WATCHMAN™
INTEGRATED LAAC SOLUTIONS

WATCHMAN™ Left Atrial Appendage Closure Devices Clinical Data

Key Studies | Outcomes | Prospective Clinical Trials

Study Glossary

WATCHMAN FLX™ Pro LAAC Device

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DAPT FLX >

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WATCHMAN FLX™ Pro

Left Atrial Appendage Closure Device

WATCHMAN FLX™ Pro CT Study

At 45 days, with no additional medical therapy beyond SAPT*, site reported data showed all patients were found to be free of DRT through the use of multiple imaging modalities. Follow up serial imaging at 3 months were concluded to be consistent with normal healing.

*The safety and effectiveness of ASA monotherapy has not been established with the WATCHMAN FLX Pro device.

WATCHMAN FLX™ Pro CT Study Design

Study Objective

To assess the healing process post-implantation of WATCHMAN FLX Pro using serial imaging by cardiac CT and TEE

Study Design	Prospective, single-arm, single-center, pre-market investigation
Primary Efficacy Endpoint	Device Tissue Coverage 45 days post implant
Site	Aurhaus University Hospital, Denmark
Number of Patients	25

Patients underwent evaluation of imaging, biomarkers and clinical outcomes according to the schedule below.
An independent core lab and clinical events committee (CEC) were used to assess serial imaging and clinical outcomes.

	BL	14d	45d	90d	1y
Imaging*	X	X	X	X	
Clinical	X	X	X	X	X†
Biomarkers‡	X	X	X	X	

*TEE and CT, MRI optional; †Telephone visit; ‡Labs include biochemical markers including measures of coagulation, platelet and endothelial activation and inflammation.

SH-1553805-AC

WATCHMAN FLX™ Pro CT Study Acute Outcomes

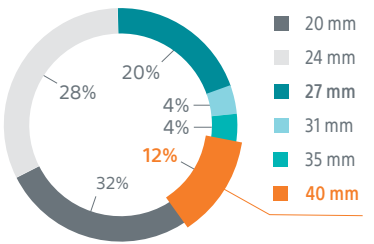
Procedure workflow: Pre-CT with **ICE-guided** implantation of WATCHMAN FLX Pro

Key Patient Characteristics (N=25)

- Age: 73.6 ± 8.4 Years
- CHA_2DS_2-VASc Score: 3.3 ± 1.1
- HAS-BLED Score: 2.8 ± 0.8
- Female: 36.0%
- Prior stroke: 40.0%
- History of major bleeding: 52.0%

Procedural Characteristics (N=25)	
Device Success*	100% (25/25)
1 Device Implanted	100% (25/25)
Discharge Medications	
DAPT	4.0% (1/25)
SAPT**	96.0% (24/25)

Implanted Device Size Mix



*Device success defined as implantation of a WATCHMAN FLX Pro device without in-hospital mortality.
**The safety and effectiveness of ASA monotherapy has not been established with the WATCHMAN FLX Pro device.
Nielsen-Kudsk, JE. Featured Clinical Science Presentation, TCT 2023.

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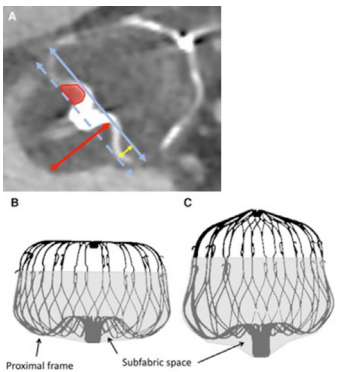
Hypoattenuated Thickening (HAT) - CT Imaging Algorithm



HAT in screw hub cove

HAT on surface

Height of HAT > Height of cove

Sessile HAT

Maximum thickness

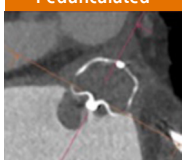
Height of HAT ≤ Height of cove

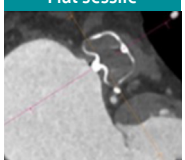
Pedunculated

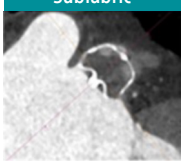
Protruding sessile

Flat sessile

Subfabric







High-grade HAT

High-grade protruding sessile characterized by no LA wall continuity and/or irregular surface

Low-grade HAT

Low-grade protruding sessile characterized by LA wall continuity and smooth surface

Might represent DRT[1]

Likely benign device healing[1]

1. Kramer et al., EHJ CV Imaging 2023;24:250-59

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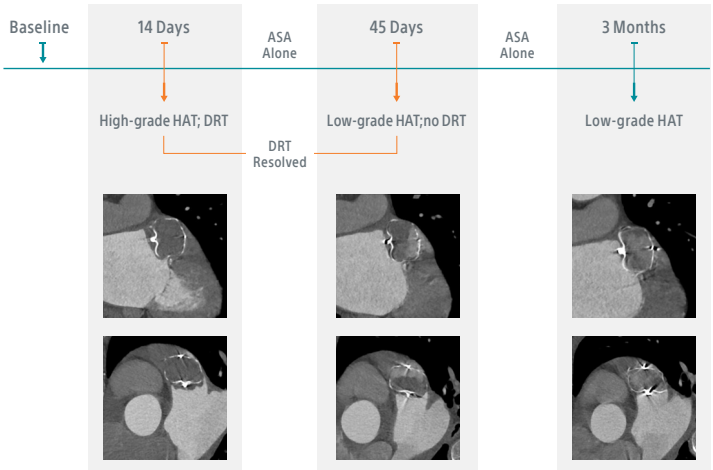
WATCHMAN FLX™ Pro Study Results

Imaging Analysis

At 45 days, with no additional medical therapy beyond SAPT*, site reported data demonstrated all patients exhibited **signs of normal healing with no DRT**

One patient at high risk for DRT had suspected DRT which **resolved by 45 days with continued ASA monotherapy**; follow-up serial imaging at 3 months confirmed to be **consistent with normal healing:**

- Male, age 81 years, CHA2DS2-VASc 3, Myelodysplastic syndrome, Thrombocytopenia
- LAA thrombus 6 months prior to LAAC; Platelet count 33x109/l→91x109/l after platelet transfusion
- ASA only
- No TE complications



*The safety and effectiveness of ASA monotherapy has not been established with the WATCHMAN FLX Pro device.

Nielsen-Kudsk, JE. Featured Clinical Science Presentation, TCT 2023

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WATCHMAN FLX™ Pro CT Study Results

Clinical Outcomes

Only one patient experienced a clinical event through 45 days as detailed below

Clinical Outcomes (N=25)

	Cumulative 14 Days (N = 25 patients)	Cumulative 45 Days (N = 25 patients)
Any Event	0	1*
All-cause Mortality	0	1*
Ischemic Stroke	0	1*
Hemorrhagic Stroke	0	0
Systemic Embolism	0	0
ISTH Major Bleeding	0	1*
ISTH Clinically Relevant Non-major Bleeding	1*	1*
Pericardial Effusion/Tamponade Requiring Pericardiocentesis or Surgery	0	0

Additional testing of stroke etiology demonstrated that severe stenosis of the carotid artery, the proposed cause of an ischemic stroke approximately two months prior to the LAAC procedure, could not be ruled out as the cause.

*Patient experienced all events as detailed below:

- No DRT observed at the 14d follow-up visit; Ischemic stroke with left-sided hemiparesis on day 33; treated with DAPT at time of event; CT angiography showed severe stenosis of the right internal carotid artery dictating that embolic origin from the neck vessels could not be ruled out
- Recent history of ischemic stroke (~2 months prior bilateral carotid artery disease and stent implantation)
- ASA only
- Subsequent thrombolysis was complicated by fatal intracerebral bleeding on day 34

Nielsen-Kudsk, JE. Featured Clinical Science Presentation, TCT 2023

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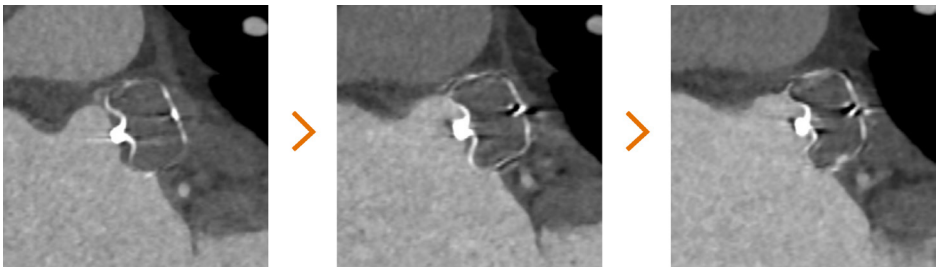
WATCHMAN FLX™ Pro CT Study Conclusion

Conclusion: At 45 days, with no additional medical therapy beyond SAPT, site reported data showed all patients were found to be free of DRT through the use of multiple imaging modalities. Follow up serial imaging at 3 months were concluded to be consistent with normal healing.

WATCHMAN FLX Pro Typical Healing Response



14 Days:
Flat Sessile HAT

45 Days:
No HAT

90 Days:
No HAT

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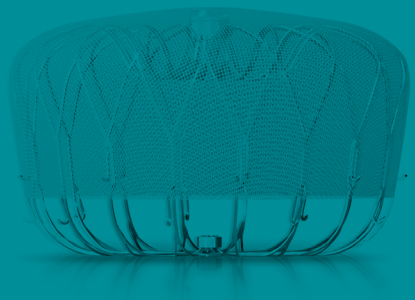

WATCHMAN FLX™

Left Atrial Appendage Closure Device

WATCHMAN FLX™ Left Atrial Appendage Closure Device Design Differentiation

Built on WATCHMAN™ LAAC Device, **the most studied and implanted LAAC device in the world,** WATCHMAN FLX LAAC Device is **designed to advance procedural performance and safety** while **expanding the treatable patient population.**

WATCHMAN FLX™ Left Atrial Appendage Closure Device Design Differentiation

WATCHMAN FLX™ LAAC Device

Treatment Range 14.0 – 31.5 mm Ostium Width

- Full Recapture and Redeployment
- Dual-Row Precision Anchors
- Closed End

18 Strut Frame

Fully-Rounded WATCHMAN FLX Ball

Legacy WATCHMAN™ LAAC Device

Treatment Range 16.8 – 30.5 mm Ostium Width

- Partial Recapture Only
- Single-Row Anchors
- Open End

10 Strut Frame

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PINNACLE FLX

PINNACLE FLX, the **WATCHMAN FLX™ Left Atrial Appendage Closure Device** US IDE Trial, demonstrated **unmatched 0.5% major adverse event rate, 100% Effective LAA Closure,** and a low **1.7% Annualized Ischemic Stroke or Systemic Embolism rate** at 24 months.[1, 2]

View Full 12-Month Results

View Full 24-Month Results

1 Kar S., Circulation, 2021.
2 Doshi et al. JAHA, 2023.

PINNACLE FLX Study Overview

A US IDE to evaluate the safety and efficacy of the WATCHMAN FLX™ Left Atrial Appendage Closure 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	45 Day	6 Months	1 Year	18 Months	2 Years
TEE	TEE	TEE*	TEE	Clinic Visit	Clinic Visit

DOAC and ASA* → **DAPT** → **ASA Ongoing**

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

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WATCHMAN FLX™ Left Atrial Appendage Closure Device: The New Standard by Which Others Must be Judged

ADVANCED SAFETY

Fully Rounded Ball for Safety

0.5%*

Major Adverse Event Rate[1]

Dual-Row Precision Anchors for Reliability

0%

Pericardial Effusions
Requiring open cardiac surgery through 24 mos[2]

0%

Device Embolization
24 Months[2]

80% more LAA Contact Points for Improved Sealing

1.8%

DRT Through 24 Months

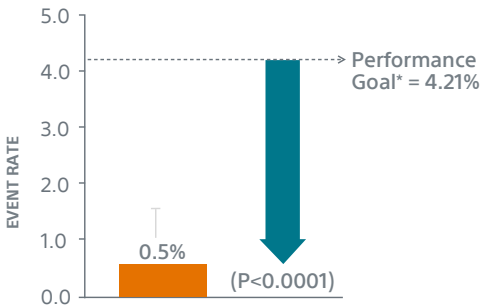
*Occurrence of one of the following events between the time of implant and within 7 days following the procedure or by hospital discharge, whichever is later: all-cause death, ischemic stroke, systemic embolism, or device or procedure related events requiring open cardiac surgery or major endovascular intervention.

1 Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.
2 Doshi et al. JAHA, 2023.

