

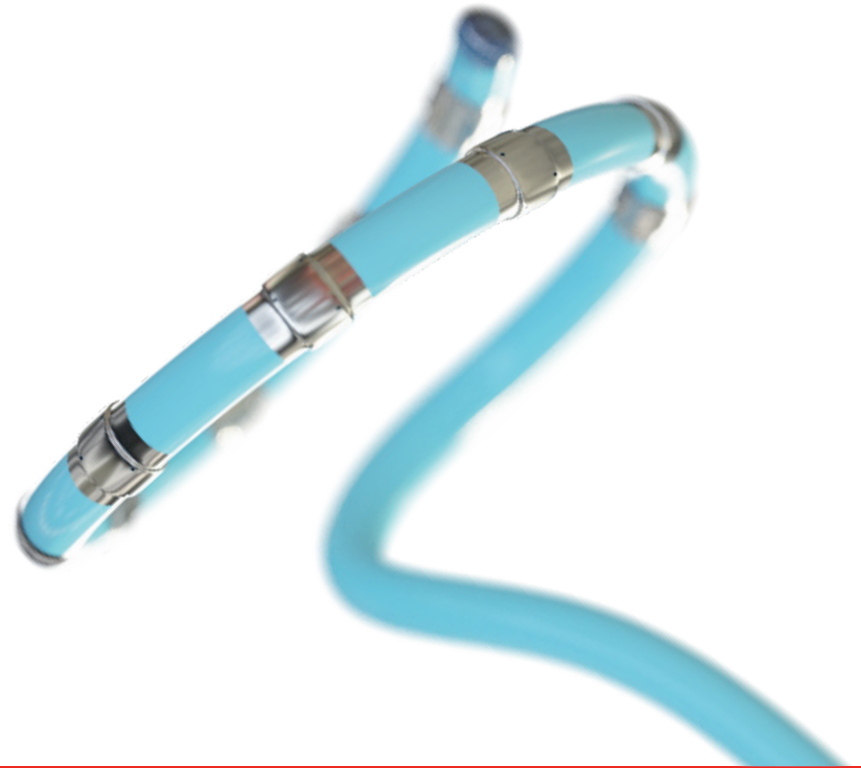
VARIPULSE™ Platform

Own the field with CARTO



Johnson & Johnson
MedTech

Intuitive.
Reliable.
Versatile.



Johnson & Johnson MedTech is bringing the first CARTO™-integrated Pulsed Field Ablation (PFA) platform with the VARIPULSE™ Catheter, an intuitive pulmonary vein isolation solution powered by the TRUPULSE™ Generator.

