

# WATCHMAN™

INTEGRATED LAAC SOLUTIONS



## WATCHMAN™ Left Atrial Appendage Closure Devices Clinical Data

Key Studies | Outcomes | Prospective Clinical Trials

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WATCHMAN FLX PRO  
LAAC DEVICE

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## Study Glossary

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[SURPASS: ICE vs. TEE >](#)

### Legacy WATCHMAN™

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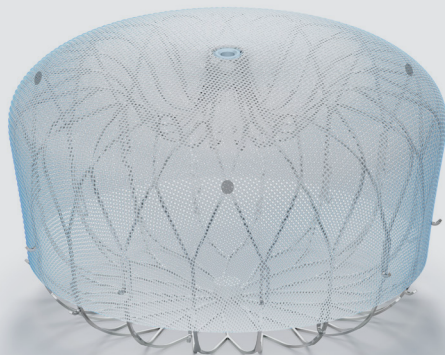
[PROTECT-AF, PREVAIL, CAP2 Leak Analysis >](#)

### LAAC Therapy

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# WATCHMAN FLX™ Pro

## Left Atrial Appendage Closure Device

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# HEAL-LAA

## Post-Market Clinical Study

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The HEAL-LAA post-market clinical study is the first report on the use of the fluoropolymer-coated WATCHMAN FLX Pro device in the US, where the primary safety and efficacy endpoints demonstrated consistent complete closure and proven safety outcomes in a real-world clinical setting.



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# HEAL-LAA Study Design

## Study Design

- The objective of the HEAL-LAA clinical study was to evaluate the safety and effectiveness of WATCHMAN FLX Pro in a commercial clinical setting.
- Prospective, multicenter, post-market clinical study.
- 32 centers in United States.
- Primary Analysis Set = first 500 patients enrolled.
- WATCHMAN TruSteer™ Access System Set = 200 HEAL-LAA patients implanted with WATCHMAN FLX Pro using the WATCHMAN TruSteer steerable sheath.

### Primary Efficacy Endpoint

The rate of leak >5 mm at 45-day post-implant TEE for the WATCHMAN FLX Pro device is less than the 5% performance goal.

### Primary Safety Endpoint

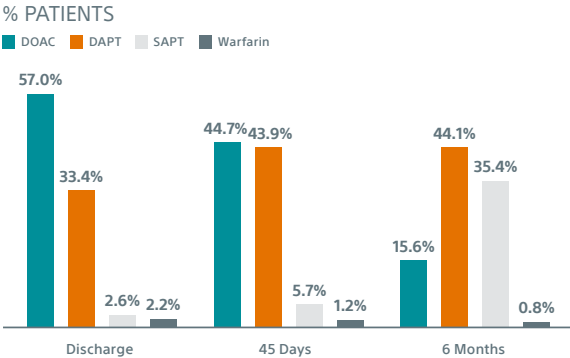
The composite rate of all-cause mortality, all stroke, systemic embolism, and major bleeding at 6 months for the WATCHMAN FLX Pro device is less than the 21% performance goal.



# HEAL-LAA Baseline Demographics

HEAL-LAA patients were generally older and at higher bleeding risk compared to prior WATCHMAN FLX studies, which may reflect the higher prevalence of DAPT usage observed at discharge and continuing through 6 months follow-up.

	HEAL-LAA <sup>1</sup> (N = 500)	PINNACLE FLX <sup>3</sup> (N = 400)
Female	38.8% (194/500)	35.5% (142/400)
Age	76.1 ± 7.7	73.8 ± 8.6
History of major bleeding	32.8% (164/500)	33% (132/400)
Paroxysmal AF	63.4% (317/500)	51.8% (207/400)
Prior ischemic stroke or TIA	19.0% (95/500)	22.3% (89/400)
CHA <sub>2</sub> DS <sub>2</sub> -VASc	4.3 ± 1.3	4.2 ± 1.5
HAS-BLED	3.0 ± 1.0	2.0 ± 1.0
DAPT usage at discharge	33.4%	0%



Results of these trials are not directly comparable. 1. Alii O, et al. Primary Safety and Efficacy Endpoints of the HEAL-LAA Post-Approval Clinical Study. LAAO Innovations Session, TCT 2024.

3. Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.



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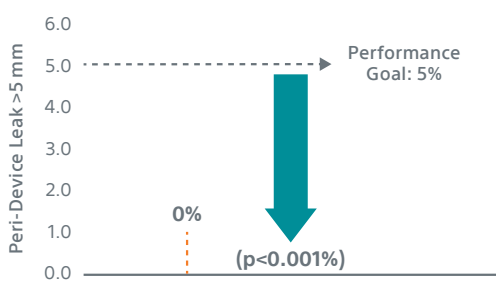
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# HEAL-LAA Primary Efficacy Endpoint

## Consistent Complete Closure

The primary efficacy endpoint was achieved as the rate of leak >5 mm was 0% at 45-days, significantly less than 5% performance goal ( $p<0.001$ ), including 82.7% complete seal and only 0.2% >3 mm.



	Post Implant	45 Days
Complete seal	92.5% (331/358)	82.7% (334/404)
>0-3 mm leak	7.5% (27/358)	17.1% (69/404)
>3-5 mm leak	0.0% (0/358)	0.2% (1/404)
>5 mm leak	0.0% (0/358)	0.0% (0/404)

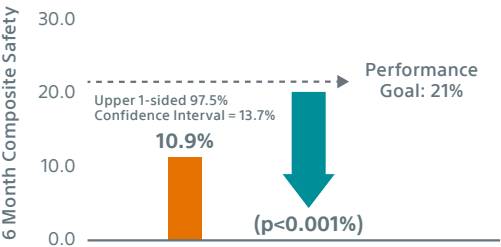
Alli O, et al. Primary Safety and Efficacy Endpoints of the HEAL-LAA Post-Approval Clinical Study. LAAO Innovations Session, TCT 2024.



# HEAL-LAA Primary Safety Endpoint

## Proven Safety Outcomes

The primary safety endpoint was achieved with a composite event rate of 10.9% at 6 months.\*



Acute Procedural Event Rate**	Discharge or 7 days, Whichever is Later
HEAL-LAA <sup>2</sup>	0.4% (2/500)***
PINNACLE FLX <sup>3</sup>	0.5% (2/400)

**NOTE:** Results of these trials are not directly comparable.

\*All cause death, stroke, systemic embolism, and major bleeding at 6-months. \*\*The 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, device- or procedure-related events requiring intervention. \*\*\*Post-hoc/not CEC adjudicated.

Alli O, et al. Primary Safety and Efficacy Endpoints of the HEAL-LAA Post-Approval Clinical Study. LAO Innovations Session, TCT 2024.

2. BSC Data on File.

3. Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.



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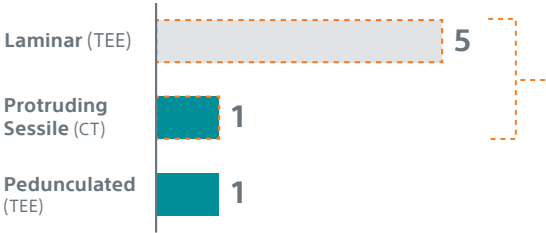


# HEAL-LAA Thrombus Characteristics

## Controlled Healing

All seven (7) (N = 448; 1.6%) thrombus detected at 45-day follow-up were asymptomatic, including 6 being characterized as laminar (TEE) or protruding sessile (CT), suggesting device healing.<sup>4</sup>

- No patients experienced related adverse events through 6 months.
- One (1) patient with core lab-identified DRT was discharged on DOAC; Six (6) patients were discharged on DAPT.
- Three (3) of the 7 DRT identified by the core lab were not characterized as DRT according to site analysis.



Using CT imaging, a JACC State of the Art Review states low-grade HAT (hypoattenuated thickening) was not associated with an increased risk for thromboembolic events.<sup>4</sup>

Alii O, et al. Primary Safety and Efficacy Endpoints of the HEAL-LAA Post-Approval Clinical Study. LAAO Innovations Session, TCT 2024.

4. Alkhouli M, et al. JACC: Cardiovascular Interventions 2023.



# HEAL-LAA Additional Clinical Outcomes

## Advancing outcomes and expanding the treatable population

Procedural performance	Broader range of anatomies <sup>‡</sup>	Controlled healing
99.5%	6.0%	0.22%
<b>Procedural success</b>	<b>More patients treated</b>	<b>Pedunculated Thrombus</b>
99.5% procedural success with the WATCHMAN TruSteer Access System with an 86% reduction in abort rate compared to other access systems. <sup>5</sup>	6% of enrolled patients (N = 500) in HEAL-LAA were <b>implanted with the new 40 mm diameter</b> WATCHMAN FLX Pro device.	<b>Only 1 (N = 448; 0.22%) pedunculated thrombus formation (TEE) at 45 days</b> characterized as having a high likelihood of DRT per JACC State-of-the-Art review. <sup>4</sup>

Alli O, et al. Primary Safety and Efficacy Endpoints of the HEAL-LAA Post-Approval Clinical Study. LAAO Innovations Session, TCT 2024.  
<sup>‡</sup> Measured maximum LAA ostium width and/or deployed closure device diameter must be ≥ 14.0 mm and ≤ 36.0 mm to accommodate available closure device sizes. LAA depth should be approximately half the labeled implant diameter or longer.  
<sup>4</sup> Alkhouli M, et al. JACC: Cardiovascular Interventions 2023.  
<sup>5</sup> Kanj M, et al. Safety and Performance of a Novel Access System for LAAO: A Sub-analysis of the HEAL-LAA Study. Moderated Abstract, TCT 2024.



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# WATCHMAN FLX™ Pro CT Study

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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.



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# 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	Aarhus 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.



