

FARAPULSETM

Pulsed Field Ablation System



The global leader in PFA clinical research



FARAPULSETM

Pulsed Field Ablation System

Clinical leadership

FARAPULSE™ Pulsed Field Ablation System has been extensively researched and is supported by more published clinical evidence than any other PFA system.



MOST ROBUST clinical trial portfolio

SELECTED STUDIES

COMPLETED

IMPULSE/PEFCAT I - II

Safety and Feasibility Study

PersAFOne I

Safety and Feasibility Study in Persistent AF

ADVENT

Randomized Trial vs. RFA and CBA

FARA-FREEDOM

Single-Arm Post-Market Trial (EU)

EU-PORIA

Multicenter Registry (n = 1,233)

MANIFEST-PF

Multicenter Registry (n = 1,568)

MANIFEST-17K

Multicenter Registry (n = 17,642)

INITIATED/PLANNED

ADVANTAGE I - II

PVI and PWA in Persistent AF with FARAPOINT™ for CTI

PersAFOne II - III

Includes FARAPOINT focal PFA for CTI

FARADISE

Prospective Registry (n = 1,000+)

AVANT GUARD

First-line PFA vs. AAD in Persistent AF with ILR

DISRUPT-AF

Registry and Randomized Workflow Study

NAVIGATE PF

FARAVIEW™ Nav-enabled Mapping Integration

OPTION-A

Concomitant WATCHMAN™ and FARAPULSE

REMATCH Trial

Redo AF with FARAWAVE™ and FARAPOINT



120+ clinical publications and counting.

Scan the code to view all the latest FARAPULSE research and findings.

Demonstrated safety

FARAPULSE enables effective ablation while eliminating risks associated with thermal procedures.



No reported thermal complications¹

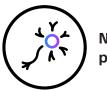
In MANIFEST-17K, the largest PFA registry study conducted to date (106 centers, 413 operators, 17,642 pts), patients treated with FARAPULSE reported zero thermal complications across all procedures.



No esophageal fistula



No pulmonary vein stenosis



No persistent phrenic nerve injury

0.98% major adverse event rate

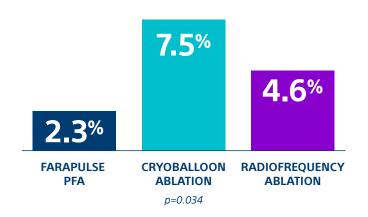
Major adverse event rate <1%¹

In the same registry, FARAPULSE demonstrated a low adverse event rate—less than one percent of all patients (173 of 17,642 pts).

Della Rocca et al., 2023

Lower minor adverse event rate vs. thermal²

In a propensity score-matched study between PFA, cryoballoon ablation (CBA) and radiofrequency ablation (RFA), FARAPULSE had a significantly lower minor complication rate.



Authors attributed the performance in large part to the ability of PFA to

SELECTIVELY TARGET MYOCARDIAL CELLS

while sparing surrounding tissue

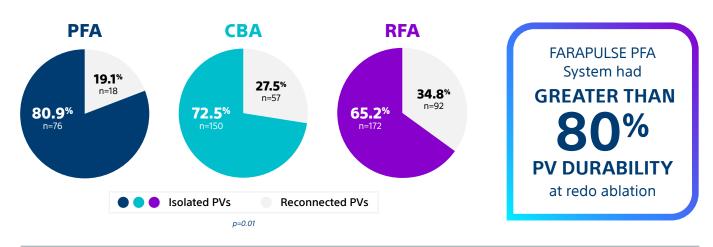
Proven PVI durability

FARAPULSE™ Pulsed Field Ablation System offers a proven dosing strategy that delivers lasting pulmonary vein (PV) isolation.

Della Rocca et al., 2023

Higher PV durability vs. thermal²

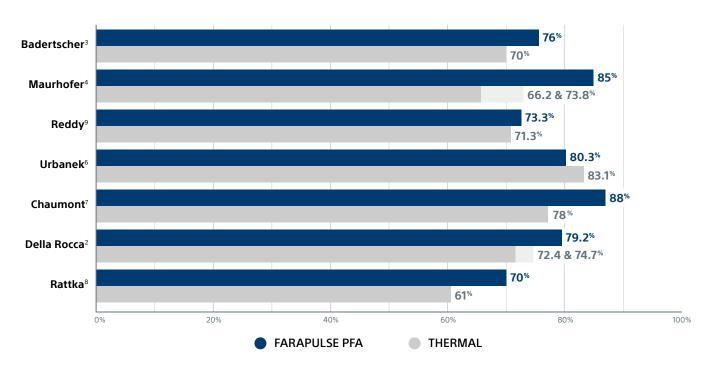
Propensity-matched analysis demonstrated that the rate of PV reconnection at repeat procedures was significantly lower among patients receiving PFA at index procedure.



