

ADVENT

PIVOTAL TRIAL

CLINICAL DATA SUMMARY



FARAPULSE™
Pulsed Field Ablation System



OBJECTIVE

- ▶ The ADVENT Pivotal Trial is the first randomised clinical trial that directly compares FARAPULSE™ PFA to standard-of-care thermal ablation devices (force-sensing radiofrequency (RFA) or cryoballoon ablation (CBA)), for the treatment of paroxysmal atrial fibrillation (PAF).

ADVENT TRIAL DESIGN¹

- ▶ Multicenter, prospective, non-inferiority randomised controlled trial ([NCT04612244](#)).
- ▶ Study sample size was 706 patients (80 Roll-ins, 626 Randomised). The primary results included the **607 patient modified Intent-to-Treat (mITT) cohort** across 30 centers and 65 operators.
 - Modified Intent-to-Treat (mITT) patients are ITT patients who received any energy delivery for pulmonary vein isolation (PVI) with the randomised endocardial ablation catheter at an Index/Rescheduled Index Procedure.
- ▶ *Primary Safety Endpoint*: A composite endpoint defined as serious adverse event related to either the use of an ablation catheter or the ablation procedure with onset within 7 days of the primary procedure and PV stenosis and atrio-esophageal fistula out to 12 months.
- ▶ *Secondary Safety Endpoint*: Aggregate pulmonary vein (PV) cross-sectional area changes from baseline to day 90.
- ▶ *Primary Effectiveness Endpoint*: Both acute and chronic procedural success through 12 months which included freedom from re-ablation or use of amiodarone. After the 90-day blanking period, chronic success required freedom from AF, AFL, AT, cardioversion and no Class I/III AAD use.

SAFETY^{2,3}

- ▶ **Primary Safety Endpoint**
 - The ADVENT study met the criterion for **non-inferiority** of PFA to thermal ablation (posterior probability >0.999).
 - The primary composite safety endpoint of serious adverse events occurred in 6 FARAPULSE versus 4 thermal ablation patients (estimated incidence, 2.1% versus 1.5% (posterior means)).
- ▶ **Secondary and Additional Safety Analysis**
 - The secondary endpoint of the ADVENT trial met the criterion for **superiority** of PFA compared to thermal ablation (posterior probability >0.999).



ADVENT met the primary safety endpoint for non-inferiority* vs thermal ablation

2.1% for PFA vs 1.5% for thermal ablation



ADVENT met the secondary safety endpoint for superiority* for less PV cross-sectional area narrowing

0.9% for PFA vs 12% for thermal ablation

* Posterior probability > .999

EFFICACY

- ▶ **Primary Efficacy Endpoint**
 - The Bayesian estimated 12-month, single-procedure, off-drug treatment success probabilities were 73.3% for FARAPULSE and 71.3% for thermal ablation meeting the criterion for **non-inferiority** (posterior probability >0.999).
- ▶ **Additional Efficacy Endpoints**
 - ▶ *12-Month Kaplan Meier Estimate*
 - The 12-month Kaplan Meier single-procedure, off-drug estimates were 73.1% for FARAPULSE, 71.3% for thermal ablation, and more specifically 73.6% for CBA and 69.2% for RFA.
 - ▶ *Effectiveness allowing Class I/III AADs*
 - The ADVENT primary efficacy endpoint did not allow Class I/III AAD use post-90 day blanking period. The Bayesian estimated single-procedure success probabilities when Class I/III AAD use was allowed were 78.5% for FARAPULSE and 76.3% for thermal ablation.



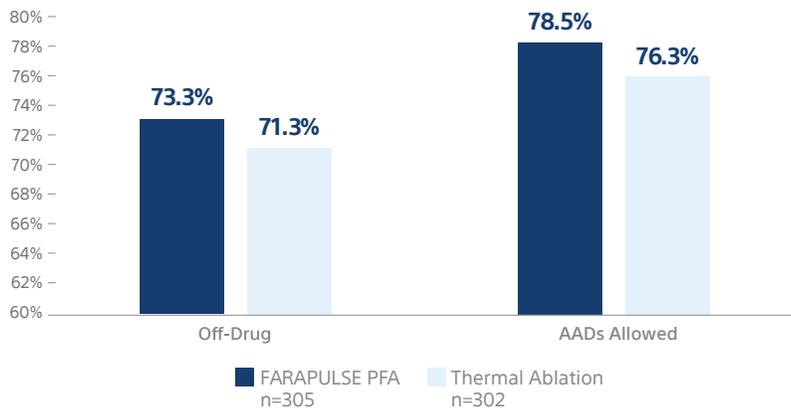
EFFICACY (cont.)

