

Outcomes in Patients with Atrial Fibrillation Randomized to Receive Left Atrial Appendage Closure or Oral Anticoagulation



Primary 3-Year Results of the CHAMPION-AF Clinical Trial

Late Breaking Clinical Trial at ACC's 75th Annual Scientific Session & Expo with simultaneous publication in the [New England Journal of Medicine](#)¹

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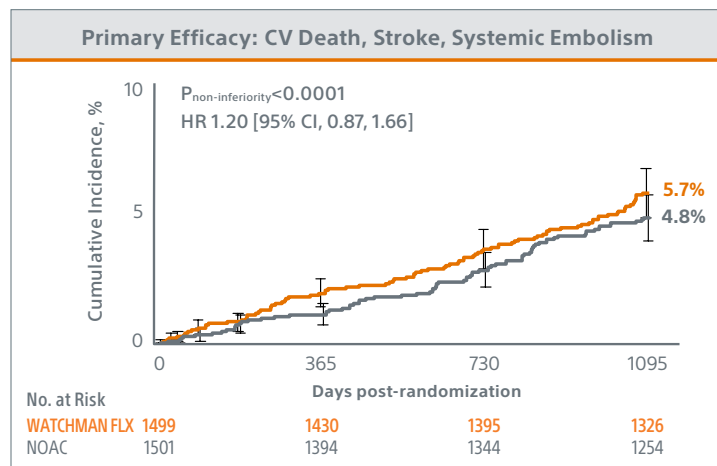
WATCHMAN™ met all trial endpoints as an alternative vs. NOACs, including a superior net clinical benefit*, 1.1% annualized ischemic stroke rate and significantly reduced bleeding (including procedural) at 36 months

*Net clinical benefit endpoint includes a composite of cardiovascular death, stroke, systemic embolism, and non-procedural ISTH major and modified clinically-relevant non-major bleeding

CHAMPION-AF Primary Endpoint Outcomes

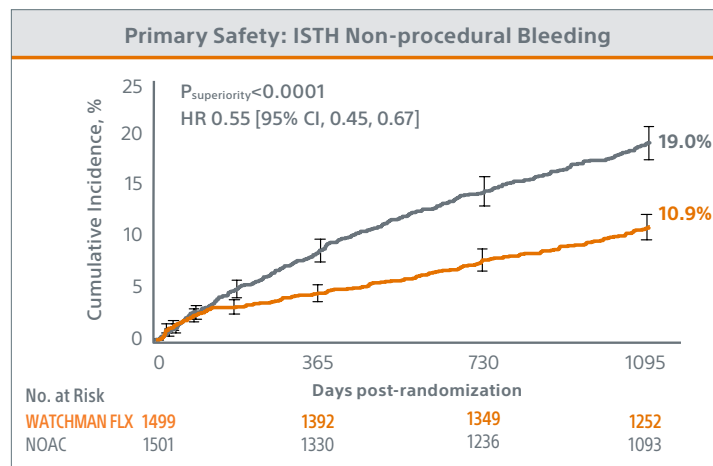
Primary Efficacy Endpoint Met

WATCHMAN FLX demonstrated statistical non-inferiority to NOACs for the occurrence of cardiovascular (CV) death (hemorrhagic and/or unexplained death), stroke (ischemic and/or hemorrhagic), and systemic embolism (5.7% vs. 4.8%; $P_{\text{non-inferiority}} < 0.0001$)



Primary Safety Endpoint Met

WATCHMAN FLX demonstrated statistical superiority to NOACs for the occurrence of ISTH non-procedural major bleeding and modified* clinically relevant non-major bleeding (10.9% vs. 19.0%; $P_{\text{superiority}} < 0.0001$)

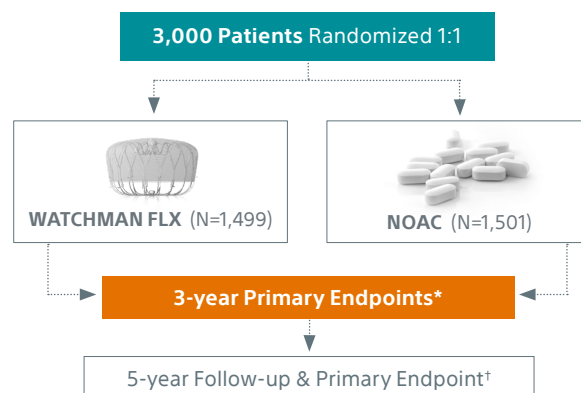


*Modified ISTH clinically relevant non-major bleeding was defined as any sign or symptom of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for the ISTH definition of major bleeding but does meet at least one of the following criteria.

