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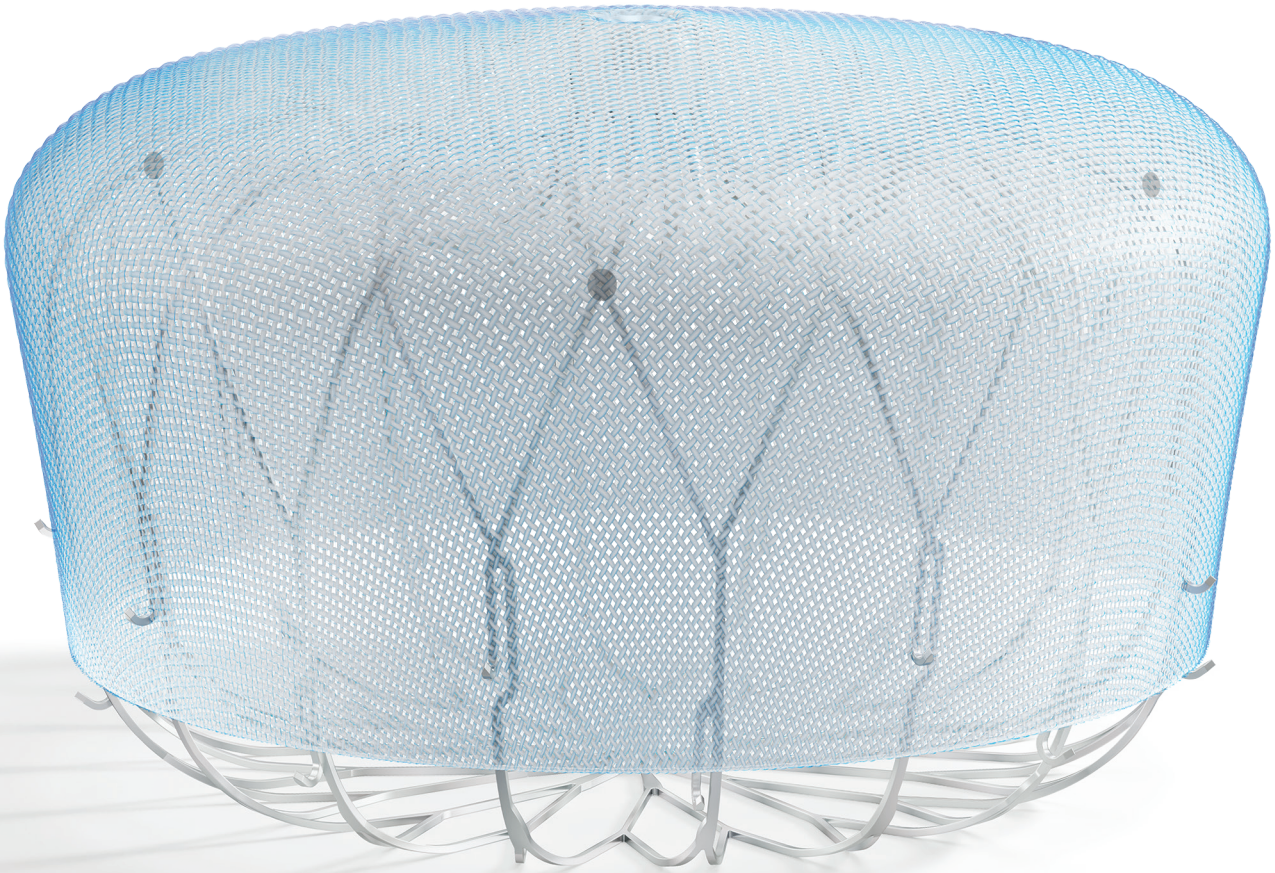


WATCHMAN FLX™ Pro

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Proven Performance. Optimized for Healing.

Featuring HEMOCOAT™ Technology

Better begins now.