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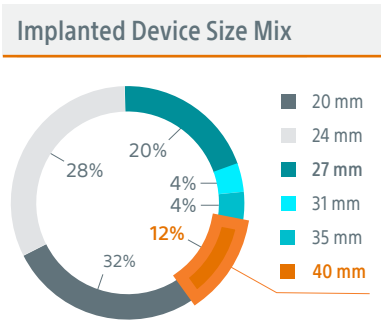
# WATCHMAN FLX™ Pro CT Study Acute Outcomes

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

## Key Patient Characteristics (N=25)

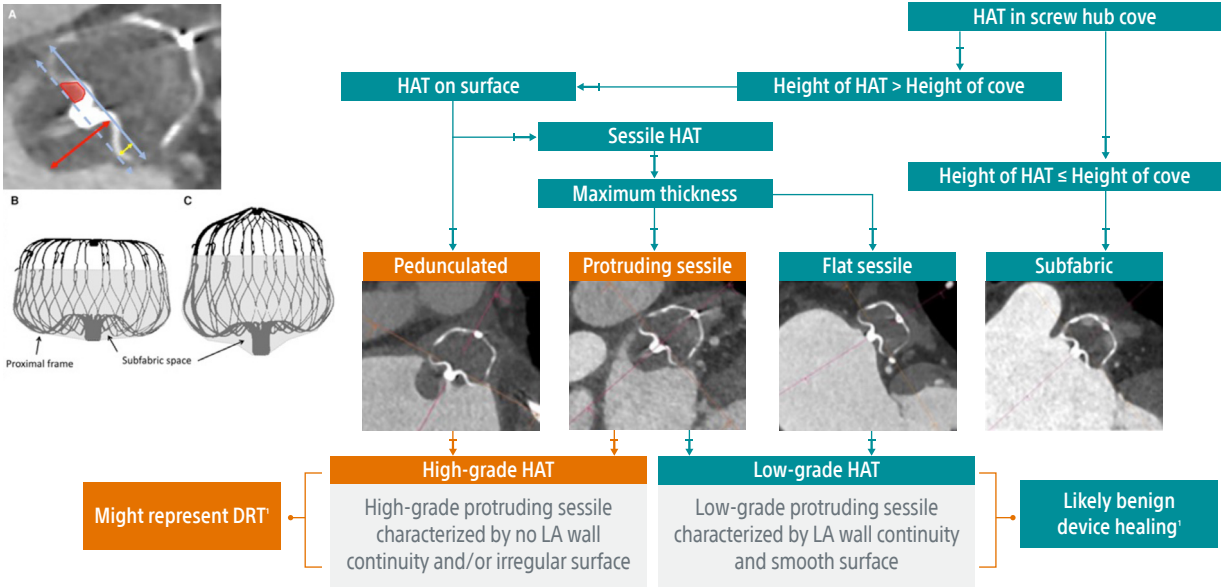
- Age: 73.6 ± 8.4 Years
- CHA<sub>2</sub>DS<sub>2</sub>-VASc Score: 3.3 ± 1.1
- HAS-BLED Score: 2.8 ± 0.8
- Female: 36.0%
- Prior stroke: 40.0%
- History of major bleeding: 52.0%

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)



\*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.

# Hypoattenuated Thickening (HAT) - CT Imaging Algorithm



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



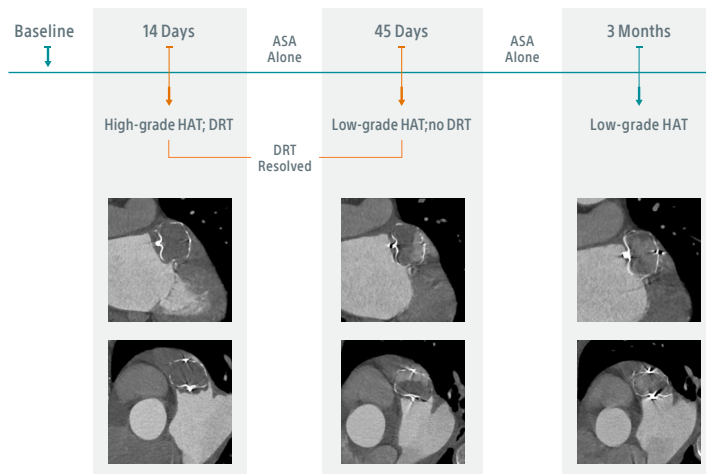
# WATCHMAN FLX™ Pro Study Results

## 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 33x10<sup>9</sup>/l → 91x10<sup>9</sup>/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



# 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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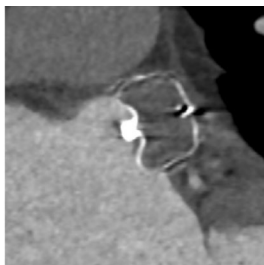
## WATCHMAN FLX™ Pro CT Study Conclusion

**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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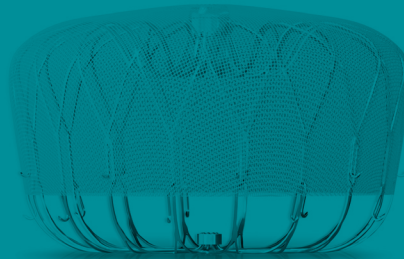
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# WATCHMAN FLX™

## Left Atrial Appendage Closure Device

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# WATCHMAN FLX™ Left Atrial Appendage Closure Device Design Differentiation

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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**.



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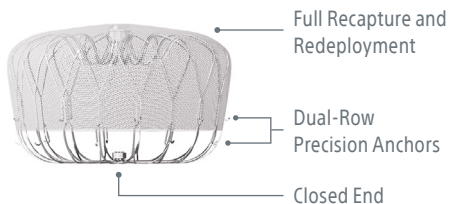
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# WATCHMAN FLX™ Left Atrial Appendage Closure Device Design Differentiation

## WATCHMAN FLX™ LAAC Device

Treatment Range 14.0 – 31.5 mm Ostium Width



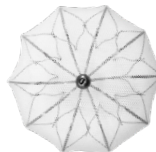
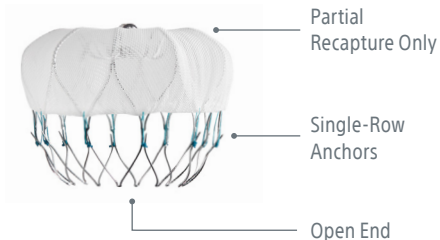
18 Strut Frame



Fully-Rounded  
WATCHMAN FLX Ball

## Legacy WATCHMAN™ LAAC Device

Treatment Range 16.8 – 30.5 mm Ostium Width



10 Strut Frame



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# OPTION Clinical Trial: Primary Outcomes

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The **OPTION Trial** is a prospective, randomized, multi-center, global investigation to **determine if left atrial appendage closure with the WATCHMAN FLX Device is a reasonable alternative to oral anticoagulation in patients after AF ablation.**

[View Full Trial Results](#)



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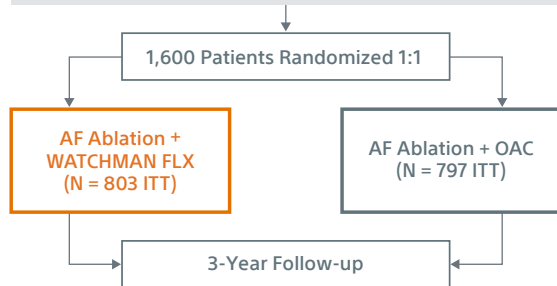
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# OPTION Trial Design

Prospective, randomized, multi-center, global investigation to determine if left atrial appendage closure with the WATCHMAN FLX Device is a reasonable alternative to oral anticoagulation in patients after AF ablation.\*



\*Thermal AFib ablation only.

## Primary Efficacy Endpoint

Stroke, all-cause mortality and systemic embolism  
**(NON-INFERIORITY)**

## Primary Safety Endpoint

Non-procedural bleeding (ISTH major bleeding and clinically relevant non-major bleeding)  
**(SUPERIORITY)**

## Secondary Safety Endpoint

ISTH major bleeding (including procedural bleeding)  
**(NON-INFERIORITY)**



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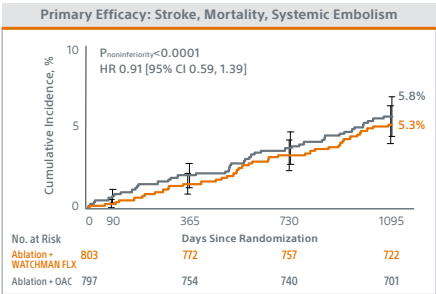
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# OPTION Trial: Primary Endpoints Met

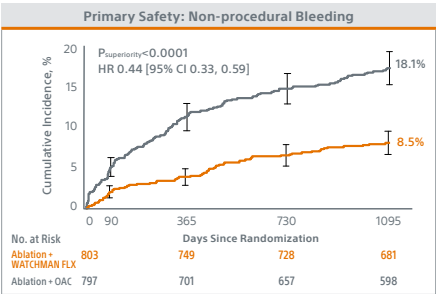
The OPTION Clinical Trial, a breakthrough study in AFib treatment, is the **first randomized, head-to-head study comparing WATCHMAN to OAC (95% DOACs) after cardiac ablation.**

The primary endpoints showed the WATCHMAN FLX™ device was **equally effective to OAC at 36 months, with a superior safety profile**, which allowed patients to eliminate continuous medication use, and significantly reduce bleeding risk while maintaining stroke protection.

## Primary Efficacy Endpoint: Non-inferiority Met



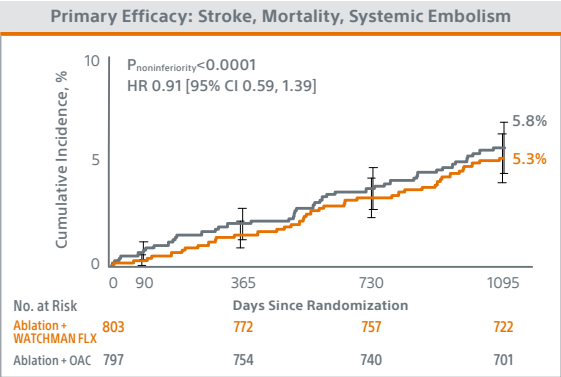
## Primary Safety Endpoint: Superiority Met



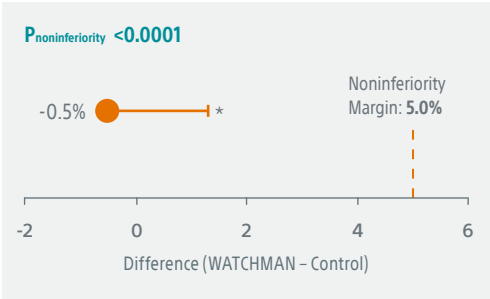
Wazni O, et al. New England Journal of Medicine, November 2024.



# OPTION Trial: Primary Efficacy Endpoint (ITT)



The trial **met the primary efficacy endpoint** of all-cause mortality, stroke or systemic embolism at 36 months, with **WATCHMAN FLX demonstrating statistical non-inferiority to OAC** (5.3% vs. 5.8%;  $P < 0.0001$ ).



