WATCHMAN™
INTEGRATED LAAC SOLUTIONS

Boston Scientific
Advancing science for life™

# 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]

*Shephal K. Doshi, MD, Saibal Kar, MD, Devi G. Nair, MD, Thomas Waggoner, MD, Himanshu Agarwal, MD, Mehran Moussavian, MD, Amir Kashani, MD, Saumil Oza, MD, Leon Feldman, MD, Ashish Sadhu, MD, David DeLurgio, MD, Oluseun Alli, MD, Jens Erik Nielsen-Kudsk, MD, Masanori Yamamoto, MD, Mohamad Alkhouli, MD, MBA, A. John Camm, MD, Megan Coylewright, MD, MPH, C. Michael Gibson, MD, Christopher B. Granger, MD, Mahmut Edip Gurol, MD, Kenneth C. Huber, MD, Moussa Mansour, MD, Andrea Natale, MD, Stuart J. Pocock, PhD, Vivek Y. Reddy, MD, Walid I. Saliba, Federico Asch, MD, Scott Wehrenberg, MS, Kate Frost, PhD, Thomas Christen, MD, Brad S. Sutton, MD, Kenneth M. Stein, MD, Martin B. Leon, MD, Kenneth A. Ellenbogen, MD.*

**WATCHMAN™ met all trial endpoints** as a first-line option 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

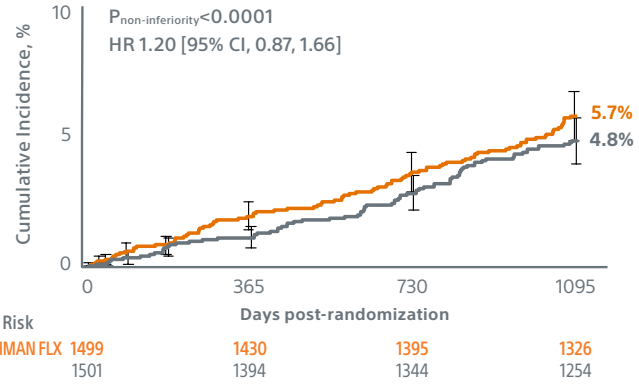
### Primary Efficacy Endpoint Met

**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%; $P_{non\text{-}inferiority}$ <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%; $P_{superiority}$ <0.0001)

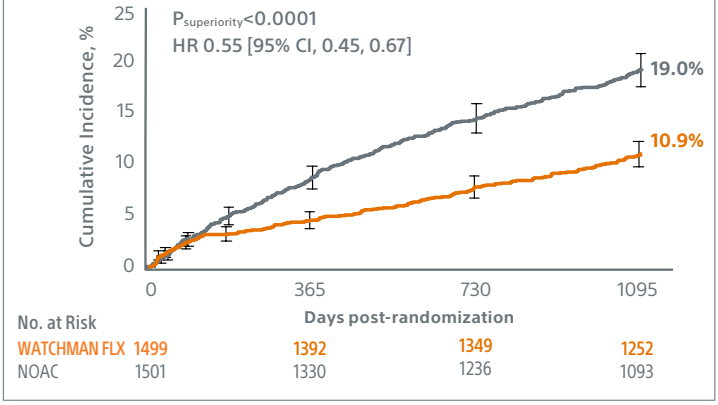
**Primary Efficacy: CV Death, Stroke, Systemic Embolism**




No. at Risk

| | | | | |
|---|---|---|---|---|
| WATCHMAN FLX | 1499 | 1430 | 1395 | 1326 |
| NOAC | 1501 | 1394 | 1344 | 1254 |

**Primary Safety: ISTH Non-procedural Bleeding**



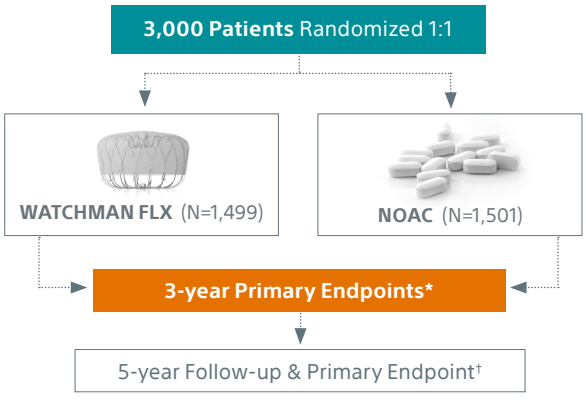

No. at Risk

| | | | | |
|---|---|---|---|---|
| WATCHMAN FLX | 1499 | 1392 | 1349 | 1252 |
| NOAC | 1501 | 1330 | 1236 | 1093 |

*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 a first-line 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.



