

## Background

- Cryoballoon catheter is the gold standard single-shot device for pulmonary vein isolation (PVI).<sup>1,2</sup>
- Pulsed-field ablation (PFA) is a tissue-selective, nonthermal cardiac ablation modality.

## Objective(s)

To assess the preclinical safety and feasibility of a novel PFA balloon catheter for PVI and circular lesions.

## Method

- The PFBalloon Catheter (EnChannel Medical, Inc.) was used in 7 swine with biphasic-bipolar 750V waveform. PFA sites were located at the right atrial appendage (RAA), superior vena cava (SVC), left superior PV (LSPV), and right superior PV (RSPV).
- The 13-Fr catheter (two sizes - 24 and 28 mm) was tested under fluoroscopy for localization. The balloon was inflated with a 10:1 saline/contrast solution.



- PFA was delivered in a small-ring, large-ring, or global-pulse configuration to generate electric fields in different directions (Figure Right). An accelerometer monitored the impact on phrenic nerve function and diaphragm.

- Thirty (30) days post-procedure, lesion durability was assessed, gross examination was performed, and tissue was excised for histologic examination (Masson's trichrome).

## Results

- Acute PVI was achieved at 93.8% (15/16), with 68.8% (11/16) durable on day 30 using the 24mm catheter. Pulse configurations were 12.5% small-ring, 37.5% large-ring, and 50% global.
- Acute PVI was achieved in 75.0% (6/8), with 62.5% (5/8) durable on day 30 using the 28mm catheter. Pulse configurations were 25.0% small-ring, 25.0% large-ring, and 50.0% global.
- The average number of PF applications per PV was 4.0. Lesion depth was 3.2 mm (range 0.5-7.6 mm).
- The small-ring ablation caused the least diaphragmatic stimulation.
- No adverse events were observed.

Catheter Size	Location	# of Samples	Acute Success	30-day Success	Mean Depth Range
24 mm balloon	SVC	4	4 (100%)	4 (100%)	1.0mm (0.6 – 1.7mm)
	RAA	4	3 (75%)	2 (50%)	3.4mm (1.0 – 7.6mm)
	LSPV	4	4 (100%)	4 (100%)	1.8mm (0.7 – 5.0mm)
	RSPV	4	4 (100%)	1 (25%)	2.4mm (1.3 – 3.3mm)
28 mm balloon	RAA	3	2 (67%)	2 (67%)	4.1mm (1.5 – 6.3mm)
	SVC	3	3 (100%)	2 (67%)	1.1mm (0.5 – 1.7mm)
	RSPV	2	1 (50%)	1 (50%)	1.5mm (0.8 – 2.1mm)

## Conclusion

The balloon catheter can deliver PFA to create circular lesions and durably isolate PVs with clinically relevant depth and no complications.

## Pulse Configurations

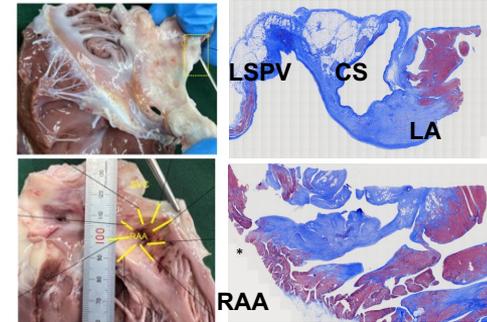


Global

Small ring

Large ring

## Gross examination and histology



## Disclosures / References

1. Urbanek et al., Circ Arrhythm Electrophysiol. 2023.
2. Su et al., Heart Rhythm. 2015