WATCHMAN FLX™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Boston Scientific
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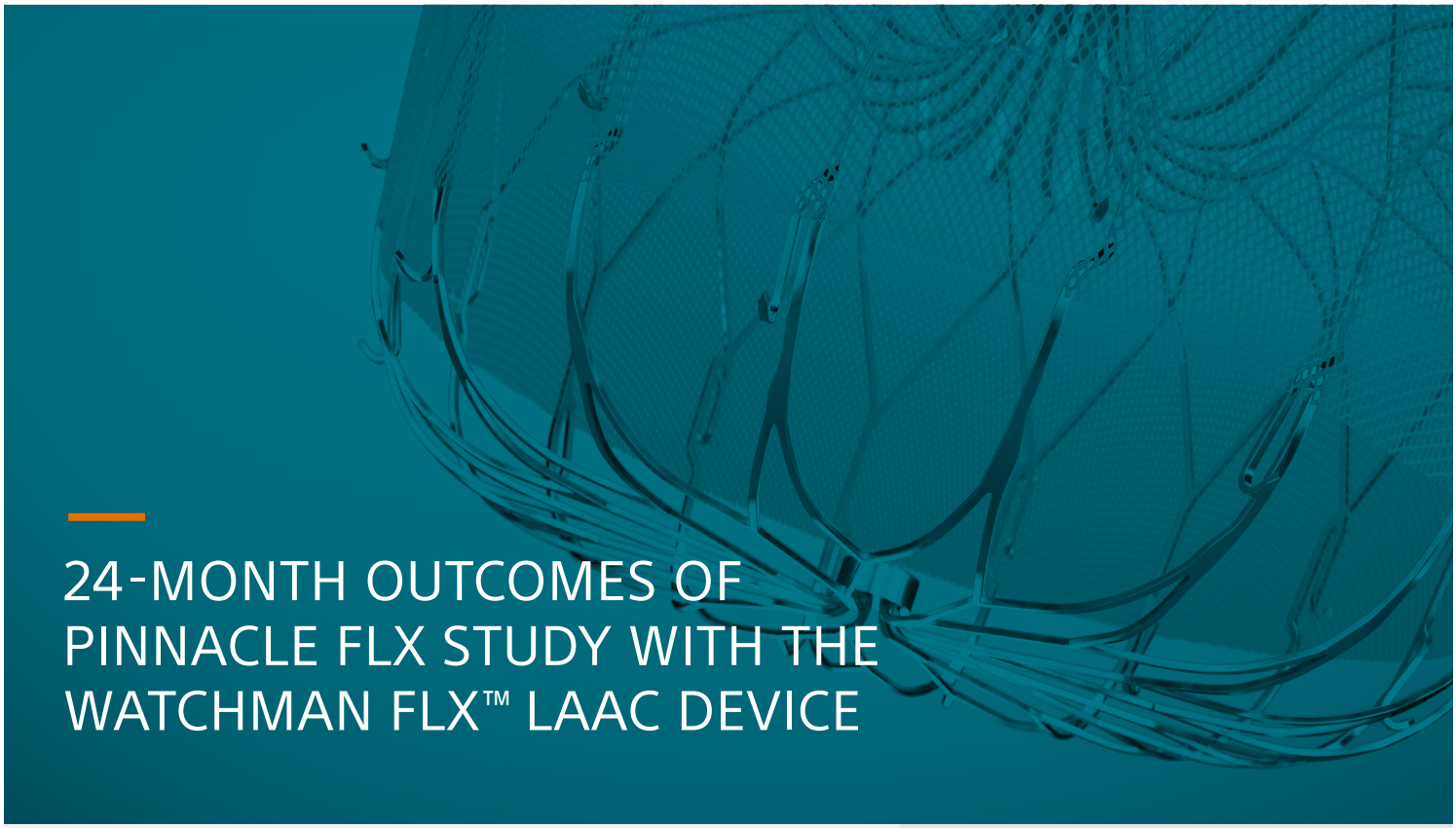


24-MONTH OUTCOMES OF PINNACLE FLX STUDY WITH THE WATCHMAN FLX™ LAAC DEVICE

SAFETY

Trial met **primary safety endpoint** with 0.5% event rate at 12 months[1]

EFFICACY

Trial met **primary efficacy endpoint** with 100% effective LAA closure at 12 months[1]

EFFICACY AT 24 MONTHS

Trial met key **secondary efficacy endpoint** with 3.4% ischemic stroke/ systemic embolism at 24 months[2]

