WATCHMANFLX™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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

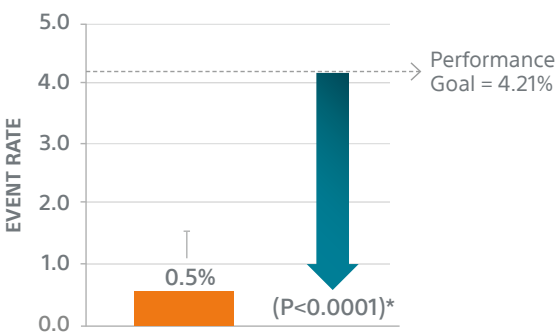
Study Design

- 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_2DS_2-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.

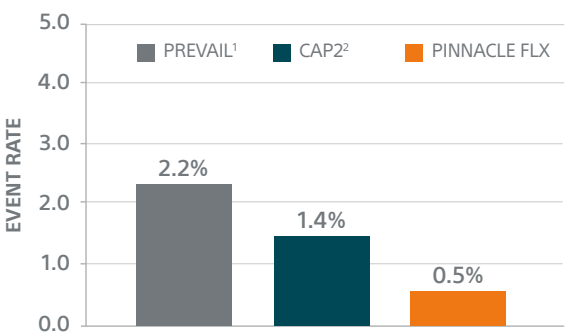
Primary Safety Endpoint*

0.5%	0%	0%	0%
Ischemic Stroke	All-cause Death	Pericardial Effusions Requiring Open Cardiac Surgery	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.*



[1] *Holmes, DR., et al. (2014). J Am Coll Cardiol 64(1): 1-12*
[2] *Holmes, DR et al. JACC 2019*

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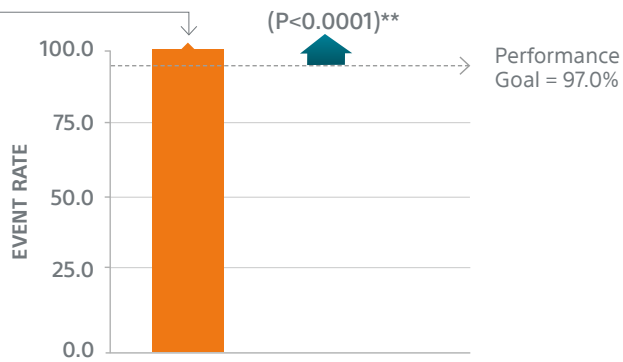
PINNACLE FLX
CLINICAL TRIAL

Primary Effectiveness Endpoint:

100%

of Subjects Demonstrated Effective LAA Closure at 12 Months*



** 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[1]	92%
CAP2/warfarin[2]	93%

[1] Holmes, DR., et al. (2014). J Am Coll Cardiol 64(1): 1-12
[2] Holmes DR et al, JACC 2019

Designed to Treat Widest Range of Patient Anatomies

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

20mm	24mm	27mm	31mm	35mm

** Devices not shown to scale*

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