WATCHMAN FLX™ Left Atrial Appendage Closure Device Demonstrated Excellent Safety and Efficacy at 12 Months[1]

Primary Safety Endpoint:

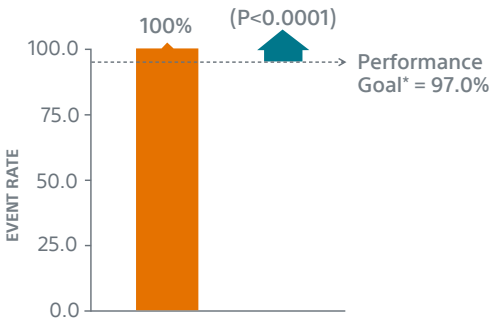
Peri-procedural Adverse Events



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.

1 Kar, S., Circulation, 2021.

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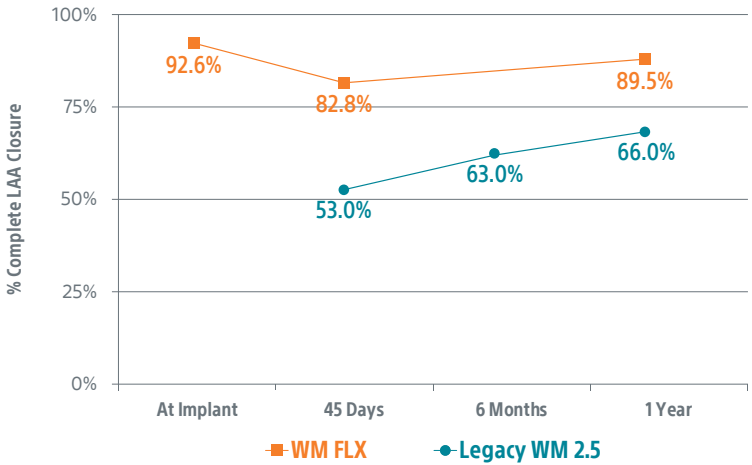
WATCHMAN FLX™ Left Atrial Appendage Closure Device Complete Closure Rates

WATCHMAN FLX LAAC Device has significantly improved complete closure rates over Legacy WATCHMAN™ Left Atrial Appendage Closure Device; any residual leak with WATCHMAN FLX LAAC Device was < 3 mm via TEE[1]

COMPLETE Closure Comparison



Note: Graph displays two separate clinical studies: PROTECT-AF AND PINNACLE FLX.

1 Kar, Circulation, 2021.

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PINNACLE FLX 24-Month Results Reinforce Long-Term Efficacy for WATCHMAN FLX™ Left Atrial Appendage Closure Device[1, 2]

PROVEN LONG-TERM EFFICACY

80% Increase in Contact Points for Sealing

1.7%

Ischemic Stroke/ Systemic Embolism (Per 100 patient yrs/annualized)[2]

Dual-Row Precision Anchors for Reliability

0%

Pericardial Effusions Requiring open cardiac surgery through 24 mos[2]

0%

Device Embolization Through 24 Months[2]

80% more LAA Contact Points for Improved Sealing Based on Effective LAA Closure at 45 Days

100%†

LAA Effective Closure[1]

96.2%

Patients Discontinued OAC at 45 Days[1]

† LAA effective closure at 12 months is defined as any peri-device flow with jet size <5mm per core laboratory-assessed TEE.

1 Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.
2 Doshi et al. JAHA, 2023.

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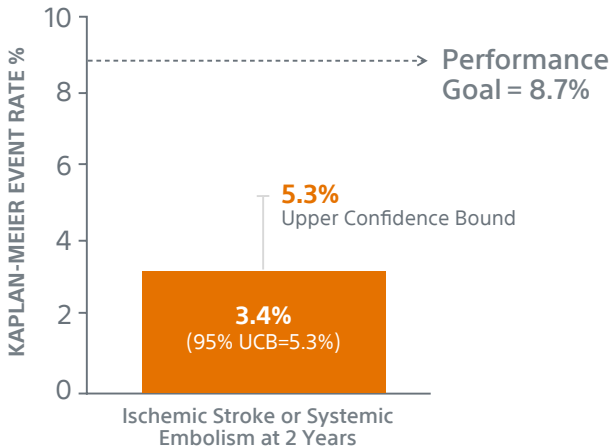
PINNACLE FLX 24-Month Data Demonstrates Proven Efficacy with a Low Annualized Stroke Rate[1]



1.7%

per 100-patient years/annualized stroke or systemic embolism rate

1 Doshi et al. JAHA, 2023.
This rate is consistent with expectations in this high stroke risk patient population.
Expected rate of 4.0% (derived from the combined PROTECT-AF, CAP, PREVAIL, and CAP-2 studies) plus a clinically relevant delta.

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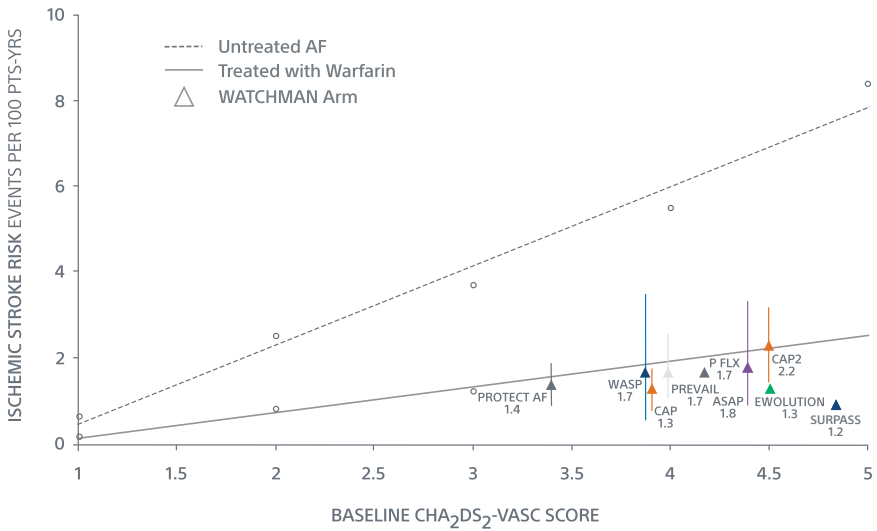
Ischemic Stroke Across WATCHMAN Trials

Long-term data continues to differentiate WATCHMAN FLX™ Left Atrial Appendage Closure Device and provides on-going clinical support for LAAC to reduce the risk of ischemic stroke in NVAF patients.



Note: Data from ASAP, WASP and EWOLUTION includes patients currently contraindicated for LAAC with WATCHMAN in the United States. Friberg. Eur Heart J (2012); NICE UK (2014). Reddy VY, et al. JACC 2017; 70(24): 2964-2975 (PROTECT AF and PREVAIL). Holmes, DR et al. JACC 2019; In Press (CAP and CAP2). Phillips KP et al. ILC Heart & Vasculature 2019; 23(100358) (WASP). Boersma LVA et al. Circulation: Arrhythmia and Electrophysiology. 2019; 12(4) : e006841. (EWOLUTION). Sharma D et al. JACC 2016; 67(18): 2190-2192 (ASAP). Late Breaking Clinical Trial at CRT 2023, Presented by Samir Kapdia. (SURPASS)

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PINNACLE FLX
Prohibitive Anatomy

97% procedural success and zero leak in 91% of WATCHMAN FLX™ Left Atrial Appendage Closure Device patients with prior prohibitive anatomy for a Legacy WATCHMAN™ Left Atrial Appendage Closure Device.[1]

View Full Study Results

1 Ellis,C. et al, Heart Rhythm, 2021.

Study Design

The purpose of this study was to evaluate the safety and efficacy of WATCHMAN FLX™ LAAC Device in patients with a failed Legacy WATCHMAN™ LAAC Device attempt or prohibitive LAA anatomy.

STUDY COHORTS

- Patients with a prior failed Legacy WATCHMAN 2.5 attempt (N=11)
- Patients with prohibitive anatomy to attempt LAAC with Legacy WATCHMAN (N=88)
- These study cohorts represented 21.6% of all patients (99 of 458) in PINNACLE FLX

CONTROL COHORT

- Patients (N=359) that did not meet the criteria for prior failed or prohibitive anatomy to receive a Legacy WATCHMAN Device
- (458 total patient – 99 in study cohorts = 359 in the control cohort)

The PINNACLE FLX study enrolled 58 roll-in patients and 400 primary study patients between May 2018 and November 2018. Outcomes in this analysis are through 1 year.

1 Ellis.C, et al, Heart Rhythm, 2021.

Study Outcomes

The purpose of this study was to evaluate the safety and efficacy of WATCHMAN FLX™ LAAC Device in patients with a failed Legacy WATCHMAN™ LAAC Device attempt or prohibitive LAA anatomy.

There was **zero leak** in 91% of the prohibitive anatomy cohort.[1]

ZERO LEAK

- **Zero leak in 90.9%** in the failed Legacy WATCHMAN cohort
- **Zero leak in 91.3%** in the prohibitive anatomy cohort
- **Zero leak in 89.5% in the control cohort**

PROCEDURAL SUCCESS

- 100% of patients (11/11) with a prior failed Legacy WATCHMAN were successfully implanted with WATCHMAN FLX LAAC Device
- 96.6% of patients (85/88) with prohibitive anatomy were successfully implanted with WATCHMAN FLX LAAC Device

1 Ellis.C, et al, Heart Rhythm, 2021.

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IDE TRIALS

PINNACLE FLX (WATCHMAN FLX™ Left Atrial Appendage Closure Device) and Amulet IDE (Amplatzer™ Amulet™ LAA Occluder)

View Full PINNACLE FLX Results

View Full Amulet IDE Results

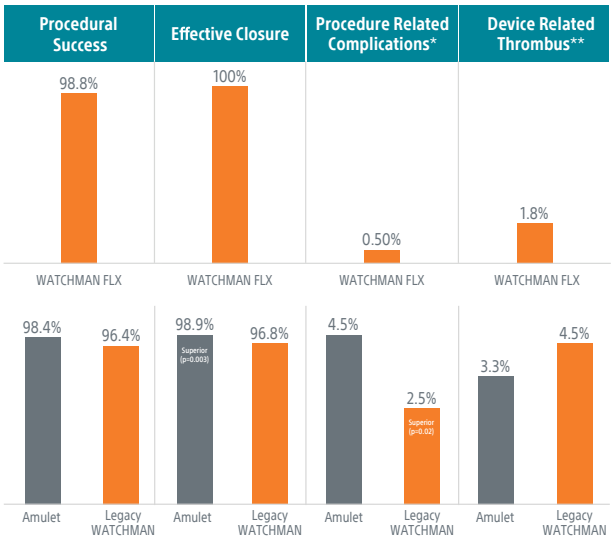
PINNACLE FLX and Amulet IDE Outcomes

PINNACLE FLX Clinicial Trial[1,2]

Characteristic	WATCHMAN FLX™
Patients	400
Age	73.8 ± 8.6
CHA_2DS_2-VASc Score	4.2 ± 1.5
HAS-BLED Score	2.0 ± 1.0

Amulet IDE[3]

Characteristic	Amulet™	Legacy WATCHMAN™
Patients	934	944
Age	75.0 ± 7.6	75.1 ± 7.6
CHA_2DS_2-VASc Score	4.5 ± 1.3	4.7 ± 1.4
HAS-BLED Score	3.2 ± 1.0	3.3 ± 1.0



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PINNACLE FLX and Amulet IDE Outcomes

1 Kar S., MD, et. al, Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device Results From the PINNACLE FLX Trial, CIRCULATION, 2021.

2 Kar S., MD, 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.

3 Primary Outcomes of the Amplatzer™ Amulet™ IDE Randomized Controlled Trial, Presented as an abstract at the European Society of Cardiology Congress, August 30, 2021.

*Procedure related complications is defined as the occurrence of one of the following events between the time of implant and within 7 days after the procedure or by hospital discharge, whichever was later: death, ischemic stroke, systemic embolism, or 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.

†Procedure related complications is defined as adverse events which are adjudicated as procedure-related and require either an invasive surgical or percutaneous intervention.

±PINNACLE FLX data measured at 24 months; Amulet IDE data measured at 18 months.

SEAL FLX
Study

WATCHMAN FLX™ Left Atrial Appendage Closure Device demonstrated **statistical superiority for complete occlusion** vs Amulet™ LAA Occluder.[1]

View Full Study Results

1 Korsholm-K et al.; TCT 2021.

Study Design

First study to exclusively compare occlusion results of WATCHMAN FLX™ LAAC Device vs Amulet™ LAA Occluder using CT imaging.[1]

- Single-center, retrospective study of LAAO implantation at Aarhus University Hospital (Denmark) between 2018-2020
  - 1st cohort: Amplatzer Amulet (N=150) 2018 – 2019
  - 2nd cohort: WATCHMAN FLX (N=150) 2019 – 2020
- Cardiac CT was performed 8 weeks after LAAO

Primary Outcome **Complete Occlusion*** Based on Cardiac CT Imaging

*Complete LAA occlusion defined as no visible peri-device leak (PDL) and absence of contrast patency in the distal LAA (LAA/left atrium Hounsfield ratio <0.25).

