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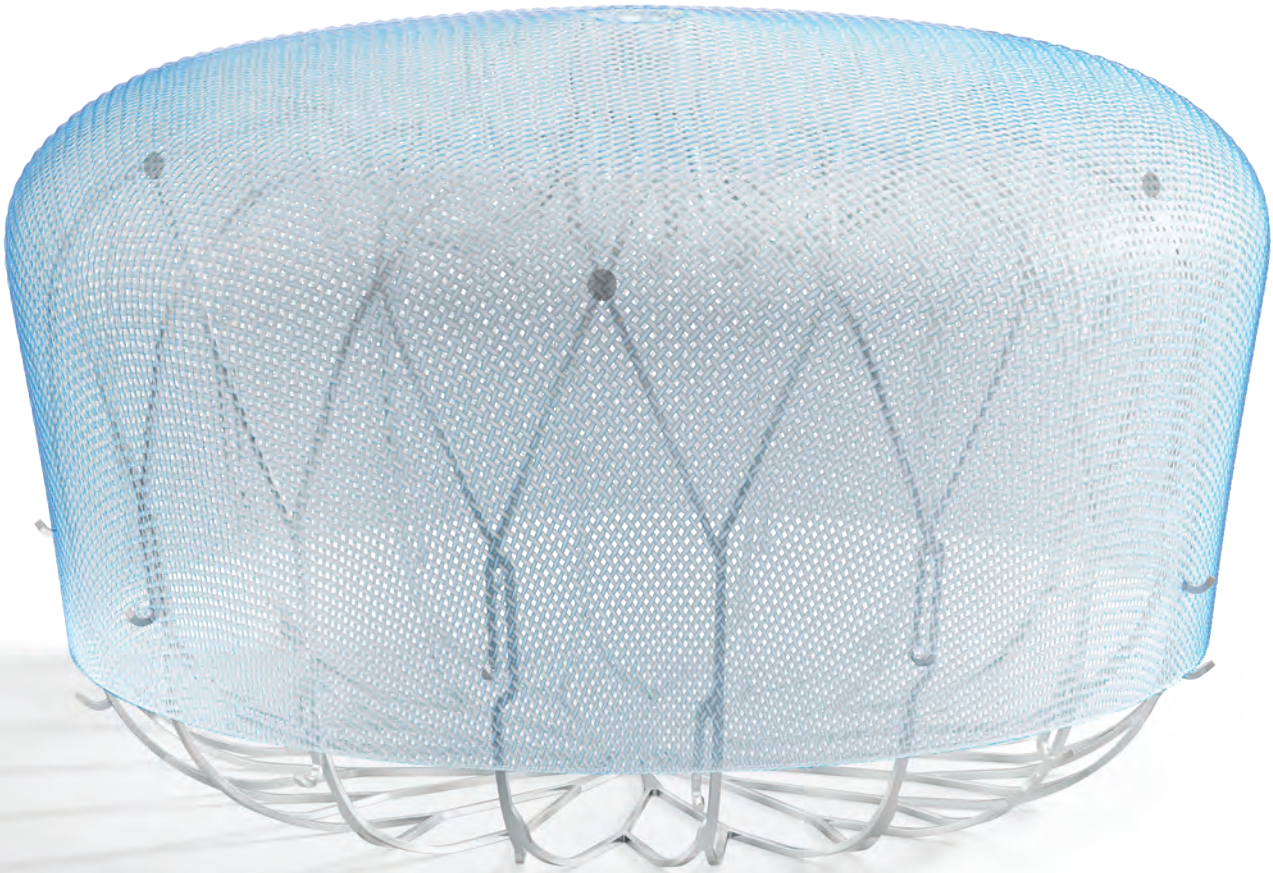


# WATCHMAN FLX™ Pro

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.

