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SINGLE SHOT CHAMPION

CLINICAL DATA SUMMARY

FARAPULSE™
Pulsed Field Ablation System

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SINGLE SHOT CHAMPION Clinical Trial Results

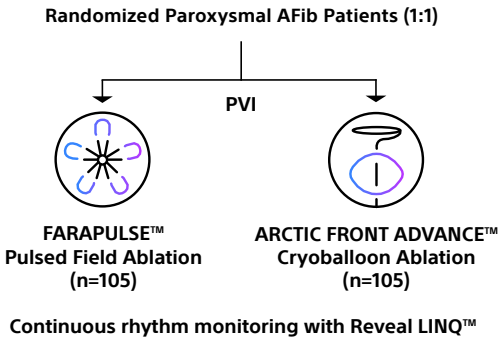
Reichlin, T et. al, 2025
Single Shot Pulmonary Vein Isolation: Comparison of Cryoballoon vs Pulsed Field Ablation in Patients with Symptomatic Paroxysmal Atrial Fibrillation – A Multi-Center Non-Inferiority Design Clinical Trial (The SINGLE SHOT CHAMPION Trial)
NCT05534581

OBJECTIVE

The Single Shot Champion trial was a randomized clinical trial that directly compared the safety and effectiveness of the FARAPULSE™ Pulsed Field Ablation System (PFA) versus Medtronic Arctic Front Advance™ Cryoballoon (CBA) to treat symptomatic, drug refractory paroxysmal atrial fibrillation (PAF) with continuous rhythm monitoring.

SINGLE SHOT CHAMPION TRIAL DESIGN

- Investigator-initiated, multi-center, patient-blinded non-inferiority trial with blinded endpoint adjudication.
- 210 patients with symptomatic, drug refractory PAF were randomized 1:1 and underwent PVI with either PFA or CBA. Non-inferiority was assessed using a margin of 20% for the difference in cumulative incidence.
- Ablation effectiveness was assessed with continuous rhythm monitoring (Medtronic Reveal LINQ™).
- No repeat ablations were allowed during the 3-month blanking period and AADs were discontinued after the blanking period.



SAFETY

The primary safety endpoint was a composite of cardiac tamponade requiring pericardiocentesis, persistent phrenic nerve palsy lasting >24 hours, serious vascular complications requiring intervention, stroke/transient ischemic attack, atria-esophageal fistula, or death within 30 days after ablation.

- The primary safety endpoint occurred in 1 (1.0%) FARAPULSE patient (ischemic stroke/TIA) and in 2 (1.9%) Arctic Front patients (cardiac tamponade requiring drainage).

THE OVERALL MAJOR ADVERSE EVENT RATES WERE **LOW**

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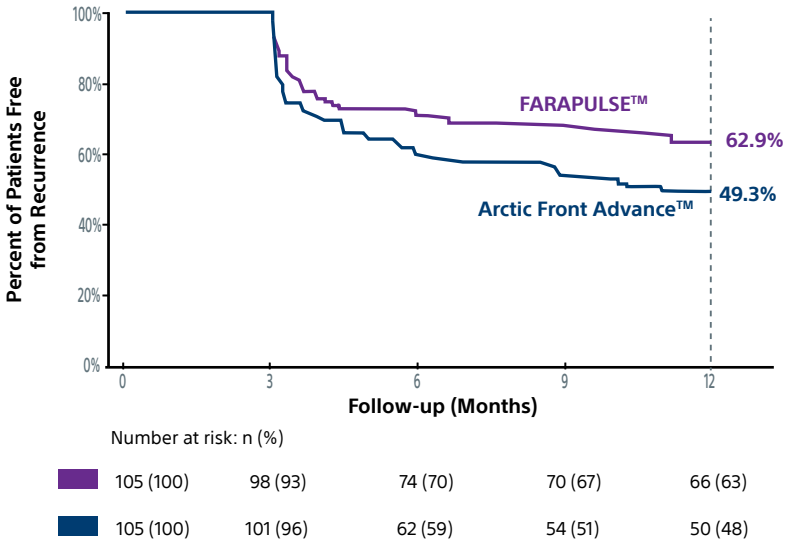
EFFICACY

Primary Efficacy Endpoint

The primary endpoint was the first recurrence of atrial tachyarrhythmia (AF/AFL/AT), (AA recurrence) after the blanking period (days 91-365) lasting >30 seconds. Non-inferiority was assessed using a margin of 20% for the difference in cumulative incidence.

- At 12 months, FARAPULSE demonstrated superiority in freedom from AA recurrence (62.9%) compared to Arctic Front Advance (49.4%), (p<0.001 for non-inferiority, p=0.046 for superiority).



