WATCHMAN FLX™ Pro

LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Boston Scientific
Advancing science for life™

Left Atrial Appendage Closure with a Novel Fluoropolymer-Coated Device: Primary Safety and Efficacy Endpoints of the HEAL-LAA Post-Approval Clinical Study[1]

LAAO Innovations at TCT® Scientific Sessions 2024.

Seun Alli, Tom McElderry, Kevin Trulock, Devi Nair, Brad Mikaelian, Robert Eckart, Manish Shah, Thomas Waggoner, Andrea Natale, Madhu Reddy, Ashish Sadhu, Jeremiah P. Depta, David Newton, Anita Sadeghpour, Krystal Leger†,Thomas Christen†, Brad Sutton†, Mohamed Kanj.

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 were met, having demonstrated consistent complete closure and proven safety outcomes in a real-world clinical setting.

Study Design

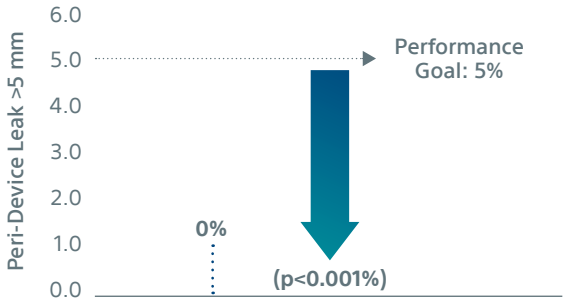
- The objective of the HEAL-LAA clinical study was to evaluate the safety and effectiveness of WATCHMAN FLX Pro in a commercial clinical setting.
- Prospective, multicenter, post-market clinical study.
- 32 centers in United States.
- Primary Analysis Set = first 500 patients enrolled.
- WATCHMAN TruSteer™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

Consistent Complete Closure

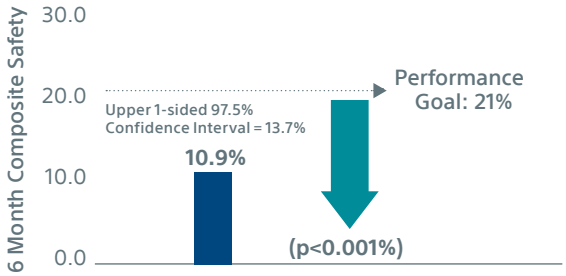
The primary efficacy endpoint was achieved as the rate of leak >5 mm was 0% at 45-days, significantly less than 5% performance goal (p<0.001), **including 82.7% complete seal and only 0.2% >3 mm.**



	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)

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[2]	0.4% (2/500)***
PINNACLE FLX[3]	0.5% (2/400)

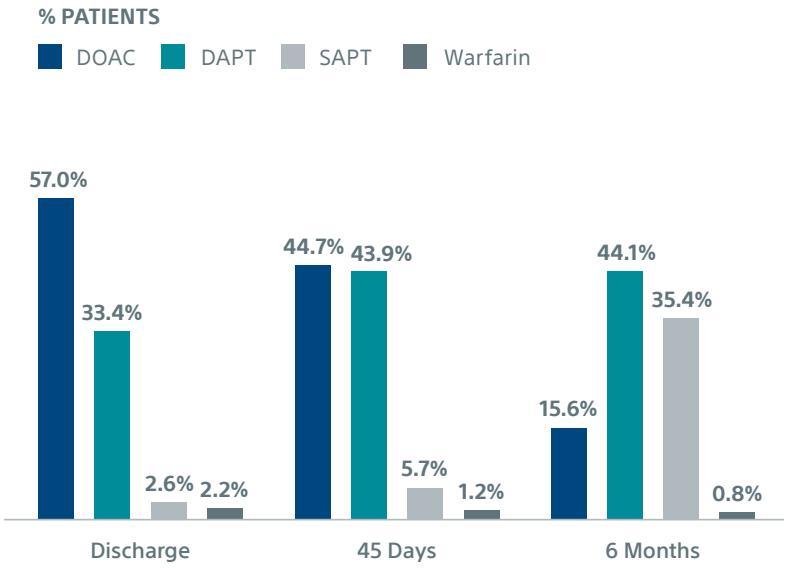
NOTE: Results of these trials are not directly comparable.

* 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.

Patient Demographics and Discharge Medications

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[1] (N = 500)	PINNACLE FLX[3] (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_2DS_2-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%**

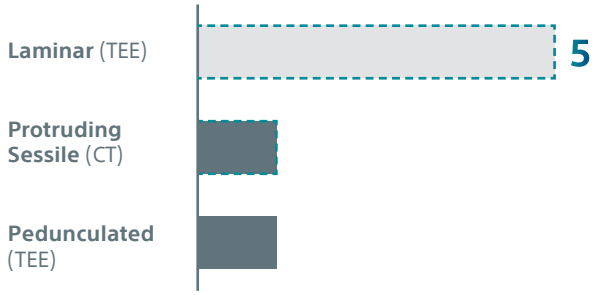


Results of these trials are not directly comparable.

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.[4]

- 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 (hypoatteniated thickening) was not associated with an increased risk for thromboembolic events.[4]

Advancing outcomes and expanding the treatable population

Procedural performance

99.5%

Procedural success

99.5% procedural success with the WATCHMAN TruSteer Access System with an 86% reduction in abort rate compared to other access systems.[5]

Broader range of anatomies‡

6.0%

More patients treated

6% of enrolled patients (N = 500) in HEAL-LAA were **implanted with the new 40 mm diameter** WATCHMAN FLX Pro device.

Controlled healing

0.22%

Pedunculated Thrombus

Only 1 (N = 448; 0.22%) pedunculated thrombus formation (TEE) at 45 days characterized as having a high likelihood of DRT per JACC State-of-the-Art review.[4]

† Boston Scientific Employees.
‡ Measured maximum LAA ostium width and/or deployed closure device diameter must be ≥ 14.0 mm and ≤ 36.0 mmto accommodate available closure device sizes. LAA depth should be approximately half the labeled implant diameter or longer.

1. Alli O, et al. Primary Safety and Efficacy Endpoints of the HEAL-LAA Post-Approval Clinical Study. LAAO 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.
4. Alkhouli M, et al. JACC: Cardiovascular Interventions 2023.
5. 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.