Boston Scientific

Advancing science for life™

Two proven procedures. One patient recovery.

AFib treatment and stroke protection with the **FARAPULSE™ Pulsed Field Ablation Platform** and the **WATCHMAN FLX™ Pro Implant**

AFib presents a growing clinical challenge

Atrial fibrillation (AFib) is an increasingly prevalent condition associated with significant mortality, and a leading cause of stroke. More than 10 million people in the United States are affected by AFib, a number that is projected to reach more than 12 million by 2030.[1]

The longer AFib goes untreated, the more advanced the disease is likely to become, leading to more frequent and severe episodes and increasing risk of stroke and heart failure.[2] AFib management requires treatment strategies that balance heart rhythm and symptom control with stroke risk reduction.

People with AFib experience a lifetime of symptoms

19.5%

mortality risk one-year post-diagnosis, 48.8% mortality risk five years post-diagnosis in Medicare beneficiaries[3]

1 in 3

will have a stroke in their lifetime[4]

2x

recurrent stroke risk post-ischemic stroke in unprotected patients[5]

Earlier intervention is shown to be key in slowing AFib progression and minimizing stroke risk

A systematic review of progression studies found that paroxysmal AFib progresses to persistent AFib in 10-20% of patients after one year, and up to 50-77% of patients after 12 years.[6] However, clinical trials have shown cardiac ablation is effective at slowing AFib progression, demonstrating that less than 3% of patients experienced AFib progression five years post-ablation.[6]

Similarly, clinical trials show that cardiac ablation is more effective than medication in restoring and maintaining a normal rhythm. According to published studies, when compared to drug therapy, cardiac ablation was associated with[7-13]:

Fewer
AFib recurrence

Reduction
in AFib symptoms like palpitations and fatigue

Reduced
need for cardioversion

Lower
mortality rates

While direct-acting oral anticoagulants (DOACs) can reduce stroke risk, long-term use can also cause serious bleeding risks.

People who take DOACs for 10 years may be at

~9x higher

risk of bleeding compared to a single year of DOAC therapy[4]

Note: Assumes constant annual bleeding risk of 2.13% and independence of yearly events.

52%

of AFib patients are on 5 or more medications (polypharmacy)[5]

Polypharmacy increases the risk of major bleeding by

16%[5]

Combined procedure options for comprehensive AFib management

While AFib management typically begins with antiarrhythmic medications (AADs) and oral anticoagulants (OACs), some patients benefit from both rhythm control with an AFib ablation and freedom from OACs with a left atrial appendage closure (LAAC) device.

2 proven procedures. 1 patient recovery.

Performing an AFib ablation with the FARAPULSE Pulsed Field Ablation (PFA) Platform and implanting a WATCHMAN LAAC Device concomitantly — known as the FARAWATCH™ approach — can effectively treat AFib and provide stroke protection in one streamlined case-and-recovery process.

Strong clinical evidence for a streamlined approach to AFib treatment

Clinical trials continue to demonstrate the patient benefits and and overall success with post-ablation LAAC implantation.*

The OPTION Clinical Trial, the first randomized, head-to-head study comparing the WATCHMAN device to OAC (95% DOACs) after cardiac ablation, demonstrated that concomitant LAAC with WATCHMAN FLX™ at the time of ablation resulted in similar procedural risk with the addition of the WATCHMAN FLX procedure following an ablation[14]:

2.1%
Ablation + WATCHMAN FLX
Procedural event rate (within 7 days)

vs

2.7%
Ablation (Only) + OAC
Procedural event rate (within 7 days)

Performing an AFib ablation and implanting a WATCHMAN LAAC Device in a single procedural setting can reduce procedural risks, improve patient outcomes and enhance patient satisfaction.

*The OPTION Clinical Trial studied thermal ablation only.

