







1 What is the CHAMPION-AF clinical trial?

The CHAMPION-AF Trial is designed to determine if LAAC with the WATCHMAN FLX Device is a reasonable alternative first-line therapy comparable to NOACs in non-valvular atrial fibrillation patients indicated for NOAC.

2 | Patient Selection

Qualified Trial Patients Must Meet all the Following Criteria:

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

Key Differences from Commercial WATCHMAN Patient:

- Patient is not required to have a reason to seek a non-pharmacologic alternative to NOAC
- There is no requirement for documented shared decision-making
- Device patients should not be included in the NCDR-LAAO Registry

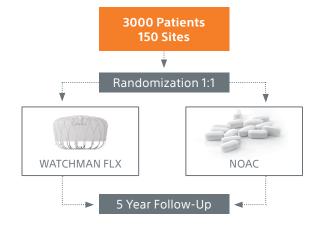
3 | Post-Implant Drug Regimen



*Or other P2Y12 inhibitor

**Discontinue OAC only if 45-day TEE shows leak ≤ 5mm

***Use of NOAC + ASA or DAPT is based on physician discretion

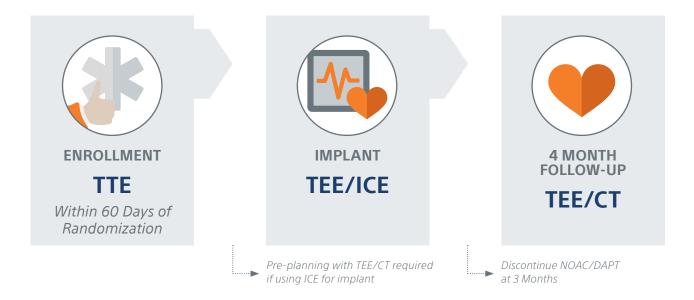








4 | Trial Imaging



The trial includes event-based imaging (both device and control). To search for causes of stroke, embolic event, or DRT, we recommend TEE/CT following the event.

5 Key Study Exclusions

This is not an inclusive list. Please refer to the CHAMPION-AF clinical trial protocol at <u>clinicaltrials.gov</u> for full study inclusion/exclusion criteria.

- Subjects who are currently enrolled in another investigational study
- The subject requires long-term anticoagulation therapy for reasons other than AF-related stroke risk reduction
- The subject is contraindicated or allergic to oral anticoagulation medication and/or aspirin
- The subject is indicated for chronic P2Y12 platelet inhibitor therapy
- The subject had or is planning to have any cardiac or non-cardiac intervention or surgical procedure within 30 days prior to or 60 days after implant
- The subject had a prior stroke (of any cause, whether ischemic or hemorrhagic) or transient ischemic attack (TIA) within the 30 days prior to enrollment
- The subject had a prior major bleeding event per ISTH definition within the 30 days prior to randomization
- The subject has an active bleed

For more information on the CHAMPION-AF clinical trial, visit watchman.com/champion-af

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. Not available for sale.

Full safety information can be found on <u>watchman.com/champion-af</u> ©2021 Boston Scientific Corporation or its affiliates. All rights reserved. SH-964403-AA