Boston Scientific

Data at Heart Rhythm 2026 highlight key Boston Scientific therapies

Positive data for FARAPULSE™ Pulsed Field Ablation and WATCHMAN™ LAAC Devices underscore therapy safety and effectiveness in late-breaking clinical trial sessions

MARLBOROUGH, Mass. and CHICAGO, April 26, 2026 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced data supporting use of the company's FARAPULSE™ Pulsed Field Ablation (PFA) Platform and WATCHMAN™ Left Atrial Appendage Closure (LAAC) technologies. All data were presented at Heart Rhythm 2026, the annual meeting of the Heart Rhythm Society, held in Chicago from April 24-26.

Results from the AVANT GUARD clinical trial of FARAPULSE™ PFA
The randomized AVANT GUARD clinical trial met all safety and effectiveness endpoints and demonstrated statistical superiority of PFA over anti-arrhythmic drugs (AADs) with significantly higher primary effectiveness. The trial is the first randomized pivotal study to evaluate patients with persistent atrial fibrillation (AF) who had not previously been treated for their condition – a historically understudied, high-risk population. Patients were randomized or assigned to receive pulmonary vein isolation (PVI) and left atrial posterior wall isolation (PWI) using the FARAWAVE™ PFA Catheter or given AADs for treatment. Results were simultaneously published in *The New England Journal of Medicine*.

Key findings from the trial:

- PFA achieved superiority over AADs with a primary effectiveness rate of 56.0% at 12 months compared to 30.1% in the AAD group.
- The primary safety endpoint was met with major adverse event rate of 5.1% at 12 months.
- Significantly more patients in the PFA group (51.7%) were free from atrial arrhythmia recurrence at 12 months, compared to 32.2% in the AAD group.

Results from the feasibility study of the FARAFLEX™ PFA Catheter
The single-arm, ELEVATE-PF feasibility trial is examining the safety and effectiveness of the FARAFLEX PFA Catheter, a novel, high-density large focal map-and-ablate catheter designed to treat complex arrhythmias, in patients with paroxysmal and persistent AF. The trial enables ongoing PFA dosing and workflow refinements based on a study design incorporating prospective high-density remapping, analyzing patients sequentially in three groups – feasibility, improved and optimized.

Key findings from this ongoing trial:

- With workflow improvements, PVI durability – the permanence of an ablation lesion over time – increased from 80.4% on a per-vein basis in the feasibility group (n=13) to 96.4% in the optimized group (n=34).
- Within the optimized group, PVI durability in patients with persistent AF was 95.6% at two months (n=17).
- There were no reports of stroke, pulmonary vein stenosis, hemolysis or coronary spasm.

Clinical outcomes associated with real-world concomitant PFA and LAAC interventions
Prospective, interim, real-world evidence from ALIGN-AF, a multi-center sub-study of the DISRUPT-AF registry, reinforced that concomitant procedures combining the FARAWAVE PFA Catheter and the WATCHMAN FLX™ Pro LAAC Device could be performed safely without compromising acute procedural success. The study, which includes 122 patients at 12 sites with 24 physicians performing the procedures, assessed peri-device leaks between 45 and 90 days following implant and will assess arrhythmia recurrence at six and 12 months.

Key findings from available data at three months:

- Ablation with the FARAWAVE PFA Catheter achieved a 100% (n=122/122) acute success rate. Ablation parameters such as lesion sets and procedure duration were consistent with those observed in standalone PFA procedures.
- LAAC with the WATCHMAN FLX Pro implant also achieved 100% (n=119/119) procedural success and 90.6% (n=96/106) complete LAA closure at a mean of 66 days with no clinically relevant leaks or device-related thrombus reported.

Sub-analysis of the CHAMPION-AF clinical trial in patients with or without prior ablation
A sub-analysis of the CHAMPION-AF trial studied LAAC therapy with the WATCHMAN FLX implant compared to non-vitamin K

antagonist oral anticoagulants (NOACs) in patients with and without prior ablation for non-valvular atrial fibrillation (NVAF). The analysis included 1,434 patients who had a cardiac ablation for AF prior to randomization and 1,565 patients who did not have a previous ablation. The results highlighted that for patients in both arms of the sub-analysis, the device provided statistically significant protection from non-procedural bleeding and had similar efficacy to NOACs.