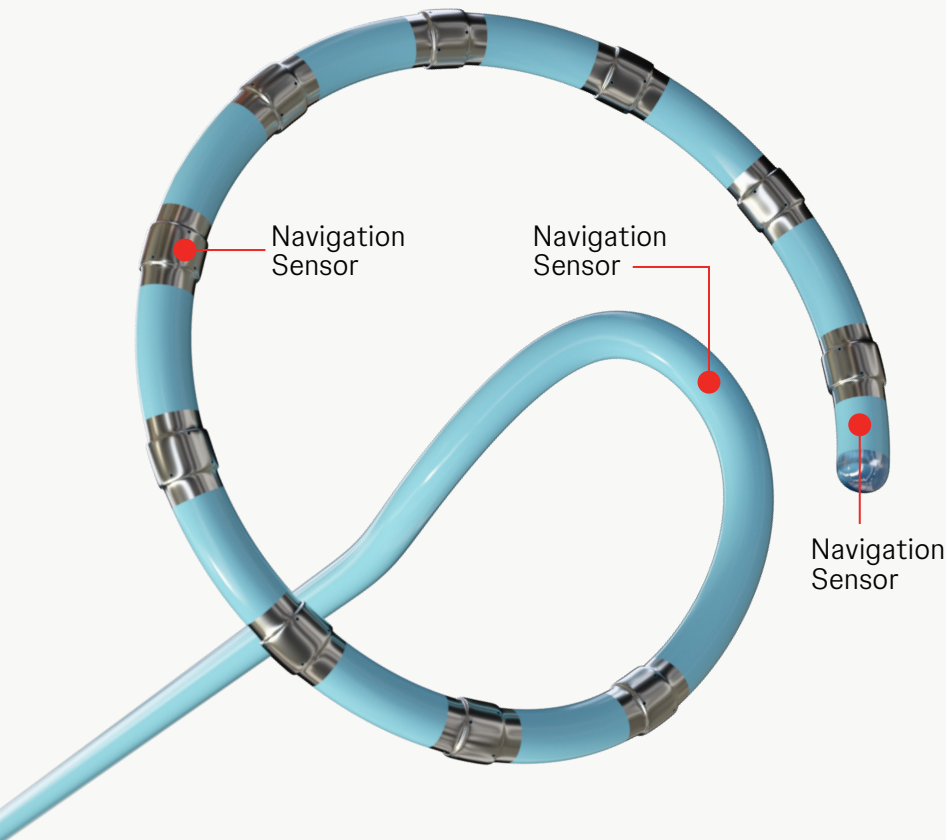
The VARIPULSE™ Platform enables efficient, patient-centric therapy delivery with a simple integration.¹ In conjunction with Johnson & Johnson MedTech's fully integrated portfolio, you have a single solution to scale between simple and complex ablations, reducing the complexity of managing your day in the lab.

VARIPULSE™ Catheter

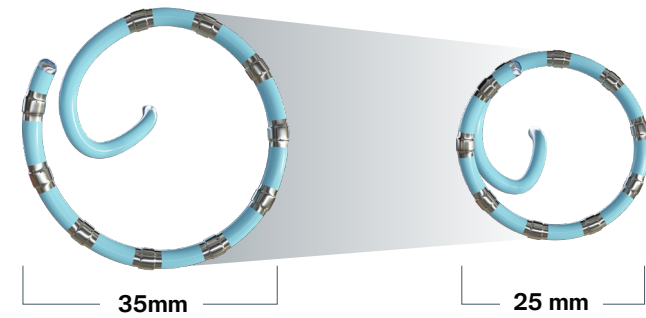
The VARIPULSE™ Catheter's full integration may reduce the need for multiple methods of catheter visualization used in one procedure, creating a streamlined workflow.²

Designed for Mapping Integration

3 Single Axis Sensor locations for accurate visualization on the CARTO™ System.



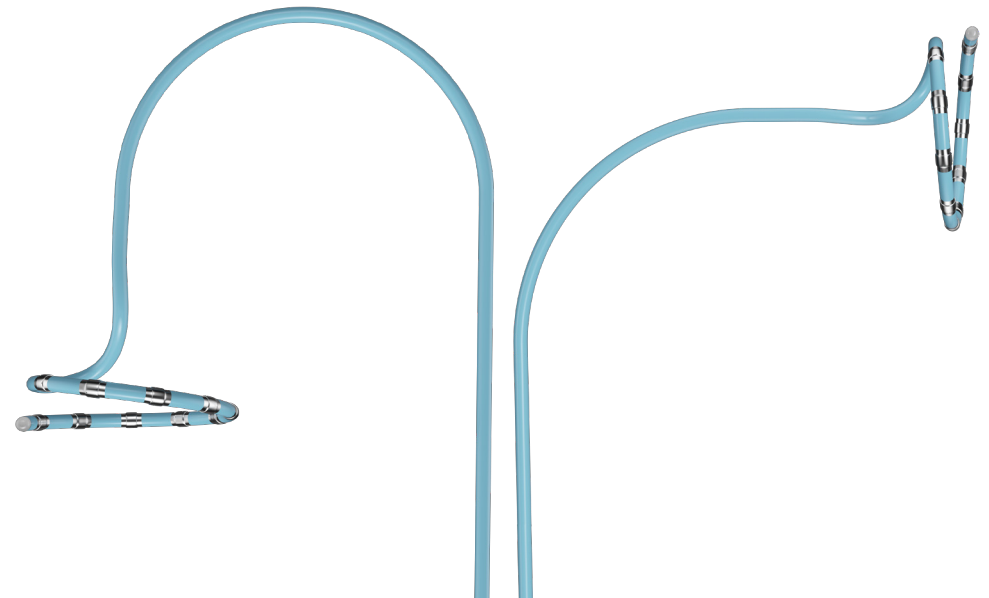
35 mm to 25 mm Variable Loop Contraction



