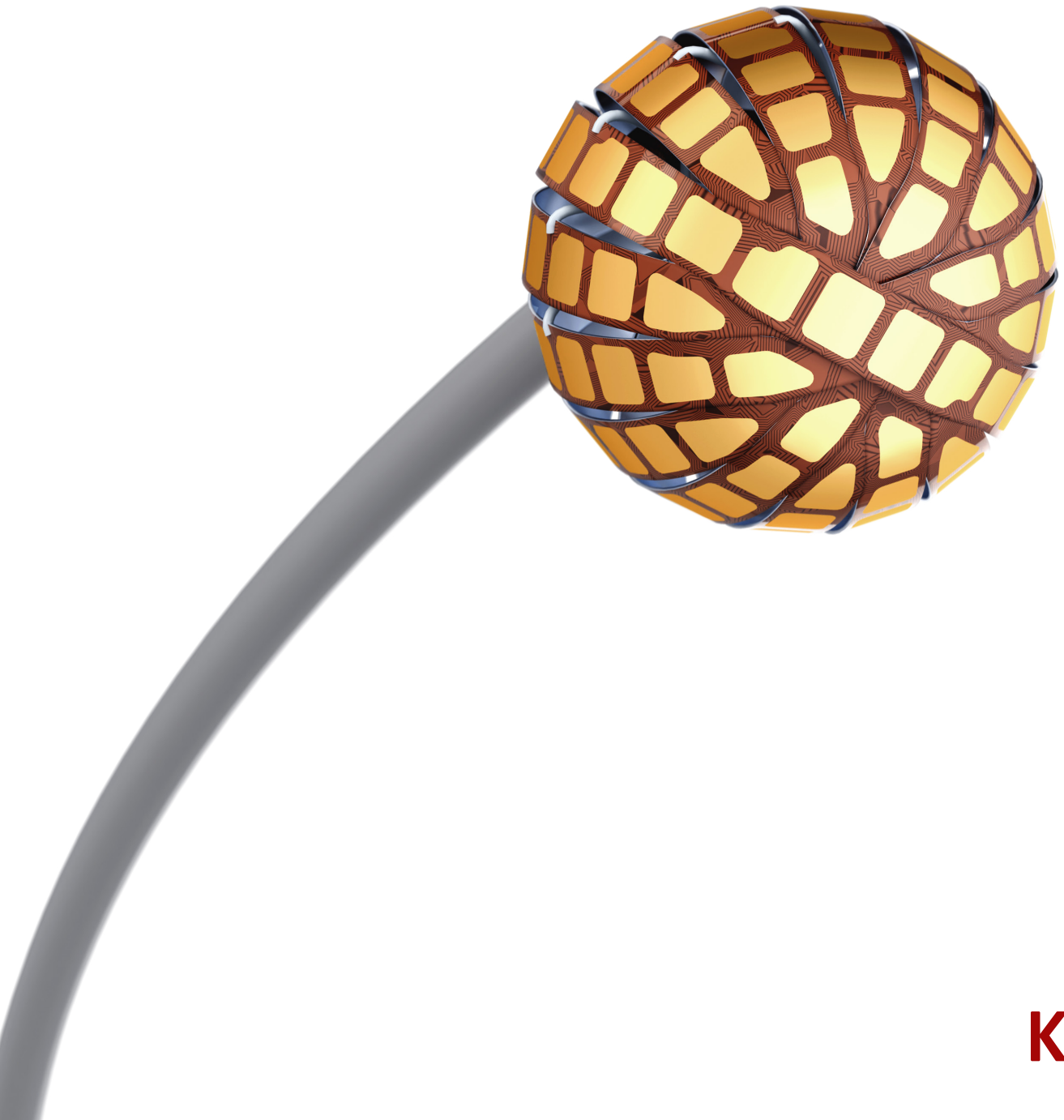
globe® By Kardium®

The Promise of PFA Delivered

Demonstrated safety and clinical excellence in one complete system



Kardium®

PULSAR-IDE

Trial summary

The global, multicenter PULSAR IDE Study generated data supporting the safety and effectiveness of the Globe® Pulsed Field System in treating patients with paroxysmal atrial fibrillation.