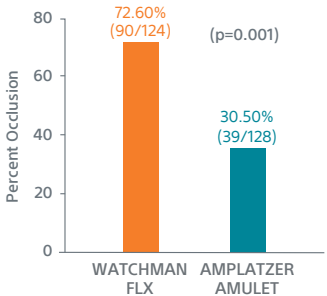
1 Korsholm-K et al.; TCT 2021.

SH-1553805-AC

Study Outcomes

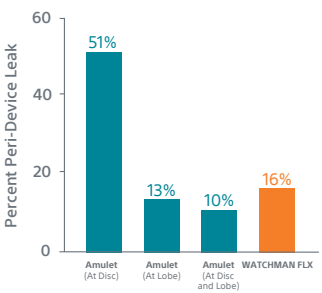
WATCHMAN FLX™ LAAC Device Demonstrated Statistically Superior Complete Occlusion* vs Amulet™ LAA Occluder (p=0.001).[1]

Complete Occlusion* at 8 Weeks (per CT)



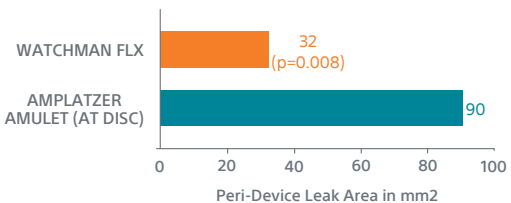
More Leak Pathways with a Two-Component Device at 8 Weeks (per CT)

Peri-Device Leak



Leak Measurements were Statistically Larger with Amulet than WATCHMAN FLX (p=0.008) at 8 Weeks (per CT)

Leak Size (mm2)



*Complete LAA occlusion defined as no visible peri-device leak (PDL) and absence of contrast patency in the distal LAA (LAA/Left Atrium Hounsfield Ratio <0.25).

1 Korsholm-K et al.; TCT 2021.

SH-1553805-AC

SWISS APERO
Study

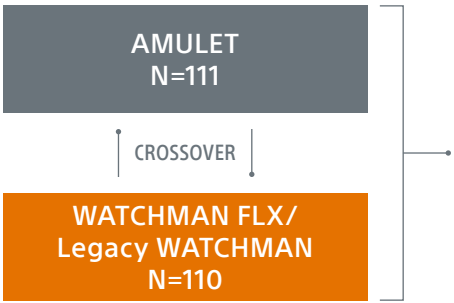
WATCHMAN FLX™ LAAC Device demonstrated **statistical superiority for procedural complications over Amulet™ LAA Occluder.**[1]

View Full Study Results

1 Presented as an abstract at TCT 2021, published Circulation, 2021.

SWISS APERO Study Design and Endpoints

Investigator-initiated, multicenter, randomized superiority trial to assess if Amulet™ LAA Occluder is superior to Legacy WATCHMAN™ LAAC Device/WATCHMAN FLX™ LAAC Device based on device crossover or complete LAA sealing.[1]



Primary Endpoints

- Composite of justified crossover to the non-randomized device
- LAA patency (via CT) at 45 days

Secondary Endpoints

- PDL at 45-day TEE
- DRT at 45-day TEE and CT
- Procedural complications
- Clinical outcomes at 45 days
  - composite of CV death, stroke or systemic embolism, all bleedings

221 patients were randomly assigned to either Amulet (N=111) or WATCHMAN (N=110) [Legacy WATCHMAN N=25, WATCHMAN FLX N=85]

1 Presented as an abstract at TCT 2021, published Circulation, 2021.

SH-1553805-AC

Study Outcomes

Procedure Related Complications and Pericardial Effusions

Statistically significantly higher rate of procedural complications with Amulet™ LAA Occluder, despite European implanter experience with the device.[1]

Primary Safety Endpoint Components	Amulet (N=111)	WATCHMAN/ FLX (N=110)	Amulet vs WATCHMAN Risk Ratio (95% CI)	P Value
Major Procedure Related Complication No. (%)*	10 (9.0%)	3 (2.7%)	3.30 (0.93-11.68)	0.047
Death, No. (%)	2 (1.8%)	0 (0.0%)		0.498
Cerebrovascular Event, No. (%)	2 (1.8%)	0 (0.0%)		0.498
Systemic Embolism, No. (%)	0 (0.0%)	0 (0.0%)		1
Major Bleeding (BARC 3-5), No. (%)	8 (7.2%)	2 (1.8%)	3.96 (0.86-18.25)	0.054
Clinically Relevant Pericardial Effusion, No. (%)	4 (3.6%)	0 (0.0%)		0.122
Device Embolization, No. (%)	1 (0.9%)	1 (0.9%)	3.99 (0.06-16.04)	0.995
Acute Kidney Injury, No. (%)	0 (0.0%)	0 (0.0%)		

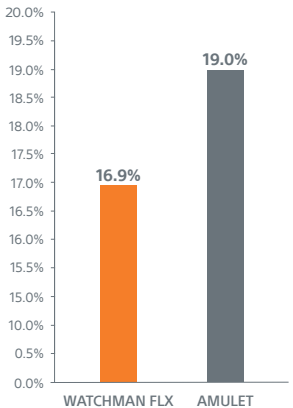
*Composite of death, CVE, systemic embolism, major bleeding, cardiac tamponade, device embolization, or acute kidney injury ocurring within 7 days or thereafter if deemed procedure-related.

All cardiac tamponades observed within 45 days after LAAC occurred in the Amulet Group.

1 Presented as an abstract at TCT 2021, published Circulation, 2021.

Peri-Device Leak

WATCHMAN FLX™ LAAC Device showed lower PDL than Amulet. No statistically significant difference in LAA patency.[1]



SH-1553805-AC

Real-World Outcomes with WATCHMAN FLX™ LAAC Device: SURPASS Early Results (45-Days)[1]

The SURPASS Early Results analysis of the NCDR-LAAO Registry reinforces the excellent safety profile WATCHMAN FLX LAAC Device in over 16,000 real-world NVAF Patients.

View Study Results

1 Late Breaking Clinical Trial, Presented at CRT 2022 by Dr. Samir Kapadia.

SURPASS Early Results Design

Objective

Assess **safety and efficacy outcomes** in patients in the NCDR-LAAO Registry who recieved **a commercial WATCHMAN FLX™ LAAC Device.**

Design

WATCHMAN FLX LAAC Device patients included in the NCDR-LAAO Registry from **AUGUST 2020 through August 2022,** will be followed through 2 years post-implant. No exclusion criteria.

THIS ANALYSIS	45-Day Outcomes, N=16,048 August 5, 2020 – March 31, 2021

Patient Characteristics and Medications

CHA_2DS_2-VASc Score	4.8 ± 1.5
HAS-BLED Score	2.4 ± 1.0
Clinically Relevant Bleeding Event, %	61.8

Antiplatelet/Anticoagulant Medications	Discharge N=16,048
Warfarin Alone, %	2.9
Warfarin + Aspirin, %	9.1
NOAC Alone, %	21.0
NOAC + Aspirin, %	49.1
DAPT, %	7.9
SAPT, %	2.5
No OAC or APT, %	0.5

SURPASS Endpoints

Safety Endpoint	Composite of all-cause death, ischemic stroke, systemic embolism, or device/procedure-related events requiring open cardiac surgery or major endovascular intervention between device implantation and 7 days or hospital discharge (whichever is later)
Effectiveness Endpoint	Occurrence of ischemic stroke or systemic embolism at 24 months post-implant
Additional Endpoints	• All-Cause Death • Stroke • Device-Related Thrombus • Systemic Embolism • Major Bleeding • Effective Device Closure • Implant Success • Device Embolization

1 Late Breaking Clinical Trial at CRT 2022, Presented by Dr. Samir Kapadia.

SH-1553805-AC

The SURPASS Early Results Data Reinforces the Outstanding Safety, Simplicity, and Seal of the WATCHMAN FLX™ Left Atrial Appendage Closure Device.

Safety

0.37%

Major Procedural Adverse Event Rate*
(60/16,048)

Simplicity

98%

Procedural Success
(16,048/16,446)

Seal

82%

Complete LAA Closure at 45 Days

95%

LAA Closure <3mm at 45 Days

*Key safety endpoint: 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 seven days or hospital discharge (whichever is later).

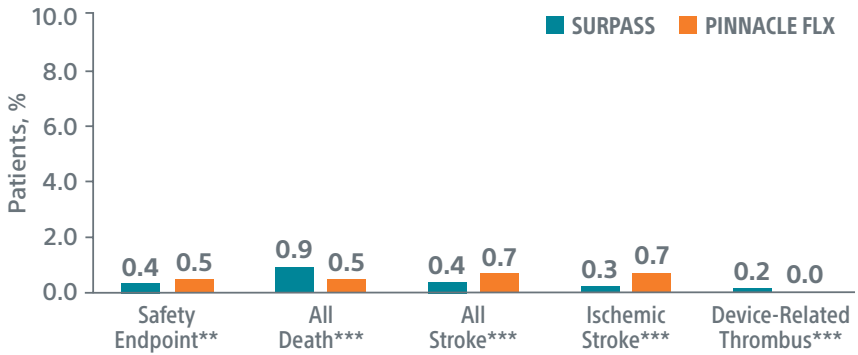
SH-1553805-AC

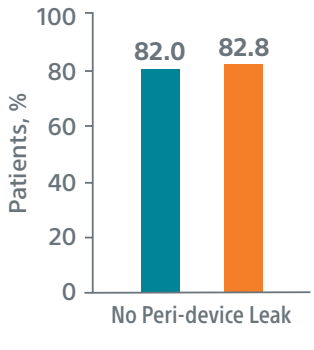
Exceedingly Low Pericardial Effusion Rates Observed in WATCHMAN FLX™ Left Atrial Appendage Closure Device's Earliest U.S. Experience

	Discharge N=16,048	45-days N=14,107
Pericardial effusion requiring either surgical or percutaneous intervention	0.32% (52/16,048)	0.51% (72/14,107)
• PE requiring open cardiac surgery	0.01% (2/16,048)	0.03% (4/14,107)
• PE requiring percutaneous treatment	0.31% (50/16,048)	0.50% (70/14,107)

SH-1553805-AC

These Real-World Data Reinforce the Excellent Safety Profile WATCHMAN FLX™ Left Atrial Appendage Closure Device Demonstrated in the PINNACLE FLX Trial*





*Results from different clinical investigations are not directly comparable.
**Safety endpoint defined as Composite of all-cause death, ischemic stroke, systemic embolism, or device/procedure-related events requiring open cardiac surgery or major endovascular intervention between device implantation and 7 days or hospital discharge (whichever is later).
***45-day outcome.

SH-1553805-AC

REAL-WORLD OUTCOMES WITH WATCHMAN FLX™ LAAC DEVICE: SURPASS 1-YEAR RESULTS

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 of the WATCHMAN FLX Device with a **0.49% major procedural adverse event rate within 7 days or hospital discharge** (whichever is later) and **98% implant success in >66,000 real-world NVAF patients.**[1]

View Study Results

1. Late Breaking Clinical Trial at CRT 2023, Presented by Samir Kapdia.

SURPASS 1-Year Design

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 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
- CHA_2DS_2-VASc: 4.8 ± 1.5
- HAS-BLED – 2.4 ± 1.0
- Women: 41%
- Clinically Relevant Bleeding: 57.7%

Safety Endpoint

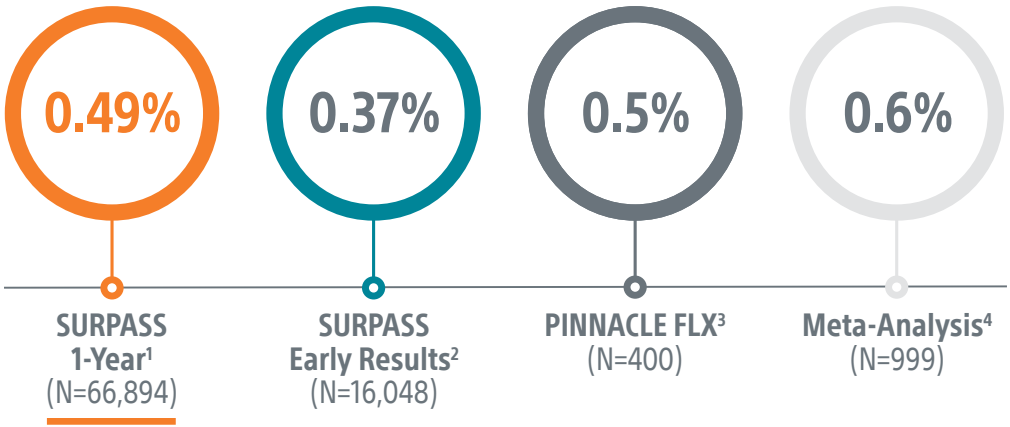
Composite of all-cause death, ischemic stroke, systemic embolism, or device/procedure-related events requiring open cardiac surgery or major endovascular intervention between device implantation and 7 days or hospital discharge (whichever is later).

