

ELEVATE-PF

Clinical Study



First-In-Human Trial of a Novel Large Focal High-Density Map-And-Ablate PFA Catheter

STUDY OBJECTIVE

Single-arm evaluation of safety and efficacy of a novel large focal high-density pulsed-field ablation catheter in paroxysmal AF (PAF) and persistent AF (PersAF) patients.

STUDY DESIGN

- ▶ Study is ongoing; to date, 109 patients have been enrolled (77.1% PersAF and 22.9% PAF). Lesion sets include PVI, PWI, CTI, MI and left atrial roof.
- ▶ The trial was designed to allow for optimization of PFA dosing and workflow across multiple cohorts.
- ▶ Lesion durability was assessed at 2-months by mandated remapping. 1-year follow-up is ongoing.

RESULTS

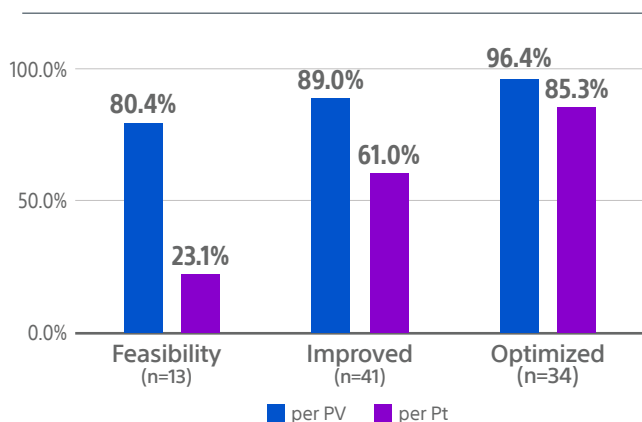
With workflow improvements,
the optimized cohort had:

96.4%
per PV durability

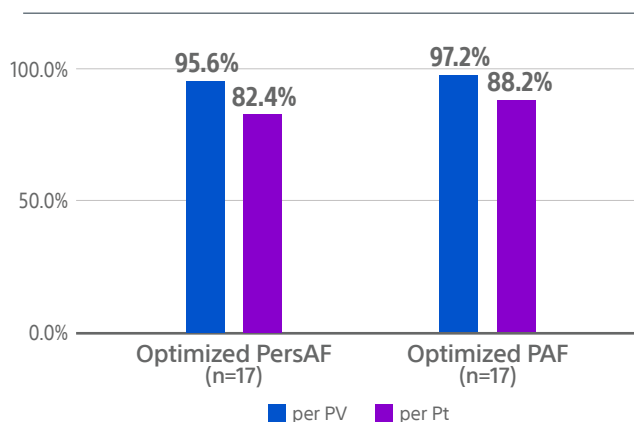
85.3%
per patient durability

There was little
difference in lesion
durability between the
optimized PersAF and
PAF cohorts.

Lesion Durability at 2-Months
Comparison Across 3 Cohorts



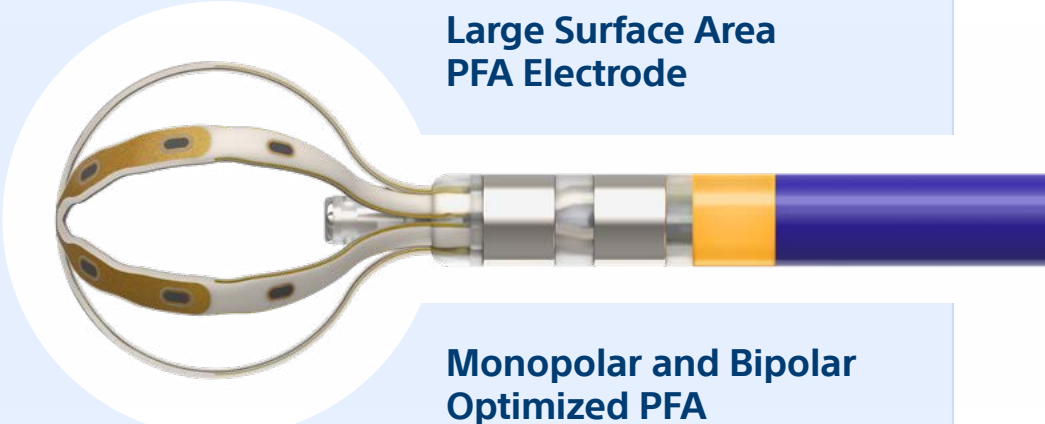
Lesion Durability at 2-Months
Optimized Comparison Across Patient Type



FARAFLEX™ Mapping and Pulsed Field Ablation Catheter

Novel large focal high-density map-and-ablate PFA catheter

Caution: FARAFLEX™ Mapping and Pulsed Field Ablation Catheter is not available for sale.



19 High Fidelity Electrodes
Including 1 Tip Electrode

Rapid Mapping

Precise Pacing

Large Surface Area PFA Electrode

Monopolar and Bipolar Optimized PFA

9mm Basket With Drip Irrigation



Integrated with OPAL HDx™



[FARAPULSE™ Pulsed Field Ablation System
Indications, Safety, and Warnings](https://www.bostonscientific.com/en-US/products/catheters--ablation/farapulse/farapulse-indications.html)

<https://www.bostonscientific.com/en-US/products/catheters--ablation/farapulse/farapulse-indications.html>

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