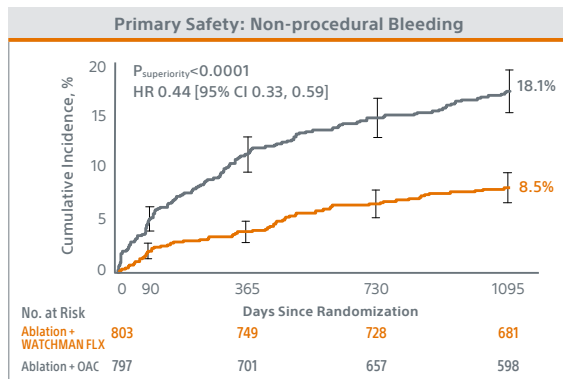
Wazni O, et al. New England Journal of Medicine, November 2024.

\*1-sided 97.5% Z upper confidence Interval = 1.8%





## OPTION Trial: Primary Safety Endpoint (ITT)



The trial **met the primary safety endpoint** of non-procedural major bleeding or clinically relevant non-major bleeding at 36 months, with **WATCHMAN FLX demonstrating statistical superiority to OAC** (8.5% vs. 18.1%;  $P < 0.0001$ ).

56%

Relative reduction in ISTH major and clinically relevant non-procedural bleeding at 36 months HR 0.44 [95% CI 0.33, 0.59]

Wazni O, et al. New England Journal of Medicine, November 2024.



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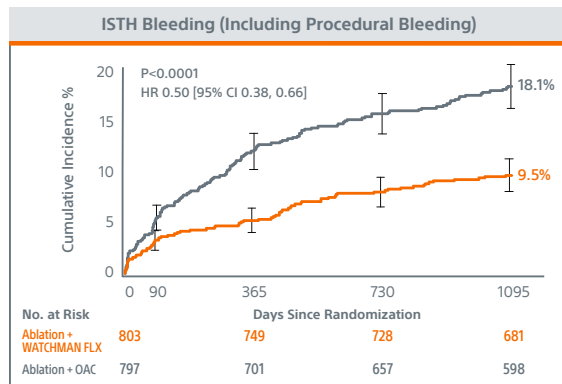
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# OPTION Trial: ISTH Bleeding (Including Procedural Bleeding)



50%  
▼

Relative reduction in ISTH major and clinically relevant non-major bleeding (including procedural) at 36 months  
HR 0.50 [95% CI 0.38, 0.66]

Wazni O, et al. New England Journal of Medicine, November 2024.



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# OPTION Trial: Conclusions and Key Takeaways

In the first head-to-head trial of WATCHMAN FLX to OAC (95% DOAC) after AF ablation:

**1 PRIMARY EFFICACY ENDPOINT MET**  
WATCHMAN FLX met the primary efficacy endpoint of stroke, all-cause mortality, and systemic embolism at 36 months, demonstrating statistical non-inferiority to OAC (5.3% vs. 5.8%;  $P < 0.0001$ ).

**2 PRIMARY SAFETY ENDPOINT MET**  
WATCHMAN FLX met the primary safety endpoint of non-procedural ISTH major bleeding or clinically relevant non-major bleeding at 36 months, demonstrating statistical superiority to OAC (8.5% vs. 18.1%;  $P < 0.0001$ ), including a significant 56% relative risk reduction (HR 0.44 [95% CI 0.33, 0.59]).

**3 SECONDARY SAFETY ENDPOINT MET**  
WATCHMAN FLX met the secondary safety endpoint of ISTH major bleeding (including procedural) at 36 months, demonstrating statistical non-inferiority to OAC (3.9% vs. 5.0%;  $P < 0.0001$ ).

**4 CONSISTENTLY HIGH PROCEDURAL SUCCESS**  
WATCHMAN FLX demonstrated a 98.8% procedural success rate, irrespective of concomitant or sequential LAAC, reaffirming the industry-leading procedural success of the WATCHMAN FLX procedure observed in PINNACLE FLX.<sup>1</sup>

Wazni O, et al. New England Journal of Medicine, November 2024.

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



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**WATCHMAN FLX  
LAAC DEVICE**

LEGACY WATCHMAN  
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# OPTION Clinical Trial: Concomitant and Sequential Cohort Sub-analysis

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This prespecified sub-analysis **compared the primary endpoint outcomes among the concomitant and sequential cohorts of the WATCHMAN FLX arm to those randomized to oral anticoagulation following AF ablation.**



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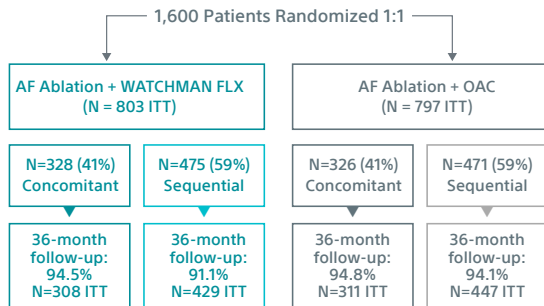
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# OPTION Trial Concomitant and Sequential Cohort Sub-analysis: Study Design and Patient Disposition



## Primary Efficacy Endpoint

Stroke, all-cause mortality and systemic embolism

## Primary Safety Endpoint

Non-procedural bleeding (ISTH major bleeding and clinically relevant non-major bleeding)

- **Concomitant:** AF ablation ± WATCHMAN FLX implantation within 10 days of randomization
- **Sequential:** AF ablation 90 to 180 days prior to randomization
- The planned ablation timing, concomitant or sequential, was not randomized but must have been specified by the investigator prior to randomizing the subject

Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2025.



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# OPTION Trial Concomitant and Sequential Cohort Sub-analysis: Positive Primary Outcomes Reaffirmed



## Primary Efficacy



## Primary Safety

Consistent with the overall primary outcomes, the **WATCHMAN FLX device demonstrated similar efficacy outcomes compared to OAC (95% DOACs) at 36 months, while significantly reducing bleeding risks irrespective of concomitant or sequential LAAC following an ablation**, providing an option for patients seeking an alternative to long-term anticoagulation regardless of the timing of LAAC relative to the ablation.

Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2025.



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# OPTION Trial Concomitant and Sequential Cohort Sub-analysis:

## Procedural Events (within 7 days) – Concomitant Cohort

Concomitant LAAC with WATCHMAN FLX at the time of ablation resulted in similar procedure related events (2.1%) compared to the ablation-only control arm (2.7%), therefore resulting in no increase in procedural risk with the addition of the WATCHMAN FLX procedure to ablation.

2.1%

**Ablation + WATCHMAN FLX**  
Procedural Event Rate (within 7 days)

VS

2.7%

**Ablation [Only] + OAC**  
Procedural Event Rate (within 7 days)

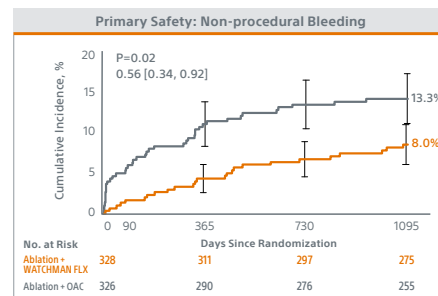
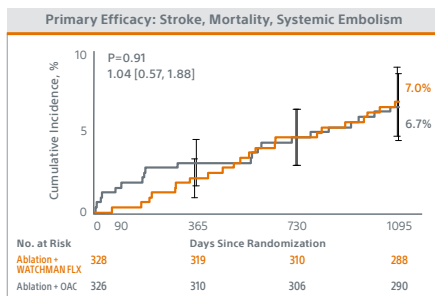
Ablation + WATCHMAN FLX	Ablation [Only] + OAC
<ul style="list-style-type: none"><li>• 3 major bleeding events</li><li>• 2 ISTH clinically-relevant non-major bleeding events</li><li>• 1 post-procedural pericarditis</li></ul>	<ul style="list-style-type: none"><li>• 31 ischemic stroke</li><li>• 3 ISTH major bleeding events</li><li>• 3 ISTH clinically-relevant non-major bleeding events</li><li>• 2 pericardial effusions</li></ul>

Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2025.



# OPTION Trial Concomitant and Sequential Cohort Sub-analysis: Concomitant Cohort Primary Endpoints

Consistent with the overall primary outcomes, **concomitant LAAC with WATCHMAN FLX** following AF ablation **showed similar efficacy to OAC**, while demonstrating a **statistically significant 44% risk reduction in bleeding events** at 36 months.



Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2023.



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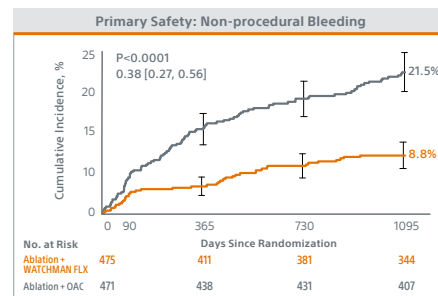
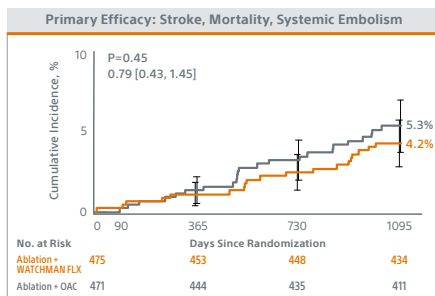
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# OPTION Trial Concomitant and Sequential Cohort Sub-analysis: Sequential Cohort Primary Endpoints

Consistent with the overall primary outcomes, **sequential LAAC with WATCHMAN FLX** following AF ablation **showed similar efficacy to OAC**, while **demonstrating a statistically significant 62% risk reduction in bleeding events** at 36 months.



Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2023.



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# OPTION Trial Concomitant and Sequential Cohort Sub-analysis: Conclusions and Key Takeaways

In the first head-to-head trial of concomitant or sequential WATCHMAN FLX to OAC (95% DOAC) after AF ablation:

**1 RESULTS CONSISTENT WITH OVERALL OUTCOMES**  
Consistent with the overall primary endpoint outcomes, the WATCHMAN FLX device demonstrated equal thromboembolic protection to OAC (95% DOACs) at 36 months, while significantly reducing bleeding risks regardless of the timing of LAAC relative to the ablation (concomitant or sequential).

**2 CONCOMITANT PROCEDURAL EVENTS ≈ ABLATION ONLY**  
Concomitant LAAC with WATCHMAN FLX at the time of ablation resulted in similar procedure related events (2.1%) compared to the ablation-only control arm (2.7%), therefore resulting in no increase in procedural risk with the addition of the WATCHMAN FLX procedure to ablation.

Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2025.



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# OPTION Trial Concomitant and Sequential Cohort Sub-analysis: Conclusions and Key Takeaways

In the first head-to-head trial of concomitant or sequential WATCHMAN FLX to OAC (95% DOAC) after AF ablation:

**3 CONCOMITANT ≠ SEQUENTIAL PATIENTS**  
Patient characteristics between the concomitant and sequential cohorts were unbalanced, suggesting the subgroups represent disparate patient populations reflected by potential selection bias based on the perceived suitability for either concomitant or sequential procedures.

