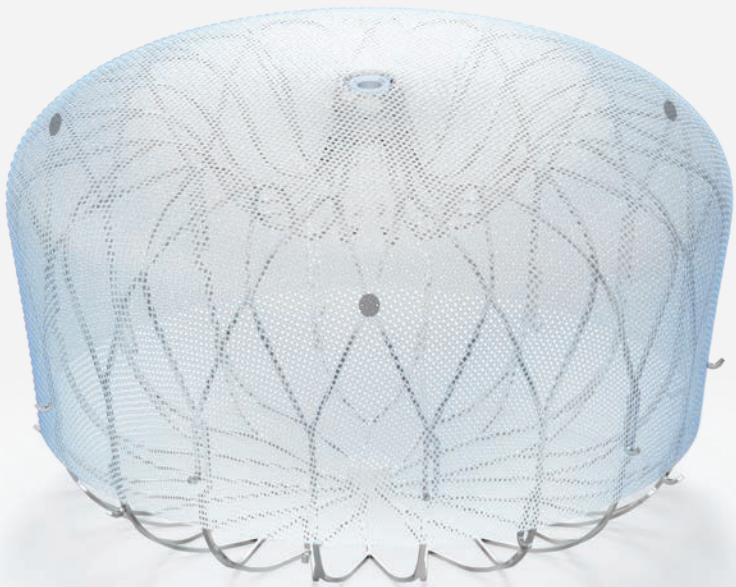
WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE IMPLANT

Boston Scientific
Advancing science for life™



NEW indication and post-implant drug regimen updates

FDA approves

New WATCHMAN FLX Pro labeling

The FDA has approved updates to the WATCHMAN FLX Pro LAAC Implant Instructions for Use (IFU), reflecting findings from the OPTION clinical trial and SURPASS study.

Key Updates:

Post-catheter ablation patients:

- Elimination of the requirement for a rationale to seek a non-pharmacologic alternative to oral anticoagulation therapy*
- Introduction of a 3-month post-implant drug regimen

Standalone WATCHMAN patients:

- 45-day NOAC-alone post-implant drug regimen option, followed by DAPT

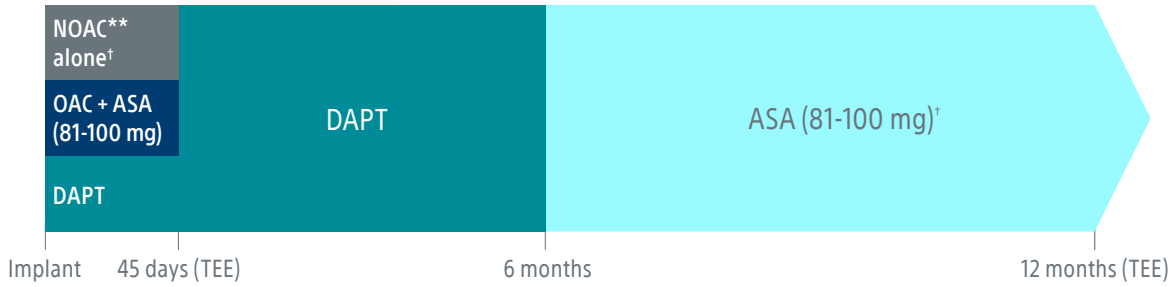
*While the WATCHMAN FLX Pro device label has an updated indication, the CMS National Coverage Determination (NCD) remains unchanged. The patient must be deemed unable to take long-term OAC and meet all criteria in NCD 20.34 to be eligible for coverage.

Post-implant drug regimen options
The Power of Choice.

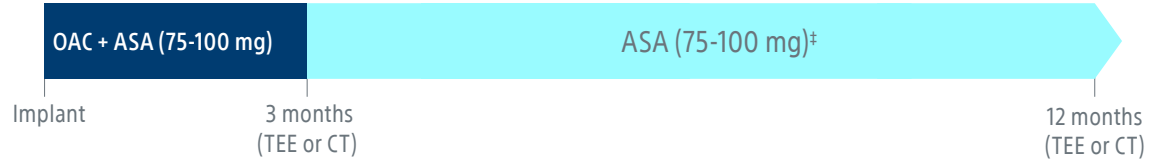
The WATCHMAN™ Implant provides the flexibility to select the ideal drug regimen that is best for individual patients with clinical outcomes that **support safety and efficacy in preventing stroke**. WATCHMAN is a one-time, minimally invasive procedure with an average hospital stay of change to 1.1 day or less.*

*Centers for Medicare and Medicaid Services. Standard Analytics File (SAF); 2022.

Standalone LAAC



Post-catheter ablation with LAAC



** Excludes Warfarin.
† Pre-procedure ASA is per physician discretion if the physician intends to prescribe NOAC alone for the patient post-procedure.
‡ Continued indefinitely.

New U.S. Instructions for Use (IFU)

The WATCHMAN Implant is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

1. Are at increased risk for stroke based on CHA2DS 2-VASc scores and is recommended for anticoagulation therapy.*
2. Are suitable for short-term anticoagulation therapy.†
3. Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy.

*Note: Does not apply to patients who receive the WATCHMAN Implant concomitantly or following an AFib ablation***

Coverage remains unchanged. Under the CMS NCD, the patient must be deemed unable to take long-term OAC and meet all criteria in NCD 20.34 to be eligible for coverage. Commercial payer coverage policy requirements will vary.

*Increased Risk = CHA_2DS_2-VASc ≥ 2 in men, ≥ 3 in women. CMS coverage criteria requires a CHA_2DS_2-VASc score ≥ 3. Providers are encouraged to read the decision memo in its entirety for additional detail Commercial Policies' medical criteria may vary.

†Option for immediate DAPT-only post-implant drug regimen for standalone WATCHMAN procedures.

**In the OPTION trial, sequential LAAC was a minimum of 90 days post AF ablation (as a protocol-driven blanking period).

WATCHMAN FLX Pro
Indications, Safety, and Warnings

www.watchman.com/en-us-hcp/watchman-flx-pro-brief-summary.html