size	Order Number (GTIN)	ID	OD	Barcode
M635WU60200	WATCHMAN FLX Pro LAAC US	20 mm	191506004583	–	12F (4.0 mm)	
M635WU60240	WATCHMAN FLX Pro LAAC US	24 mm	191506004590	–	12F (4.0 mm)	
M635WU60270	WATCHMAN FLX Pro LAAC US	27 mm	191506004606	–	12F (4.0 mm)	
M635WU60310	WATCHMAN FLX Pro LAAC US	31 mm	191506004613	–	12F (4.0 mm)	
M635WU60350	WATCHMAN FLX Pro LAAC US	35 mm	191506004620	–	12F (4.0 mm)	
M635WU60400	WATCHMAN FLX Pro LAAC US	40 mm	191506004637	–	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 more information.

WATCHMAN FLX™ PRO SYSTEM



WATCHMAN FLX Pro 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

BRIEF SUMMARY

WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device

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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

INTENDED USE

WATCHMAN FLX Pro is intended for percutaneous, transcatheter closure of the left atrial appendage.

INDICATIONS FOR USE

The WATCHMAN FLX Pro 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[1] scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy; and;
- 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 Pro Device 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.
- The LAA anatomy will not accommodate a Closure Device (see Step 7 in the IFU).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section in the IFU) such that the use of the WATCHMAN FLX Pro 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 anticoagulation therapy, aspirin, or P2Y12 inhibitor.

WARNINGS

Implantation of the WATCHMAN FLX Pro 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 Pro Physician Training program.

- For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the Closure Device and/or lead to Closure Device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the Closure Device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Closure Device may lead to injury, illness, or death of the patient.
- 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 Pro Device from the core wire unless all release criteria (Step 15 in the IFU) 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.
- If thrombus is observed on the device, anticoagulation therapy is recommended until resolution of thrombus is demonstrated by TEE.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section for further detail.
- Do not use if the temperature exposure indicator dot on the pouch label is red or missing, indicating Closure Device performance may have been compromised.

PRECAUTIONS

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Pro 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 Pro 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).
- Use caution when manipulating the Delivery System. Excessive counterclockwise rotation of the deployment knob or Delivery System hub independent from the rest of the Delivery System can cause premature implant detachment.

ADVERSE EVENTS

Potential adverse events 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.

97097061 A.1

Boston Scientific
Advancing science for life™

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-1561901-AC