SH-1553805-AC

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.

Key Safety Endpoints

(Within 7 Days or Discharge)

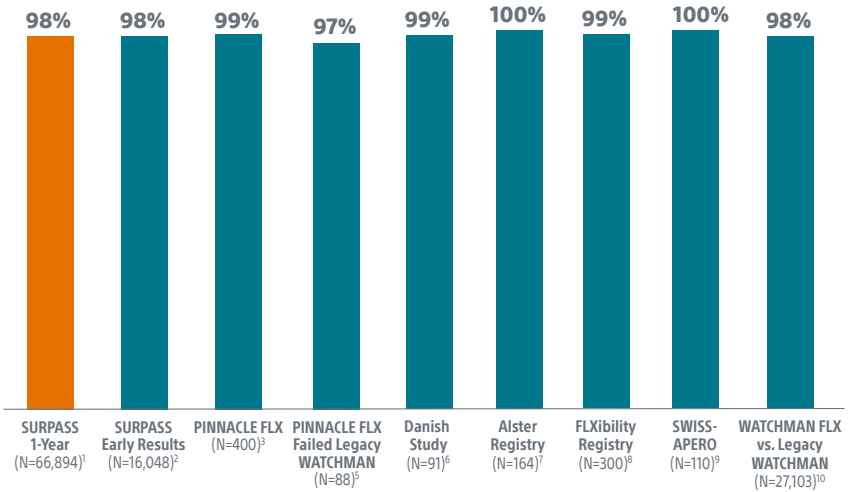


1 Late Breaking Clinical Trial at CRT 2023, Presented by Samir Kapdia. 2 Kapadia, CRT 2022. 3 Kar, Circulation 2021. 4 Della Rocca et al. Heart Rhythm 2022.

SH-1553805-AC

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



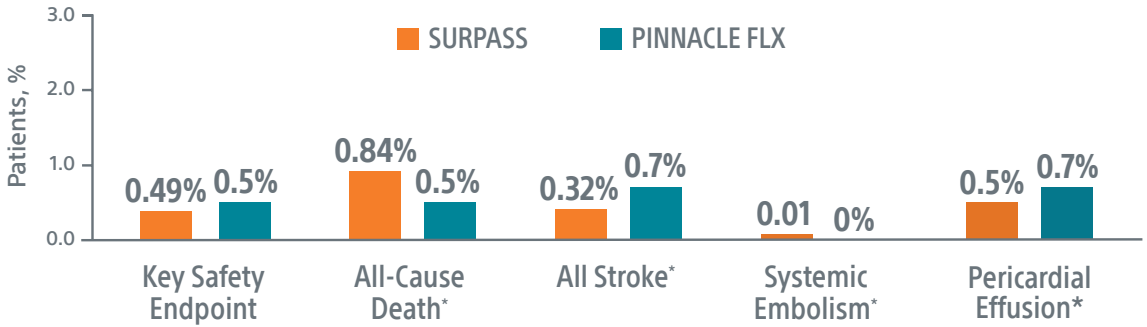
1 Late Breaking Clinical Trial at CRT 2023, Presented by Samir Kapdia. 2 Kapadia, CRT 2022. 3 Kar, Circulation 2021. 4 Della Rocca et al. Heart Rhythm 2022. 5 Ellis, Heart Rhythm, 2021. 6 Korsholm, WM FLX First Experience, JACC, 2020. 7 Bergmann, Alster Registry, Presented ePCR 2021. 8 Betts, EHRA 2022. 9 Galea, SWISS APERO Trial, Cirulation, 2021. 10 Freeman, HRS 2022.

SH-1553805-AC

The 1-Year SURPASS Data confirms the excellent safety profile the WATCHMAN FLX™ Device demonstrated in the PINNACLE FLX trial, with the largest (N=66,894) WATCHMAN FLX Device patient population to date.

Comparison with PINNACLE FLX[1]

45-Day Outcomes



*Results from different clinical investigations are not directly comparable.

1 Kar, Circulation 2021.

SH-1553805-AC

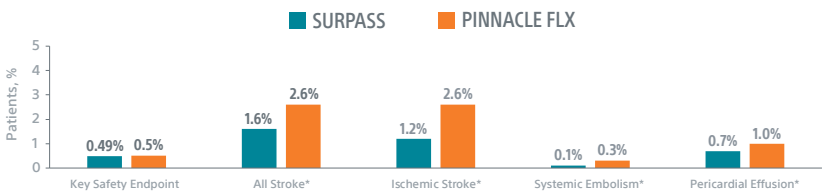
The WATCHMAN FLX™ Device delivers proven stroke reduction and positively sustained outcomes at 1 year in the largest and highest-risk patient population studied to date.

1-Year Stroke Rates

1.6%
All Stroke

1.2%
Ischemic Stroke

1-Year Outcomes Comparison with PINNACLE FLX[1]



1 Kart et al. Circulation 2021.
*1-Year Outcomes (KM Rates). Results from different studies are not directly comparable. For illustration purposes only.

SH-1553805-AC

Procedural and Short-Term Follow-up Outcomes of Amplatzer Amulet™ LAA Occluder vs WATCHMAN FLX™ LAAC Device: A Meta-Analysis[1]

The largest comparison of peri-procedural success and short-term outcomes of WATCHMAN FLX LAAC Device vs Amplatzer Amulet LAA Occluder reveals superior procedural safety, higher procedural success, and better LAA closure with WATCHMAN FLX LAAC Device.

View Full Study Results

1 Della Rocca,D.G, Heart Rhythm, February 2022.

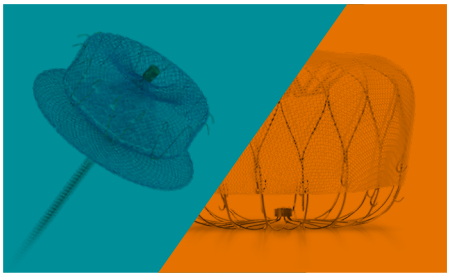
Study Design

Meta-Analysis of 4186 Patients from 21 Studies

- 3187 Amulet implants
- 999 WATCHMAN™ FLX LAAC Implant Device

No Difference in Thromboembolic Risk Between Groups

- CHA_2DSC_2-VASc: 4.3 ± 1.5 for Amulet LAA Occluder
- CHA_2DSC_2-VASc: 4.2 ± 1.5 for WATCHMAN FLX LAAC Device



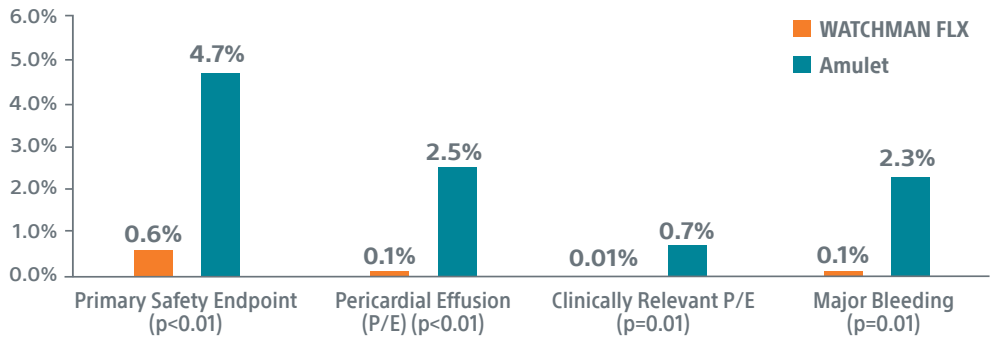
Safety endpoint was the occurrence of death, stroke, major bleeding, myocardial infarction, major vascular complications, device embolization, or pericardial effusion within 7 days post-procedure.

Data from a first imaging study performed within 3-month were used to assess the incidence of peri-device leaks >5mm and device-related thrombosis (DRT).

Key Results: Safety

WATCHMAN FLX™ Left Atrial Appendage Closure Device showed a significantly lower incidence of peri-procedural complications. (p<0.01)

Adverse Events within 7 days of Implant

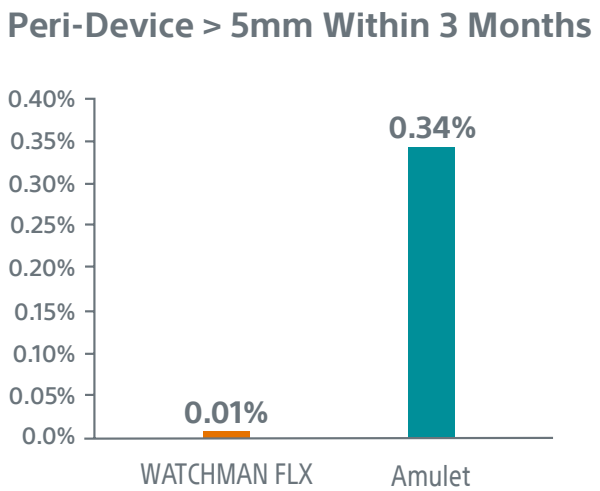


- 0 device embolizations occurred with WATCHMAN FLX LAAC Device vs.15 with Amulet™ Occluder
- WATCHMAN FLX™ LAAC Device demonstrated lower DRT than Amulet Occluder (1% vs 1.6%)
- No difference was observed for death or stroke between groups

SH-1553805-AC

Key Results: Seal

WATCHMAN FLX™ Left Atrial Appendage Closure Device demonstrated fewer peri-device leaks >5mm than Amplatzer Amulet™ LAA Occluder (0.01% vs 0.34%, p=0.06).



SH-1553805-AC

The ALSTER-FLX Registry: 3-Month Outcomes Following Left Atrial Appendage Occlusion Employing a Next-Generation Device, a Matched-Pair-Analysis to EWOLUTION[1]

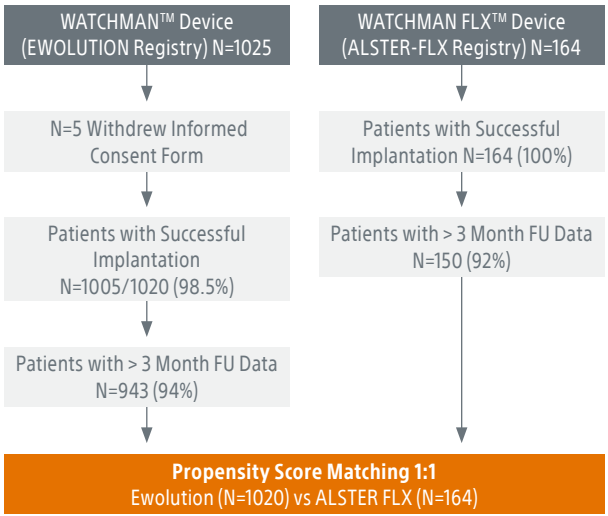
WATCHMAN FLX™ LAAC Device showed significant improvement for safety, simplicity and seal vs Legacy WATCHMAN™ LAAC Device in this retrospective registry analysis comparing early experience with both devices.

View Full Study Results

1 Paitazoglou C., MD, Heart Rhythm, Feb. 2022.

Study Design

Comparison



Patient Characteristics

Compared to the patients in the EWOLUTION Registry, the ALSTER-FLX Registry had statistically higher:

- Bleeding risk (EWOLUTION 2.3 ± 1.2 vs ALSTER FLX 3.2 ± 0.8, p <0.001)
- History of major bleeding (EWOLUTION 31% vs ALSTER FLX 77.4%, p <0.001)
- History of ischemic stroke (EWOLUTION 19% vs ALSTER FLX 34.1%, p <0.001)

SH-1553805-AC

All outcomes were improved with WATCHMAN FLX™ LAAC Device vs Legacy WATCHMAN™ LAAC Device despite a higher morbidity (higher risk) patient population in the WATCHMAN FLX LAAC Device group.

