Boston Scientific
Advancing science for life™

# FARAPULSE™
## Pulsed Field Ablation System

# ADVENT
## Pivotal Trial
## Clinical Data Summary

# ADVENT Clinical Trial Results –
## PFA against standard-of-care thermal ablation therapies

### 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 DESIGN[1]

- Multicentre, 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 centres and 65 operators.
  - 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 seven 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-abalation 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 six FARAPULSE versus four 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 >0.999

### EFFICACY

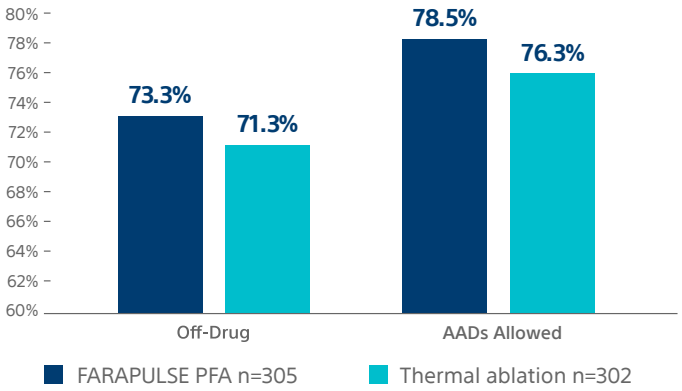
- **Primary efficacy endpoint**
  - The Bayesian estimated 12-month, single-procedure, off-drug treatment success probabilities were 73.3% for FARAPULSE and 71.3% for thermal ablation meeting the criterion for non-inferiority (posterior probability >0.999).
- **Additional efficacy endpoints**
  - **12-month 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.

# ADVENT Clinical Trial Results –
## PFA against standard-of-care thermal ablation therapies

### 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**

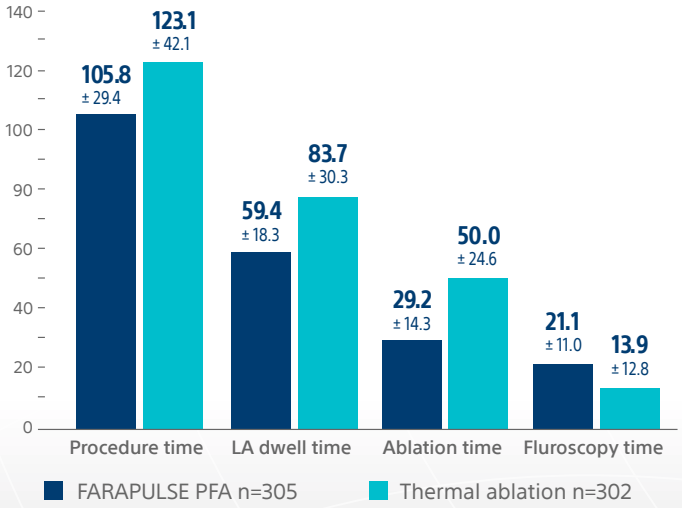
73.3% for PFA vs
71.3% for thermal ablation

*Posterior probability >0.999

### 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.

**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

# ADVENT Clinical Trial Results –
## PFA against standard-of-care thermal ablation therapies

### 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 >0.999


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). *In press.*


Boston Scientific
Advancing science for life™




Produced by Gosling.

CE 0459

**www.bostonscientific.eu**





EP-1679804-AA.