

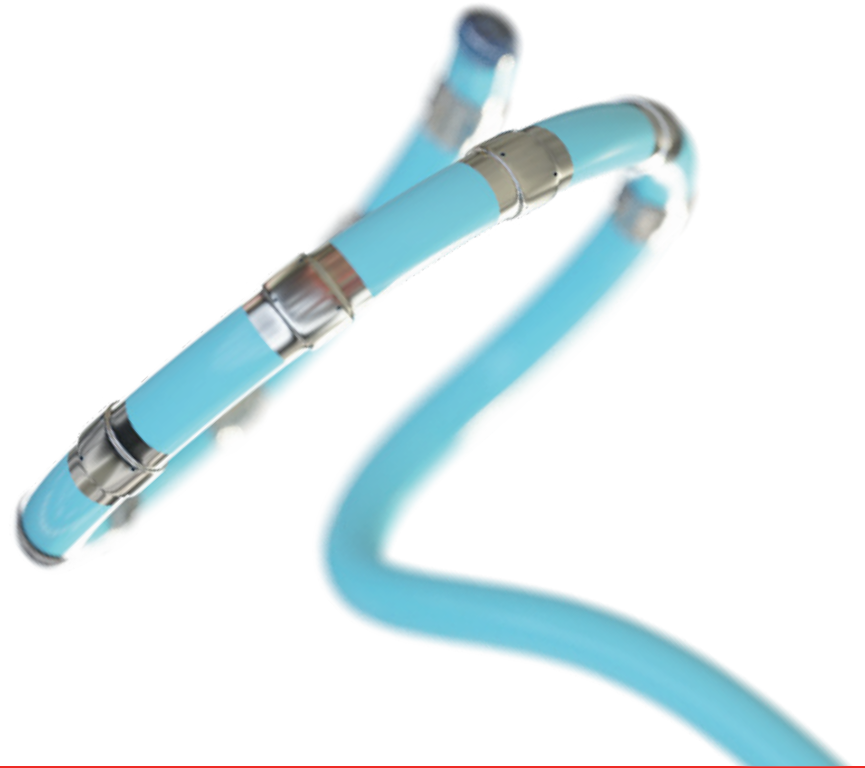
# VARIPULSE™ Platform

Pulsed Field Ablation.  
CARTO integration.



Johnson & Johnson  
MedTech

# Intuitive. Versatile. Reproducible.



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.

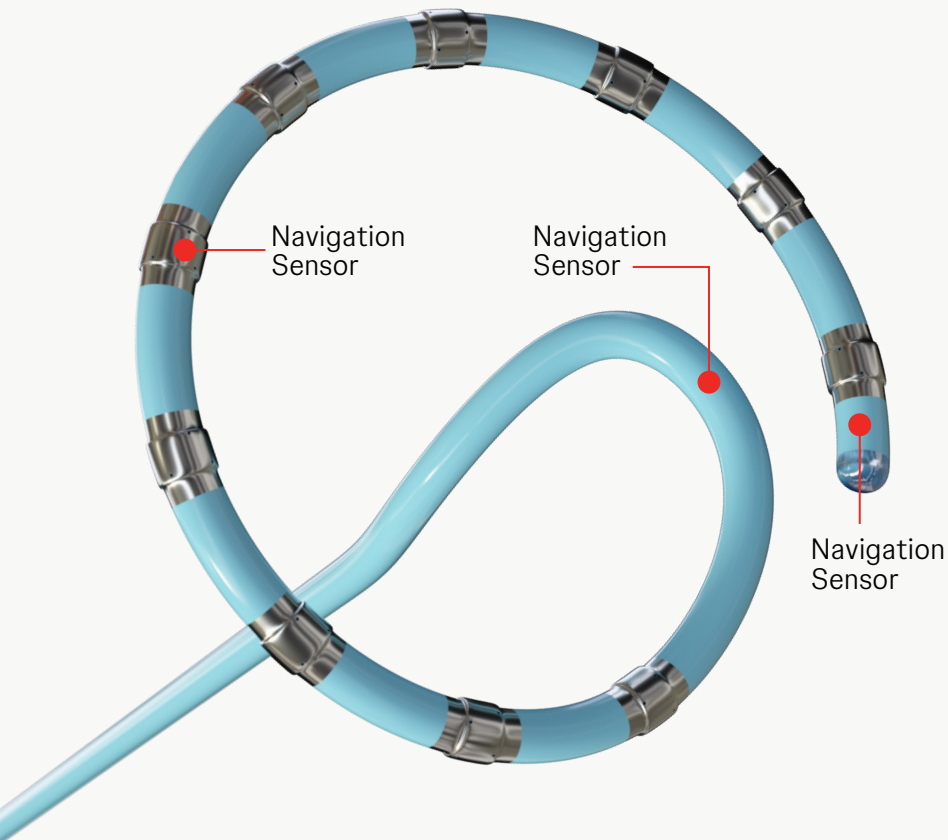
The VARIPULSE™ Platform enables efficient, patient-centric therapy delivery with a simple integration. In conjunction with Johnson & Johnson MedTech's fully integrated portfolio, you have a single solution to scale between simple and complex ablations, reducing the complexity of managing your day in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