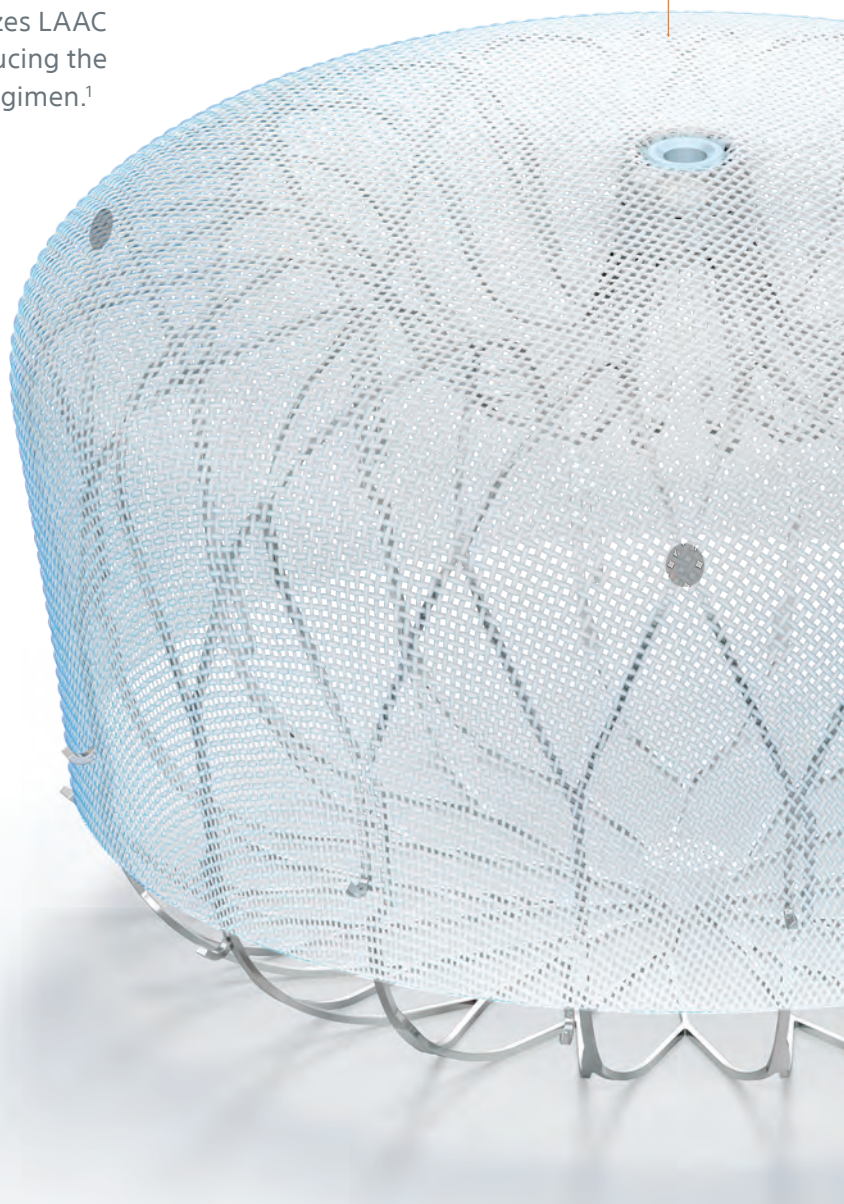
### HOW DOES HEMOCOAT TECHNOLOGY WORK?

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.

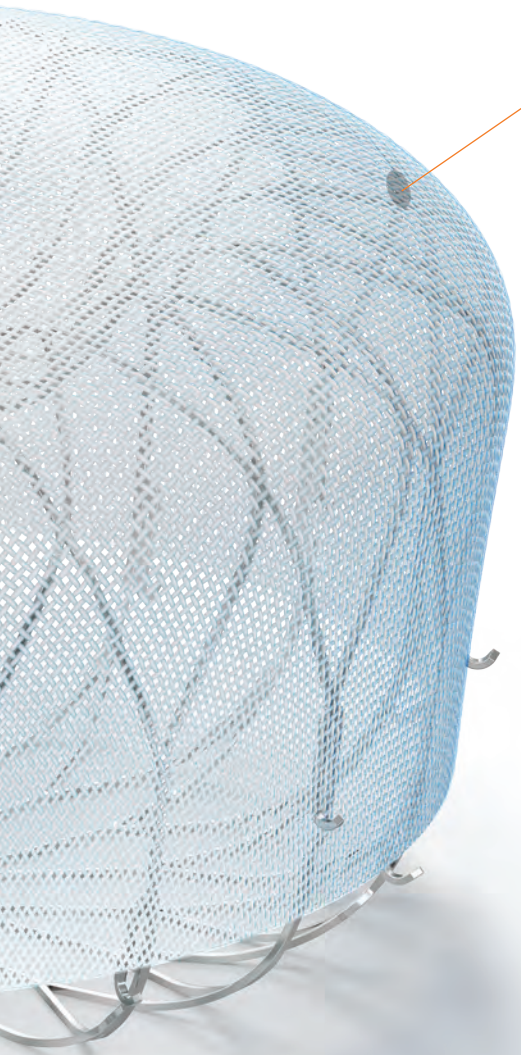
**Optimize your sealing performance through better device placement. Three new radiopaque markers help position and anchor the device with a new level of visual accuracy.**

### 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 "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 fibrill tion who:

• Are at increased risk for stroke and systemic embolism based on $CHADS_2$ or $CHA_2DS_2$-VASc 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 e ectiveness 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 45 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 anticoagulation therapy, aspirin, or P2Y12 inhibitor.

**WARNINGS**

Implantation of the WATCHMAN FLX Device should only be performed by interventional cardiologists and/or electrophysiologists who are trained in percutaneous and transseptal procedures 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 signifi ant exposure to x-rays and the use of anticoagulation medication.

• Device selection should be based on accurate LAA measurements obtained using echocardiographic imaging guidance in multiple views (TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]) to avoid improper Closure Device sizing.

• Do not release (i.e., unscrew) the WATCHMAN FLX Device from the core wire unless all release criteria are satisfi d 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 e ectiveness (and benefi -risk profile) of the ATCHMAN 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 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 e ectiveness 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 fibrill tion (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 fibrill tion are provided in their respective Instructions for Use. Of note:

• The safety and e ectiveness (and benefi -risk profile) of the ATCHMAN FLX Device has not been established in patients for whom long-term anticoagulation 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 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/ amponade, Pleural effusion Prolonged bleeding from a laceration, Pulmonary edema, Renal failure, Respiratory insufficiency ailure, 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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