Built on the industry-leading safety profile of the WATCHMAN FLX™ Left Atrial Appendage Closure Device, WATCHMAN FLX™ Pro featuring HEMOCOAT™ Technology is making the best device even better. Designed with three first-ever features, this next-generation device promotes faster, more controlled healing and optimizes the therapy for more patients.

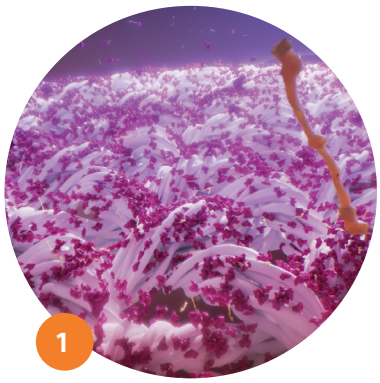
50%

Increase in endothelial coverage at 45 days in a pre-clinical study[1]

Setting a new standard of healing.

The body's natural healing response to permanent implants has five distinct stages. Through first-of-its-kind thromboresistent HEMOCOAT™ Technology, the WATCHMAN FLX™ Pro device alters the first stage of healing — protein adsorption — leading to less platelet activation, less inflammation, and less thrombus throughout the healing process.

See how one change can lead to better results at every stage of the healing process, compared to an uncoated LAAC device, as demonstrated in challenging pre-clinical studies.



Protein Adsorption

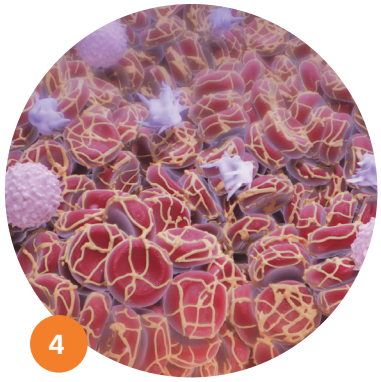
HEMOCOAT Technology preferentially binds albumin proteins, which lack platelet binding receptors, setting the stage for reduced platelet activation.

Platelet Binding

Favored albumin adsorption drove >25% less platelet activation.[1] (p<0.01)

Acute Inflammation

Less platelet activation resulted in 85% reduction in inflammation.[1] (p<0.01)



Thrombus Formation and Resolution

A diminished inflammatory response yielded 70% less thrombus at 14 days.[1] (p=0.02)

Endothelialization

A more controlled healing response resulted in 50% faster, more complete endothelialization, potentially reducing the risk of DRT.[1] (p=0.05)

Scan to see an animated video of how HEMOCOAT Technology positively impacts the five stages of healing.

Coated for controlled healing.

The WATCHMAN FLX™ Pro Device's HEMOCOAT™ Technology is a durable, thromboresistant coating that results in less inflammation and leads to faster, more complete endothelialization, as demonstrated in a challenging pre-clinical model.[1]

WHAT IS HEMOCOAT TECHNOLOGY?

HEMOCOAT Technology is a PVDF-HFP fluoropolymer coating, used without the presence of a drug, that promotes endothelialization.

HOW DOES HEMOCOAT TECHNOLOGY WORK?

By altering the first stage of the healing process, HEMOCOAT Technology promotes less platelet activation, less inflammation, and less thrombus throughout healing, ultimately resulting in more complete endothelialization.[1]

WHY HEMOCOAT TECHNOLOGY?

A faster, more complete healing process optimizes LAAC therapy for more patients, while potentially reducing the risk of DRT and simplifying post-implant drug regimen.[1]

HEMOCOAT TECHNOLOGY

Established

Robust history of safe use on permanently implanted, blood-contacting medical devices in over 20 million patients[3]

Stable

Non-active and non-eluting, its thin coating maintains the pore size and mechanical performance of the WATCHMAN FLX platform[4]

Demonstrated

Impressive performance in challenging pre-clinical models[1]

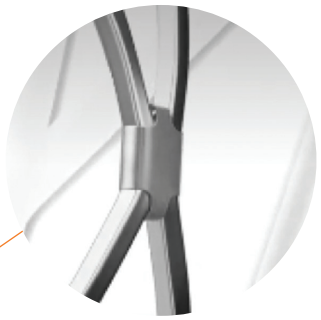
Experience next-level visibility.