Safety

- 0% stroke and 0% device embolization in the ALSTER-Registry compared to EWOLUTION (stroke 0.5%, device embolization 0.4%)
- Lower DRT with ALSTER FLX patients (2.4%) as compared to EWOLUTION patients (3.7%)

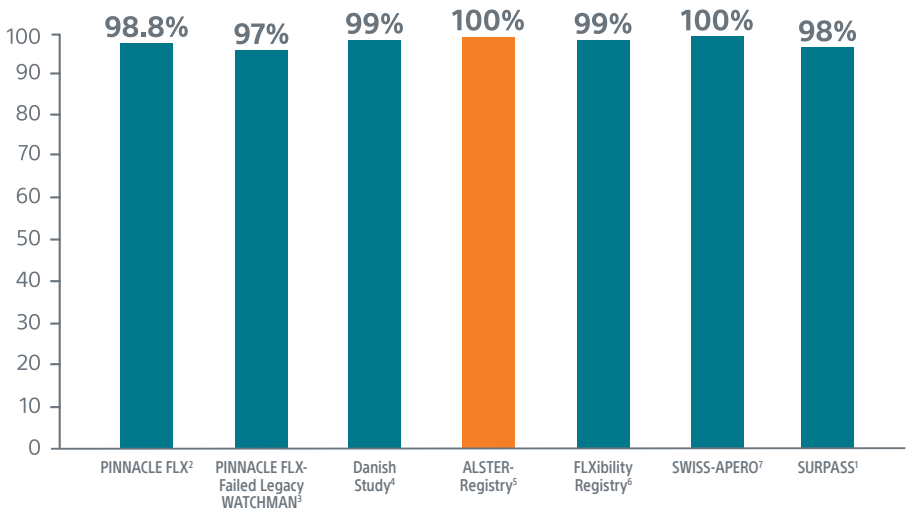
Simplicity

- 100% Procedural Success vs in the ALSTER-Registry compared to 99% in EWOLUTION

Seal

- Statistically-significantly higher complete sealing rate in the ALSTER-Registry compared to EWOLUTION at three months (ALSTER FLX 90% vs EWOLUTION 79.4%, p=0.039 after matching)

High Procedural Success Across Multiple WATCHMAN FLX™ Left Atrial Appendage Closure Device Studies



1 Late Breaking Clinical Trial at CRT 2022, Presented by Dr. Samir Kapadia. 2 Kar, PINNACLE FLX; 12 Month Outcomes, CIRCULATION, 2021. 3 Ellis, Structural Heart, 2021.
4 Korsholm, WM FLX First Experience, JACC, 2020. 5 Bergmann, Alster-Registry, Presented ePCR 2021. 6 Betts, Poster Presentation HRS, 2021. 7 Galea, SWISS-APERO Trial, CIRCULATION, 2021.

SH-1553805-AC

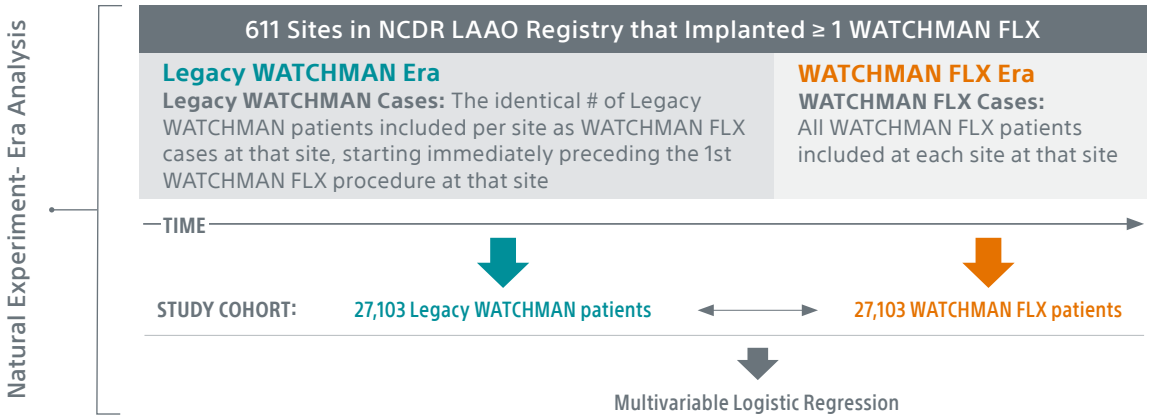
Safety and Acute Procedural Outcomes of LAAO with the First-Generation WATCHMAN and Next-Generation WATCHMAN FLX™ Devices

In-Hospital Outcomes for the WATCHMAN FLX LAAC Device Compared with the Legacy WATCHMAN™ LAAC Device.

View Full Study Results

Key Results: Safety

The purpose of this study was to compare the safety and acute procedural success of the first-generation Legacy WATCHMAN™ device vs the next-generation WATCHMAN FLX™ device.[1]



Primary Endpoint: In-hospital major adverse events (MAE) Composite of death, cardiac arrest, stroke, TIA, ICH, SE, major bleeding, major vascular complication, MI, pericardial effusion requiring intervention, and device embolization.

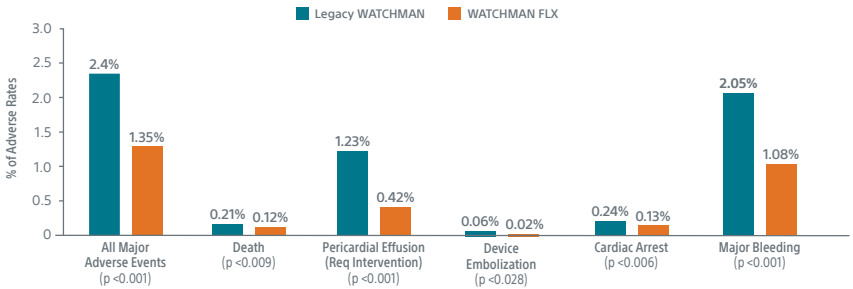
1 Late Breaking Clinical trial at HRS 2022 presented by Dr James Freeman.

SH-1553805-AC

Study Outcomes

The purpose of this study was to compare the safety and acute procedural success of the first-generation WATCHMAN 2.5 device vs the next-generation WATCHMAN FLX device.[1]

In-Hospital Adverse Event Rates



- In a natural experiment era analysis, WATCHMAN FLX associated with a significant 43% fewer in-hospital adverse events
- WATCHMAN FLX associated with significantly lower rates of several components of MAEs
  - Death
  - Pericardial effusion requiring intervention
  - Cardiac arrest
  - Major bleeding
  - Device embolization

1 Late Breaking Clinical trial at HRS 2022 presented by Dr James Freeman.

CHAMPION-AF Clinical Trial

The **CHAMPION-AF** trial evaluates LAAC vs NOAC in the broadest NVAF patient population to establish **WATCHMAN FLX™ Left Atrial Appendage Closure Device** as a first-line option to reduce stroke risk.

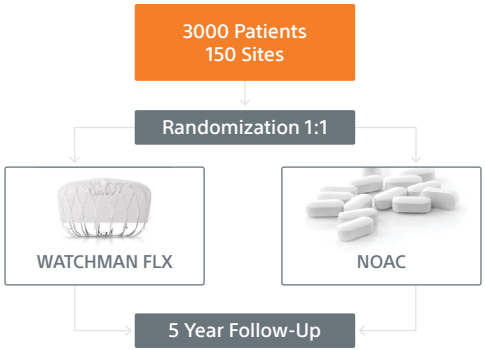
View Trial Design and Rationale

CHAMPION-AF: Study Objective and Design

OBJECTIVE

The primary objective of the CHAMPION-AF Trial is to determine if left atrial appendage closure with the **WATCHMAN FLX™ LAAC Device** is a reasonable alternative compared with non-vitamin K oral anticoagulants (NOACs) in patients with non-valvular atrial fibrillation.

DESIGN



SH-1553805-AC

CHAMPION AF: Primary Endpoints and Patient Selection Criteria

PRIMARY ENDPOINTS

- WATCHMAN FLX™ LAAC Device is non-inferior for the occurrence of stroke (including ischemic and/or hemorrhagic), cardiovascular (CV) death (including unexplained death), and systemic embolism at 36 months
- WATCHMAN FLX LAAC Device is superior for non-procedural bleeding (ISTH* major bleeding and clinically relevant non-major bleeding) at 36 months
- WATCHMAN FLX LAAC Device is non-inferior for the occurrence of ischemic stroke and systemic embolism at 60 months

PATIENT SELECTION

Enrollment Completed

- Patient has documented non-valvular atrial fibrillation (i.e., atrial fibrillation in the absence of moderate or greater mitral stenosis or a mechanical heart valve)
- CHA_2DS_2-VASc score of ≥ 2 for men and ≥ 3 for women
- Patient is deemed to be suitable for long-term NOAC

*International Society of Thrombosis and Hemostasis, Bleeding Assessment Tool.

SH-1553805-AC

OPTION Clinical Trial

The **OPTION Trial** evaluates LAAC with the **WATCHMAN FLX™ Left Atrial Appendage Closure Device** as a **reasonable alternative to OAC following catheter ablation** for patients with NVAF.

View Trial Design and Rationale

OPTION Trial[1]

OBJECTIVE:

To determine if LAAC with the WATCHMAN FLX™ Left Atrial Appendage Closure Device is a reasonable alternative to oral anticoagulation following catheter ablation for patients with NVAF.

1600 randomized subjects at 130 sites world-wide (enrollment completed)
Randomized 1:1 (Device to OAC)
Follow-Up at 3, 12, 24, and 36 months

MEDICATION REGIMENS

Device Group
Market approved OAC and aspirin (75-100mg recommended) for 90 days followed by aspirin through at least 12-months post-implant (recommended for duration of the trial).

Control (OAC) Group
Market approved OAC used per IFU for atrial fibrillation stroke prevention for the duration of the trial.

PRIMARY ENDPOINTS

Non-inferiority: All cause death, stroke, SE through 36 months
Superiority: Major non-procedural bleeding through 36 months

1 Study protocol, manuscript in development for publication.

SH-1553805-AC

DAPT FLX

Comparative Effectiveness of Post-Procedure Medications Following Left Atrial Appendage Occlusion: A DAPT Analysis with the WATCHMAN FLX™ Device[1]

Among **over 7,000 patients**, there were **no differences in rates of death, stroke, major bleeding or DRT** among those treated with DAPT vs. warfarin or DOAC plus aspirin at 45 days following LAAO with WATCHMAN FLX.

View Study Results

DAPT FLX Design

Objective

- To evaluate if dual antiplatelet therapy (DAPT) as an alternative post-implant drug regimen option is safe

Design

- National Cardiovascular Data LAAO Registry (NCDR) patients undergoing WATCHMAN FLX implant were included in unmatched and 1:1 propensity matched analyses comparing discharge on DAPT vs. Aspirin and OAC (Warfarin or DOAC)
- Inclusion criteria
  - Successful WATCHMAN FLX implant (defined as device margin residual leak ≤ 5 mm at time of implant)
  - CHA_2DS_2-VASc ≥2 in men or ≥3 in women
  - Prescribed either DAPT, DOAC + Aspirin or Warfarin + Aspirin at discharge
- Differences in the composite endpoint were evaluated between groups

Primary Outcome
Composite endpoint between discharge and 45 days:

- All cause death
- Stroke
- Major bleed
- Systemic embolism

SH-1553805-AC

Adjusted Baseline Characteristics

To adjust for differences in baseline characteristics, 1:1 propensity score matching between groups (DAPT vs warfarin + Aspirin; DAPT vs DOAC + Aspirin) was performed. Variables included age, gender, race/ethnicity, CHA_2DS_2VASc and HAS BLED score components, atrial fibrillation pattern, diabetes, fall risk, history of bleeding, chronic lung disease, sleep apnea, cardiomyopathy, coronary artery disease, prior ablation, LVEF and post implant device margin residual leak.

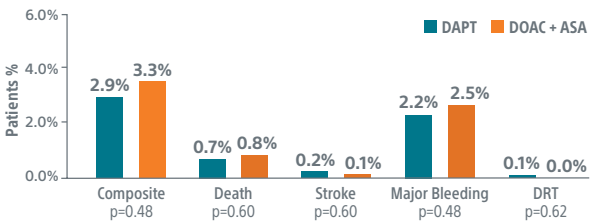
	DAPT N = 2,122	DOAC + ASA N = 2,122	P-Value	DAPT N = 1,407	Warfarin + ASA N = 1,407	P-Value
Age, y	77.1 ± 7.5	76.9 ± 7.7	0.27	76.7 ± 7.6	76.7 ± 7.6	0.88
Female sex, %	42.0	41.1	0.53	39.9	38.8	0.49
CHA_2DS_2-VASC	5.06 ± 1.4	5.04 ± 1.5	0.75	5.0 ± 1.5	4.9 ± 1.4	0.21
Vascular disease, %	59.9	59.7	0.88	58.0	57.5	0.79
Coronary artery disease, %	51.9	51.1	0.60	50.2	49.5	0.71
Prior stroke, %	25.4	24.8	0.65	25.4	23.1	0.16
History of clinically relevant bleeding, %	81.5	80.9	0.61	72.3	71.5	0.64

SH-1553805-AC

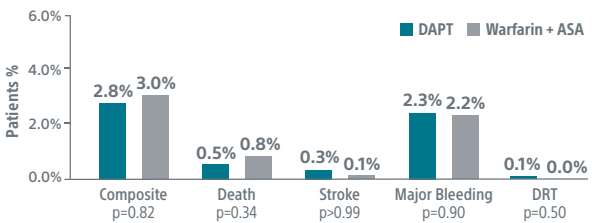
Study Outcomes

No differences in death, stroke, bleeding or DRT between DAPT and DOAC + ASA or Warfarin + ASA at 45 days following LAAO with the WATCHMAN FLX™ Device.

