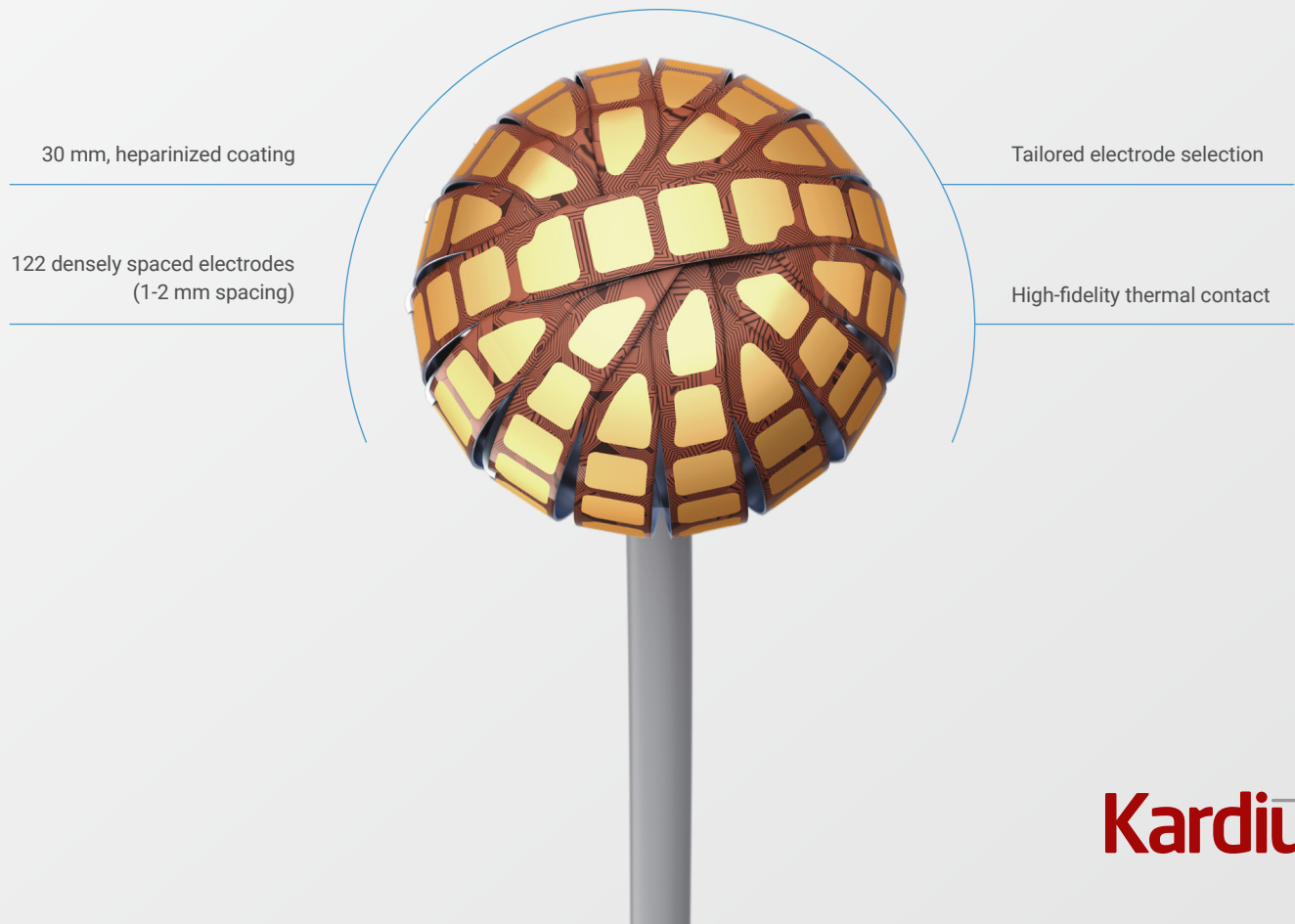


Globe® Pulsed Field System

Delivering the most complete solution for atrial fibrillation

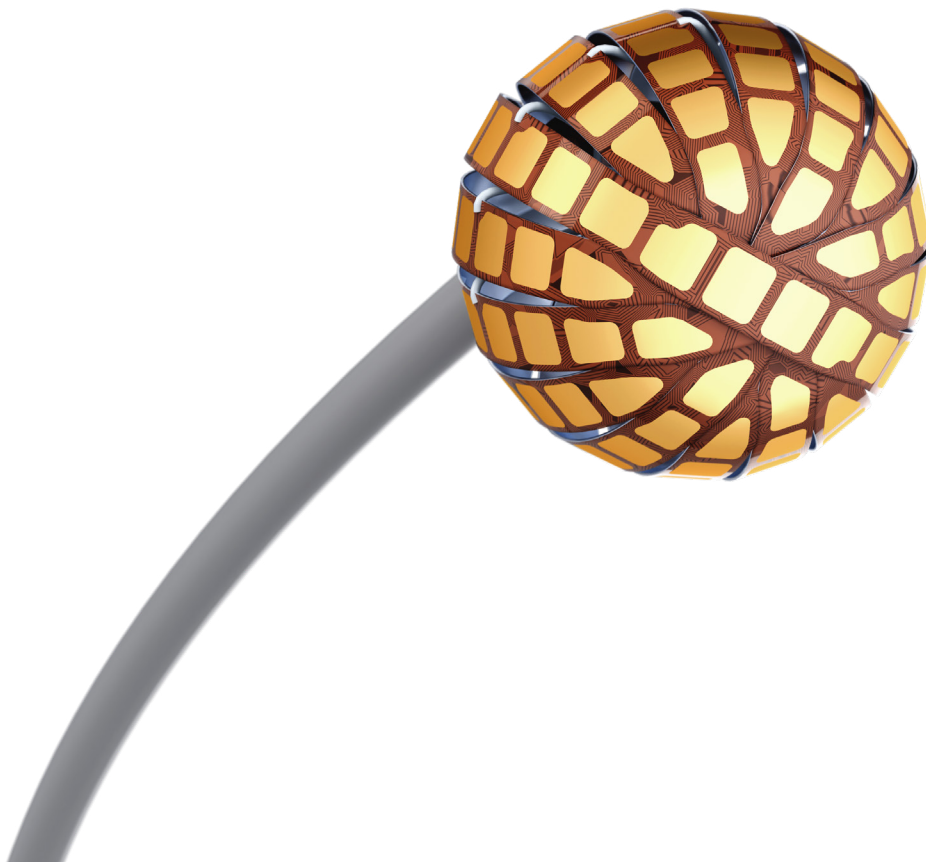
The Globe Pulsed Field System is a fully integrated cardiac mapping and ablation solution.

