WATCHMAN FLX™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Boston Scientific
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Real-world Experience with the WATCHMAN FLX Device: Outcomes At One-Year From SURPASS[1]

CRT Scientific Sessions: Late Breaking Clinical Trial

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The SURPASS 1 Year Outcomes analysis of the NCDR-LAAO Registry now includes the largest number of commercial WATCHMAN FLX™ Device patients to date. These data continue to support the best-in-class safety and long-term efficacy of the WATCHMAN FLX Device with a **0.49% major procedural adverse event rate within 7 days or hospital discharge and 1.2% ischemic stroke rate at one year in >66,000 real-world NVAF patients.**

Trusted Safety

0.49%

Major Procedural Adverse Event Rate (Key Safety Endpoint)

Proven Efficacy

1.2%

Ischemic Stroke Rate at 1 Year

Study Design

- The objective of this SURPASS analysis is to assess long term safety and efficacy outcomes at one year with WATCHMAN FLX in a routine, real-world setting.
- This analysis includes the largest commercial WATCHMAN FLX Device patient population to date, with 66,894 patients implanted between August 5, 2020 and March 31, 2022.

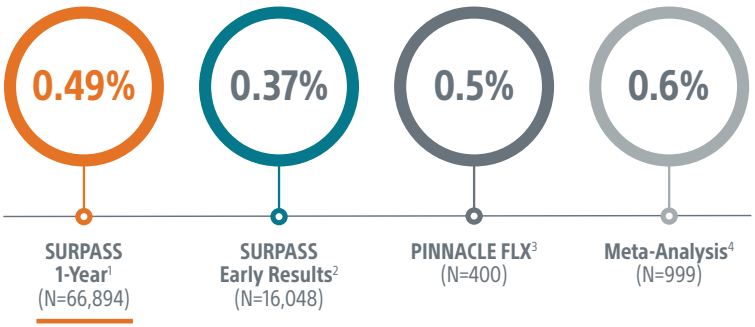
Patient Characteristics

- **Age:** 76.2 ±7.9 Years
- **CHA2DS2-VASc Score:** 4.8±1.5
- **HAS-BLED Score:** 2.4±1.0
- **Women:** 41%
- **Clinically Relevant Bleeding:** 57.7%

Key Safety Endpoint
Composite of all-cause death, ischemic stroke, systemic embolism, or device or procedure related events requiring open cardiac surgery or major endovascular intervention between device implantation and seven days or hospital discharge (whichever is later).

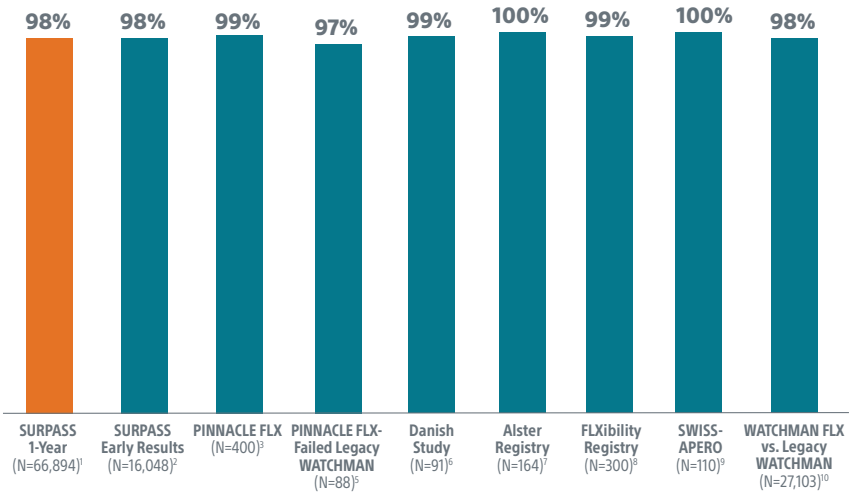
(SURPASS Outcomes Continued)

The 0.49% major procedural adverse event rate within 7 days or hospital discharge demonstrated in the SURPASS 1 Year Outcomes analysis further supports the unmatched safety profile observed in separate controlled and real-world analyses.



SURPASS data reinforces the WATCHMAN FLX™ Device procedural success with 98% of patients implanted (N=66,894)[1] across nearly all anatomies in a real-world setting, confirming the WATCHMAN FLX Device real-world experience replicates clinical trial outcomes.

Procedural Success



The WATCHMAN FLX Device delivers proven stroke reduction in the largest and highest-risk patient population studied to date across the WATCHMAN platform.

1.6%
All Stroke

1.2%
Ischemic Stroke

References:
1. Kapadia et al. Real-world Experience with WATCHMAN FLX: Outcomes At One-Year From SURPASS. Late Breaking Clinical Trial, CRT 2023.
2. Kapadia et al. Real-world Outcomes with WATCHMAN FLX: Early Results from SURPASS. Late Breaking Clinical Trial, CRT 2022.
3. Kar et al. Circulation 2021.
4. Della Rocca et al. Heart Rhythm 2022.
5. Ellis, Structural Heart, 2021.
6. Korsholm, WM FLX First Experience, JACC, 2020.
7. Bergmann, Alster Registry, Presented ePCR 2021.
8. Betts, EHRA 2022.
9. Galea, SWISS APERO Trial, Cirulation, 2021.
10. Freeman, HRS 2022.

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 $CHADS_2$ 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 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 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 significant 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 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 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 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/ 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), Valvular or vascular damage, Vasovagal reactions

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

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