DAPT vs. DOAC+ASA Adjusted Outcomes
(Discharge to 45 ± 14 days)



DAPT vs. Warfarin+ASA Adjusted Outcomes
(Discharge to 45 ± 14 days)



SH-1553805-AC

THE ICE LAA STUDY

Intracardiac Echocardiography (ICE) can be used to successfully guide WATCHMAN FLX™ procedures, with **excellent procedural success**, a **high rate of effective closure**, and **minimal periprocedural complications.**[1]

View Study Results

1 Nielsen-Kudsk JE et al. JACC: CI, Mar. 2023.

ICE LAA Study Design

Objective and Design

- The objective of the ICE LAA Study was to investigate the efficacy and safety of ICE-guided LAAC with the WATCHMAN FLX™ device.
- Prospective, non-randomized, single-arm, multi-center.
- 100 patients enrolled at 7 centers in Europe.
- Independent adjudication of echocardiographic data by a core laboratory and clinical events by a clinical events committee.

Patient Characteristics

- Age: 76 ± 8 years
- CHA_2DS_2-VASc: 4.0 ± 1.5
- HAS-BLED: 2.5 ± 0.9
- Female: 33%

Primary Endpoint

The primary endpoint was effective closure defined as significant peri-device leak (>5 mm) based on the 45-day post-implant TEE and assessed by the echocardiographic core laboratory.

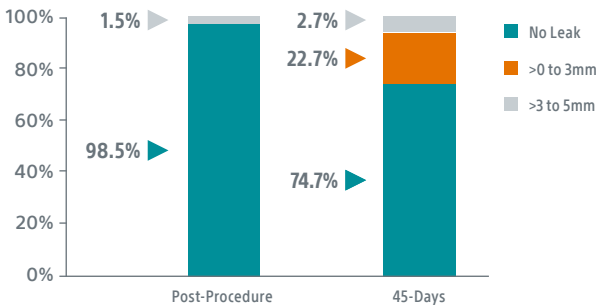
SH-1553805-AC

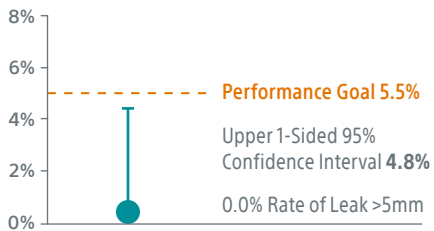
The ICE LAA results confirmed the safety of ICE-guided WATCHMAN FLX™ implant with excellent procedural success and low rates of short-term complications.

Primary Endpoint

The primary endpoint was met as the rate of leak >5 mm was 0.0% with an upper one-sided confidence interval of 4.8%, which is lower than the performance goal of 5.5% (p=0.01). (Performance goal was a post-hoc analysis).

Peri-Device Leak





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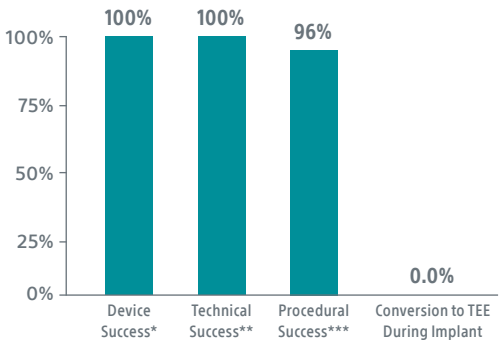
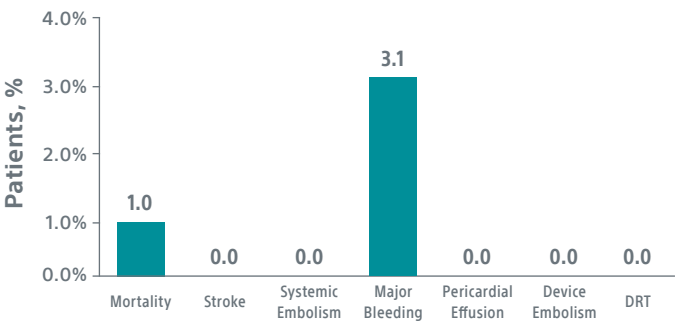
The ICE LAA results confirmed the safety of ICE-guided WATCHMAN FLX™ implant with excellent procedural success and low rates of short-term complications.

Key Procedural and 45 Day Outcomes

Procedural Outcomes



45-Day Outcomes



*Implantation of WATCHMAN FLX without in-hospital mortality **(Successful deployment and release, no conversion to TEE and effective closure of LAA at implant [no leak <5mm]) ***(Device success plus absence of in-hospital device or procedure-related CEC adjudicated events). 1 Nielsen-Kudsk JE et al. JACC: CI, Mar. 2023.

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OUTCOMES AT 45 DAYS IN ~40,000 PATIENTS FROM THE NCDR LAAO REGISTRY™

ICE-guided WATCHMAN FLX™ procedures **achieved similar safety and efficacy** as TEE-guided procedures both acutely and at 45-days post procedure.[1]

1 Ferro EG et al. ACC, Mar. 2023.

SURPASS ICE vs. TEE: Study Design

Objective and Design

- The objective of this analysis from the SURPASS NCDR LAAO Registry™ was to assess ICE as an alternative intraprocedural imaging modality based on outcomes through 45 days in relation to TEE-guided procedures.
- Nationwide, multicenter, prospective, non-randomized post-market surveillance registry for LAAO devices.
- 39,759 procedures with the WATCHMAN FLX™ device from October 2020 to September 2021 were included in the analysis.

Key Safety Endpoints

- Composite Major Adverse Events at 45 Days
- All-Cause Mortality at 45 Days
- Pericardial Effusion at 45 Days

Key Efficacy Endpoints

- Successful LAAO Device Implant
- Complete Seal at 45 Days (PDL = 0 mm)
- Use of General Anesthesia

1 Ferro EG et al. ACC, Marr. 2023.

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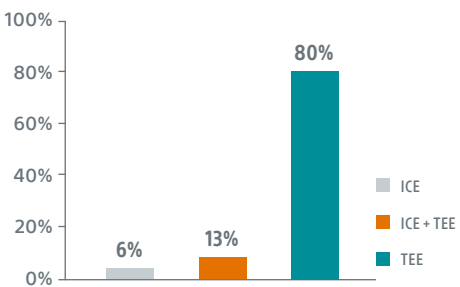
SURPASS ICE vs. TEE: Study Design

Periprocedural and Patient Characteristics

- Overall, 31,835 cases (80%) were performed with TEE guidance alone.
  - 2,272 cases (5.7%) were performed with ICE guidance alone.
  - 5,652 cases (12.7%) were performed with combined ICE and TEE.
- ICE cases had longer procedural times, however required less general anesthesia use.

LAAO Imaging Use

% Cases



Variable	ICE (N=2,272)	TEE (N=31,835)	p-Value
Age, years [Mean ± SD (N)]	75.8 ± 8.0	76.4 ± 7.9	0.0005
Female sex [% (N)]	907 (39.9%)	13,018 (40.9%)	0.36
CHA2DS2-VASc Score [Mean ±SD (N)]	4.8 ± 1.5	4.8 ±1.5	0.24
HAS-BLED Score [Mean ± SD (N)]	2.5 ± 1.0	2.4 ±1.0	<0.0001
Procedure Time, minutes [Mean ±SD (N)]	81.9 ± 34.8	77.8 ± 65.6	<0.001
Contrast Volume, mL [Mean ±SD (N)]	43.5 ± 33.6	41.9 ± 36.2	0.03
Minimal Sedation (anxiolysis) [% (N)]	12 (0.53%)	29 (0.09%)	
Moderate Conscious Sedation [% (N)]	869 (38.3%)	393 (1.2%)	<0.001
General Anesthesia [% (N)]	1,387 (61.1%)	31,327 (98.7%)	
LAA Orifice Max Width, mm [Mean ±SD]	21.8 ± 5.1	20.9 ± 4.2	<0.001
1 LAAO Device Used [% (N)]	2,046 (90.1%)	27,374 (86.0%)	<0.001

1 Ferro EG et al. ACC, Marr. 2023.

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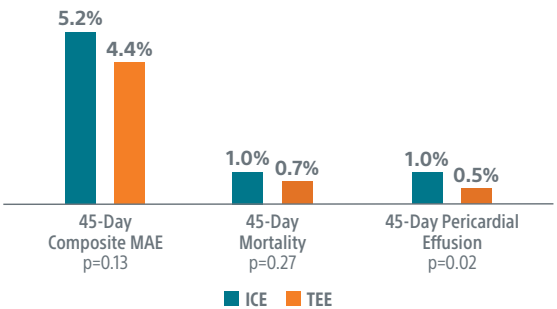
SURPASS ICE vs. TEE: Study Design

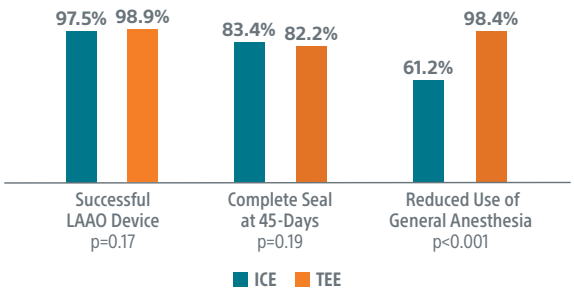
Key Safety and Efficacy Outcomes

- ICE- and TEE-guided WATCHMAN FLX™ procedures achieved similar safety and effectiveness, although, pericardial effusion rates were significantly higher in ICE-guided procedures, however, were found to decline with increasing operator experience.

ICE vs. TEE Safety



ICE vs. TEE Efficacy



1 Ferro EG et al. ACC, Marr. 2023.

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Legacy WATCHMAN™
Left Atrial Appendage Closure Device

PROTECT-AF and PREVAIL Clinical Trials

These **Legacy WATCHMAN™ LAAC Device** pivotal IDE trials in the U.S. established the **WATCHMAN LAAC Device as a safe and effective alternative** to OAC in NVAF patients intolerant to long-term OAC use.[1]

View Full Trial Results

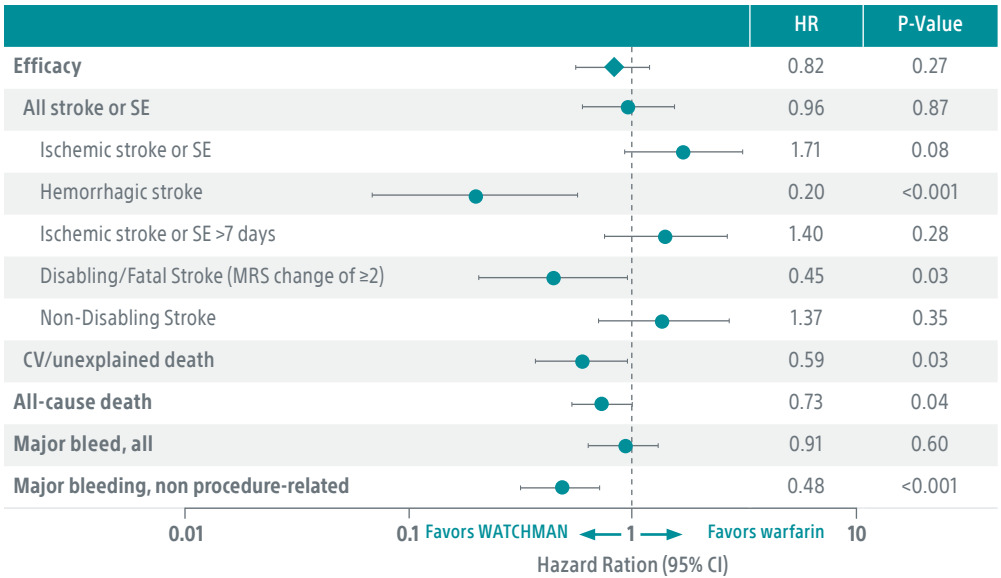
1 Reddy et al. Left Atrial Appendage Closure for Stroke Prevention, JACC, 2017:2964-75.