- Requiring medical intervention by a healthcare professional
- Leading to hospitalization or increased level of care (e.g., ER visit, diagnostic procedures, medication change)

CHAMPION-AF Trial Design

CHAMPION-AF is a prospective, randomized, multi-center, global investigation to study left atrial appendage closure with the WATCHMAN FLX™ LAAC Device as an alternative to oral anticoagulation in a broad non-valvular atrial fibrillation population, including those who are at low-to-moderate risk of bleeding from the use of oral anticoagulation.



*Study success is defined as meeting both 3-year primary endpoints

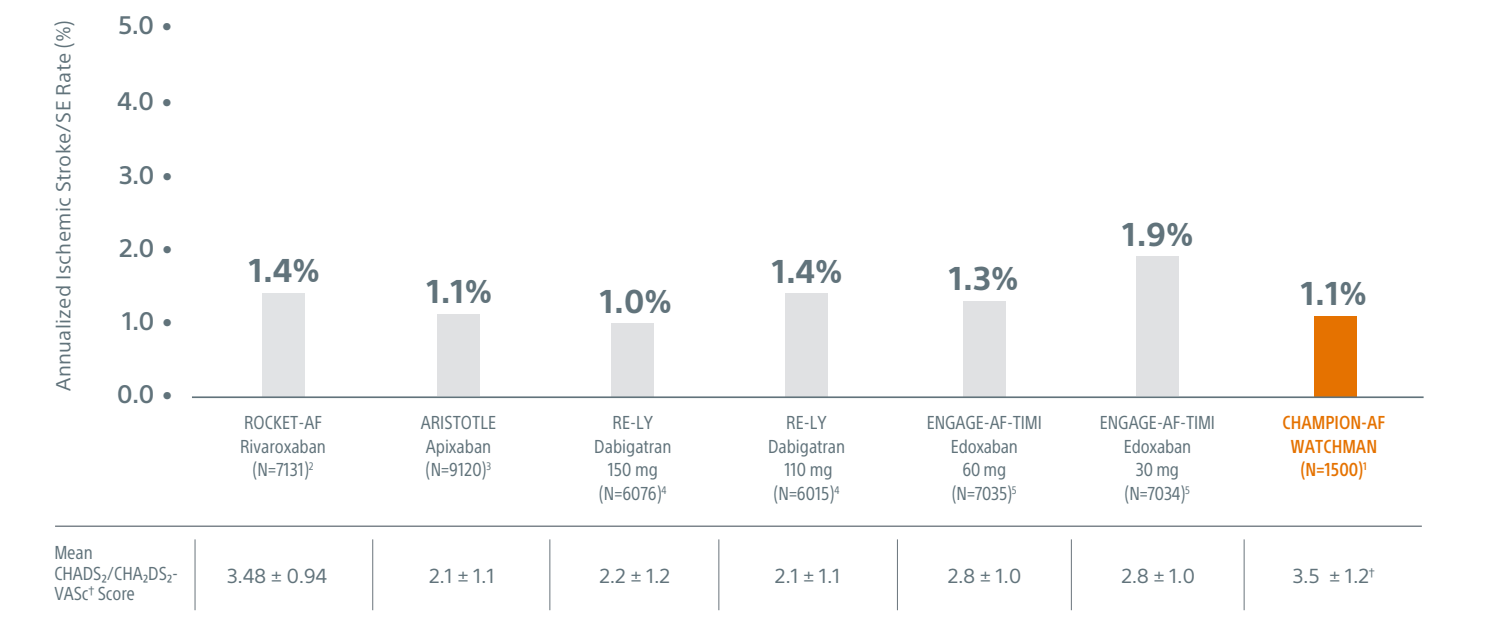
† 5-year primary endpoint is non-inferiority for the occurrence of ischemic stroke or systemic embolism

Primary & Secondary Endpoints (Kaplan-Meier Estimates)

Endpoint	Analysis	NOACs (n=1501)	WATCHMAN FLX (n=1499)	Difference (2-sided 95% CI)	Hazard Ratio (2-sided 95% CI)	P-value
		no. of patients (%)				
Primary Endpoints						
Efficacy: CV death, stroke, and systemic embolism	Non-inferiority	65 (4.8)	81 (5.7)	0.9 (-0.8, 2.6)	1.20 (0.87, 1.66)	<0.0001
CV death		36 (2.7)	38 (2.7)	0.0 (-1.2, 1.2)	1.01 (0.64, 1.59)	--
All stroke		33 (2.5)	50 (3.6)	1.1 (-0.2, 2.4)	1.46 (0.94, 2.27)	--
Systemic embolism		2 (0.1)	0 (0.0)	--	--	--
Safety: ISTH non-procedural bleeding	Superiority	260 (19.0)	154 (10.9)	-8.1 (-10.8, -5.5)	0.55 (0.45, 0.67)	<0.0001
ISTH major bleeding		87 (6.4)	71 (5.1)	-1.4 (-3.1, 0.4)	0.78 (0.57, 1.06)	--
Modified ISTH clinically-relevant non-major bleeding		193 (14.2)	99 (7.0)	-7.1 (-9.4, -4.8)	0.48 (0.37, 0.61)	--
Secondary Endpoints						
Safety: ISTH major bleeding (including procedural)	Non-inferiority	87 (6.4)	83 (5.9)	-0.6 (-2.4, 1.2)	0.92 (0.68, 1.24)	<0.0001
Net clinical benefit: CV death, stroke, systemic embolism and ISTH non-procedural bleeding	Non-inferiority → Superiority	300 (21.8)	215 (15.1)	-6.7 (-9.6, -3.8)	0.66 (0.56, 0.79)	<0.0001