Optimize your sealing performance through better device placement. Three new radiopaque markers help position and anchor the device with a new level of visual accuracy.

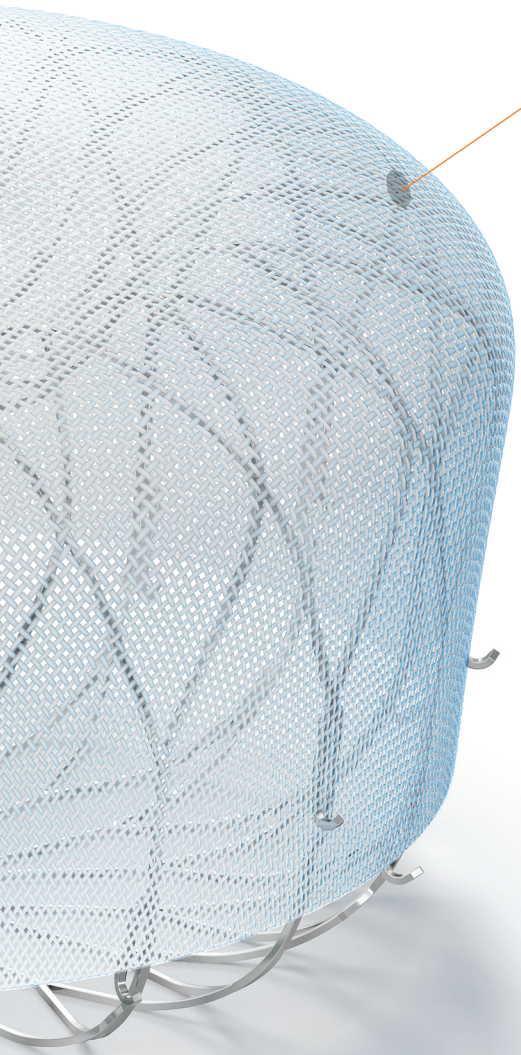
ENHANCE DEPLOYMENT PRECISION
57% increased visibility for more accurate device positioning.[4]

ENSURE DEVICE STABILITY
Improved assessment of device anchoring when performing tug test.

ENABLE CONFIDENT RELEASE
Improved visualization of device orientation and alignment.

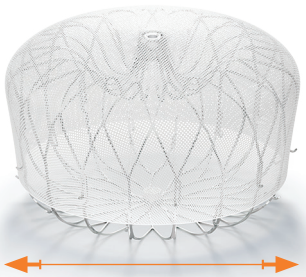


RADIOPAQUE MARKERS



Close with confidence.

To better treat more patients with larger anatomies, WATCHMAN FLX™ Pro features our first-ever 40mm device.



NEW 40MM DEVICE ACTUAL SIZE

- ✓ 25% LARGER SIZE RANGE
- ✓ EXPAND YOUR TREATABLE PATIENT POPULATION BY 6%
- ✓ SAME SAFETY PROFILE OF THE WATCHMAN FLX DEVICE

Scan to see the pre-clinical data.

Sources

1. Saliba, W. et al. JACC EP, May 2023. Enhanced Thromboresistance and Endothelialization of a Novel Fluoropolymer-Coated Left Atrial Appendage Closure Device (In a Challenging Canine Model).
2. Wagner et al., Biomaterials Science: An Introduction to Materials in Medicine, 4th Edition, 2020
3. Data on file at Boston Scientific. Represents total global sales of the PROMUS (Boston Scientific) and XIENCE (Abbott) stents since 2006
4. Data on file.

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 "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 (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 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 transfusion, Misplacement of the device/improper seal of the appendage/movement of device from appendage wall, Myocardial erosion, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pulmonary edema, 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), Valvularor vascular damage, Vasovagal reactions

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

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