WATCHMAN FLX™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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Outcomes With WATCHMAN FLX In Everyday Clinical Practice From the NCDR LAAO Registry

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In the largest and highest-risk contemporary cohort of WATCHMAN FLX™ Device patients studied to date (N=97,185), clinical outcomes reflect those observed in the PINNACLE FLX study, demonstrating that favorable outcomes achieved in the pivotal approval study can be replicated in routine clinical practice.

Study methods and design

- The objective of the study was to evaluate the (1) safety and (2) outcomes through 1 year after implantation of the WATCHMAN FLX device in routine clinical practice in a large, contemporary cohort in the United States using the National Cardiovascular Data Registry's (NCDR) left atrial appendage (LAA) occlusion (LAAO) Registry
- Patients in the NCDR LAAO Registry who had an attempt for the WATCHMAN FLX implant procedure between August 2020 and September 2022 were included in this analysis

Study endpoints

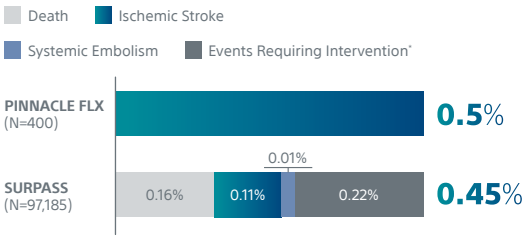
Key safety endpoint	The key safety end point was Defined as the occurrence of all-cause death, ischemic stroke, systemic embolism, or device or procedure-related events requiring open cardiac surgery or major endovascular intervention between device implantation and 7 days or hospital discharge (whichever is later); patients may have experienced >1 safety end point.
Major adverse events	Major adverse events including death, myocardial infarction, pericardial effusion requiring intervention, systemic embolism, device embolization, major vascular complication, hemorrhagic stroke, ischemic stroke, undetermined stroke, transient ischemic attack, intracranial hemorrhage, or major bleeding were also reported.
Additional endpoints	Additional clinical endpoints through 45 days post-implant included implant success (defined as device release and deployment), and PDL.

Key baseline patient characteristics (N=97,185)

- Age (y): 76.4 ± 7.9 y
- CHA_2DS_2-VASc Score: 4.8 ± 1.5
- HAS-BLED Score: 3.0 (1; 4)
- Female: 40,168 (41.3%)
- Prior stroke: 20,004 (20.6%)
- Clinically relevant bleeding: 54,452 (56.1%)

SURPASS key acute outcomes:

0.45%
Key Safety Endpoint
(Binary Rate)

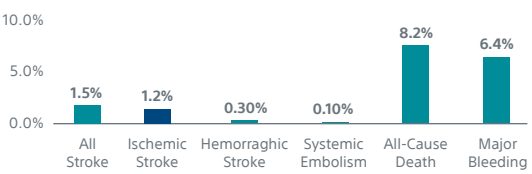


An exceedingly low **0.45% key safety endpoint rate** and 1.3% major in-hospital adverse event rate was seen in 97,185 real-world patients, confirming the trusted safety profile observed in the pivotal PINNACLE FLX trial in a broader clinical practice setting.

* Events requiring intervention defined as device or procedure-related events requiring open cardiac surgery or major endovascular intervention such as pseudoaneurysm repair, arteriovenous fistula repair or another major endovascular repair.

1.2% **1 Year Ischemic Stroke**
(Kaplan Meier Rate)

1-Year Outcomes (KM Rates)



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

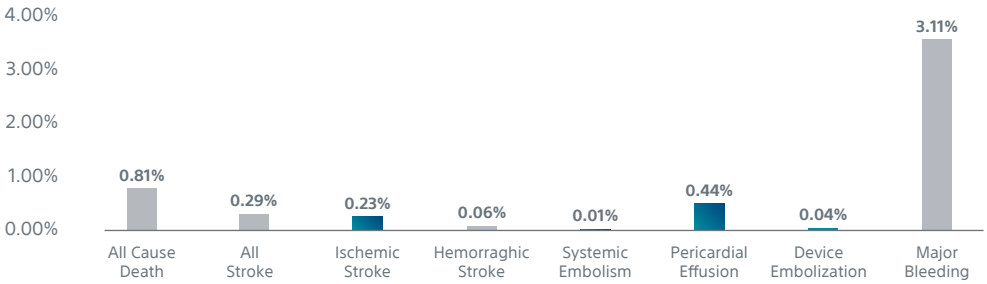
SURPASS key acute outcomes (continued):

98%
Procedural Implant Success*
*Defined as device release and deployment

Excellent procedural success was observed with **98% of patients successfully implanted,** reinforcing the ease of use and low procedure-related complication rate of WATCHMAN FLX in this large real-world experience.