- 10 electrodes that electro-anatomically map, emit pulsed field for ablation and allow pacing per electrode.
- Variable loop size (25mm-35mm) to adjust to fit the patient's anatomy.

Bi-Directional Deflection

The VARIPULSE™ Catheter is built on a bi-directional, 8 Fr platform compatible with the CARTO VIZIGO™ Sheath or similar 8.5 F inner lumen sheath.



TRUPULSE™ Generator



The TRUPULSE™ Generator is the cornerstone of your PFA procedures. The system delivers a unique bi-polar, bi-phasic pulse sequence specifically tailored for the VARIPULSE™ Catheter design.²



Automatically detects which catheter is connected and loads the correct pulse sequence



Maximize lab uptime with field upgradeable software and on-screen troubleshooting



Connect two touch screen monitors for management from both the operating theatre and the control room



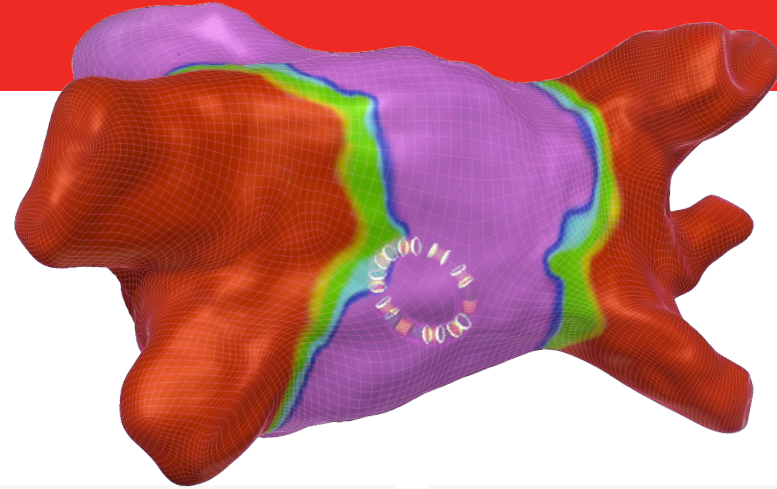
Control ablation via the foot pedal or the touch screen monitors



Select from 33 different languages for onscreen display

Pulsed Field Ablation. CARTO™ Integration.²

The integrated VARIPULSE™ Platform is designed to deliver ablations at precise locations to potentially maximize safety and effectiveness.*² Accurate visualization of the VARIPULSE™ Catheter within the patient's anatomy supports the physician's ability to place ablations in specific locations for pulmonary vein (PV) isolation.**²

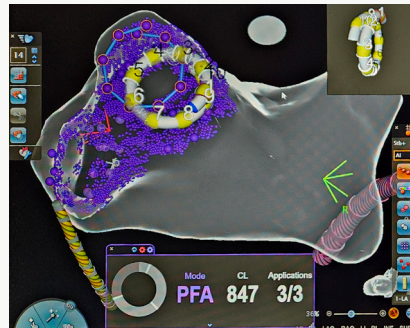


Tissue Proximity Indicator



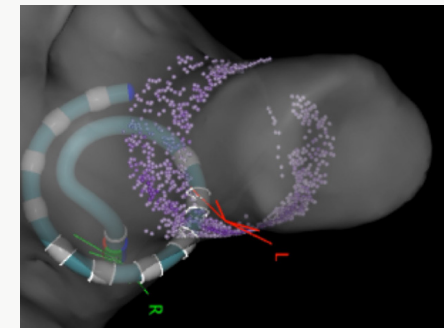
Through pre-clinical studies, Johnson & Johnson MedTech has demonstrated that contact is important to create consistent lesion depth during the ablation.† The Tissue Proximity Indicator is designed to visually show the sections of the loop that have contact prior, during and after ablation.