PINNACLE FLX Study Overview

A US IDE to evaluate the safety and efficacy of the WATCHMAN FLX™ Device

400 NVAF Patients
29 US Sites

Primary Safety Endpoint:
7-day/Discharge Adverse Event

Primary Efficacy Endpoint:
Effective Seal at 1 year

Secondary Efficacy Endpoint:
Ischemic Stroke or Systemic Embolism at 2 Years

7 Day or Discharge TEE

45 Day TEE

6 Months TEE*

1 Year TEE FDA APPROVAL: WATCHMAN FLX™

18 Months Clinic Visit

2 Years Clinic Visit

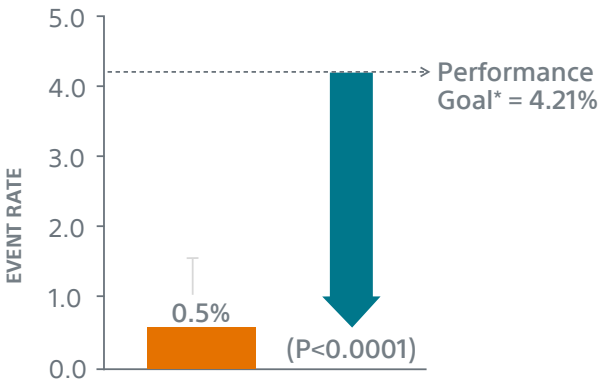
DOAC + ASA* | DAPT | ASA Ongoing

*If no effective seal (defined as leak =<5mm) is observed at 45 days, patients continued on DOAC+ASA & had 6-month TEE; additional imaging performed as medically necessary after 1 year (ie, in case of an event)

WATCHMAN FLX™ LAAC Device Demonstrated Excellent Safety and Efficacy at 12 Months[1]

Primary Safety Endpoint:

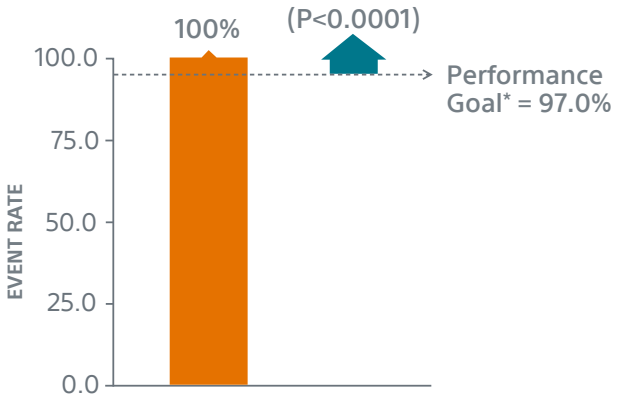
Peri-procedural Adverse Events



Defined as major adverse events between implant and 7d/discharge. N=400.
*Based on the combined rate observed in PREVAIL and CAP2, plus a clinically acceptable delta

Primary Efficacy Endpoint:

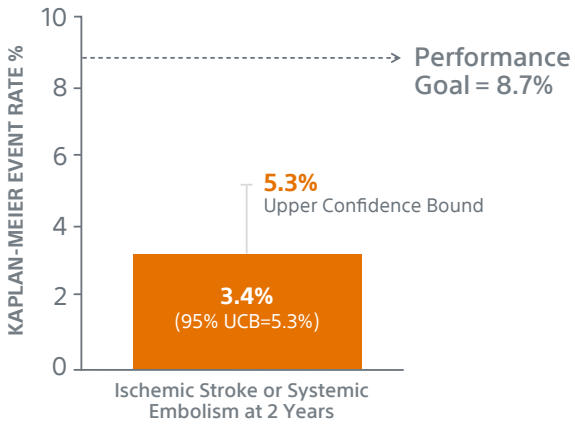
Effective LAA Closure at 12-Months



Defined as any per-device flow with jet size ≤5mm on TEE; all observed leaks were ≤3mm by core lab adjudication. N=344.
*Based on the combined rate observed in PREVAIL and CAP2, minus a clinically acceptable delta

WATCHMAN FLX Meets Key Secondary Efficacy Endpoint at 24 Months[2]

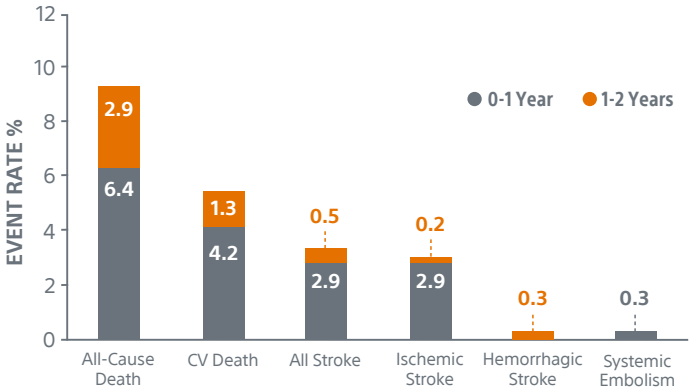
24-month data demonstrates an ischemic stroke event rate well below the performance goal of 8.7%[2] , therefore, **the secondary endpoint has been met**.



Expected rate of 4.0% (derived from the combined PROTECT-AF, CAP, PREVAIL, and CAP-2 studies) plus a clinically relevant delta.

The WATCHMAN FLX LAAC Device continued to demonstrate excellent safety and efficacy outcomes at 24 months[2]

- 1 additional hemorrhagic and 1 additional ischemic stroke after 12 months
- No additional DRT, Pericardial Effusions, Systemic Embolisms after 12 months
- 0% Device Embolization



References:
1 Kar S., Circulation, 2021.
2 Kar S., 24-Month Outcomes of PINNACLE FLX Study with the WATCHMAN FLX™ Left Atrial Appendage Closure Device Presented as Late-Breaking Clinical Science, Presented at TVT July 21, 2021.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

There are risks associated with the use of the WATCHMAN FLX Left Atrial Appendage Closure Device. Please review the full IFU for complete safety and indication information at watchman.com/hcp.

CE 2797 **CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.