Two industry-leading solutions

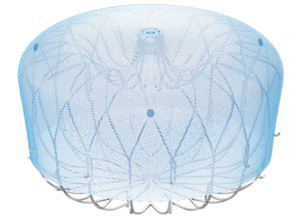
FARAPULSE™ PFA Platform

FARAPULSE PFA Platform is the next generation of cardiac ablation technology. FARAPULSE PFA delivers quick pulses of electrical energy targeting cardiac tissue for irreversible electroporation (IRE), inducing cell death and durable lesions to block signals causing irregular heartbeats. Unlike traditional thermal ablation methods that use extreme heat or cold, FARAPULSE PFA uses a non-thermal approach that minimizes the risk of damage to collateral structures, providing peace of mind for both you and your patients.

- **500,000+** patients treated
- **< 0.63% Real-World Major Adverse Event Rate*[15]**
- **No reports of esophageal fistula, pulmonary vein stenosis, or persistent phrenic nerve injury[15]**
- **15+** BSC-sponsored clinical studies
- **250+** clinical trials and publications

*Due to the retrospective nature of the registry, the adverse event rate was not reported at a pre-specified time-point.

WATCHMAN™ LEFT ATRIAL APPENDAGE CLOSURE IMPLANT



More than 90% of stroke-causing clots that come from the left atrium are formed in the left atrial appendage (LAA). The WATCHMAN Left Atrial Appendage Closure (LAAC) Implant is a one-time, minimally invasive procedure intended to reduce the risk of stroke in patients with non-valvular AFib. WATCHMAN is intended for patients who are at increased risk of stroke and recommended for anticoagulation therapy, deemed by their physicians to be suitable for short-term OACs and have an appropriate rationale to seek a non-pharmacologic alternative to long-term OACs† (due to history of bleeding, risk of bleeding or increased risk of stroke).

- **600,000+** patients treated
- **0.2% major adverse event rate[16]**
- **20+ years clinical experience**
- **Non-inferior efficacy, superior safety to OACs post ablation (95% DOACs)[17]**
- **15+** BSC-sponsored clinical studies
- **1,000+** total clinical studies and publications

†An appropriate rationale to seek a non-pharmacologic alternative to anticoagulants does not apply to patients who recieve the WATCHMAN Implant concomitantly or sequentially with an AF ablation.

FARAWATCH procedure overview

1 Access

Using a standard percutaneous technique, a guidewire and vessel dilator are inserted into the femoral vein. The interatrial setum is crossed using a standard transseptal access system.

2 Ablate

The FARAWAVE™ Pulsed Field Ablation Catheter is guided through a sheath into the left atrium to treat the pulmonary veins and posterior wall, if appropriate The uniquely flexible catheter design adapts to variable patient anatomy, delivering durable lesions across the pulmonary vein antrum and ostium.

3 Implant

For the WATCHMAN Implant, the access sheath is advanced over the guidewire into the left atrium and then navigated into the distal portion of the LAA over a pigtail catheter. The WATCHMAN Implant is deployed and released in the LAA.

4 Heal

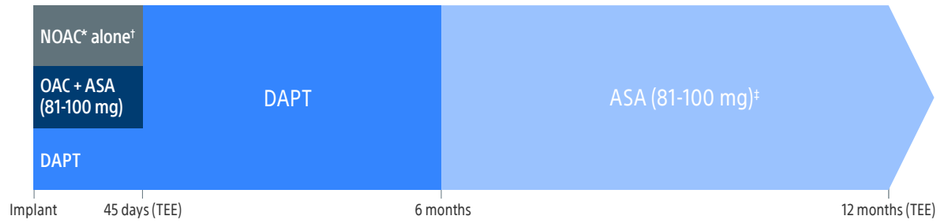
Following the concomitant procedure, most patients experience a brief hospital stay before returning home. Patients will then follow the post-implant drug regimen as prescribed by their physician. Heart tissue grows over the implant and the LAA is permanently sealed.