12 Sites

19 Operators

4 Countries

United States, Canada, Germany, Czechia

183 Patients

Trial design

- Prospective, multicenter, single-arm Investigational Device Exemption trial
- 183 total patients with symptomatic paroxysmal atrial fibrillation enrolled
- 164 of 183 patients included in the safety and effectiveness analysis, with 19 as lead-in cohort
- All patients underwent pulmonary vein isolation only

12-month follow-up

- Weekly and symptomatic transtelephonic monitoring
- 12-lead ECG at 3, 6, and 12 months
- 24-hour Holter monitoring at 6 and 12 months

At a glance

0.6%
Primary Safety Event Rate

0%
Device-Related Primary Safety Event Rate

77.8%
12-Month Primary Effectiveness, Paroxysmal Cohort

Safety

No device-related primary adverse safety events reported

- Zero reports of cardiac tamponade, atrio-esophageal fistula, or phrenic nerve injury
- One non-device-related incident of a hemorrhagic stroke following ablation in a patient with severe hypertension

0/164 Death
0/164 Cardiac tamponade/perforation
0/164 Heart block
0/164 Major vascular access complication
0/164 Major bleeding
0/164 Myocardial infarction (MI)
0/164 Pericarditis requiring intervention
0/164 Pulmonary edema
0/164 Transient ischemic attack (TIA)
0/164 Vagal nerve injury resulting in gastroparesis
0/164 Stoke/cerebrovascular accident
0/164 Atrioesophageal fistula*
0/164 Diaphragmatic paralysis/phrenic nerve injury†
0/164 Severe PV stenosis‡
0/164 Any Globe PF System-related or PF procedure-related cardiovascular and/or pulmonary adverse event within 7 days that prolongs or requires hospitalization for more than 48 hours§

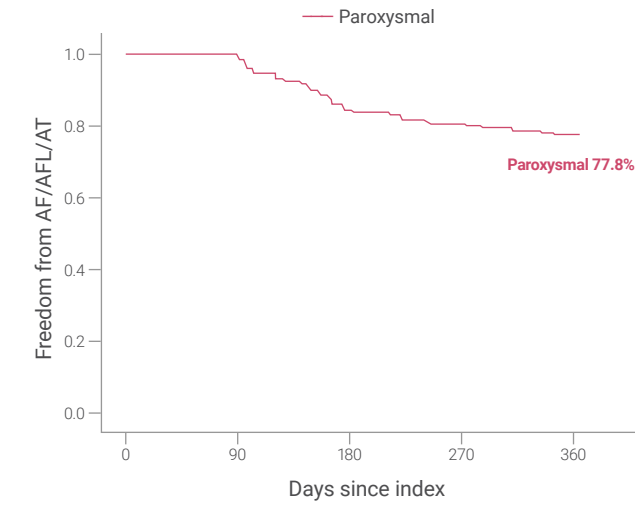
Effectiveness

77.8% freedom from atrial arrhythmias at 1 year

The primary effectiveness endpoint was defined as freedom from AF/AFL/AT at 12 months, acute procedure failure, direct current cardioversion, antiarrhythmic drug failure, redo-ablation due to recurrent AF/AFL/AT, and surgical treatment for AF/AFL/AT.

Durable isolation

- Only 6% of patients required repeat ablation¶
- 95% (35/37) of assessed veins remained durably isolated upon repeat procedures¶



* within 2 months of ablation procedure

† unresolved at 6 months

‡ within 6 months of ablation procedure

§ excluding recurrent AF/AFL/AT

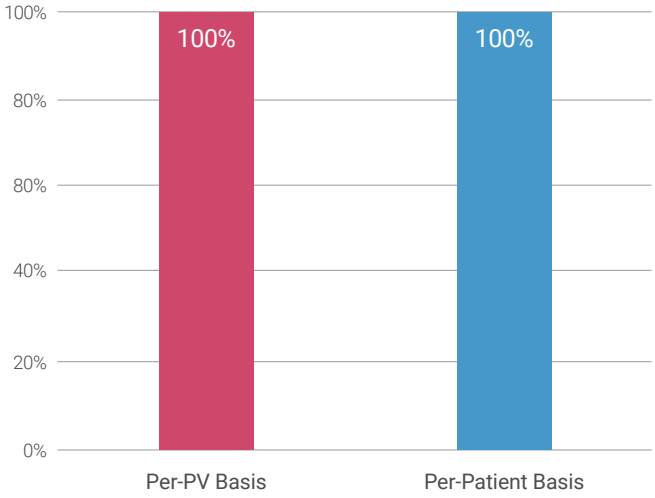
¶ n=10

100% Acute Procedural Success*

* Defined as acute isolation of all accessible targeted PV, confirmed by entrance and/or exit block with the Globe Catheter.