**4 FIRST INSIGHT ON CONCOMITANT VIA RCT**  
This subanalysis provides the first perspective on outcomes of concomitant ablation and WATCHMAN FLX in a large, multi-year, randomized trial.

Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late Breaking Clinical Trial, AF Symposium 2025.



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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.<sup>1, 2</sup>

[View Full 12-Month Results](#)

[View Full 24-Month Results](#)

<sup>1</sup> Kar S., Circulation, 2021.

<sup>2</sup> Doshi et al. JAHA, 2023.



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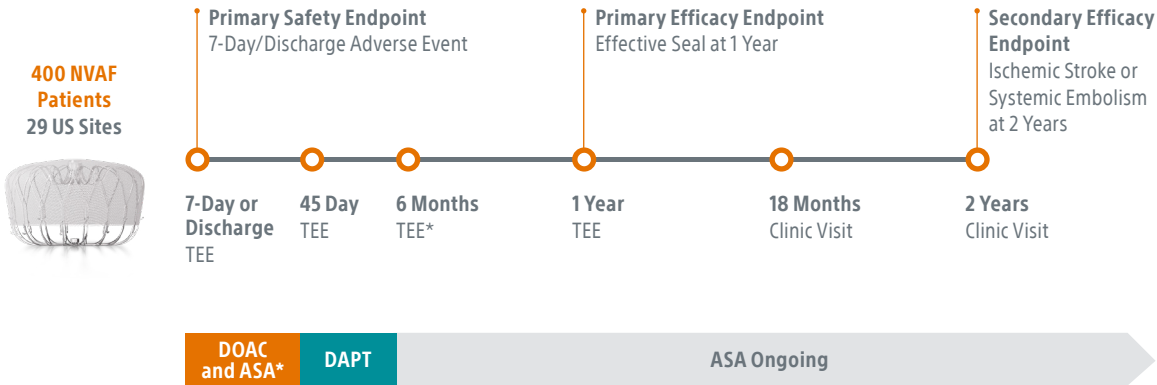
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# PINNACLE FLX Study Overview

A US IDE to evaluate the safety and efficacy of the WATCHMAN FLX™ Left Atrial Appendage Closure Device



\*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<sup>1</sup>



Dual-Row Precision Anchors  
for Reliability

**0%**

Pericardial  
Effusions

Requiring open  
cardiac surgery  
through 24 mos<sup>2</sup>

**0%**

Device  
Embolization  
24 Months<sup>2</sup>



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.

<sup>1</sup> Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.

<sup>2</sup> Doshi et al. JAHA, 2023.



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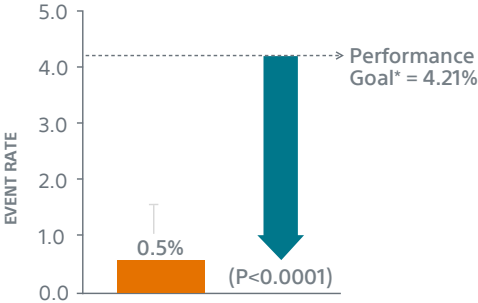
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# WATCHMAN FLX™ Left Atrial Appendage Closure Device Demonstrated Excellent Safety and Efficacy at 12 Months<sup>1</sup>

## Primary Safety Endpoint:

Peri-procedural Adverse Events

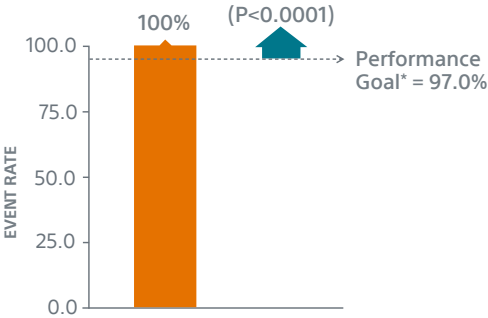


Defined as major adverse events between implant and 7d/discharge. N=400.

\*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.

<sup>1</sup> Kar, S., Circulation, 2021.



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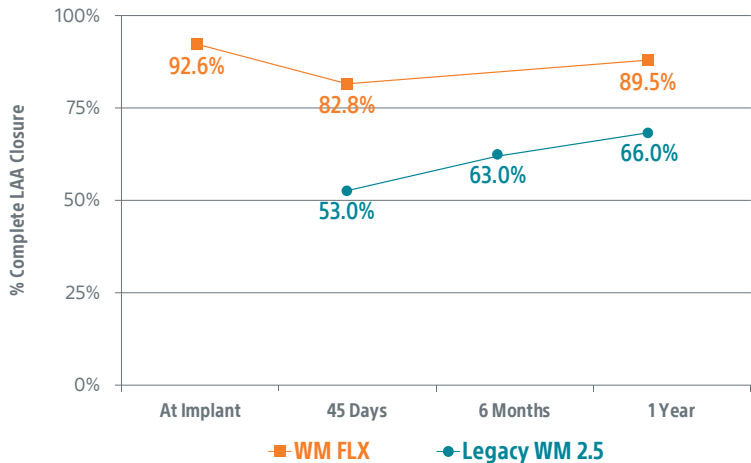
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# WATCHMAN FLX™ Left Atrial Appendage Closure Device Complete Closure Rates

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<sup>1</sup>

## 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<sup>1, 2</sup>

## PROVEN LONG-TERM EFFICACY



80% Increase in Contact Points for Sealing

**1.7%**

Ischemic Stroke/  
Systemic Embolism  
(Per 100 patient  
yrs/annualized)<sup>2</sup>



Dual-Row Precision Anchors  
for Reliability

**0%**

Pericardial  
Effusions  
Requiring open  
cardiac surgery  
through 24 mos<sup>2</sup>

**0%**

Device  
Embolization  
Through 24 Months<sup>2</sup>



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

**100%†**

LAA Effective  
Closure<sup>1</sup>

**96.2%**

Patients  
Discontinued  
OAC at 45 Days<sup>1</sup>

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

<sup>1</sup> Kar, S., et al, Primary Outcome Evaluation of the Next Generation LAAC Device: Results from the PINNACLE FLX Trial, Circulation, 2021.

<sup>2</sup> Doshi et al. JAHA, 2023.



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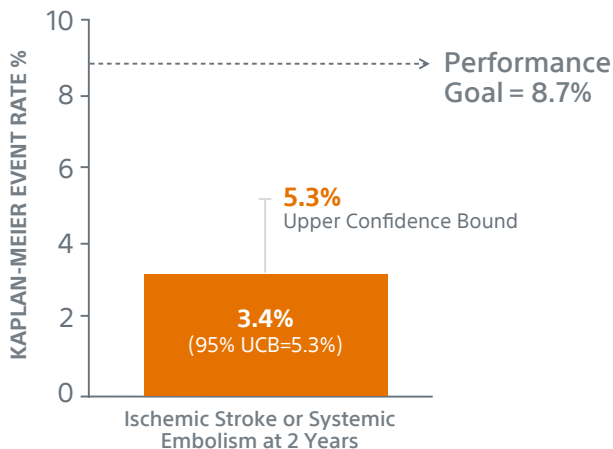
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# PINNACLE FLX 24-Month Data Demonstrates Proven Efficacy with a Low Annualized Stroke Rate<sup>1</sup>



**1.7%**  
per 100-patient  
years/annualized  
stroke or systemic  
embolism rate

<sup>1</sup> 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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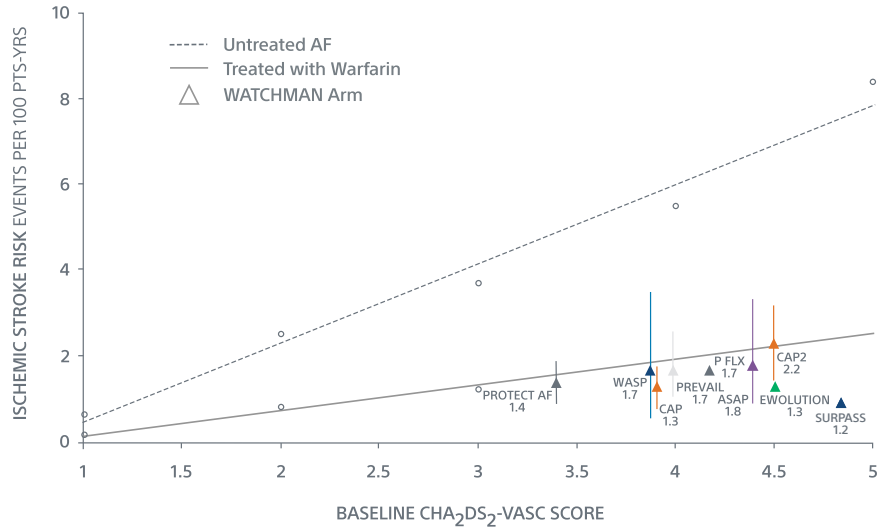
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# Ischemic Stroke Across WATCHMAN Trials

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 & Vasculture 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 Kapadia. (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.<sup>1</sup>**

[View Full Study Results](#)

<sup>1</sup> Ellis, C. et al, Heart Rhythm, 2021.



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# 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.

<sup>1</sup> 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.<sup>1</sup>

## 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

<sup>1</sup> Ellis.C, et al, Heart Rhythm, 2021.



# IDE TRIALS

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## 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](#)



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# PINNACLE FLX and Amulet IDE Outcomes

## PINNACLE FLX Clinical Trial<sup>1,2</sup>

Characteristic	WATCHMAN FLX™
Patients	400
Age	73.8 ± 8.6
CHA <sub>2</sub> DS <sub>2</sub> -VASc Score	4.2 ± 1.5
HAS-BLED Score	2.0 ± 1.0

## Amulet IDE<sup>3</sup>

Characteristic	Amulet™	Legacy WATCHMAN™
Patients	934	944
Age	75.0 ± 7.6	75.1 ± 7.6
CHA <sub>2</sub> DS <sub>2</sub> -VASc Score	4.5 ± 1.3	4.7 ± 1.4
HAS-BLED Score	3.2 ± 1.0	3.3 ± 1.0





# 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

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WATCHMAN FLX™ Left Atrial Appendage Closure Device demonstrated **statistical superiority for complete occlusion** vs Amulet™ LAA Occluder.<sup>1</sup>

[View Full Study Results](#)

<sup>1</sup> Korsholm-K et al.; TCT 2021.



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# Study Design

First study to exclusively compare occlusion results of WATCHMAN FLX™ LAAC Device vs Amulet™ LAA Occluder using CT imaging.<sup>1</sup>

- 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).