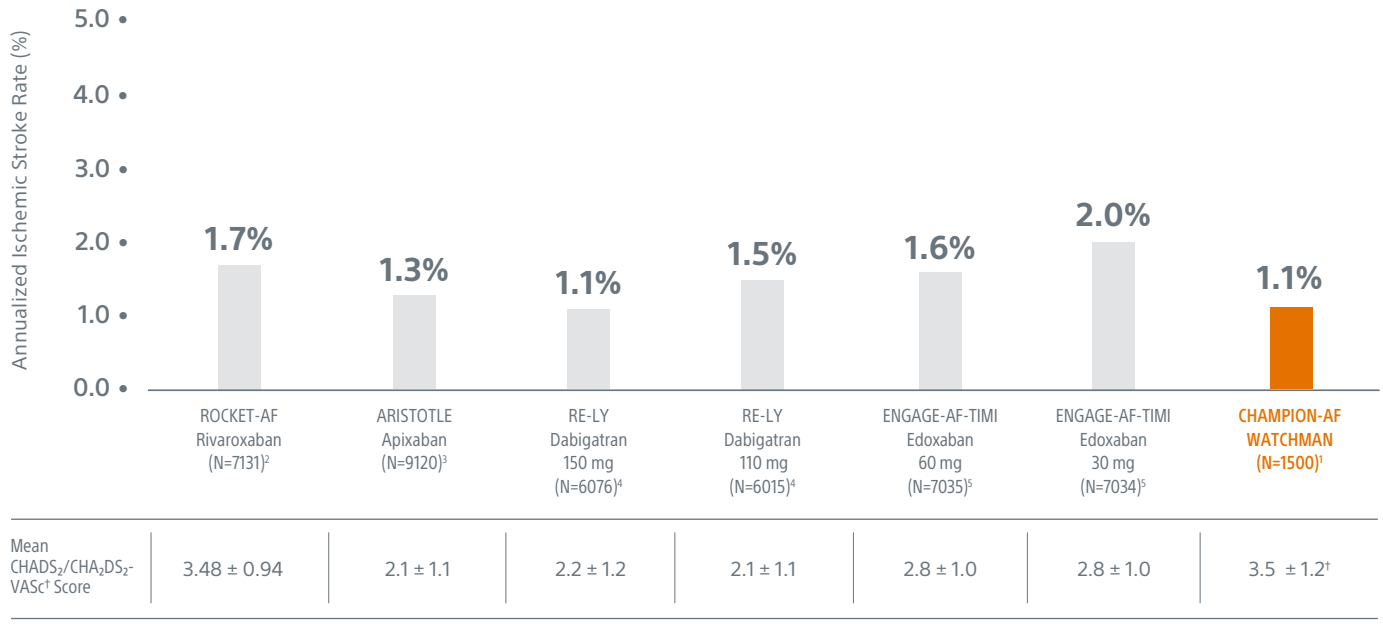

*Study success is defined as meeting both 3-year primary endpoints
† 5-year primary endpoint is non-inferiority for the occurrence of ischemic stroke or systemic embolism

## 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.

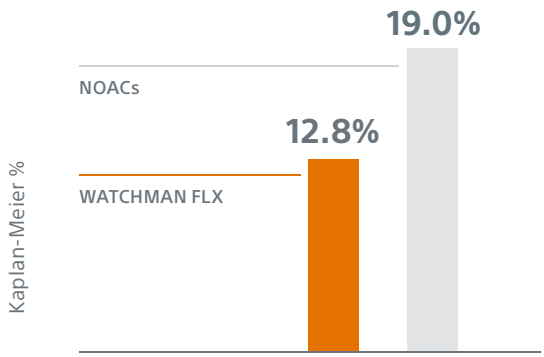



Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.
CHAMPION-AF NOAC arm annualized ischemic stroke/SE rate: 0.7%

† $CHA_2DS_2$-VASc score used in CHAMPION-AF trial only; $CHADS_2$ score used in NOAC trials

## ISTH Bleeding (Including Procedural)

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).




# 34%

The 34% reduction (HR 0.66 [0.54, 0.80]) in ISTH bleeding (including procedural) at 36 months further reaffirms superiority of WATCHMAN FLX for bleeding risk reduction compared to NOACs

## 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% |
| $CHA_2DS_2$-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. Doshi SK, et al. Outcomes in Patients with Atrial Fibrillation Randomized to Receive Left Atrial Appendage Closure or Oral Anticoagulation: Primary Results of the CHAMPION-AF Clinical Trial Late Breaking Clinical Trial, American College of Cardiology Scientific Session & Expo 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.

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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.