Key findings from the sub-analysis:

- The WATCHMAN FLX device provided statistically significant protection from non-procedural bleeding, including major and clinically relevant non-major bleeding (CRNMB), compared to NOACs in patients who had a prior ablation (9.0% vs. 17.0%) and in patients with no prior ablation (12.8% vs. 20.8%).
    - CRNMB is defined within the trial as life-impacting non-major bleeds that require medical intervention, hospitalization or an increased level of care.

- The WATCHMAN FLX device had similar efficacy to NOACs for the occurrence of stroke, cardiovascular or unexplained death, or systemic embolism, regardless of whether they had a prior ablation (3.9% for both the device and NOACs in patients with prior ablation; 7.5% for the device group vs. 5.7% for the NOAC group in patients with no prior ablation).

Long-term outcomes after LAAC therapy in patients not eligible for anticoagulation
Five-year follow-up data from the ASAP-TOO trial provided evidence on the legacy WATCHMAN LAAC device (n=284) or the WATCHMAN FLX LAAC device (n=20) compared to a single antiplatelet (SAPT) medication or no medication in reducing the risk of ischemic stroke or systemic embolism in patients with NVAF who were deemed unsuitable for oral anticoagulation (OAC) medication. While the findings contribute new clinical data on LAAC and stroke protection, interpretation is limited as the trial ended early due to slow enrollment driven by physician preference for the device over SAPT/no medication, not safety-related factors, and variability in long-term follow-up.

Key findings from the trial:

- There was a lower rate of occurrence of stroke or systemic embolism with an LAAC device compared to the control group (7.8% vs. 11.4%).
    - LAAC therapy was associated with significantly fewer disabling strokes compared to the control group (1.1% vs. 3.8%).

- The device group had a rate of 1.0% for all-cause death, ischemic stroke, systemic embolism or device- or procedure-related events requiring open cardiac surgery or major endovascular intervention within discharge or seven days.

Results from the investigator-sponsored PRAETORIAN DFT study of the EMBLEM™ MRI Subcutaneous Implantable Defibrillator (S-ICD) were also presented as a late-breaking clinical trial, meeting the primary endpoint. Findings from the trial achieved non-inferiority in the likelihood of failed therapy when omitting defibrillation testing as guided by the PRAETORIAN score – an estimate of successful delivery of life-saving therapy – in patients receiving the device for the first time.[1]

"The data presented at Heart Rhythm 2026 reflect the continued momentum of our cardiovascular portfolio and underscores our commitment to advancing innovation through comprehensive clinical evidence across the spectrum of cardiac care," said Kenneth Stein, M.D., senior vice president and global chief medical officer, Boston Scientific. "These findings support the potential expansion of our FARAPULSE PFA Platform into more complex patient populations, highlight the value of a combined therapeutic approach with our WATCHMAN FLX Pro LAAC Device, may enhance the implant experience with the EMBLEM MRI S-ICD and position us to deliver a broader portfolio of differentiated solutions for physicians treating patients with cardiovascular diseases."

About Boston Scientific
Boston Scientific transforms lives through innovative medical technologies that improve the health of patients around the world. As a global medical technology leader for more than 45 years, we advance science for life by providing a broad range of high-performance solutions that address unmet patient needs and reduce the cost of healthcare. Our portfolio of devices and therapies helps physicians diagnose and treat complex cardiovascular, respiratory, digestive, oncological, neurological and urological diseases and conditions. Learn more at **www.bostonscientific.com** and follow us on **LinkedIn**.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans and product performance and impact, and clinical trials. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied

by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: economic conditions, including the impact of foreign currency fluctuations; future U.S. and global political, competitive, reimbursement and regulatory conditions, including changing trade and tariff policies; geopolitical events, conflicts and tensions; manufacturing, distribution and supply chain disruptions and cost increases; disruptions caused by cybersecurity events; disruptions caused by public health emergencies or extreme weather or other climate change-related events; labor shortages and increases in labor costs; variations in outcomes of ongoing and future clinical trials and market studies; new product introductions; expected procedural volumes; the closing and integration of acquisitions; demographic trends; intellectual property; litigation; financial market conditions; the execution and effect of our business strategy, including our cost-savings and growth initiatives; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements, except as required by law. This cautionary statement is applicable to all forward-looking statements contained in this document.

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[1] The manufacturer recommended VF conversion testing during EMBLEM S-ICD implant, replacement, and concomitant device implants is being evaluated based on the PRAETORIAN DFT trial results and additional available data.
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https://news.bostonscientific.com/2026-04-26-Data-at-Heart-Rhythm-2026-highlight-key-Boston-Scientific-therapies