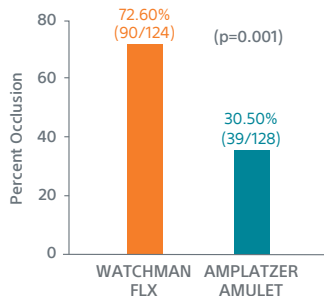
<sup>1</sup> Korsholm-K et al.; TCT 2021.



# Study Outcomes

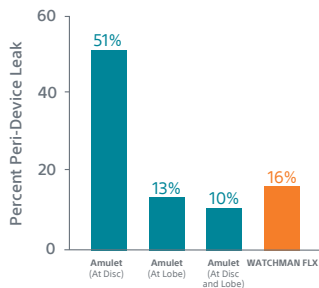
WATCHMAN FLX™ LAAC Device Demonstrated Statistically Superior Complete Occlusion\* vs Amulet™ LAA Occluder ( $p=0.001$ ).<sup>1</sup>

Complete Occlusion\*  
at 8 Weeks (per CT)



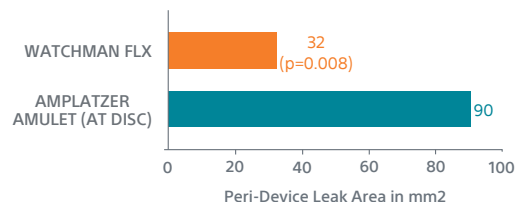
More Leak Pathways  
with a Two-Component Device  
at 8 Weeks (per CT)

Peri-Device Leak



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

Leak Size (mm<sup>2</sup>)



\*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).

<sup>1</sup> Korsholm-K et al.; TCT 2021.



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# SWISS APERO Study

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**WATCHMAN FLX™ LAAC Device demonstrated statistical superiority for procedural complications over Amulet™ LAA Occluder.<sup>1</sup>**

[View Full Study Results](#)

<sup>1</sup> Presented as an abstract at TCT 2021, published Circulation, 2021.



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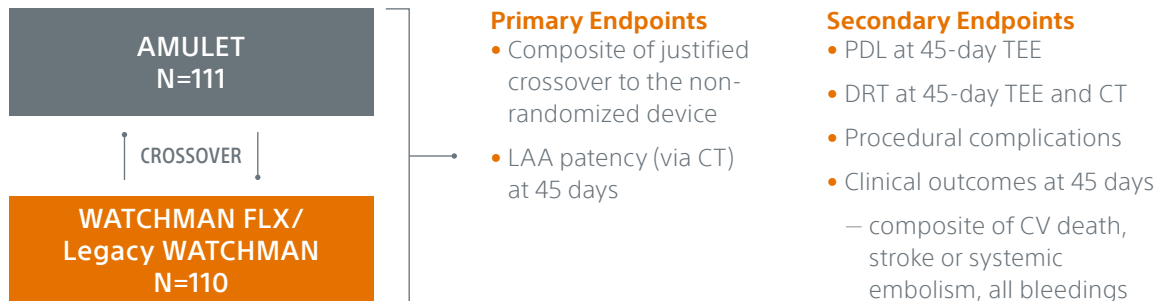
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# SWISS APERO Study Design and Endpoints

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.<sup>1</sup>



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

<sup>1</sup> Presented as an abstract at TCT 2021, published Circulation, 2021.



# 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.<sup>1</sup>

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. (%) <sup>*</sup>	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%)		

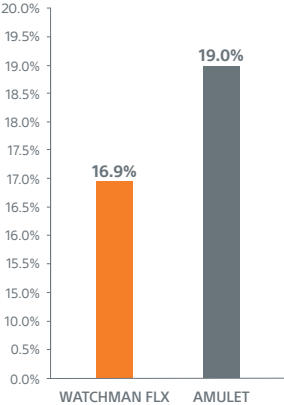
<sup>\*</sup>Composite of death, CVE, systemic embolism, major bleeding, cardiac tamponade, device embolization, or acute kidney injury occurring within 7 days or thereafter if deemed procedure-related.

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

<sup>1</sup> 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.<sup>1</sup>



# 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.**<sup>1</sup>

[View Study Results](#)

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



STUDY  
GLOSSARY

WATCHMAN FLX PRO  
LAAC DEVICE

**WATCHMAN FLX  
LAAC DEVICE**

LEGACY WATCHMAN  
LAAC DEVICE

LAAC  
THERAPY

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# 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:  $76.2 \pm 7.9$  Years
- CHA<sub>2</sub>DS<sub>2</sub>-VASc:  $4.8 \pm 1.5$
- HAS-BLED –  $2.4 \pm 1.0$
- Women: 41%
- Clinically Relevant Bleeding: 57.7%

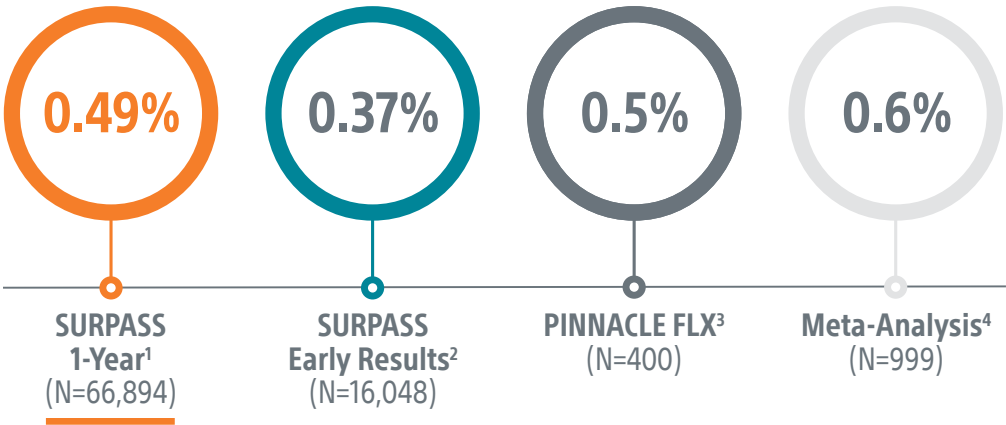
## Safety Endpoint

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).



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 Kapadia. 2 Kapadia, CRT 2022. 3 Kar, Circulation 2021. 4 Della Rocca et al. Heart Rhythm 2022.



STUDY  
GLOSSARY

WATCHMAN FLX PRO  
LAAC DEVICE

**WATCHMAN FLX  
LAAC DEVICE**

LEGACY WATCHMAN  
LAAC DEVICE

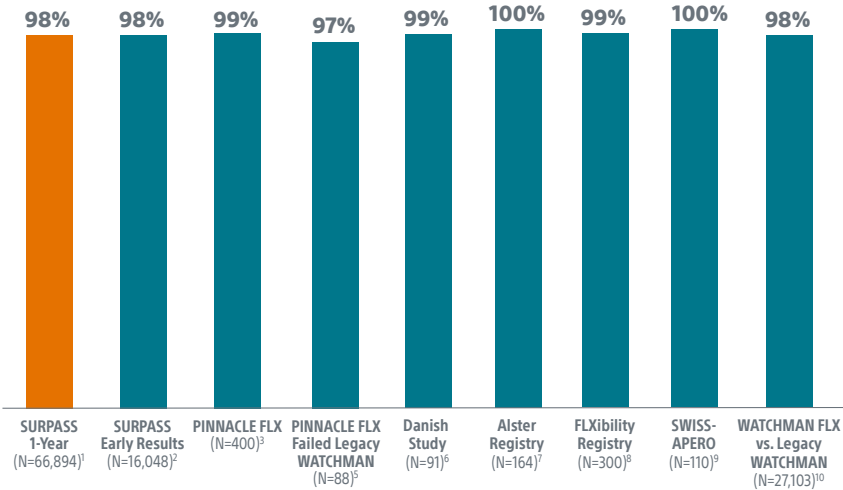
LAAC  
THERAPY

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SURPASS data reinforces the WATCHMAN FLX™ Device procedural success with 98% of patients implanted (N=66,894)<sup>1</sup> 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 Kapadia. 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, Circulation, 2021. 10 Freeman, HRS 2022.



STUDY  
GLOSSARY

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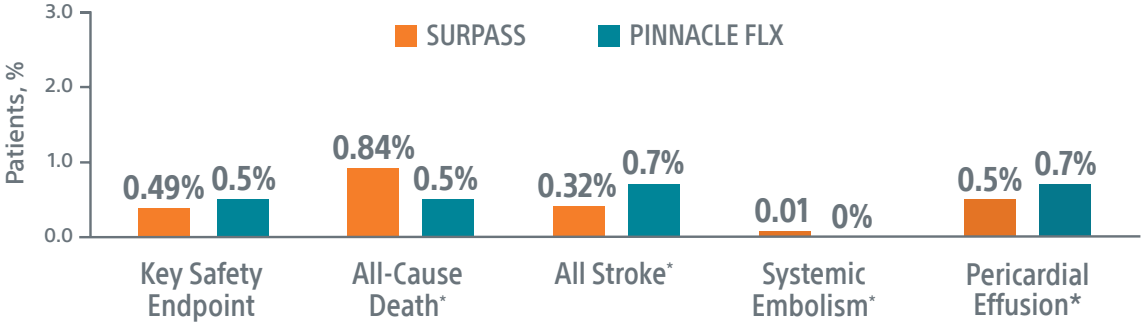
CLINICAL  
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The 1-Year SURPASS Data confirms the excellent safety profile the WATCHMAN FLX™ Device demonstrated in the PINNACLE FLX trial, with the largest (N=66,894) WATCHMAN FLX Device patient population to date.

Comparison with PINNACLE FLX<sup>1</sup>

45-Day Outcomes



*\*Results from different clinical investigations are not directly comparable.*

<sup>1</sup> Kar, Circulation 2021.



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.

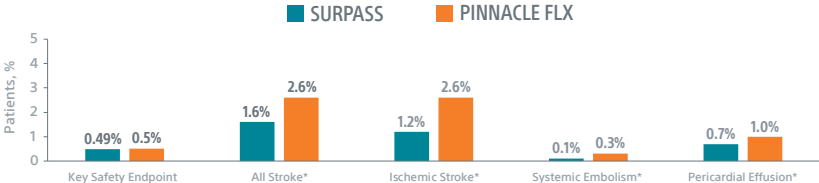
1-Year Stroke Rates

1.6%  
All Stroke



1.2%  
Ischemic Stroke

1-Year Outcomes Comparison with PINNACLE FLX<sup>1</sup>



<sup>1</sup> Kart et al. Circulation 2021.

\*1-Year Outcomes (KM Rates). Results from different studies are not directly comparable. For illustration purposes only.



