CARTO SOUND™ FAM-Guided Pulsed Field Ablation for Paroxysmal Atrial Fibrillation: An Exploratory Study

NCT Number: Not yet assigned

Document Date: April 2, 2026

Protocol Version: V 2.2 / April 2, 2026

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1. STUDY OBJECTIVES

Primary objective: To evaluate the acute success of pulmonary vein isolation (PVI) using pulsed field ablation (PFA) guided by the CARTO SOUND™ FAM system in patients with paroxysmal atrial fibrillation (AF).

Secondary objectives: (1) 30-day safety (serious adverse events related to the system/procedure); (2) procedure efficiency metrics (total procedure time, mapping time, ablation time, fluoroscopy time); (3) catheter contact quality; (4) tissue proximity indicator (TPI) performance.

2. STUDY DESIGN

Prospective, multicenter, single-arm, feasibility study.

Sample size: 70 participants.

Enrollment period: 11 months; Follow-up: 1 month post-procedure.

3. ELIGIBILITY CRITERIA

Inclusion:

• Diagnosis of paroxysmal AF with indication for catheter ablation.

• Age 18-80 years.

• Signed informed consent.

• Willing to comply with all study visits and assessments.

Exclusion:

• Valvular AF, untreated thyroid disease, acute coronary syndrome, or AF secondary to cardiomyopathy.

• Contraindications to catheter ablation (e.g., left atrial thrombus, coagulopathy, severe organ dysfunction).

• Pregnancy or breastfeeding.

• BMI >40 kg/m² or severe sleep apnea.

• Participation in another clinical trial.

• Any contraindication to study devices per instructions for use.

4. INTERVENTION

All participants undergo PVI using the Varipulse™ PFA catheter under the guidance of the CARTO SOUND™ FAM system. The system uses intracardiac echocardiography (ICE) and an AI algorithm to reconstruct a 3D model of the left atrium and pulmonary veins. The VIZIGO™ steerable sheath may be used.

5. OUTCOME MEASURES

Primary endpoint (acute success):

Composite endpoint requiring all of the following:

(1) successful left atrial model construction using the study catheter;

(2) electrical isolation of all target pulmonary veins (entry block confirmed);

(3) completion of ablation using only study devices (no cross-over to other tools).

Secondary endpoints:

(1) Incidence of 30-day serious adverse events (SAEs) related to CARTO SOUND™ FAM or PFA procedure.

(2) Total procedure time; mapping time; ablation time; fluoroscopy time.

(3) Catheter contact quality assessed by ICE.

(4) Percentage of positive tissue proximity indicator (TPI) sites.

6. STATISTICAL PLAN

Descriptive statistics will be used. The primary endpoint will be reported as frequency with exact 95% confidence interval. Continuous variables will be expressed as mean±SD or median (IQR). For mapping time, comparison with historical data (4.5±1.0 min) will be performed using one-sample t-test or Wilcoxon test. SAE incidence will be calculated with exact binomial 95% CI. Subgroup analyses (by site, operator experience)

and exploratory logistic regression may be performed. Significance level: α=0.05 (two-sided). Software: R version 4.3.

7. STUDY TIMELINE

Anticipated study start: July 2026

Primary completion: June 2027

Study completion: July 2027

8. ETHICS AND DATA MANAGEMENT

The study will be conducted in accordance with the Declaration of Helsinki, GCP, and Chinese regulations. Ethics approval will be obtained from the Institutional Review Board of Fuwai Hospital before study initiation. Written informed consent will be obtained from every participant. Data will be double-entered and encrypted. Individual participant data (IPD) will not be shared due to lack of consent and institutional policies.