FROzEN-AF US IDE clinical trial results

Boston Scientific
Advancing science for life™

OBJECTIVE

- Evaluate the safety and effectiveness of the Boston Scientific **POLARx™ Cryoablation System** for treatment of symptomatic, drug refractory, recurrent, paroxysmal atrial fibrillation (PAF).

FROzEN-AF TRIAL DESIGN[1]

- Global, prospective, non-randomized, single-arm study (NCT04133168)
- 385 patients (325 primary, 60 roll-in subjects) across 44 sites in 10 countries
- **POLARx™ FIT** extension arm[2]
  - 50 patients were treated to collect safety and effectiveness data on the **POLARx FIT** expandable (28 mm and 31 mm) cryoballoon (CB) catheter

PROCEDURAL CHARACTERISTICS

- The FROzEN-AF and extension study procedural characteristics are shown in **Table 1**
- The LA dwell time was 8 minutes shorter and fluoroscopy time was 6 minutes shorter in the FIT extension arm
- There was an increase in grade 4 occlusion and single-shot success with the 31 mm CB

Table 1. Procedural Characteristics

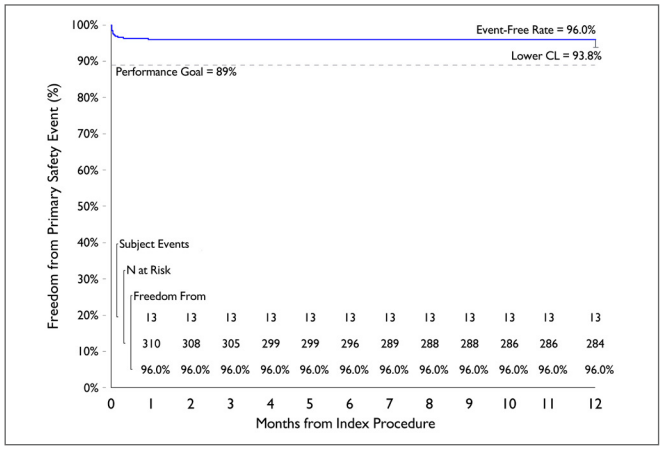
	FROzEN-AF (28 mm balloon)	POLARx FIT Extension Arm (28 mm/ 31 mm balloon)
General Anesthesia (%)	78.5%	100%
Conscious Sedation/MAC (%)	21.5%	-
Procedure Time (min)	91 min	101 min
LA Dwell Time (min)	59 min	51 min
Fluoroscopy Time (min)	13 min	7 min
Grade 3-4 Occlusion* (%)	95.9% (69.9% – Grade 4)	97.7% (66.4% / 77.6% – Grade 4)
Single Shot Success* (%)	55.9%	35.3% / 62.1%

Mean ± SD
*Only ablations with duration >60S included in ablation counts

PROCEDURAL AND LONG-TERM SAFETY

- The primary safety event-free rate was 96.0%‡ for the FROzEN-AF (12-month) **(Figure 1)** and 100% for the FIT extension arm (12-month)
- There were no reports of moderate or severe PV stenosis, persistent phrenic nerve palsy, or esophageal fistulas in both patient cohorts

Figure 1. Procedural and Long-term Safety



No reported:
- PV stenosis
- Persistent phrenic nerve palsy
- Esophageal fistulas

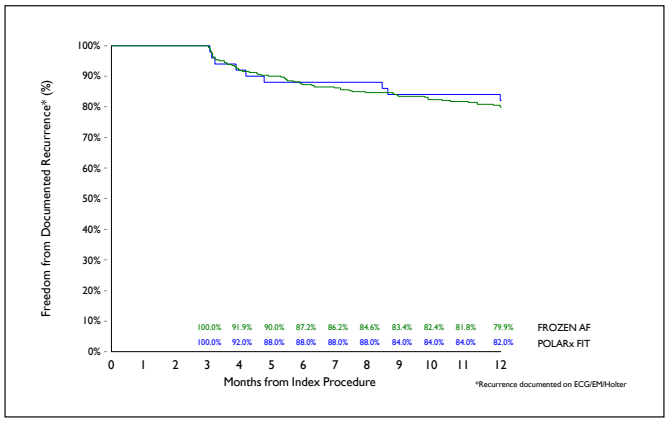
FROzEN-AF US IDE clinical trial results

Boston Scientific
Advancing science for life™

EFFICACY

- The 12-month freedom from documented atrial arrhythmias was 79.9% (AF 82.7%, AFL 96.5%, AT 98.1%) **(Figure 2)**
- The FIT extension arm 12-month freedom from documented atrial arrhythmias was 82.0% (AF 84%, AFL 94%, AT 100%)
- Electroanatomic mapping (EAM) was used in 184/325 cases; examination of recurrence in these patients revealed a trend (p=0.08) toward higher freedom from recurrence (83.7%) when EAM was used, compared to 75.9% when not