STUDY  
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LAAC DEVICE

LEGACY WATCHMAN  
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# Procedural and Short-Term Follow-up Outcomes of Amplatzer Amulet™ LAA Occluder vs WATCHMAN FLX™ LAAC Device: A Meta-Analysis<sup>1</sup>

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](#)

<sup>1</sup> Della Rocca, D.G., Heart Rhythm, February 2022.



STUDY  
GLOSSARY

WATCHMAN FLX PRO  
LAAC DEVICE

**WATCHMAN FLX  
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LEGACY WATCHMAN  
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# 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<sub>2</sub>DSC<sub>2</sub>-VASC:  $4.3 \pm 1.5$  for Amulet LAA Occluder
- CHA<sub>2</sub>DSC<sub>2</sub>-VASC:  $4.2 \pm 1.5$  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).



STUDY  
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WATCHMAN FLX PRO  
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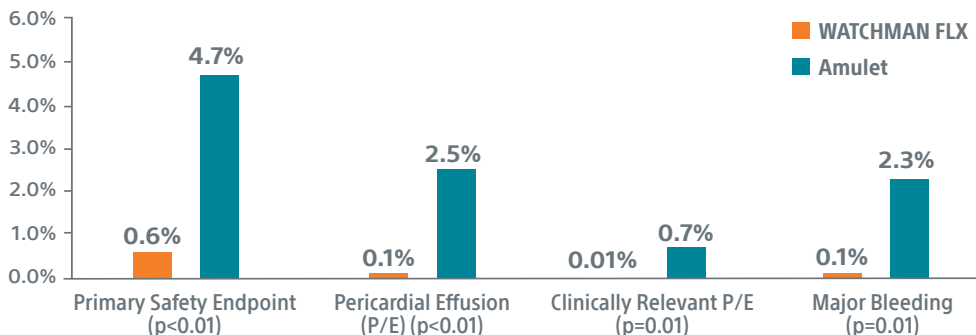
CLINICAL  
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## Key Results: Safety

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

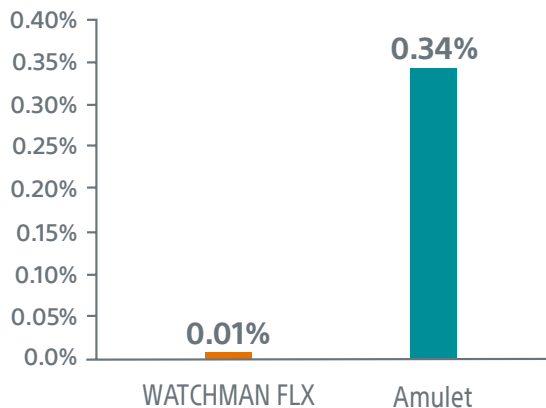




## Key Results: Seal

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

### Peri-Device > 5mm Within 3 Months



STUDY  
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# The ALSTER-FLX Registry: 3-Month Outcomes Following Left Atrial Appendage Occlusion Employing a Next-Generation Device, a Matched-Pair-Analysis to EWOLUTION<sup>1</sup>

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](#)

<sup>1</sup> Paitazoglou C., MD, Heart Rhythm, Feb. 2022.



STUDY  
GLOSSARY

WATCHMAN FLX PRO  
LAAC DEVICE

WATCHMAN FLX  
LAAC DEVICE

LEGACY WATCHMAN  
LAAC DEVICE

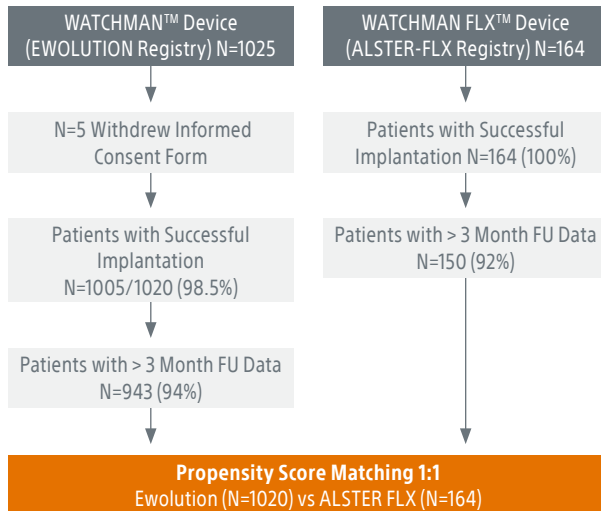
LAAC  
THERAPY

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SUMMARY

# Study Design

## Comparison



## Patient Characteristics

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

- Bleeding risk (EWOLUTION  $2.3 \pm 1.2$  vs ALSTER FLX  $3.2 \pm 0.8$ ,  $p < 0.001$ )
- 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%,  $p < 0.001$ )



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

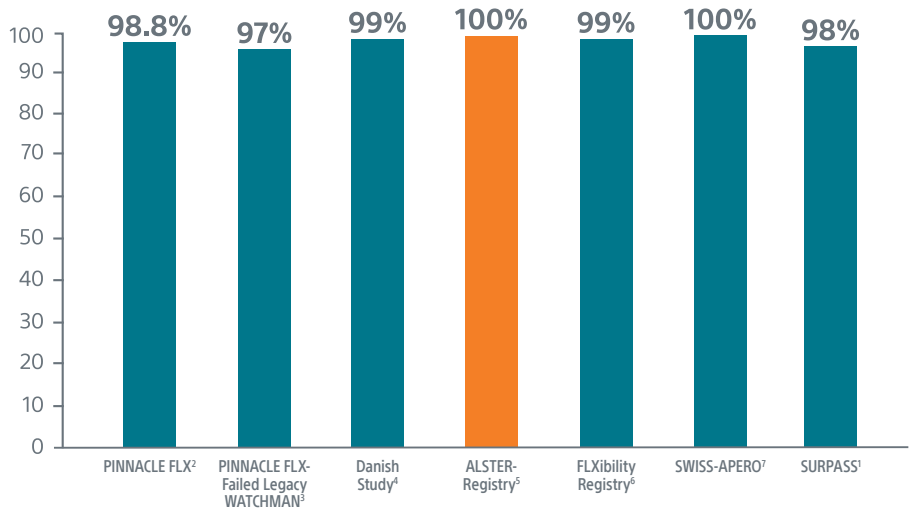
- 100% Procedural Success vs in the ALSTER-Registry compared to 99% in EWOLUTION

### 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.



STUDY  
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WATCHMAN FLX PRO  
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# 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](#)



STUDY  
GLOSSARY

WATCHMAN FLX PRO  
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**WATCHMAN FLX  
LAAC DEVICE**

LEGACY WATCHMAN  
LAAC DEVICE

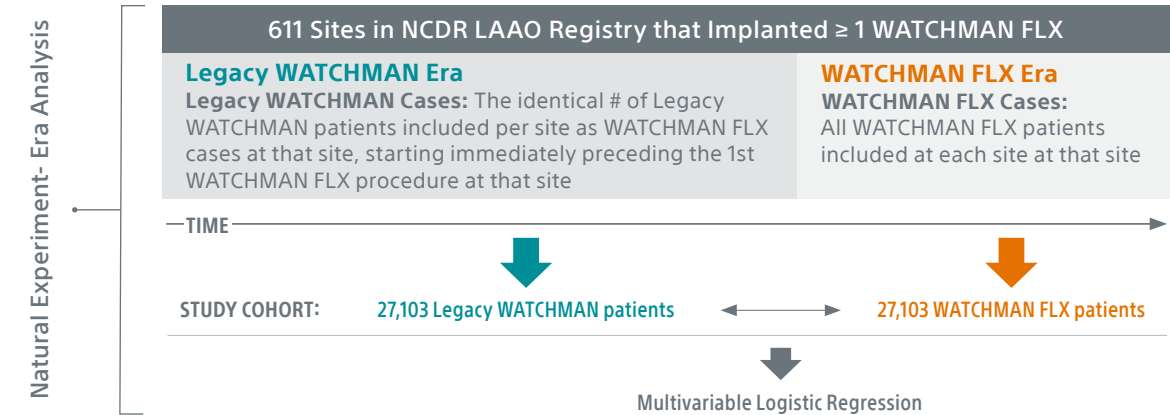
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# Key Results: Safety

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.<sup>1</sup>



**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.

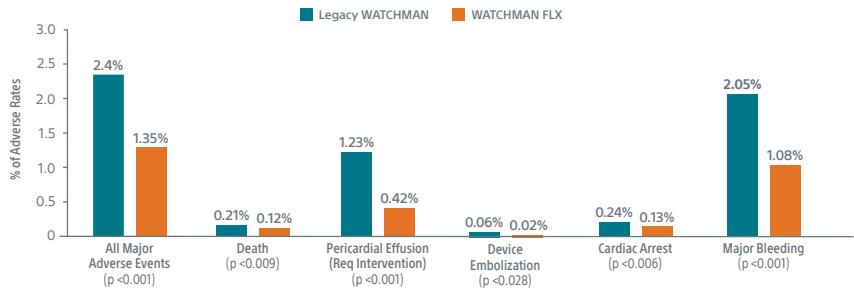
<sup>1</sup> Late Breaking Clinical trial at HRS 2022 presented by Dr James Freeman.



# 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.<sup>1</sup>

## 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

<sup>1</sup> Late Breaking Clinical trial at HRS 2022 presented by Dr James Freeman.





