

## Characterization of atrial lesion safety and efficacy utilizing a circular catheter and the IRE generator with an in vivo porcine model

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### Introduction/Objectives:

Pulsed field ablation (PFA) is a non-thermal ablative method that delivers high voltage, very-short duration pulses that cause pore formation in the cytoplasmic membrane and cell death. The tissue selectivity of PFA is expected to reduce the risk of collateral tissue injury compared to radiofrequency catheter ablation (RFCA), while maintaining effectiveness. The objective of this study was to perform pulmonary vein (PV) isolation in a porcine model to characterize the safety and performance of a novel, fully-integrated biphasic PFA system. The system is comprised of a multi-channel generator, a variable loop circular catheter, and an integrated irreversible electroporation (IRE) mapping software module.

**Methods:** The study evaluated safety and efficacy of IRE in 8 healthy swine. First, to evaluate safety, multiple ablations were performed at various cardiac structures, including within the lumen of the right pulmonary vein (RIPV), at the right superior pulmonary vein (RSPV) ostium, and adjacent to the esophagus. Second, to evaluate efficacy, animals were recovered and followed for 30 ( $\pm$ 3) days, then re-mapped. Gross pathological and histopathological examinations were performed to assess for procedural injury, chronic thrombosis, tissue ablation, depth of penetration, healing, and level of inflammatory response.

**Results:** All 8 swine survived for the 30 ( $\pm$ 3) day follow up (FU) period. There were no acute (day of procedure) incidents of pulmonary vein narrowing of  $>70\%$ , nor at 30 d follow-up (FU), even when ablation was purposefully performed directly deep to the ostium of the vein. No injury was seen grossly or histologically in the adjacent esophagus. All PVs were durably isolated as confirmed by bidirectional block at the 30 ( $\pm$ 3) day re-map procedure, and histological examination showed complete, transmural necrosis around the entire circumference of the ablated section of the right PVs [Figure].

**Conclusion(s):** This pre-clinical evaluation of a fully integrated PFA system demonstrated effective and durable ablation of cardiac tissue and PV isolation with no collateral damage to adjacent structures. Notably, histological staining confirmed complete transmural cell necrosis around the circumference of the ostial PV at 30 days.

Abstract Figure. PVI maps (A) histology (B) and safety(C)