▶ Acute PVI, Re-Ablation and PV Durability

- The acute PV isolation rate was 99.6% (1208/1213 PVs) for FARAPULSE and 99.8% (1182/1184 PVs) for thermal ablation.
- Repeat ablations were performed in 4.6% of FARAPULSE patients and 6.6% in thermal ablation patients. The PVI durability in re-ablated patients was 64.8% per vein (28.6% per patient) for FARAPULSE and 64.9% per vein (26.3% per patient) for thermal ablation.

12-Month Effectiveness Outcomes (%)

Bayesian Estimates



✓ **ADVENT met the primary efficacy endpoint for non-inferiority* vs thermal ablation**

73.3% for PFA vs
71.3% for thermal ablation

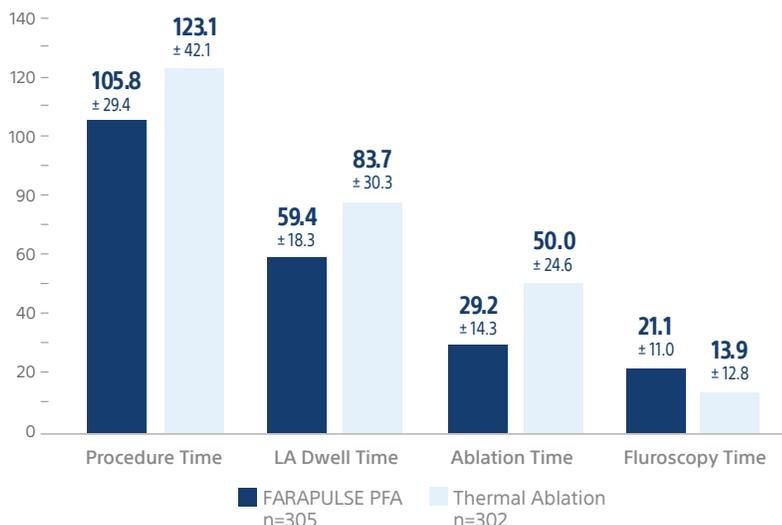
* Posterior probability > .999

PROCEDURAL CHARACTERISTICS

- ▶ The FARAPULSE AF ablation procedure time (105.8 ± 29.4 min) and catheter LA dwell time (59.4 ± 18.3 min) were significantly shorter than thermal ablation (123.1 ± 42.1 min and 83.7 ± 30.3 min, respectively). Both included a protocol mandated 20-min waiting period. *(Bayesian credible interval (BCI) does not contain zero)
- ▶ The time from first ablation to last ablation was significantly shorter with FARAWAVE™ PFA Catheter (29.2 ± 14.3 min) versus thermal ablation (50.0 ± 24.6 min).
- ▶ Pulsed field ablation required a longer duration of fluoroscopy versus thermal ablation, as expected with operators who are new to the PFA system.

Procedural Characteristics

Procedure and LA Dwell times include a 20 minute protocol-mandated waiting period



✓ **FARAPULSE PFA procedure times were significantly* shorter with less variability than thermal ablation.**

105.8 ± 29.4 min for PFA vs
123.1 ± 42.1 min for thermal ablation

* BCI does not contain zero



CONCLUSIONS

The ADVENT RCT included an experienced group of thermal ablators with limited clinical experience with the novel FARAPULSE technology. In this RCT, FARAPULSE demonstrated:

- ▶ Non-inferiority for both the primary safety and effectiveness outcomes compared to thermal ablation technology.*
- ▶ Significantly less pulmonary vein cross-sectional narrowing compared to thermal ablation.*
- ▶ Significantly shorter procedure times, reduced LA dwell time and total ablation time versus thermal ablation. Lower standard deviations across these characteristics also indicate less variability within the PFA procedures.

* Posterior probability > .999

1. Reddy, Vivek Y., et al. "A randomized controlled trial of pulsed field ablation versus standard-of-care ablation for paroxysmal atrial fibrillation: The ADVENT trial rationale and design." *Heart Rhythm* O2 4.5 (2023): 317-328.
2. Reddy et al. Pulsed Field Ablation or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation. Presented at: ESC 2023; August 27, 2023, Amsterdam, NL.
3. Reddy, et al., Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation. *New England Journal of Medicine* (2023).

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. 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.

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