Your patients deserve options

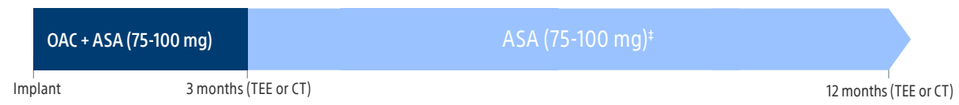
Based on findings from the OPTION Clinical Trial and SURPASS study, physicians have the flexibility to select the ideal post-implant drug regimen for standalone, sequential and concomitant procedures.

Post-implant drug regimen options

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.

2023 ACC/AHA/ACCP/HRS Guidelines for the Diagnosis and Management of Atrial Fibrillation

Catheter Ablation

Catheter ablation is now an established therapy for AFib and continues to advance with new technologies. While earlier guidelines distinguished between persistent and paroxysmal AFib, recent evidence shows catheter ablation is more effective than antiarrhythmic drugs for both.[12] Early rhythm control improves outcomes, and patient-centered goals, such as reducing AF burden and enhancing quality of life.

Left Atrial Appendage Occlusion

Left Atrial Appendage (LAA) Occlusion Devices were upgraded to a 2a Class of Recommendation for patients with a contraindication to long-term OACs. This upgrade in recommended indication is based on additional safety and efficacy data for left atrial appendage occlusion devices, which includes the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Implant.

A 2b Class of Recommendation was added for patients with a high risk of major bleeding.

Scan QR code for the 2023 AFib guidelines.

8.4 AF Catheter Ablation

Recommendations for AF Catheter Ablation
Referenced studies that support the recommendations are summarized in the Online Data Supplement.

COR	LOE	RECOMMENDATIONS
1	A	1. In patients with symptomatic AF in whom antiarrhythmic drugs have been ineffective, contraindicated, not tolerated or not preferred, and continued rhythm control is desired, catheter ablation is useful to improve symptoms.[1-10]
1	A	2. In selected patients (generally younger with few comorbidities) with symptomatic paroxysmal AF in whom rhythm control is desired, catheter ablation is useful as first-line therapy to improve symptoms and reduce progression to persistent AF.[11-16]
1	A	3. In patients with symptomatic or clinically significant AFL, catheter ablation is useful for improving symptoms.[17-19]
2a	B-NR	4. In patients who are undergoing ablation for AF, ablation of additional clinically significant supraventricular arrhythmias can be useful to reduce the likelihood of future arrhythmia.[17,18,20-27]
2a	B-R	5. In patients (other than younger with few comorbidities) with symptomatic paroxysmal or persistent AF who are being managed with a rhythm-control strategy, catheter ablation as first-line therapy can be useful to improve symptoms.[11-13,28]

6.5.1. Percutaneous Approaches to Occlude the LAA

Recommendations for Percutaneous Approaches to Occlude the LAA Referenced studies that support the recommendations are summarized in the Online Data Supplement.

COR	LOE	RECOMMENDATIONS
2a	B-NR	1. In patients with AF, a moderate to high risk of stroke (CHA2DS2-VASc score ‡2), and a contraindication (Table 14) to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAAO (pLAAO) is reasonable.[1-4]
2b	B-N	2. In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive.[1-3,5,6]