# CHAMPION-AF

## Clinical Trial

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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](#)



STUDY  
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WATCHMAN FLX PRO  
LAAC DEVICE

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**LAAC DEVICE**

LEGACY WATCHMAN  
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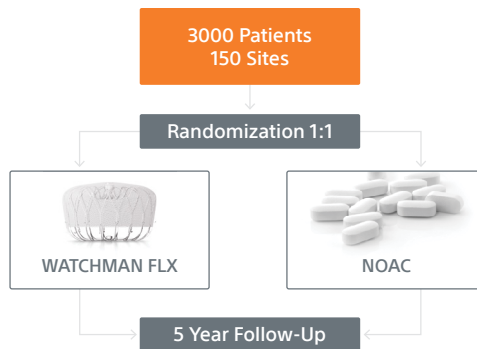
# CHAMPION-AF: Study Objective and Design

## 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



# 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<sub>2</sub>DS<sub>2</sub>-VASc score of  $\geq 2$  for men and  $\geq 3$  for women
- Patient is deemed to be suitable for long-term NOAC

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



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# DAPT FLX

## Comparative Effectiveness of Post-Procedure Medications Following Left Atrial Appendage Occlusion: A DAPT Analysis with the WATCHMAN FLX™ Device<sup>1</sup>

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](#)



STUDY  
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WATCHMAN FLX PRO  
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LEGACY WATCHMAN  
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# 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  $\leq 5$  mm at time of implant)
  - CHA<sub>2</sub>DS<sub>2</sub>-VASC  $\geq 2$  in men or  $\geq 3$  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

N = 17,369

DAPT = 2,122

DOAC + ASA = 13,113

Warfarin + ASA = 2,134



STUDY  
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Adjusted Baseline Characteristics

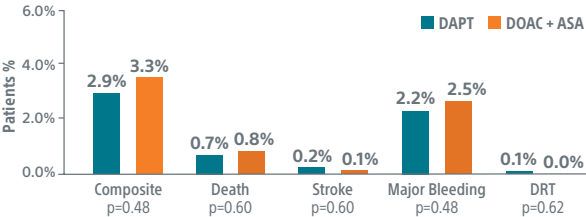
To adjust for differences in baseline characteristics, 1:1 propensity score matching between groups (DAPT vs warfarin + Aspirin; DAPT vs DOAC + Aspirin) was performed. Variables included age, gender, race/ethnicity, CHA<sub>2</sub>DS<sub>2</sub>-VASC and HAS BLED score components, atrial fibrillation 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 <sub>2</sub> DS <sub>2</sub> -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

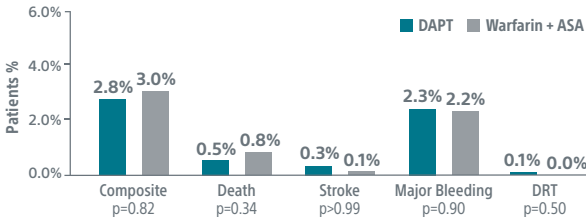
# Study Outcomes

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)



# THE ICE LAA STUDY

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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**.<sup>1</sup>

[View Study Results](#)

<sup>1</sup> Nielsen-Kudsk JE et al. JACC: CI, Mar. 2023.



STUDY  
GLOSSARY

WATCHMAN FLX PRO  
LAAC DEVICE

WATCHMAN FLX  
LAAC DEVICE

LEGACY WATCHMAN  
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# 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:  $76 \pm 8$  years
- CHA<sub>2</sub>DS<sub>2</sub>-VASc:  $4.0 \pm 1.5$
- HAS-BLED:  $2.5 \pm 0.9$
- 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.

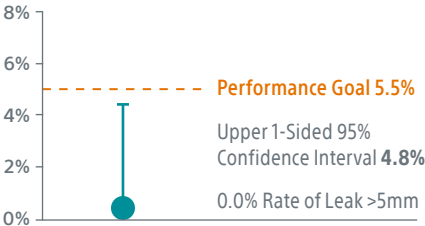
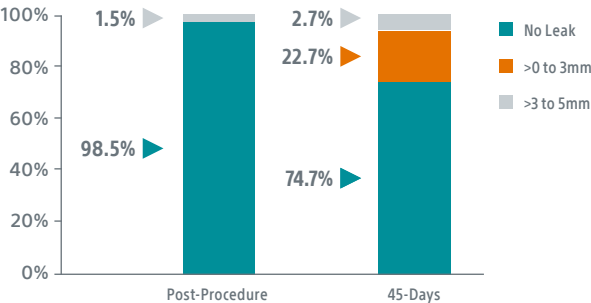


# The ICE LAA results confirmed the safety of ICE-guided WATCHMAN FLX™ implant with excellent procedural success and low rates of short-term complications.

## 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



STUDY  
GLOSSARY

WATCHMAN FLX PRO  
LAAC DEVICE

WATCHMAN FLX  
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LAAC DEVICE

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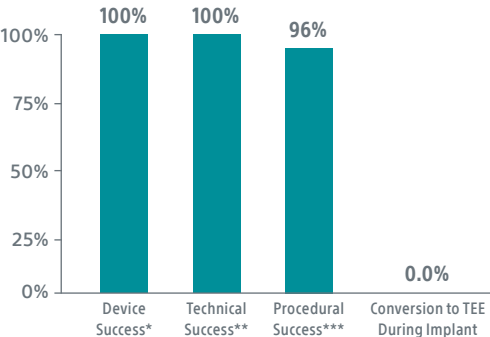
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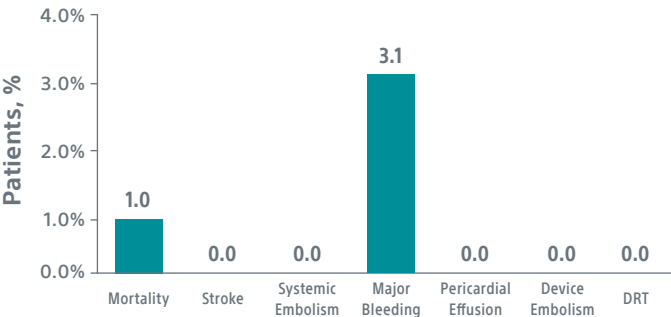
# The ICE LAA results confirmed the safety of ICE-guided WATCHMAN FLX™ implant with excellent procedural success and low rates of short-term complications.

## 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.



# 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.<sup>1</sup>

[View Full Study Results](#)

<sup>1</sup>Ferro EG et al. ACC, Mar. 2023.



STUDY  
GLOSSARY

WATCHMAN FLX PRO  
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# 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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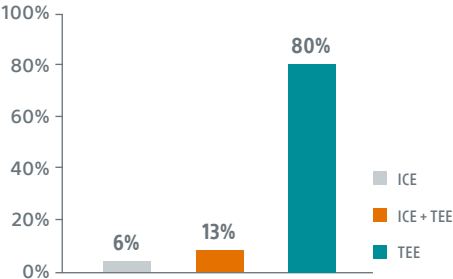
# SURPASS ICE vs. TEE: Study Design

## 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



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

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



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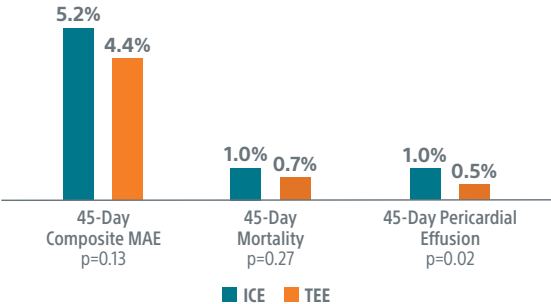
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# SURPASS ICE vs. TEE: Study Design

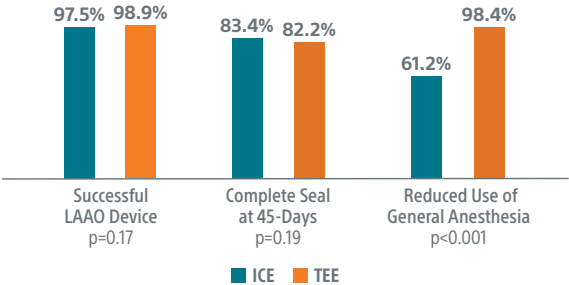
## Key Safety and Efficacy Outcomes

- 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.



# Legacy WATCHMAN™

## Left Atrial Appendage Closure Device

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# 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.<sup>1</sup>

[View Full Trial Results](#)

<sup>1</sup> Reddy et al. Left Atrial Appendage Closure for Stroke Prevention, JACC, 2017;29:64-75.



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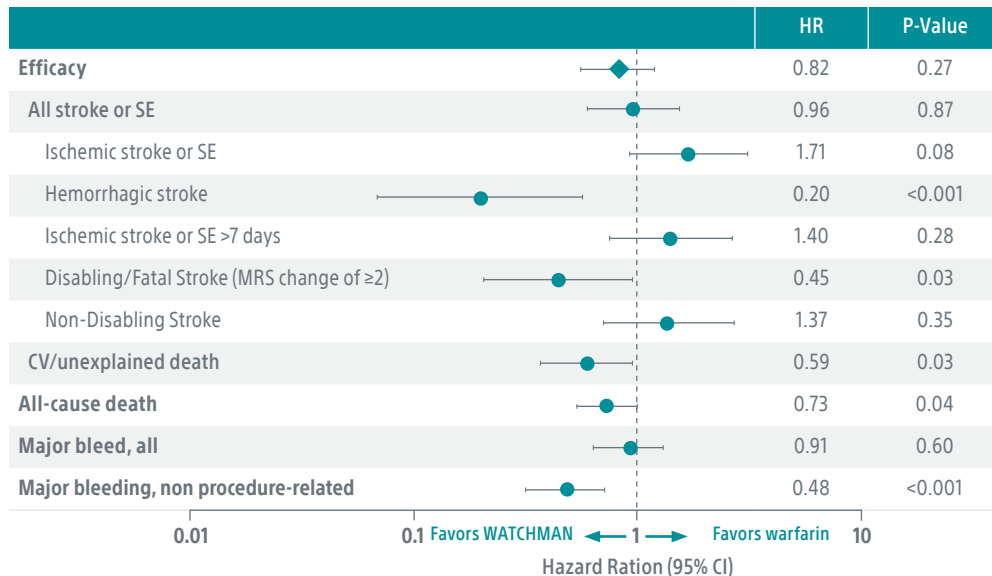
# PROTECT-AF and PREVAIL Clinical Trials<sup>1</sup> (U.S. Legacy WATCHMAN™ Left Atrial Appendage Closure Device IDE trials)

	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	<ul style="list-style-type: none"><li>• Effectiveness: Stroke, systemic embolism and cardiovascular/unexplained death</li><li>• Safety: Life-threatening events, which include device embolization requiring retrieval and bleeding events</li></ul>	<ul style="list-style-type: none"><li>• Effectiveness: Stroke, systemic embolism and cardiovascular/unexplained death</li><li>• Effectiveness: Ischemic stroke or systemic embolism, occurring after 7 days post-randomization or WATCHMAN implant procedure</li><li>• Safety: Death, ischemic stroke, systemic embolism and procedure/device-related complications within 7 days of implantation procedure</li></ul>

<sup>1</sup> 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)<sup>1</sup>



## 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

<sup>1</sup> 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.<sup>1,2</sup>

[View Full Early Results](#)

[View Full Long-Term Results](#)

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

<sup>2</sup> Virtual Presentation at ACC 2021 by Dr. Matthew Price.