Multiple studies

Freedom from recurrence vs. thermal

Across multiple studies, FARAPULSE patients have trended towards a lower rate of arrhythmia recurrence at 12 months compared to thermal ablation.



Significantly reduced atrial arrhythmia (AA) burden vs. thermal 9,10



Quality of Life

Significantly greater QoL improvement in patients with AA Burden <0.1% vs. ≥10%



Healthcare Utilization

Significantly lower risk for redo ablation, cardioversion and hospitalization with AA Burden <0.1% vs. ≥0.1%



Ablation Modality

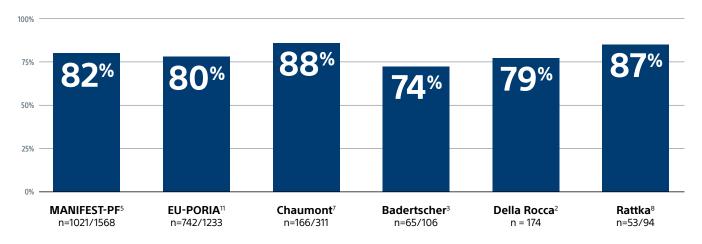
FARAPULSE patients significantly more likely to have AA Burden <0.1% vs. RFA or CBA

Multiple studies

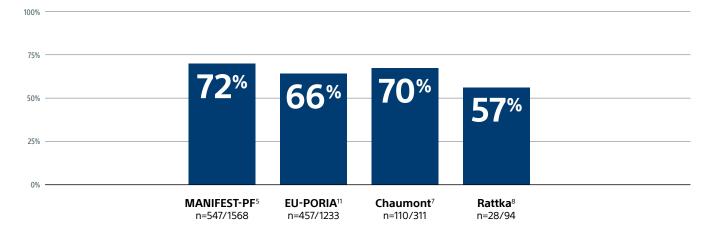
High real-world freedom from recurrence (1 year)

FARAPULSE has demonstrated a high one-year freedom from recurrence rate, consistent across numerous clinical settings and trial sizes.

PAROXYSMAL AF



PERSISTENT AF



Predictable procedures

FARAPULSE™ Pulsed Field Ablation System delivers a consistent, predictable operator experience—for any workflow.

Reddy et al., 2023

Optimized for consistency

FARAPULSE PFA System excels at achieving optimal placement, regardless of pulmonary vein anatomy. This maneuverability translates to limited LA dwell time, with FARAPULSE requiring 42% less time to perform PVI compared with thermal.⁹

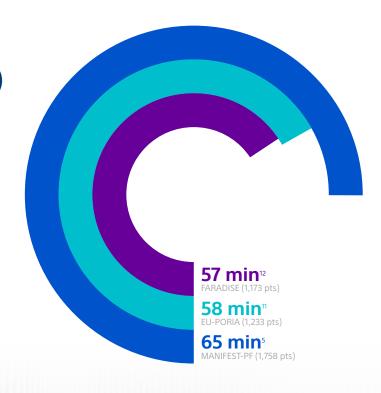
	PFA	Thermal
Ablation time	29.2 ± 14.3	50.0 ± 24.6
LA dwell time	59.4 ± 18.3	83.7 ± 30.3
Procedure time	105.8 ± 29.4	123.1 ± 42.1
Fluoro. time	21.1 ± 11.0	13.9 ± 12.8

Procedure time and LA dwell time include the mandated 20-minute wait period, per study protocol

Multiple studies

Real-world procedure times (large registries)

Across multiple large-registries (>1,000 pts), FARAPULSE's procedure times remained consistent—allowing for more predictable, efficient workflows.



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- 6. Urbanek L, Bordignon S, Schaack D, et al. Pulsed field versus cryoballoon pulmonary vein isolation for atrial fibrillation: Efficacy, safety, and long-term follow-up in a 400-patient cohort. Circulation: Arrhythmia and Electrophysiology 16.7 (2023): 389-398.

- Chaumont C, McDonnell E, Boveda S, et al. Prospective 1-year results of atrial fibrillation ablation using the pentaspline pulsed field ablation catheter: The initial French experience. Arch Cardiovasc Dis. Mar 5 2024;doi:10.1016/j.acvd.2024.01.005.
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- **10.** Reddy VY, Mansour M, Calkins H, et al. Pulsed Field vs Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation: Recurrent Atrial Arrhythmia Burden. *J Am Coll Cardiol*. Published online May 6, 2024. doi:10.1016/j.jacc.2024.05.001.
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- 12. Boresma, et al., Real World Data Collection in Subjects Treated with the FARAPULSE Pulsed Field Ablation System (FARADISE). HRS 2024.

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