Number at risk: n (%)

FARAPULSE™	105 (100)	98 (93)	74 (70)	70 (67)	66 (63)
Arctic Front Advance™	105 (100)	101 (96)	62 (59)	54 (51)	50 (48)

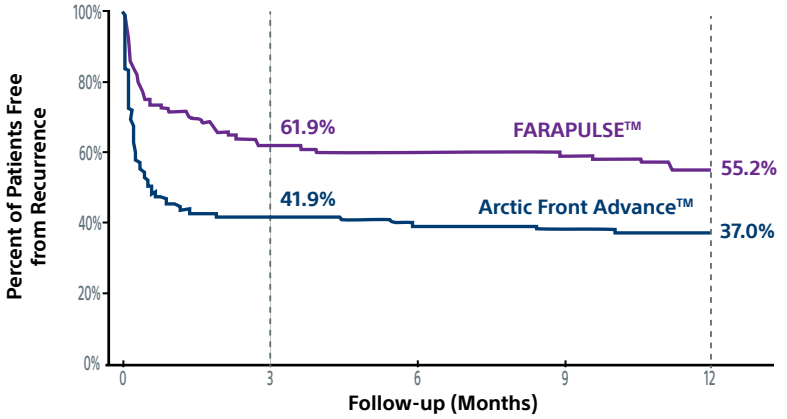
FARAPULSE SIGNIFICANTLY REDUCED AA RECURRENCE

FARAPULSE treatment resulted in a 13.6% reduction in AA recurrence (p=0.046) at 12 months vs Arctic Front Advance

Secondary Efficacy Endpoints

Additional secondary endpoints included the first recurrence of atrial tachyarrhythmia (AF/AFL/AT) during days 1-90 and days 1-365; atrial arrhythmia burden (% time in atrial arrhythmia) during days 1-90 and days 91-365.

- There was a 20% reduction in atrial arrhythmia recurrence during the 3-month blanking period (days 1-90). The recurrence-free rate for FARAPULSE was 61.9% and 41.9% for Arctic Front Advance (95% CI, -33.2 to -6.8%).
- At 12 months, inclusive of the blanking period (days 1-365), there was an 18.2% reduction in atrial arrhythmia recurrence. The recurrence-free rate for FARAPULSE was 55.2% and 37.0% for Arctic Front Advance (95% CI< -31.5% to -4.9%).



Number at risk: n (%)

FARAPULSE™	105 (100)	65 (62)	63 (60)	62 (59)	58 (55)
Arctic Front Advance™	105 (100)	44 (42)	41 (39)	38 (36)	37 (35)

FARAPULSE showed a **REDUCTION** in AA recurrence vs Arctic Front Advance **DURING THE BLANKING PERIOD**

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ADDITIONAL ENDPOINTS

Clinical Interventions and Quality of Life (QoL)

- There were no significant differences in the number of hospitalizations or cardioversions for AA recurrence or repeat ablations between patients treated with PFA or CBA.
- There was no significant health-related QoL difference at 3 and 12 months between patients treated with FARAPULSE vs Arctic Front Advance.

PROCEDURAL CHARACTERISTICS

- The FARAPULSE ablation procedure time (54.8 ± 22.7 min) and catheter LA dwell time (36.1 ± 16.6 min) were 18 minutes and 15 minutes shorter than Arctic Front Advance (73.2 ± 26.7 min and 51.5 ± 20.0 min, respectively).
- Troponin levels were significantly higher in the FARAPULSE group (1920 ± 954 vs 1114 ± 419; difference 823; 95% CI 612-1034).

	FARAPULSE™ (n=105)	Arctic Front Advance™ (n=105)
Procedure time (min)	54.8 ± 22.7	73.2 ± 26.7
LA dwell time (min)	36.1 ± 16.6	51.5 ± 20.0
Fluoroscopy time (min)	14.6 ± 7.2	15.1 ± 7.9
Increase in hsTroponin on day 1 (ng/L)	1920 ± 954	1114 ± 419
Total # of applications	36 (32-40)	5 (5-7)
CTI ablation (%)	14 (13.3)	12 (11.4)

