ADVANTAGE AF US IDE Clinical Trial Results (Phase I)

Primary Endpoints Met

Boston Scientific
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ADVANTAGE met the safety and effectiveness endpoints for treating patients with persistent atrial fibrillation (PersAF) with the FARAPULSE™ Pulsed Field Ablation System.

CAUTION: Investigational Device. Limited by Federal (or US) law to investigational use only. Ablation of patients with persistent atrial fibrillation or ablation beyond pulmonary vein isolation are outside the labeled indication(s) for use of the FARAWAVE PFA Catheter with the FARAPULSE PFA System.

2.3%
Primary Safety Event Rate
at 12 months

63.5%
Primary Effectiveness Event Rate
at 12 months

SAFETY: A composite endpoint defined as serious adverse events related to either the use of an ablation catheter or the ablation procedure with onset within 7 days of the primary procedure and pulmonary vein stenosis or atrio-esophageal fistula out to 12 months.

EFFECTIVENESS: A composite endpoint defined as acute and chronic ablation success through 12 months. After the 90-day blanking period, chronic success was defined as freedom from AF, AFL or AT, re-ablation, cardioversion and use of a new or escalated dose of Class I/III AADs or Amiodarone.

ABLATION INFORMATION AVERAGES

PVI
27 minutes
45 applications

PWA
18 minutes
32 applications

43
US/OUS Sites

87
Investigators
(67% no FARAPULSE experience)

260
PersAF Patients

LESION SETS

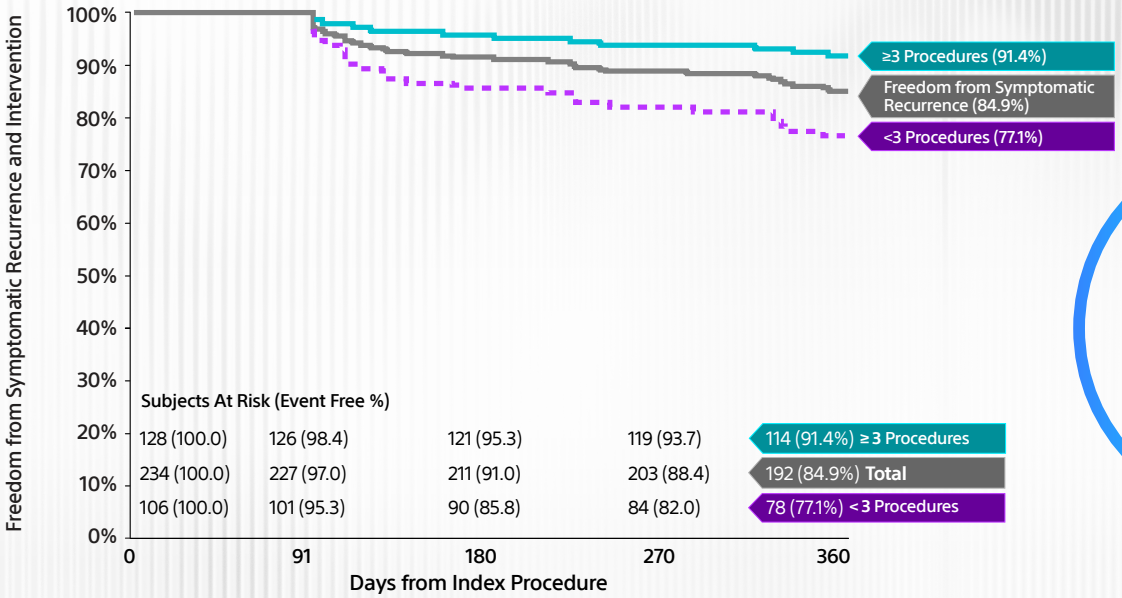
- Pulmonary vein isolation (PVI)
- Posterior wall ablation (PWA)
- CTI (RFA) when indicated

4.6%
LA Re-Ablation Rate
at 12 months

84.4%
PV Durability at Redo
(68.8% of patients)

68.8%
PW Durability at Redo

Freedom from Symptomatic Recurrence Stratified by Operator Experience at Time of Procedure



91.4%
Freedom from symptomatic recurrence when physicians performed
3 or more
FARAPULSE procedures

- No reports of stroke, PV stenosis, esophageal fistula or major vascular access complications
- 64.5% of patients had an estimated AA burden below 0.1%

Reddy, V., Gerstenfeld, E., Schmidt, B., et al., Pulsed Field Ablation for Persistent Atrial Fibrillation: 1-Year Results of ADVANTAGE AF. *JACC*. 2025 May, 85 (17) 1664–1678. https://doi.org/10.1016/j.jacc.2025.03.515