Figure 2. Freedom from Documented Recurrence of Atrial Arrhythmias



FROzEN (n = 325)
12-Month
79.9%

FIT Extension (n = 50)
12-Month
82.0%

POLARx™ FIT voltage single-center experience[3]

- A single-center characterized lesions with high-density voltage maps on 14 patients (8 ablated with the 31 mm CB and 6 with the 28 mm CB)
- Voltage maps revealed wide antral lesions around all veins (100%)
- Lesion assessment of atrial scar burden revealed a statistically significant difference in the fractional antral scar, 68% (31 mm) vs. 60.5% (28 mm) (p = 0.048) indicating a significantly larger lesion being created by the 31 mm CB **(Figure 3)**

Figure 3. High Density Maps of Atrial Scar Burden of the 28 mm and 31 mm CB

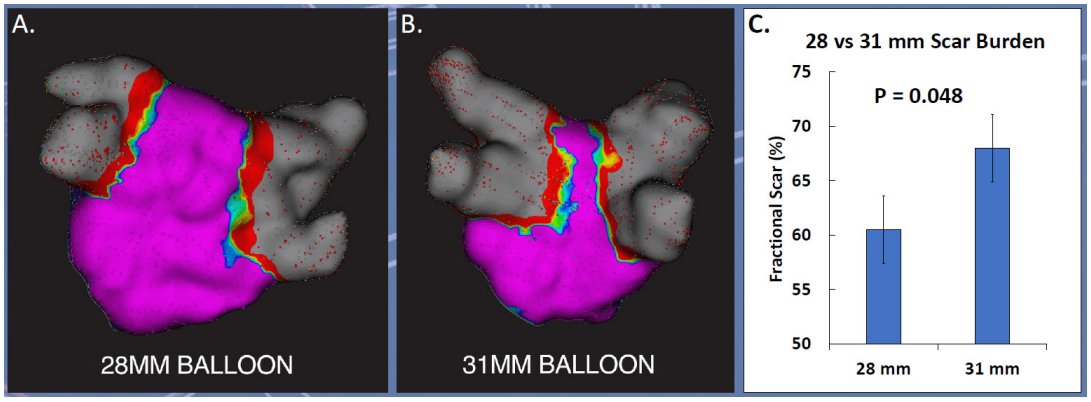


Figure Legend. High-density voltage maps from 28 mm (A) and 31 mm (B). C. scar burden analysis.

CONCLUSION

- The choice of balloon sizes (31 and 28 mm) with **POLARx FIT** may assist in overcoming challenges related to variability in patient PV size and geometry with the 31 mm CB achieving high-grade 3-4 vein occlusion, lowering the LA dwell and fluoroscopy times and increasing the single-shot isolation rate
- The primary safety event-free rate was 96.0%‡ (FROzEN-AF) and 100% (FIT extension arm) with no reported PV stenosis, persistent phrenic nerve palsy, or esophageal fistulas
- The documented atrial arrhythmia recurrence rate was low with 20.1% (FROzEN-AF) and 18% (FIT extension) at 12 months
- In the single-center experience, **POLARx FIT** produced significantly larger, more antral lesions and the 31 mm balloon and sheath maneuverability allowed greater control of balloon occlusion and lesion placement

POLARx™ Cryoablation System
Indications, Safety, and Warnings

‡Updated analysis with corrected data

1. Ellenbogen KA, Mittal S, Varma N, et al. One-year outcomes of pulmonary vein isolation with a novel cryoballoon: Primary results of the FROZEN AF trial. *J Cardiovasc Electrophysiol*. Online ahead of print.
2. Su, et al. Clinical application of a novel 31 mm cryoballoon for pulmonary vein isolation for paroxysmal atrial fibrillation: procedural data from the FIT arm of FROzEN-AF. Presented at: Heart Rhythm Society 2023; May 19-21, 2023; New Orleans, LA, USA.
3. Makati, et al. Voltage mapping of a novel 31 mm cryoballoon for pulmonary vein isolation to manage paroxysmal atrial fibrillation: a single center experience. Presented at: AF Symposium 2023; Feb. 2-4, 2023; Boston, MA, USA.

Boston Scientific
Advancing science for life™

Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.888.272.1001

EP-1576508-AC