CONCLUSIONS

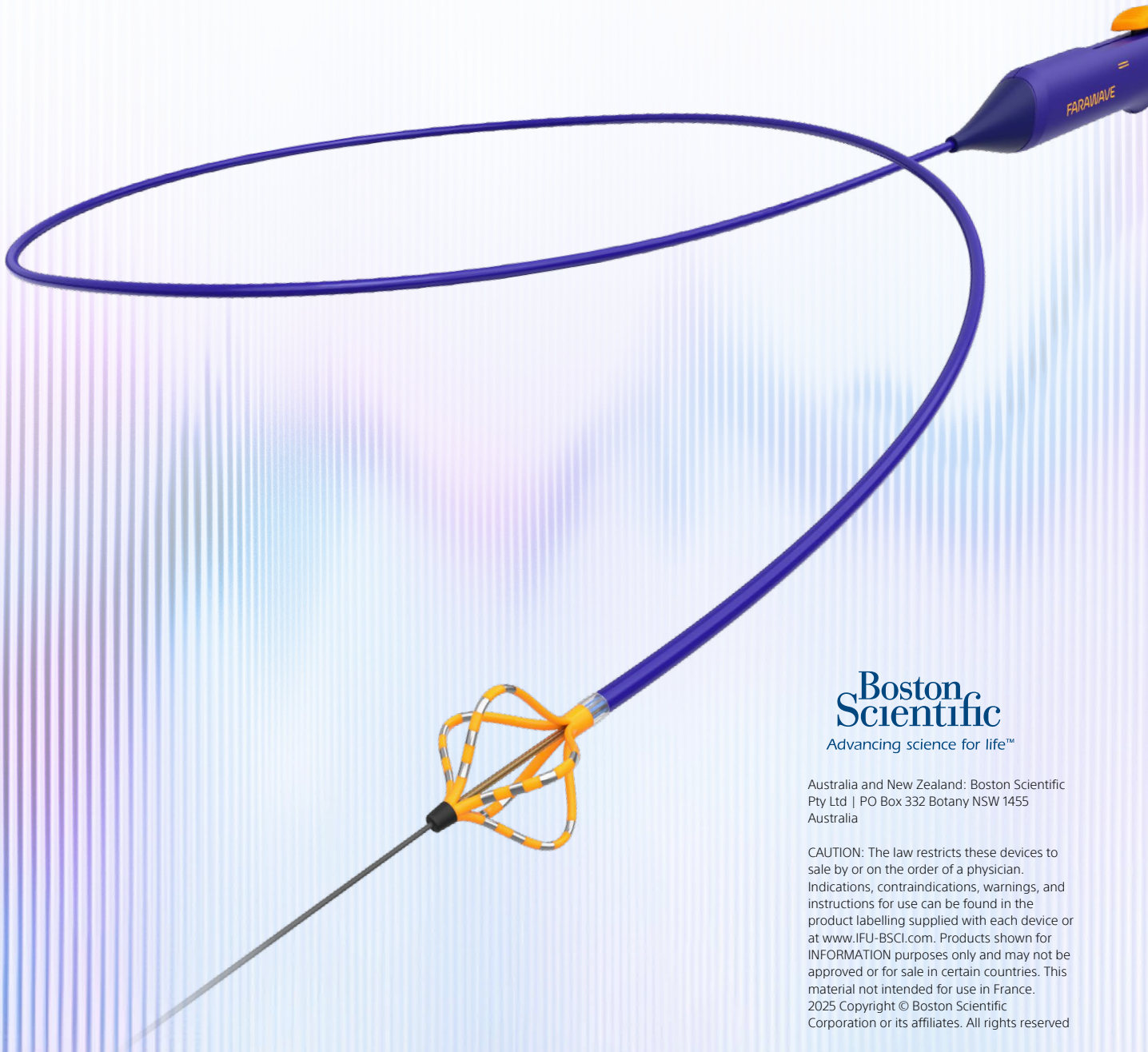
- Single Shot Champion was a randomized study where patients treated with FARAPULSE or Arctic Front Advance were monitored with a continuous monitoring device designed to eliminate sampling error, aimed at giving a comprehensive assessment of ablation efficacy.
- This study also had a stringent primary efficacy endpoint of first recurrence of atrial arrhythmia after the blanking period lasting >30 seconds.
- The SINGLE SHOT CHAMPION trial, using a stringent monitoring strategy and endpoint definition, demonstrated that significantly more patients treated with FARAPULSE (62.9%) were recurrence-free, compared to those treated with Arctic Front Advance (49.3%), (p=0.046), resulting in a 13.6% reduction in AA recurrence at 12 months.
- Additionally, there was a significant reduction in AA recurrence during the blanking period in patients treated with FARAPULSE (recurrence-free rate 61.9%) vs Arctic Front Advance (recurrence-free rate 41.9%), (95% CI, -33.2 to -6.8%).
- When the blanking period was included, there was an 18.2% reduction in AA recurrence of FARAPULSE vs Arctic Front Advance at 12 months (95% CI, -31.5% to -4.9%).
- There were no significant differences in the primary safety endpoint, clinical interventions or QoL between patients treated with FARAPULSE or Arctic Front Advance.
- FARAPULSE procedures were 18 minutes shorter on average than Arctic Front Advance and Troponin levels post-ablation were significantly higher (95% CI, 612 to 1034).

FARAPULSE vs ARCTIC FRONT ADVANCE

- **FARAPULSE SIGNIFICANTLY REDUCED AA RECURRENCE:**
  - 13.6% post-blanking (day 91-365) (95% CI -13.6)
  - 20% during the blanking period (day 1-90) (95% CI -20)
  - 18.2% throughout the full 12 months (day 1-365) (95% CI -18.2)
- There was **no significant difference** in major adverse event rates, clinical interventions or QoL.

SINGLE SHOT CHAMPION was supported by an unrestricted research grant from BSC.

Reference:
Reichlin, Tobias, et al. (in press). "Pulsed Field or Cryoballoon Ablation for Paroxysmal Atrial Fibrillation." *New England Journal of Medicine*.



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