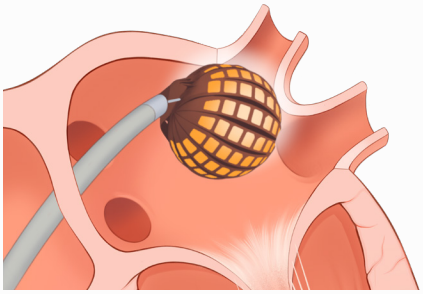
Acute PVI

(At index procedure)

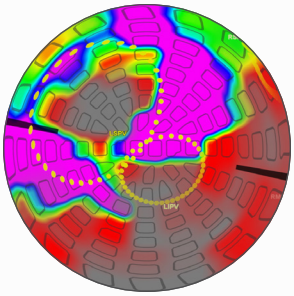


Follow-Up and Compliance

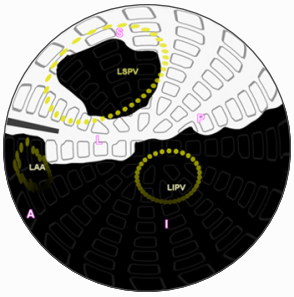
- Completed 12-month follow-up compliance of **99%**
- Weekly and symptomatic transtelephonic monitoring (TTM) with a compliance of **71%**
- 12-lead ECG at 3, 6, and 12 months with a compliance of **95%**
- 24-hour Holter monitoring at 6 and 12 months with a compliance of **91%**



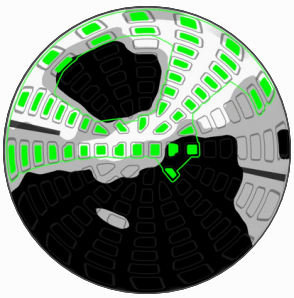
Live local array
provides localized beat-by-beat data on region of interest



CONTACT™ Scan
confirms electrode-tissue contact for therapy planning

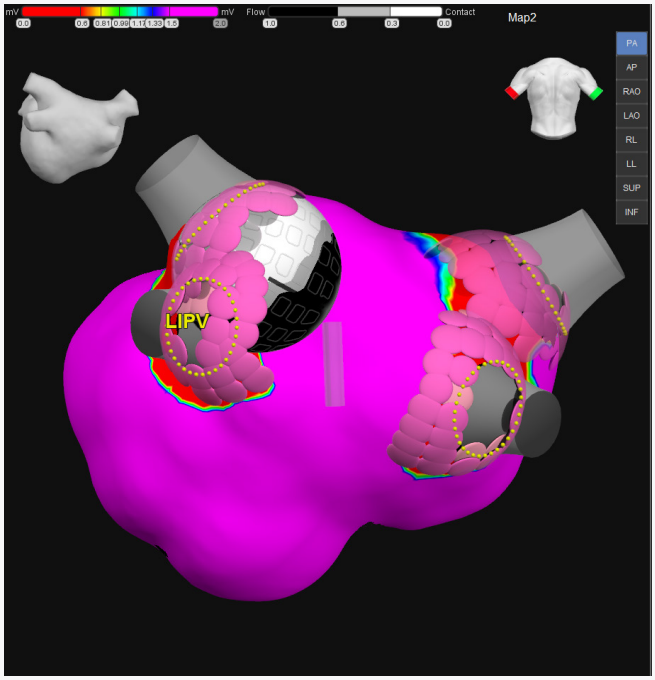


Tailored electrode selection,
ensures only the intended tissue is targeted



Efficiency

The Globe Pulsed Field System provides true single-shot ablation, averaging one application per vein.



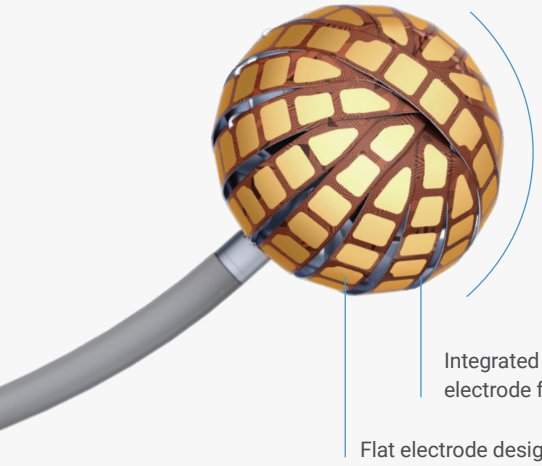
Average of 1.18 pulsed field applications per vein to achieve successful acute isolation of the targeted PV

25 min
Average Transpired Ablation Time

9 min
Average Fluoroscopy Time

See the anatomy. See the target. See the contact.

With fully integrated HD mapping, the Globe System creates fast, real-time visuals of atrial anatomy and activity.



Characteristics	PVI only (n = 164)
Procedure time, min	95.8 ± 20.7
Left atrial dwell time, min	59.9 ± 11.6
Transpired ablation time, min	25.5 ± 9.9
PFA delivery time, s	49.2 ± 10.2
Fluoroscopy time, min	9.2 ± 7.5

Values are presented as mean ± SD.
PFA = pulsed field ablation; PVI = pulmonary vein isolation.

The Globe® PF System is investigational and not approved for sale in any geography.

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.

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