PROTECT-AF and PREVAIL Clinical Trials[1] (U.S. Legacy WATCHMAN™ Left Atrial Appendage Closure Device IDE trials)

	PROTECT-AF	PREVAIL
Enrollment	2005-2008	2010-2012
Purpose	Demonstrate safety and effectiveness of the WATCHMAN implant compared to long-term warfarin	Demonstrate safety and effectiveness of the WATCHMAN implant compared to long-term warfarin
Study Design	2:1 Randomized, non-inferiority	2:1 Randomized, non-inferiority
Primary Endpoints	• Effectiveness: Stroke, systemic embolism and cardiovascular/unexplained death • Safety: Life-threatening events, which include device embolization requiring retrieval and bleeding events	• Effectiveness: Stroke, systemic embolism and cardiovascular/unexplained death • Effectiveness: Ischemic stroke or systemic embolism, occurring after 7 days post-randomization or WATCHMAN implant procedure • Safety: Death, ischemic stroke, systemic embolism and procedure/device-related complications within 7 days of implantation procedure

1 Reddy VY, et al. JACC 2017; 70(24): 2964-2975.

Legacy WATCHMAN™ Left Atrial Appendage Closure Device – PROTECT-AF and PREVAIL Clinical Trials (5-Year Meta-analysis)[1]



55%
Relative Risk Reduction in Disabling Strokes, Compared to Warfarin

72%
Relative Risk Reduction in Bleeding*, Compared to Warfarin

27%
Relative Risk Reduction in All-Cause Mortality, Compared to Warfarin

1 Reddy VY, et al. JACC 2017; 70(24): 2964-2975.

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NCDR-LAAO Registry™

Real-world registry data for the **Legacy WATCHMAN™ Left Atrial Appendage Closure Device** shows a **low procedural adverse event rate** and **ischemic stroke rates** comparable to prior Legacy WATCHMAN studies.[1, 2]

View Full Early Results

View Full Long-Term Results

1 Virtual presentation at ACC 2020 by Dr. James Freeman. Late Breaking Clinical Trial, March 29, 2020.
2 Virtual Presentation at ACC 2021 by Dr. Matthew Price.

National Cardiovascular Data Registry (NCDR)-LAAO Registry™

Baseline clinical characteristics of Legacy WATCHMAN™ LAAC Device patients enrolled in the NCDR-LAAO Registry within the first 3 years[1]

	NCDR LAAO Registry (N=36,681)
Age, mean	76.0±8.1
Female Sex (%)	15,086 (41.1)
CHA_2DS_2 VASc Score	4.8±1.5
HAS-BLED Score	3.0±1.1

- NCDR-LAAO Registry provides commercial device FDA surveillance for LAAO devices with active follow up of adverse events and clinical outcomes.
- All U.S. LAAO implants must be included in this Registry and is mandated for CMS reimbursement.
- The NCDR-LAAO Registry was developed through a collaboration with:
  - American College of Cardiology (ACC)
  - Society for Coronary Angiography and Intervention (SCAI)
  - Food and Drug Administration (FDA)
  - Centers for Medicare and Medicaid Services (CMS)
  - Boston Scientific

1 Virtual presentation at ACC 2020 by Dr. James Freeman. Late Breaking Clinical Trial, March 29, 2020.

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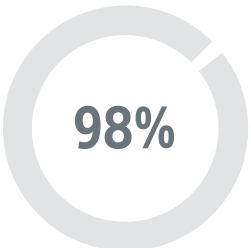
Review of the First 3 Years of Registry Data[1]

This three-year registry analysis of >38,000 Legacy WATCHMAN™ LAAC Device in a high-risk patient population showed low acute adverse events and high procedural success.

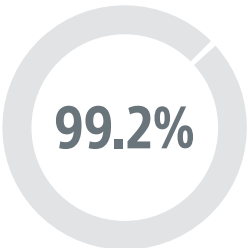
Adverse Event Rate

4.8%	4.1%	4.2%	3.8%	2.8%	2.2%
PROTECT AF[1]	CAP[1]	PREVAIL[1]	CAP2[1]	EWOLUTION[2]	NCDR-LAA[3]

Procedural Success



Closed with Leak <5mm



1 WATCHMAN FDA Panel Sponsor Presentation. Oct 2014.
2 Boersma, et al, Heart Rhythm, Vol 14, No 9. September 2017.
3 Freeman, JACC, March 2020, Vol 75, No. 13, 2020.

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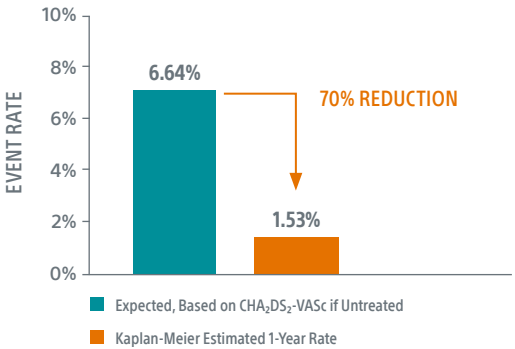
1-Year Clinical Outcomes[1]

>36,000 real-world Legacy WATCHMAN™ patient's studies at 1-year show an ischemic stroke rate comparable to prior WATCHMAN studies and better than what would be expected in untreated patients with the same stroke risk.

Rate of 1-Year Ischemic Stroke in NCDR-LAAO Reigistry Compared with Imputed Placebo



Ischemic Stroke

WATCHMAN Ischemic Stroke rate represented a >70% reduction compared to the expected ischemic stroke rate* in this patient population.

The **1-year** Kaplan-Meier estimate of the **ischemic stroke rate was 1.53%.**

This low rate represented a >70% reduction compared to the expected ischemic stroke rate in this patient population.

*The imputed placebo method used to determine the expected event rate was derived from baseline thromboembolic risk and has been used in multiple prior publications.

1 Virtual Presentation at ACC 2021 by Dr. Matthew Price.

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PROTECT-AF, PREVAIL, CAP2 Leak Analysis

This analysis showed **Legacy WATCHMAN™ LAAC Device patients with and without leak continued to demonstrate a meaningful stroke reduction through 5 years.**[1]

View Full Study Results

1 Presented at AHA, 2021, Vivek Reddy, M.D.

Study Design

Retrospective, post-hoc analysis of the Legacy WATCHMAN™ Left Atrial Appendage Closure Device using the PROTECT-AF, PREVAIL studies and CAP2 registry data.[1]

Assessment of peri-device leak (PDL) impact at 45 days and 12 months on long-term ischemic stroke or systemic embolism outcomes.

Peri-device leak from pooled patient data was categorized at 45 days and 1-year based on:

- Severity of leak (0mm vs >0-3mm vs >3-5mm vs >5mm)
- No leak vs any leak (>0mm to 5mm)

1 Presented at AHA, 2021, Vivek Reddy, M.D.
CAP-1 was not included because leak assessment was not consistently captured.
>5mm leaks were excluded from this analysis as larger leaks are established as associated with adverse outcomes.

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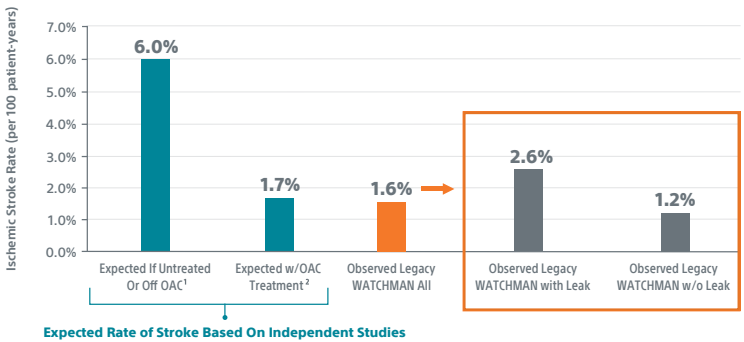
Study Outcome

There was meaningful stroke reduction at 5 years in patients with and without leak, with a combined annualized risk of 1.6% per year versus an expected ~6% risk for untreated patients.*[3]

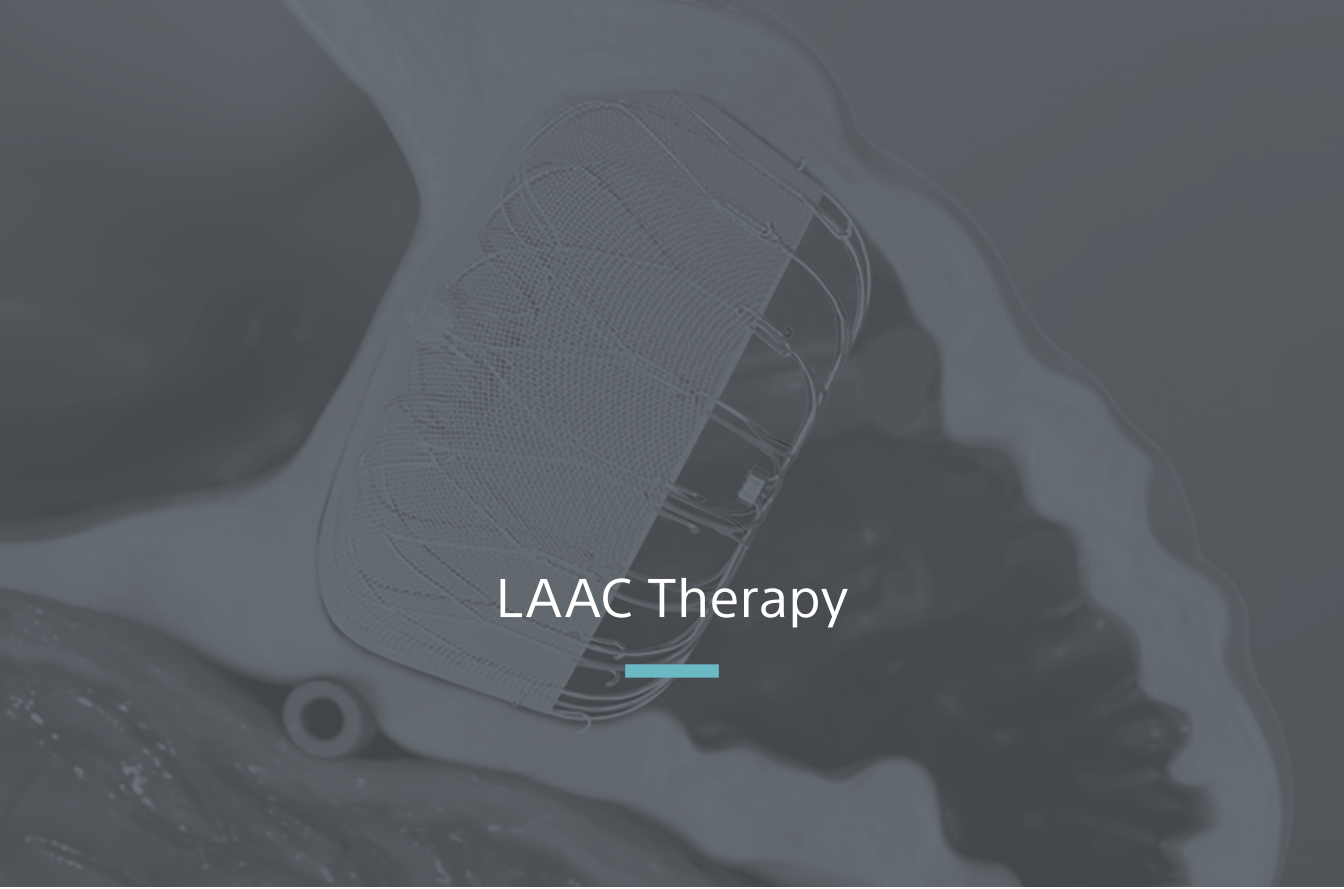
Expected vs Observed Ischemic Stroke Rate for Leak



- There was no association between leak at 45 days and long-term outcomes (similar- to findings from the previous published PROTECT-AF study)
- Peri-device leak at 1-year was associated with an increased risk of ischemic stroke or systemic embolism with the Legacy WATCHMAN™ Left Atrial Appendage Closure Device

*Expected annualized rate of ischemic stroke for a patient population with identical baseline CHADSVASC score.

1 Freiberg et al. European Heart Journal (2012) 33, 1500–1510.
2 Oleson et al. Thromb Haemost 2011; 106: 739–749.
3 Presented at AHA, 2021, Vivek Reddy, M.D.