Pulsed Field Tag Coloring



The VARIPULSE™ Service Pack Software provides automatic 3D visual information about application locations during and after ablation. Pulsed Field (PF) tag coloring provides application feedback during the ablation, the inter-tag connectors show pulsed energy contiguity between electrodes and contact filtering removes tags that were not in close proximity to the tissue during the ablation.‡

Precise Energy Delivery



Identification of lesion placement is only part of procedure workflow. There is also a need to identify any areas of the pulmonary vein ostium that have not been ablated. The VARIPULSE™ Platform enables precise energy delivery and identification of gaps to complete PVI efficiently, providing physicians with the confidence of an accurate CARTO™ ecosystem they know.²

* Precise in that it is marked on CARTO™ screen.
** When used with the CARTO™ 3 System.
† Based on internal benchtop data. TR-0042284
‡ When used with VARIPULSE™ Catheter.

Proven to Deliver.



The VARIPULSE™ Platform has a proprietary pulse sequence which has been proven in robust preclinical work to have tissue selective properties and preserves the tissue architecture.

In the insPIRE and admIRE trials, VARIPULSE™ Platform did not damage the esophagus, the phrenic nerve, or the pulmonary vein ostium.^{3,4}

Notably High Safety

admIRE Trial⁴

2.9% primary adverse events

insPIRE Trial³

0% primary adverse events

Full CARTO™ Integration Minimizes Fluoroscopy Exposure

admIRE Trial⁴

7.1 minutes mean fluoroscopy time

insPIRE Trial²

7.8 minutes mean fluoroscopy time

12-month Effectiveness with Stringent Monitoring

admIRE Trial⁴

85% peak 12-month effectiveness with 73–96 PFA applications for PVI*

*admIRE trial: n=85; 74.6% 12-month primary effectiveness (n=255).

insPIRE Trial³

80% 12-month freedom from AF/AT/AFL with optimal PF applications*

*insPIRE trial: n=158 with ≥ 4 ablations per vein; 75.6% 12-month primary effectiveness (n=186).

Short Ablation Times

admIRE Trial⁴

31 minutes mean PF ablation time

insPIRE Trial²

27 minutes mean PF ablation time

Ordering Information

CARTO™ 3 System V8

Ordering #	Product Name	Description
KT5400600	CARTO™ 3 System V8 Base Upgrade Kit	CARTO™ 3 System V8 Base Upgrade Kit
KT5400631	VARIPULSE™ Service Pack Software	VARIPULSE™ Service Pack V8 Kit

VARIPULSE™ Catheter

Ordering #	Product Name	Description
D141201	VARIPULSE™ Bi-Directional Catheter	Multielectrode, variable loop pulsed field ablation catheter

