

# 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

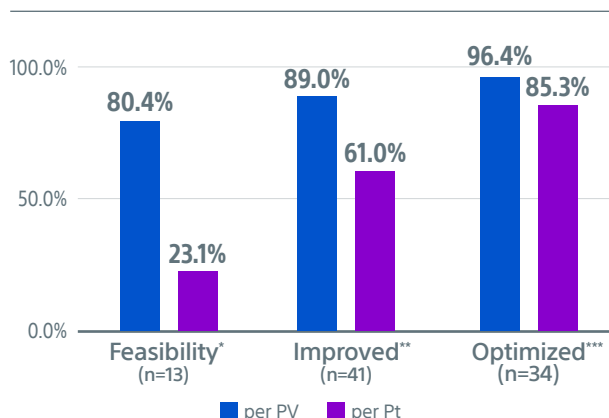
With workflow improvements,  
the optimized cohort had:

**96.4%**  
per PV durability

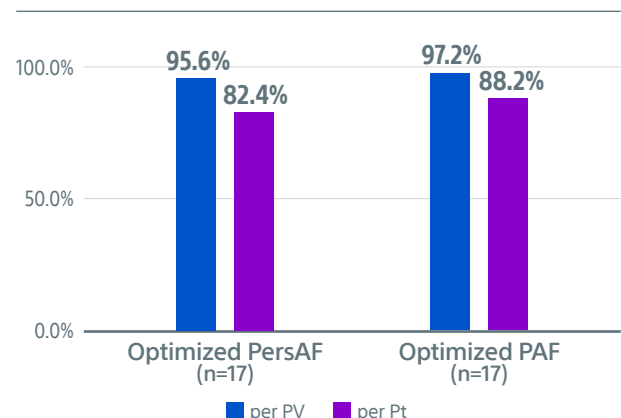
**85.3%**  
per patient durability

Lesion durability  
between the  
optimized PersAF  
and PAF cohorts  
was similar.

**Lesion Durability at 2-Months**  
Comparison Across 3 Cohorts



**Lesion Durability at 2-Months**  
Optimized Comparison Across Patient Type

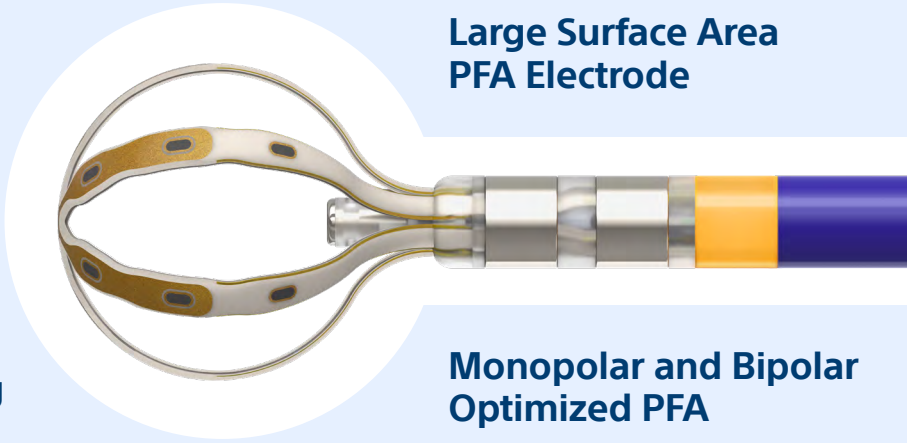


\* Feasibility: 2 application overlap, varied procedural characteristics under study.  
 \*\* Improved: Majority of pts with 3 applications overlap, focused on procedural and workflow improvements.  
 \*\*\* Optimized IDE workflow: 2 applications overlap with reinforcement at operator discretion, "optimized" efficient workflow with high durability.

# 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

**Large Surface Area PFA Electrode**

**Rapid Mapping**

**Precise Pacing**

**Monopolar and Bipolar Optimized PFA**

**9mm Basket With Drip Irrigation**



**Integrated with OPAL HDx™**

**Boston Scientific**  
Advancing science for life™

[www.bostonscientific.eu](http://www.bostonscientific.eu)

© 2026 Boston Scientific Corporation or its affiliates. All rights reserved.

EP-2491404-AA

OPAL HDx CE 2797  
FARAFLEX – Pending CE mark

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at [www.IFU-BSCI.com](http://www.IFU-BSCI.com). Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.