WATCHMAN FLX™

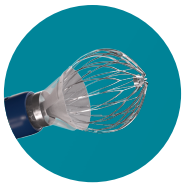
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Boston Scientific

Advancing science for life™

ADVANCE SAFETY
ADVANCE PROCEDURAL PERFORMANCE
EXPAND TREATABLE PATIENT POPULATION

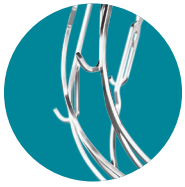
Procedural benefits include:



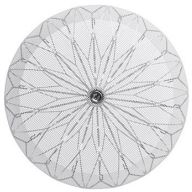
WATCHMAN FLX™ ball – **fully rounded** designed to safely advance and maneuver within the LAA

Full recapture, reposition and redeploy capabilities for precise placement

77% reduced metal exposure



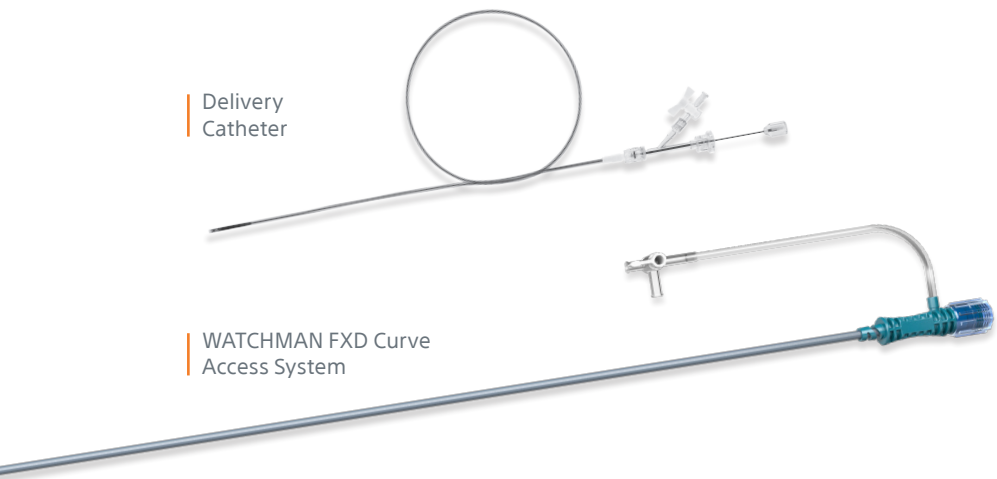
Dual-row precision anchors designed to provide optimal device engagement with LAA tissue for long-term stability



80% more contact points for sealing

Product Information

WATCHMAN FLX System	Material
WATCHMAN FLX Device	Nitinol frame with Polyethylene Terephthalate (PET) fabric cover
Delivery Catheter	Sheath material braided Pebax® with PTFE liner and platinum/iridium marker band
WATCHMAN FXD Curve™ Curve Access System	**Material**
Hub	Pebax® with polycarbonate cap
Sheath	Braided Pebax® with PTFE liner and platinum/iridium marker band
Dilator	High density polyethylene (HDPE)/low density polyethylene (LDPE) 50:50 blend



WATCHMAN FLX Device

Product List

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 $P2Y_{12}$ 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.

- 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, Intratracheal bleeding, Major bleeding requiring transfusion4, 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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