TRUPULSE™ Generator

Ordering #	Core System Kit	
D141701	TRUPULSE™ Generator Kit, Worldwide	
D143201	TRUPULSE™ Remote Monitor, Worldwide	+ = included in Core System Kit
D139701	nGEN™ Pump, Worldwide	o = not included and recommended
Ordering #	Installation Accessories	
MA5402330	Ablation Cart	o
MA5402340	Arm to allow installation of nGEN™ Monitor on Ablation Cart	o
M549104SP	Clamp, Pump to IV Pole	+
M717701SP	Foot Pedal with Ferrite, 4.9 m (for use with nGEN™ or TRUPULSE™ Generators)	+
Ordering #	Catheter Interface Cables	
D133701	Interface Cable, VARIPULSE™ Catheter to Generator (Orange – Orange)	o
Ordering #	System Interface Cables	
M589709SP	USB communication cable from console to monitor	+
M581001SP	Generator to CARTO™ 3 System cable	+
M581101SP	Cable, ECG Stimulator, 2 m (6.5 ft)	+
M589704SP	Ethernet cable, 10 m (33 ft)	+
M589705SP	Ethernet cable, 23 m (75 ft)	+
M589710SP	Ethernet cable, 46 m (150 ft)	
M717801SP	Ethernet Cable Isolator & Locker	+
M600301SP	Cable, Console to Pump, 5 m (16.4 ft) (Blue - Blue)	+
M5831151SP	Remote monitor USB Fiber Optic Cable, 30 m (100 ft)	+
M5831152SP	Remote monitor HDMI Fiber Optic Cable, 30 m (100 ft)	+
M5831211SP	Remote monitor USB Fiber Optic Cable, 10 m (33 ft)	
M5831157SP	Remote monitor HDMI Fiber Optic Cable, 10 m (33 ft)	
M5831212SP	Remote monitor USB Fiber Optic Cable, 50 m (165 ft)	
M5831158SP	Remote monitor HDMI Fiber Optic Cable, 50 m (165 ft)	+
CW098015F	Adapter to connect both TRUPULSE™ and nGEN™ Generators to CARTO™ 3 System Workstation	o
Ordering #	System Power Adapters	
M714610SP	AC Power Cord, Generator Power Supply Unit, 3 m (10 ft) - EU Standard	+
M714602SP	AC Power Cord, Generator Power Supply Unit, 3 m (10 ft) - United Kingdom	
M714606SP	AC Power Cord, Generator Power Supply Unit, 3 m (10 ft) - Israel	
M714607SP	AC Power Cord, Generator Power Supply Unit, 3 m (10 ft) - Switzerland	
M714612SP	AC Power Cord, Generator Power Supply Unit, 3 m (10 ft) - Denmark	
M5831109SP	Power Supply Cable, Console to Primary Monitor, 2 m (6.5 ft)	+
M649010SP	AC Power Cord, nGEN™ Pump, 3 m (10 ft) - EU Standard	+
M649002SP	AC Power Cord, nGEN™ Pump, 3 m (10 ft) - United Kingdom	
M649006SP	AC Power Cord, nGEN™ Pump, 3 m (10 ft) - Israel	
M649007SP	AC Power Cord, nGEN™ Pump, 3 m (10 ft) - Switzerland	
M649012SP	AC Power Cord, nGEN™ Pump, 3 m (10 ft) - Denmark	
M5831156SP	Power Supply Cable, Remote Monitor Adapter	+
M5831149SP	TRUPULSE™ Remote Monitor Power Supply Cable SP	+
Ordering #	Irrigation Tubing	
SAT001	Irrigation Tubing Set	o

VARIPULSE™ Platform

1. Grimaldi M, Quadrini F, Caporusso N, et al. Deep sedation protocol during atrial fibrillation ablation using a novel variable-loop biphasic pulsed field ablation catheter. *Europace*. 2023;25(9):eoad222.
2. Duytschaever M, De Potter T, Grimaldi M, et al. Paroxysmal Atrial Fibrillation Ablation Using a Novel Variable-Loop Biphasic Pulsed Field Ablation Catheter Integrated With a 3-Dimensional Mapping System: 1-Year Outcomes of the Multicenter insPIRE Study. *Circ Arrhythm Electrophysiol*. 2023;16(3):e011780.
3. De Potter T, Grimaldi M, Duytschaever M, et al. Predictors of Success for Pulmonary Vein Isolation With Pulsed-field Ablation Using a Variable-loop Catheter With 3D Mapping Integration: Complete 12-month Outcomes From insPIRE. *Circ Arrhythm Electrophysiol*. 2024;17(5):e012667.
4. Reddy V, Calkins H, Mansour M, et al. Pulsed field ablation to treat paroxysmal atrial fibrillation: safety and effectiveness in the AdmiRE pivotal trial. *Circulation*. 24;150(15):1174-1186.

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions. This publication is not intended for distribution outside of the EMEA region.

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