LAAC Therapy

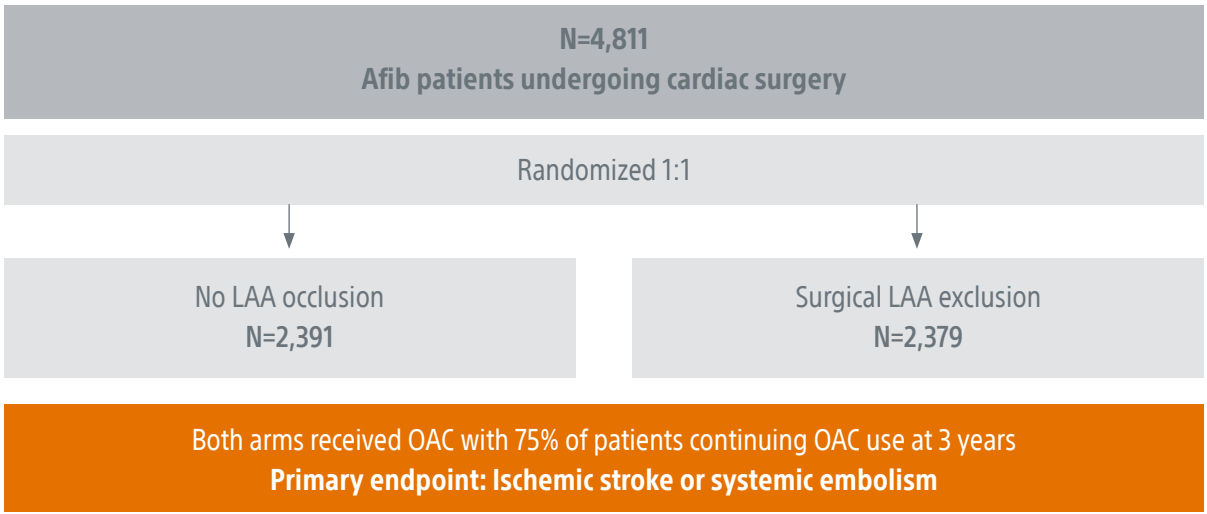
LAA Occlusion Study (LAAOS III) Trial

The **LAAOS III trial** confirms that surgical **LAA occlusion reduced the risk of ischemic stroke and systemic embolism** in patients with atrial fibrillation.[1]

View Full Trial Results

1 Presented by Dr. Richard Whitock at ACC Virtual 2021, Published – Whitlock R NEJM, 2021.

Study Design



1 Presented by Dr. Richard Whitock at ACC Virtual 2021, Published – Whitlock R NEJM, 2021.

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Study Primary Outcome at 3.8 years

The LAAOS III trial confirms that LAA occlusion had a statistically-significant reduction in the risk of ischemic stroke or systemic embolism vs no LAA occlusion in patients with atrial fibrillation.

	LAAO (%)	No LAAO (%)	Risk Reduction	P-Value
Ischemic Stroke or Systemic Embolism	**4.8**	**7.0**	**33%**	**0.001**
Ischemic Stroke	4.6	6.9	34%	
Systemic Embolism	0.3	0.3	14%	
Landmark Analysis				
Ischemic Stroke or Systemic Embolism within 30 Days after Surgery	2.2	2.7	18%	
Ischemic Stroke or Systemic Embolism beyond 30 Days after Surgery	**2.7**	**4.6**	**42%**	

1 Presented by Dr. Richard Whitock at ACC Virtual 2021, Published – Whitlock R NEJM, 2021.

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PRAGUE 17
4-Year Outcomes

Confirms the clinical benefit of LAAC in high-risk NVAF patients over NOAC therapy.[1]

View Full Study Results

1 Presented TCT 2021, Published – Pavel Osmancik, MD, et al, JACC 2022, 4-Year Outcomes After LAAC Versus NOAC for Atrial Fibrillation.

Study Design

Design:

Investigator-initiated, multi-center (10 centers/Czech Republic), prospective, randomized non-inferiority study.

Objective:

Evaluate if LAAC (Amplatzer Amulet™ LAA Occluder/Legacy WATCHMAN™ Left Atrial Appendage Closure Implant Device) in a high-risk NVAF patient population [mean CHA_2DS_2-VASc score 4.7] is non-inferior to NOAC for:

Primary Endpoint (composite of):

- Stroke or transient ischemic attack (TIA)
- Systemic Embolism
- Clinically significant bleeding*
- Cardiovascular death, or
- Significant peri-procedural or device-related complication

*Clinically-significant bleeding = ISTH major or non-major clinically significant bleeding.

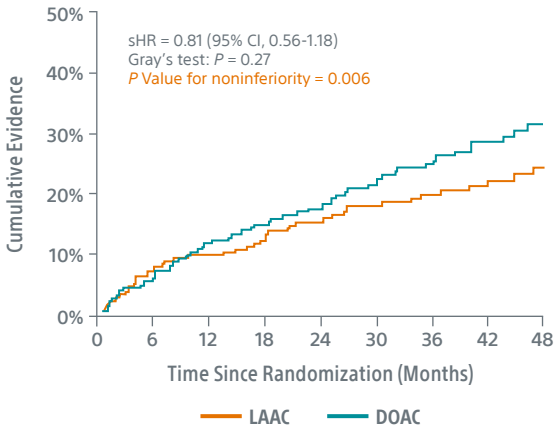
1 Presented TCT 2021, Published – Pavel Osmancik, MD, et al, JACC 2022, 4-Year Outcomes After LAAC Versus NOAC for Atrial Fibrillation.

Study Outcome at 48 Months

Confirms the clinical benefit of LAAC in high-risk NVAF patients over NOAC therapy.[1]

Primary Endpoint

Stoke, TIA, SE, CV Death, Bleeding or Complications



- 4-year primary outcomes show non-inferiority for LAAC vs NOAC in a very high risk NVAF patients, Mean CHA_2DS_2-VASc score 4.7
- Non-procedural bleeding was significantly reduced with LAAC

1 Presented TCT 2021, Published – Pavel Osmancik, MD, et al, JACC 2022, 4-Year Outcomes After LAAC Versus NOAC for Atrial Fibrillation.

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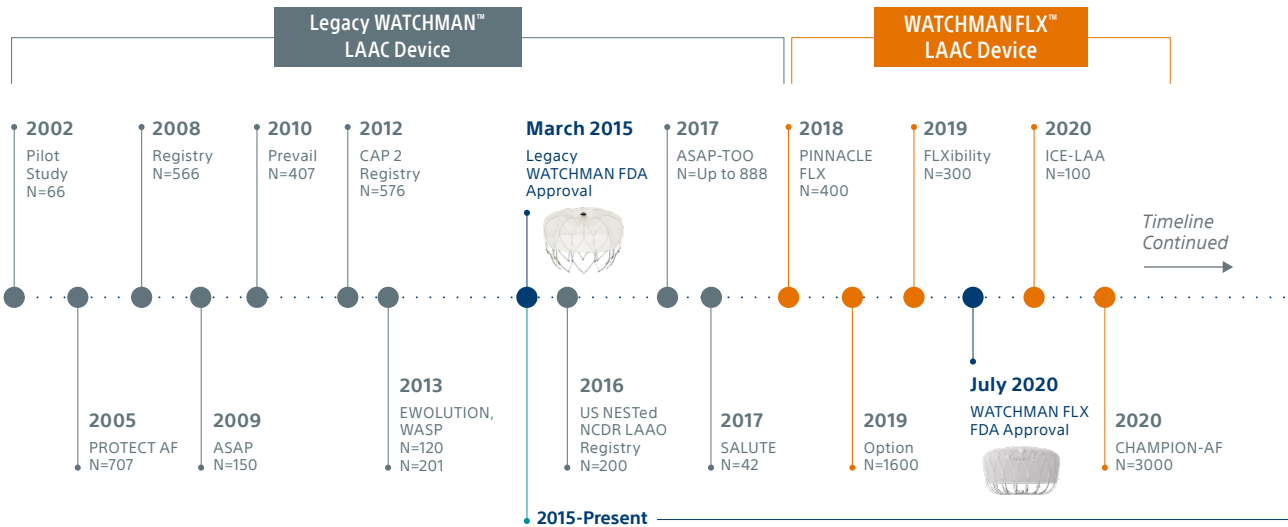
CLINICAL TIMELINE

Over **9,000 patients studied** and **20 years of experience** with WATCHMAN™ Left Atrial Appendage Closure Device

WATCHMAN™ Left Atrial Appendage Closure Device Clinical Timeline



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WATCHMAN™ Left Atrial Appendage Closure Device Clinical Timeline

WATCHMAN FLX™ Pro LAAC Device

September 2023

WATCHMAN FLX Pro
FDA Approval

2015-Present

NCDR for Legacy WATCHMAN and WATCHMAN FLX US Implants
(including SURPASS Analysis)

SH-1553805-AC

WATCHMAN™ Left Atrial Appendage Closure Device Clinical Timeline

1 Pilot Study, N=66, Non-randomized, Feasibility and Safety,Sick, P.B., et al, Initial Worldwide Experience with the WATCHMAN LAAC device, JACC, 2007; 49:1490-5.

2 PROTECT AF, N=707, Randomized Comparison: warfarin, Reddy VY, et al. JACC 2017; 70(24): 2964-2975. PREVAIL, N=407,Randomized Comparison: warfarin, Reddy VY, et al. JACC 2017; 70(24): 2964-2975.

3 CAP Registry, N=566, Non-randomized add'l patients and follow-up, Holmes, DR et al. JACC 2019. CAP2 Registry, N=576, Non-Randomized, add'l patients and follow-up, Holmes, DR et al. JACC 2019.

4 ASAP Trial, N=150, Non-randomized, Patients Contra-indicated to warfarin*, Sharma D et al. JACC 2016; 67(18): 2190-2192 (ASAP).

5 EWOLUTION, WASP Registries, N=1020, N=201, Non-randomized, Real-world, All comers, Boersma LVA et al. Circulation: Arrhythmia and Electrophysiology. 2019; 12(4) e006841. (EWOLUTION), Phillips KP et al. ILC Heart and Vasculature 2019; 23(100358) (WASP).

6 US NESTed NCDR LAAO Registry, N=2000, Post-approval statistical analysis, Poster Presentation by Dr. Kenneth Ellenbogen at HRS 2021.

7 ASAP TOO, N= Up to 888, Randomized US Indication Expansion, Worldwide study, unpublished to date.

8 SALUTE, N= 42, Non-randomized, Japanese Approval Study, Kazutaka Aonuma, et al, CIRC, 2020.

9 PINNACLE FLX, N=400, Non-randomized, WATCHMAN FLX Device US IDE, Kar, S. Et al, Circulation, 2021.

10 OPTION, N=1600, Ongoing study in post-ablation patients, Randomized Efficacy and Bleeding Comparison: OAC vs WATCHMAN FLX Device, enrollment complete.

11 FLXibility Registry, N=300, Non-randomized, EU Post-Market Registry with WATCHMAN FLX Device, Presented at HRS 2021 by Dr. T. Betts.

12 ICE-LAA, N=100, Non-randomized, Assessing safety and efficacy of ICE.

13 CHAMPION-AF, N= 3000, Randomized, WATCHMAN FLX vs. NOACs in a broader NVAF population, inclusive of lower risk patients, currently enrolling.

14 NCDR Late Breaking Clinical trial at HRS 2022 presented by Dr James Freeman.

Brief Summary

WATCHMAN FLX™ Left Atrial Appendage Closure Device with Delivery System and WATCHMAN™ Access System

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 CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy;
- 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 62 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 proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized 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 transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]); For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium.

Brief Summary (continued)

- 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 690 kPa (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.

Brief Summary (continued)

- 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 medication, 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, Myocardial infarction, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Radiation injury, 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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Brief Summary

WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device

INTENDED USE

WATCHMAN FLX Pro is intended for percutaneous, transcatheter closure of the left atrial appendage.

INDICATIONS FOR USE

The WATCHMAN FLX Pro 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 CHA_2DS_2-VASc[1] 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 Pro Device if:

- Intracardiac thrombus is present.
- An atrial septal defect repair or closure device is present.
- A patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a Closure Device (see Step 7 *in the IFU*).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section *in the IFU*) such that the use of the WATCHMAN FLX Pro 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 $P2Y_{12}$ inhibitor.

WARNINGS

Implantation of the WATCHMAN FLX Pro Device should only be performed by interventional cardiologists and/or electrophysiologists who are proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized and who have completed the WATCHMAN FLX Pro Physician Training program.

- For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the Closure Device and/or lead to Closure Device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the Closure Device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Closure Device may lead to injury, illness, or death of the patient.
- 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.

Brief Summary (continued)

- Device selection should be based on accurate LAA measurements obtained using transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]; For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium.
- Do not release (i.e., unscrew) the WATCHMAN FLX Pro Device from the core wire unless all release criteria (Step 15 in the IFU) 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.
- If thrombus is observed on the device, anticoagulation therapy is recommended until resolution of thrombus is demonstrated by TEE.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section for further detail.
- Do not use if the temperature exposure indicator dot on the pouch label is red or missing, indicating
  Closure Device performance may have been compromised.

PRECAUTIONS

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Pro 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 Pro 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 690 kPa (100 psi).
- Use caution when manipulating the Delivery System. Excessive counterclockwise rotation of the
  deployment knob or Delivery System hub independent from the rest of the Delivery System can cause premature implant detachment.

ADVERSE EVENTS

Potential adverse events 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 medication, 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,

Brief Summary (continued)

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, Myocardial infarction, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Radiation injury, 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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