REFERENCES

1. Colilla S, Crow A, Petkun W, Singer DE, Simon T, Liu X. Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. *Am J Cardiol.* 2013 Oct 15;112(8):1142-1147. doi: 10.1016/j.amjcard.2013.05.063.
2. FAQ About AFib. American Heart Association, Inc., 2023. Available at: www.heart.org/-/media/Files/Health-Topics/Atrial-Fibrillation/FAQ-About-AFib.pdf. Accessed June 10, 2024.
3. Piccini JP, Hammill BG, Sinner MF, et al. Clinical course of atrial fibrillation in older adults: the importance of cardiovascular events beyond stroke. E*ur Heart J.* 2014;35(4):250-256. doi:10.1093/eurheartj/eht483
4. Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg.* 1996;612:755–759. doi:10.1016/0003-4975(95)00887-X
5. Zheng S, Yao B. Impact of risk factors for recurrence after the first ischemic stroke in adults. *J Clin Neurosci.* 2019;60:24-30. doi:10.1016/j.jocn.2018.10.026
6. Proietti, Riccardo, et al. "A systematic review on the progression of paroxysmal to persistent atrial fibrillation: shedding new light on the effects of catheter ablation." *JACC: Clinical Electrophysiology* 1.3 (2015): 105–115.
7. AlTurki A, Proietti R, Dawas A, Alturki H, Huynh T, Essebag V. Catheter ablation for atrial fibrillation in heart failure with reduced ejection fraction: a systematic review and meta-analysis of randomized controlled trials. *BMC Cardiovasc Disord.* 2019;19(1):18. doi:10.1186/s12872-019-0998-2
8. Asad ZUA, Yousif A, Khan MS, et al. Catheter ablation versus medical therapy for atrial fibrillation: a systematic review and meta-analysis of randomized controlled trials. *Circ Arrhythm Electrophysiol.* 2019;12(9):e007414. doi:10.1161/CIRCEP.119.007414
9. Khan SU, Rahman H, Talluri S, Kaluski E. *Catheter ablation and mortality and morbidity in atrial fibrillation*: a systematic review and meta-analysis. *JACC Clin Electrophysiol.* 2018;4(5):626–635. doi:10.1016/j.jacep.2018.01.012
10. Chen C, Zhang Y, Liang Z, et al. Effect of catheter ablation versus antiarrhythmic drugs on cognitive function in atrial fibrillation patients. J *Interv Card Electrophysiol.* 2018;52(1):9–18. doi:10.1007/s10840-018-0346-6
11. Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Heart Rhythm.* 2017;14(10):e275–e444. doi:10.1016/j.hrthm.2017.05.012
12. Allan KS, Aves T, Henry S, et al. Health-related quality of life in patients with atrial fibrillation treated with catheter ablation or antiarrhythmic drug therapy: a systematic review and meta-analysis. *CJC Open.* 2020;2(4):286–295. doi:10.1016/j.cjco.2020.03.013
13. Packer DL, Mark DB, Robb RA, et al., et al. "Effect of catheter ablation vs antiarrhythmic drug therapy on mortality, stroke, bleeding, and cardiac arrest among patients with atrial fibrillation: the CABANA randomized clinical trial." *JAMA* 2019;321(13):1261-1274. doi:10.1001/jama.2019.0693.
14. Saliba W, et al. Comparison of Left Atrial Appendage Closure and Oral Anticoagulation after Catheter Ablation for Atrial Fibrillation: Concomitant and Sequential Cohorts of the OPTION Randomized Controlled Trial. Late-Breaking Clinical Trial, AF Symposium 2025.
15. Turagam, Mohit K., et al. "Multicenter Study on the Safety of Pulsed Field Ablation in Over 40,000 Patients: MANIFEST-US." *JACC* (2025)
16. Piccini et al. Poster Presentation. HRS 2025. *Defined as the occurrence of all-cause death, ischemic stroke, systemic embolism, or device or procedure-related events requiring open cardiac surgery or major endovascular intervention between device implantation and seven days or hospital discharge (whichever is later). Includes device or procedure-related events requiring open cardiac surgery or major endovascular intervention such as pseudoaneurysm repair, AV fistula repair or other major endovascular repair.
17. Wazni OM, Saliba WI, Nair DG, et al. Left atrial appendage closure after ablation for atrial fibrillation. *N Engl J Med.* DOI: 10.1056/NEJMoa2408308

FARAPULSE PFA System
Indications, Safety and Warnings
qrco.de/bfsrJX

WATCHMAN FLX Pro
Indications, Safety and Warnings
watchman.com/en-us-hcp/watchman-flx-pro-brief-summary.html

Boston Scientific
Advancing science for life™

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
www.bostonscientific.com

Customer Service
United States: 1-888-272-1001
Canada: 1-888-359-9691

SH-2153410-AB