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# 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<sup>1</sup>

NCDR LAAO Registry (N=36,681)	
Age, mean	76.0±8.1
Female Sex (%)	15,086 (41.1)
CHA <sub>2</sub> DS <sub>2</sub> 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

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



# Review of the First 3 Years of Registry Data<sup>1</sup>

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%**

PROTECT AF<sup>1</sup>

**4.1%**

CAP<sup>1</sup>

**4.2%**

PREVAIL<sup>1</sup>

**3.8%**

CAP2<sup>1</sup>

**2.8%**

EWOLUTION<sup>2</sup>

**2.2%**

NCDR-LAA<sup>3</sup>

## Procedural Success

**98%**

## Closed with Leak <5mm

**99.2%**

<sup>1</sup> WATCHMAN FDA Panel Sponsor Presentation, Oct 2014.

<sup>2</sup> Boersma, et al, Heart Rhythm, Vol 14, No 9, September 2017.

<sup>3</sup> Freeman, JACC, March 2020, Vol 75, No. 13, 2020.



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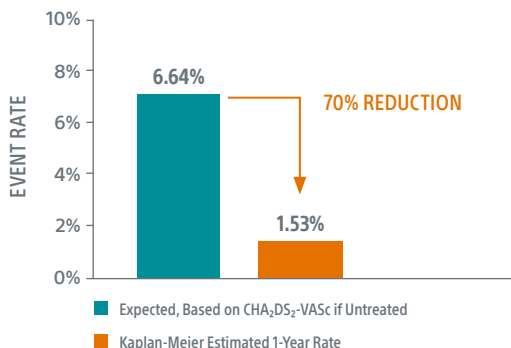
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# 1-Year Clinical Outcomes<sup>1</sup>

>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 Registry 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.

<sup>1</sup> 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.<sup>1</sup>

[View Full Study Results](#)

<sup>1</sup> Presented at AHA, 2021, Vivek Reddy, M.D.



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## 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.<sup>1</sup>

**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)

<sup>1</sup> Presented at AHA, 2021, Vivek Reddy, M.D.

CAP-1 was not included because leak assessment was not consistently captured.

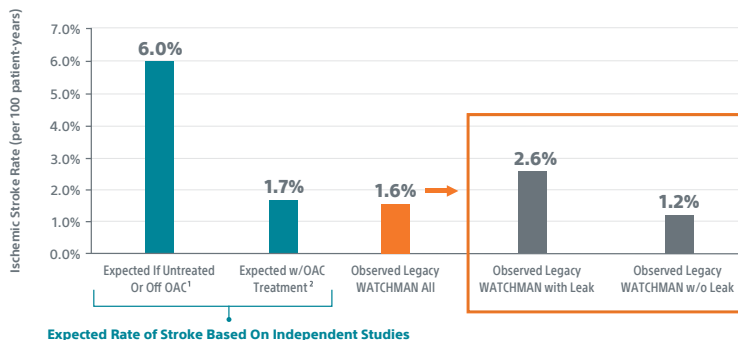
>5mm leaks were excluded from this analysis as larger leaks are established as associated with adverse outcomes.



## 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.\*<sup>3</sup>

### 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.

<sup>1</sup> Freiberg et al. European Heart Journal (2012) 33, 1500-1510.

<sup>2</sup> Oleson et al. Thromb Haemost 2011; 106: 739-749.

<sup>3</sup> Presented at AHA, 2021, Vivek Reddy, M.D.





# LAAC Therapy



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# 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.<sup>1</sup>

[View Full Trial Results](#)

<sup>1</sup> Presented by Dr. Richard Whitlock at ACC Virtual 2021, Published – Whitlock R NEJM, 2021.



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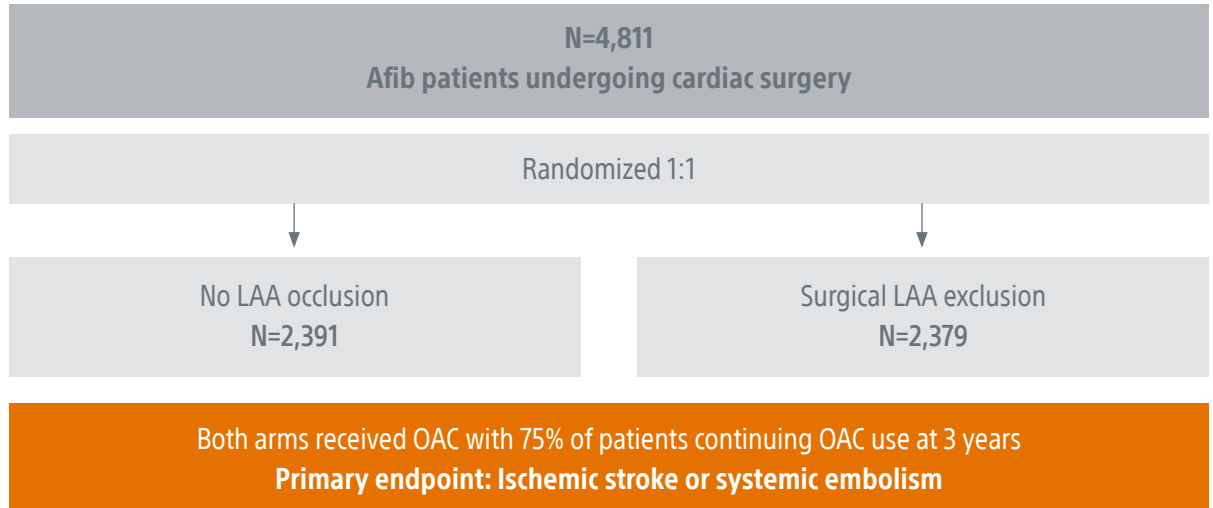
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# Study Design



<sup>1</sup> Presented by Dr. Richard Whitlock 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
<b>Ischemic Stroke or Systemic Embolism</b>	<b>4.8</b>	<b>7.0</b>	<b>33%</b>	<b>0.001</b>
Ischemic Stroke	4.6	6.9	34%	
Systemic Embolism	0.3	0.3	14%	
<b>Landmark Analysis</b>				
Ischemic Stroke or Systemic Embolism within 30 Days after Surgery	2.2	2.7	18%	
<b>Ischemic Stroke or Systemic Embolism beyond 30 Days after Surgery</b>	<b>2.7</b>	<b>4.6</b>	<b>42%</b>	

<sup>1</sup> Presented by Dr. Richard Whitlock 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.<sup>1</sup>**

[View Full Study Results](#)

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



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# 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<sub>2</sub>DS<sub>2</sub>-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 Osmančík, MD, et al, JACC 2022, 4-Year Outcomes After LAAC Versus NOAC for Atrial Fibrillation.



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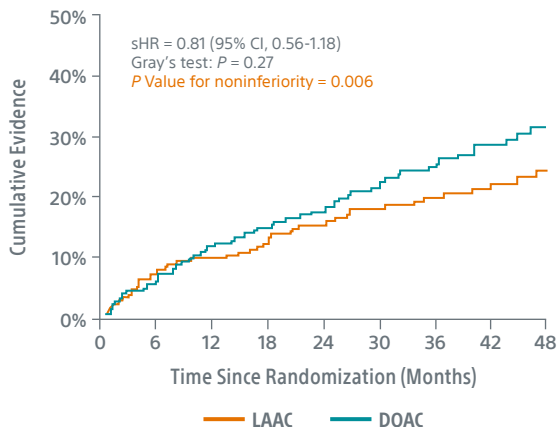


# Study Outcome at 48 Months

Confirms the clinical benefit of LAAC in high-risk NVAf patients over NOAC therapy.<sup>1</sup>

## Primary Endpoint

Stroke, 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<sub>2</sub>DS<sub>2</sub>-VAsc score 4.7
- Non-procedural bleeding was significantly reduced with LAAC

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



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# CLINICAL TIMELINE

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



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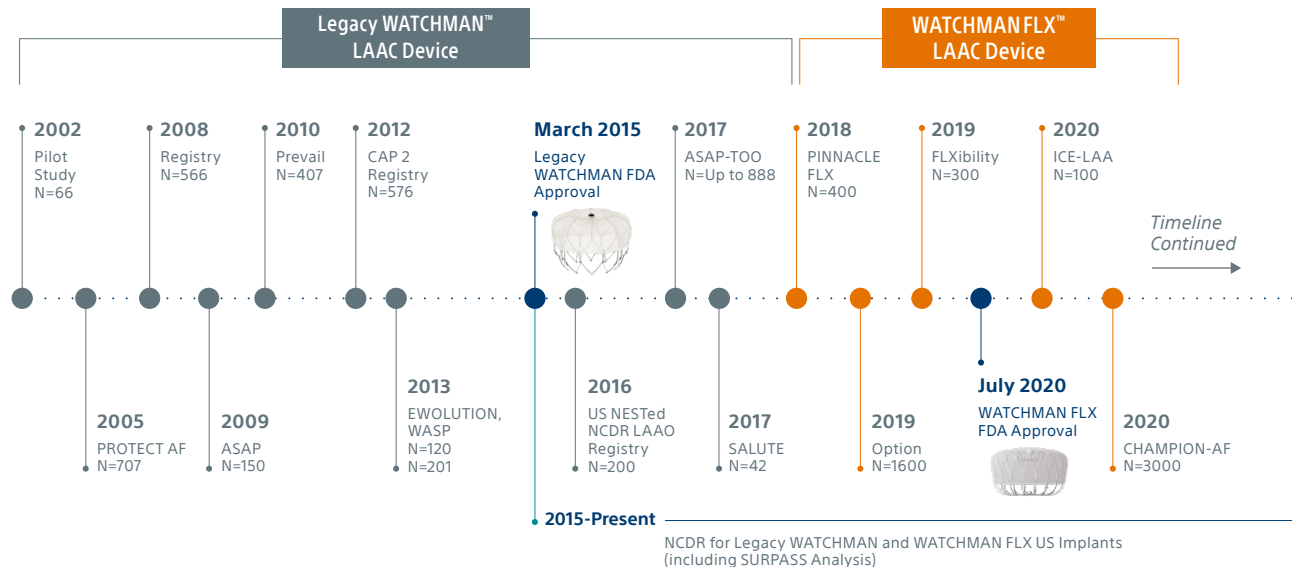
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# WATCHMAN™ Left Atrial Appendage Closure Device Clinical Timeline



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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)



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# 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 Vasculture 2019; 23(100358) (WASP).
- 6 US NESTed NCDR LAAC 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.



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# 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<sub>2</sub>DS<sub>2</sub>-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.



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## 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<sub>2</sub>DS<sub>2</sub>-VASc 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) 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<sub>12</sub> 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.
- 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.



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# Brief Summary (continued)

- 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.

## MRI Safety Information

A person with the Boston Scientific WATCHMAN FLX Pro Closure Device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	WATCHMAN FLX Pro Closure Device
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)



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Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/ scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of up to 8 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

## 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, 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.

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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.  
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