

# **FARAPULSE**<sup>TM</sup>

**Pulsed Field Ablation System** 



# The global leader in PFA clinical research



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# 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 complications<sup>1</sup>

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.







0.98% major adverse event rate

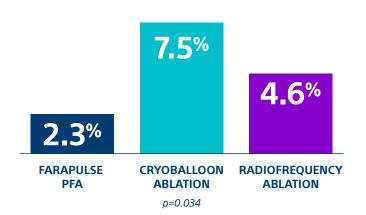
# Major adverse event rate <1%<sup>1</sup>

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. thermal<sup>2</sup>

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

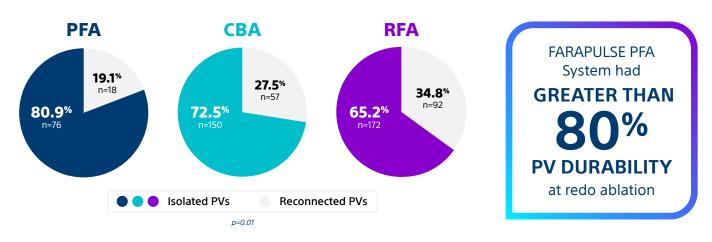
# Proven PVI durability

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. thermal<sup>2</sup>

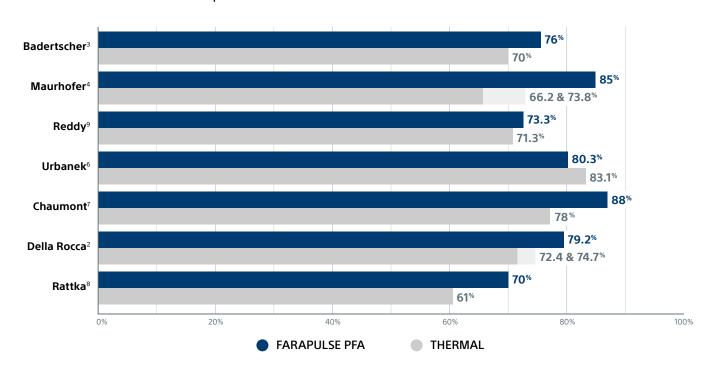
Propensity-matched analysis demonstrated that the rate of PV reconnection at repeat procedures was significantly lower among patients receiving PFA at index procedure.



# **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**

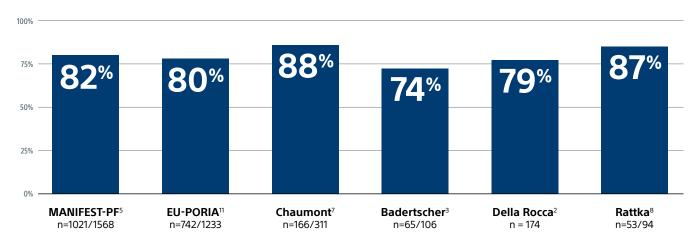
FARAPULSE patients significantly more likely to have AA Burden <0.1% vs. RFA or CBA

# **Multiple studies**

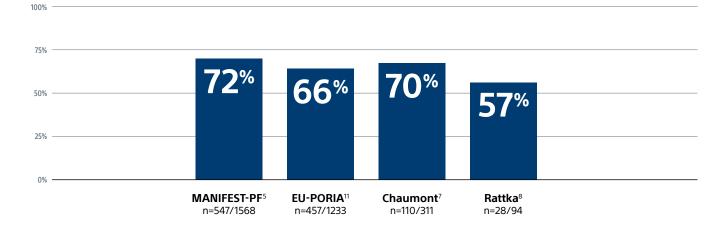
# High real-world freedom from recurrence (1 year)

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.<sup>9</sup>

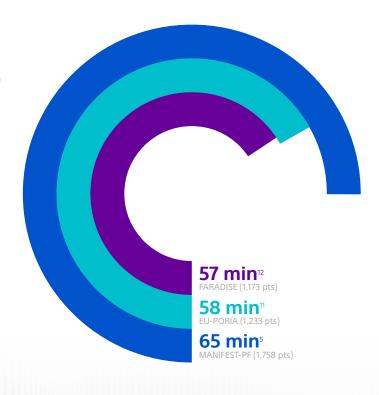
	PFA	Thermal
Ablation time	29.2 ± 14.3	50.0 ± 24.6
LA dwell time	<b>59.4</b> ± 18.3	83.7 ± 30.3
Procedure time	105.8 ± 29.4	123.1 ± 42.1
Fluoro. time	21.1 ± 11.0	13.9 ± 12.8

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.





# FARAPULSE™ Pulsed Field Ablation System Indications, Safety, and Warnings

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- **3.** Badertscher P, Weidlich S, Knecht S, et al. Efficacy and safety of pulmonary vein isolation with pulsed field ablation vs. novel cryoballoon ablation system for atrial fibrillation. *Europace* 25.12 (2023): euad329.
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- 7. 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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## Cardiology 300 Boston Scientific Way Marlborough, MA 01752-1234 bostonscientific.com

Medical Professionals: 1.800.CARDIAC (227.3422) Customer Service: 1.888.272.1001

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