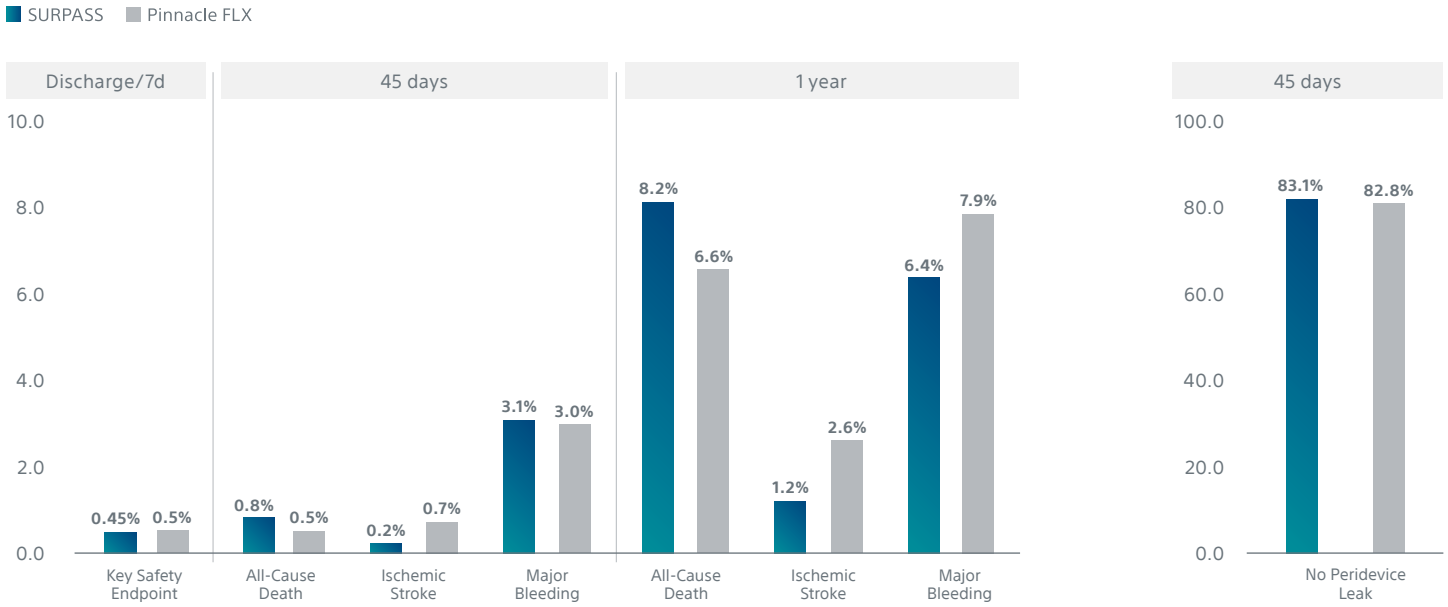
Key Clinical Events at 45 Days

Time-to-event rates in patients implanted with WATCHMAN FLX



SURPASS data demonstrated low adverse event rates with a **0.23% ischemic stroke** rate and **0.44% pericardial effusion** rate at 45 days.

Comparison with PINNACLE FLX Through 1 Year



* Results from different studies are not directly comparable. For illustration purposes only.

The outcomes from the SURPASS NCDR LAAO Registry reflect those observed in the PINNACLE FLX pivotal approval study, reaffirming the excellent safety and sealing profile of the WATCHMAN FLX device in the largest (N=97,185) and highest-risk contemporary cohort of real-world patients studied to date.