



## PINNACLE FLX: The US IDE Trial Designed to Evaluate the Procedural Safety and Closure Efficacy with the WATCHMAN FLX Device.

### Study Design

- 400 patient, 29 US site, single arm, non-randomized trial evaluating WATCHMAN FLX for non-inferiority to safety and efficacy performance goals based on the WATCHMAN™ device.
- Follow-up: 45 days (+TEE), 6 months, 12 months (+TEE), 18 months, and 24 months
- Patient Characteristics: Average CHA<sub>2</sub>DS<sub>2</sub>-VASc of 4.2±1.5, Average HAS-BLED of 2.0±1.0
- Post Implant Drug Regimen: NOAC/ASA for 45 days, Clopidogrel/ASA to 6 months, ASA post 6 months
- **Primary Safety Endpoint:** All-cause death, ischemic stroke, systemic embolism, or device- or procedure-related adverse events requiring surgery or major endovascular intervention within 7 days following the procedure or by hospital discharge, whichever is later.
- **Primary Efficacy Endpoint:** The rate of effective LAA closure defined as any peri-device flow ≤5mm demonstrated by TEE at 12 months
- **Secondary Efficacy Endpoint:** The occurrence of ischemic stroke or systemic embolism at 24 months from the time of enrollment
- Inclusion/exclusion criteria is consistent with WATCHMAN clinical study inclusion/exclusion criteria. Patients must be eligible for short-term NOAC vs warfarin in previous clinical studies.

### Primary Safety Endpoint\*

0.5%

Ischemic Stroke

0%

All-cause Death

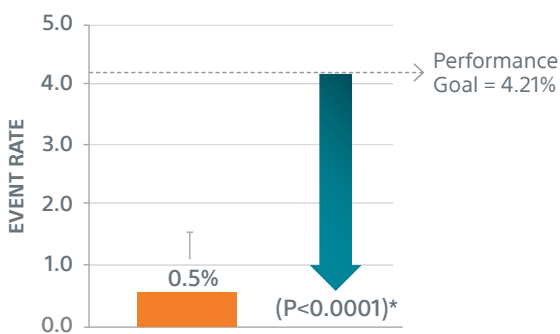
0%

Pericardial Effusions  
Requiring Open  
Cardiac Surgery

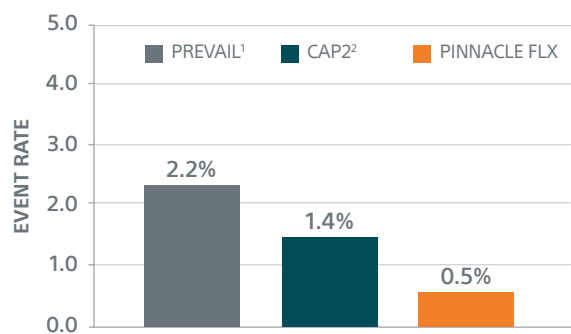
0%

Device Embolization

\*All-cause death, ischemic stroke, systemic embolism, or device- or procedure-related adverse events requiring surgery or major endovascular intervention within 7 days following the procedure or by hospital discharge, whichever is later.



\*Based on the combined rate observed in PREVAIL(1) and CAP2(2), plus a clinically acceptable delta.

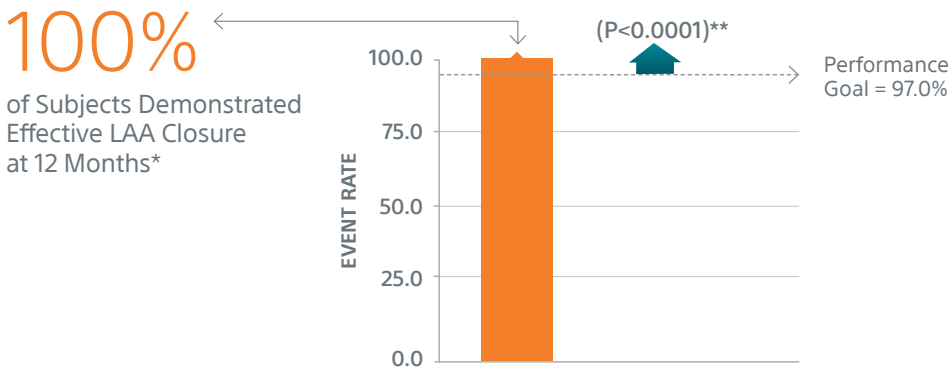


<sup>1</sup> Holmes, DR., et al. (2014). J Am Coll Cardiol 64(1): 1-12

<sup>2</sup> Holmes, DR et al. JACC 2019

Continued →

**Primary Effectiveness Endpoint:**



\* LAA closure at 12 months is defined as any peri-device flow with jet size ≤ 5mm per core laboratory-assessed TEE  
 \*\* Performance goal based on the rates observed in PREVAIL(1) and CAP2(2), minus a clinically relevant delta

**Procedure Performance**

Procedure/Implant Success

**98.8%**

Implant Success (395/400)

Implant success defined as successful delivery and release of a WATCHMAN FLX device into the LAA

**NOAC Discontinuation**

**96.2%** of Patients Discontinued NOAC at 45-day Follow-up

Study/OAC	Event Rate
PINNACLE FLX/NOAC	96.2%
PREVAIL/warfarin <sup>1</sup>	92%
CAP2/warfarin <sup>2</sup>	93%

<sup>1</sup> Holmes, DR., et al. (2014). J Am Coll Cardiol 64(1): 1-12  
<sup>2</sup> Holmes DR et al, JACC 2019

**Designed to Treat Widest Range of Patient Anatomies**

WATCHMAN FLX sizes range from (20mm – 35mm)\*



\* Devices not shown to scale