The atraumatic, spherical array contains 122 gold-plated electrodes, each capable of mapping, pacing, ablating and sensing contact. Create fast, real-time visuals of atrial anatomy and activity to guide patient-specific care. Deliver true single-shot ablation and customized lesions for anatomical variations.



Globe[®] Catheter

Order number	
601-01000	Globe Catheter
Catheter Specifications	
Catheter type	Spherical array
Energy	Pulsed field
Shaft outer diameter	16F (5.3 mm)
Shaft length	116 cm
Array diameter	30 mm
Number of electrodes	122
Electrode size	3 x 4 mm
Electrode spacing	1-2 mm
Electrode selection	For ablation delivery, select a minimum of 2 and maximum of 64 simultaneous electrodes
Coating	Heparinized coating on surface of array
Electrode configuration	Bipolar, biphasic
Compatibility	
Sheath	Globe [®] Introducer (601-01001)
Generator	Globe [®] PF Generator (601-00060)
Mapping system	Globe [®] Controller (601-00048) and Globe [®] Workstation (601-00064)



Globe® Introducer



Order number	
601-01001	Globe Introducer

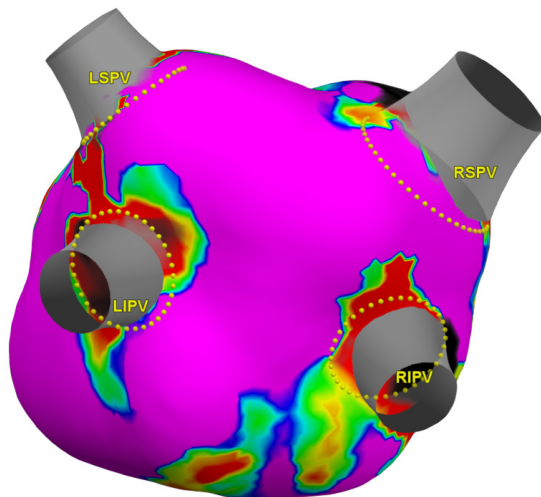
Introducer Specifications	
Usable length	71 cm
Overall length	116 cm
Inner diameter	16F (5.3 mm)
Deflection	Bidirectional
Coating	Hydrophilic coating on entire outer surface of sheath tube

Dilator Specifications	
Dilator length	102 cm
Inner diameter	0.89 mm (0.035 in)

Compatibility	
Guidewire	0.89 mm (0.035 in), 230 cm minimum length
Catheter	Globe® Catheter (601-01000)

Globe® Pulsed Field System Accessories and Capital Equipment

The Globe® Software offers a comprehensive set of visualization capabilities to enhance procedural workflow and confirm treatment success.



Fully Integrated High-Fidelity Mapping

Create fast, real-time visuals of atrial anatomy and activity, capturing over 2,500 points per minute to support patient-specific treatment.

Accessories

Order Number	Component	Details
601-00046	Globe® Catheter Cable	Nonsterile, reusable, 3.8 m cable used in the sterile field after it is covered with a sterile catheter cable cover.
601-00067	Globe® Catheter Cable Support	Nonsterile, reusable, resting support for the Globe Catheter Cable. It consists of a clamp to secure the support to the patient table, and a cable saddle to hold the Catheter Cable.
601-00066	Globe® Platform	Nonsterile, reusable flat surface to place over the patient facilitating positioning of the Globe Catheter. Requires support pillows and a sterile drape.
601-00036	Globe® Positioning System (GPS™) Cable	Nonsterile, reusable, 3.5 m extension cable for GPS™ Electrodes for localization system (of GPS™ Module).
601-00037	Globe® Positioning System (GPS™) Electrodes	Six nonsterile, single-use patient surface electrodes provided in sets of four that are used for the localization system (or GPS™ Module).

Capital Equipment

601-00048	Globe® Controller
601-00060	Globe® PF Generator
601-00064	Globe® Workstation

Globe Pulsed Field System (Globe PF System) Brief Statement

Indications for Use

The Globe Catheter is indicated for anatomical and electrophysiological mapping and stimulation of cardiac tissue, and for the delivery of ablation energy for the treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation, when used in conjunction with the Globe Pulsed Field System.

Contraindications

The Globe PF System is contraindicated for:

- Pediatric patients
- Patients with material in or around the atrium that could become dislodged during the procedure, such as intracardiac thrombus, myxoma, or tumor
- Patients suffering from active systemic infection (sepsis)
- Patients with intolerance to anticoagulation medications

Other Prescription and Safety Information

Prior to use, refer to the Instructions for Use (IFU) supplied with the Globe PF System devices for full indications for use, contraindications, potential adverse effects, warnings, and precautions.

Only use the Globe PF System (including the Globe Catheter and Globe Introducer) with compatible devices specified in the IFU. Use with incompatible components may result in patient injury or death.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.



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