Ischemic Stroke/Systemic Embolism (SE) Rates Across Landmark Trials

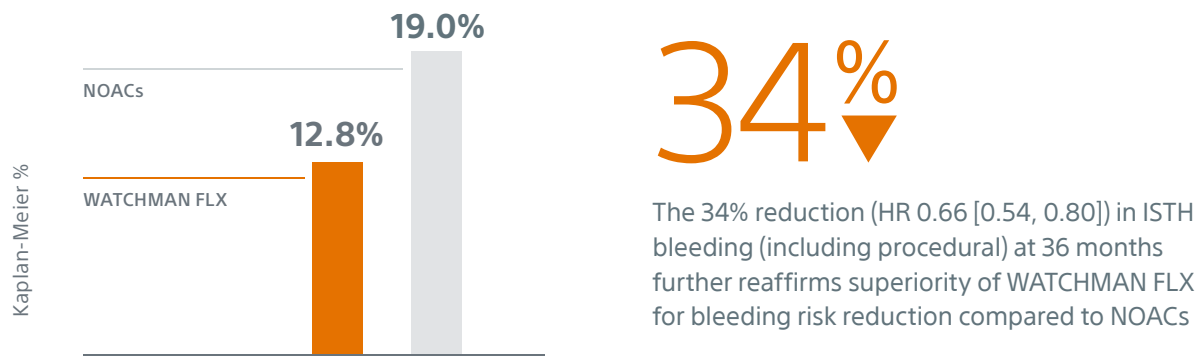
Stroke rates from both the WATCHMAN FLX and NOAC arms were low. **The WATCHMAN FLX device demonstrated a 1.1% annualized ischemic stroke/SE rate, aligned with ischemic stroke rates observed in prior, seminal clinical trials of NOACs,** suggesting both strategies may be effective for patients seeking a stroke risk reduction therapy.



Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.
CHAMPION-AF NOAC arm annualized ischemic stroke/SE rate: 0.7%
† CHA₂DS₂-VASC score used in CHAMPION-AF trial only; CHADS₂ score used in NOAC trials

Total ISTH Bleeding (Including Procedural Bleeding)

Reaffirming superiority of the primary safety endpoint, WATCHMAN FLX demonstrated a **statistically significant 34% risk reduction in ISTH bleeding (including procedural)** at 36 months, (12.8% vs. 19.0%; P<0.0001).



Key Baseline Characteristics (ITT):

Characteristic	NOACs (n=1501)	WATCHMAN FLX (n=1499)
Age – yr (Avg ± SD)	71.8 ± 7.5	71.6 ± 7.5
Female	31.5%	32.4%
CHA ₂ DS ₂ -VASc Score (Avg ± SD)	3.5 ± 1.3	3.5 ± 1.2
HAS-BLED Score (Avg ± SD)	1.3 ± 0.8	1.3 ± 0.8
Prior ischemic stroke	7.6%	7.9%
History of major bleeding	3.3%	3.5%
Paroxysmal AF	68.5%	69.3%
Persistent AF	25.4%	23.9%
Permanent AF	6.1%	6.8%
Prior atrial fibrillation ablation	46.9%	48.7%



[WATCHMAN FLX Pro LAAC Device](#)
[Implanter- Indications, Safety and Warnings](#)

References
1. SK Doshi et al. Left Atrial Appendage Closure or Anticoagulation for Atrial Fibrillation. New England Journal of Medicine, March 2026
2. Patel, M. Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation. NEJM 2011; 365(10):883-891.
3. Granger, C. Apixaban versus Warfarin in Patients with Atrial Fibrillation. NEJM 2011; 365(11):981-992
4. Connolly, S. Dabigatran versus Warfarin in Patients with Atrial Fibrillation. NEJM 2009; 361(12): 1139-1151
5. Giugliano, R. Edoxaban versus Warfarin in Patients with Atrial Fibrillation. NEJM 2013; 369(22): 2093-2104.

WATCHMAN FLX is an FDA approved device being studied for an expanded indication as a first line therapy vs NOAC for NVAF patients. The use of WATCHMAN or WATCHMAN FLX as a first-line therapy for stroke risk reduction in NVAF patients is considered investigational. Caution: Investigational Device. Limited by US law to investigational use only.

CE 2797 CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device or at [www.IFU-BSCI.com](#). Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.