# VARIPULSE™ Catheter

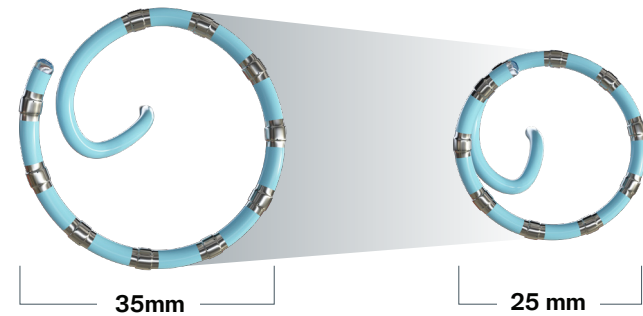
The VARIPULSE™ Catheter's full integration may reduce the need for multiple methods of catheter visualization used in one procedure, creating a streamlined workflow.

## Designed for mapping integration

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



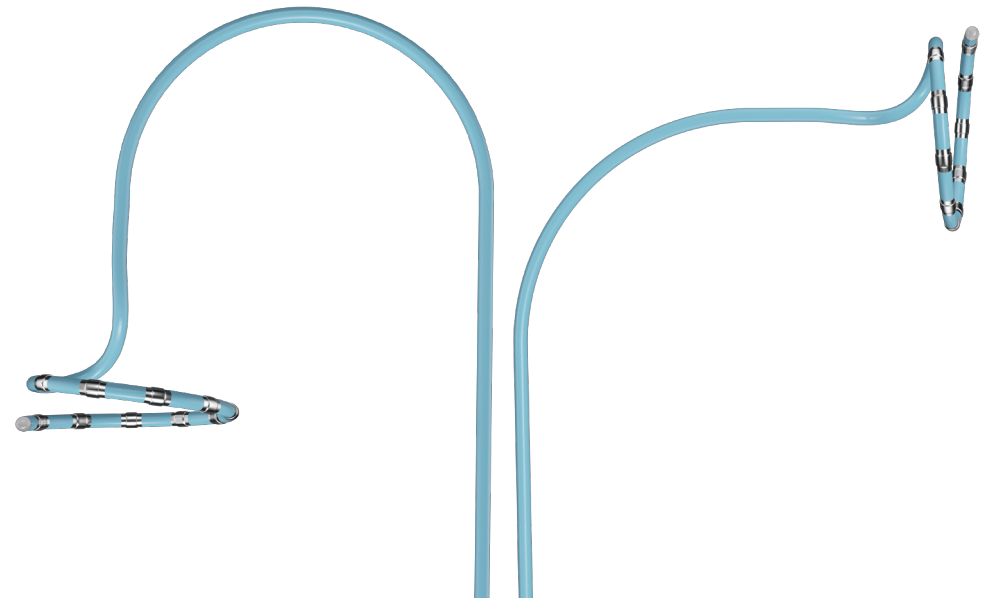
## 35 mm to 25 mm variable loop contraction



- 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.

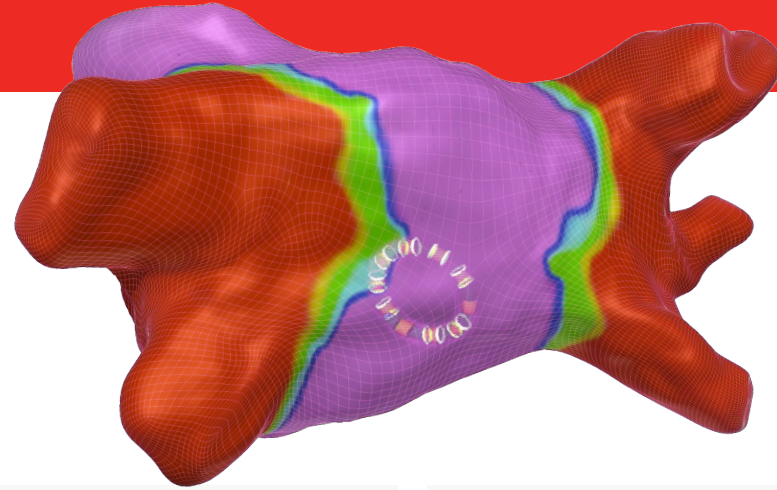
## Bi-directional deflection

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

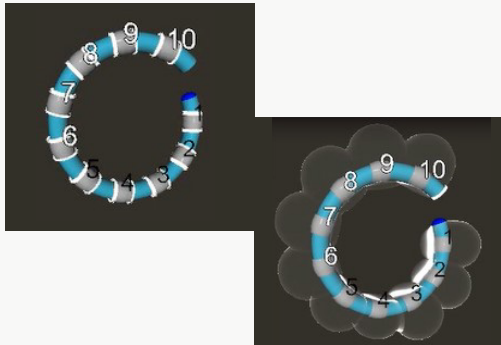


# Pulsed Field Ablation. CARTO integration.

The integrated VARIPULSE™ Platform is designed to deliver ablations at precise locations.\* 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.<sup>‡2</sup>

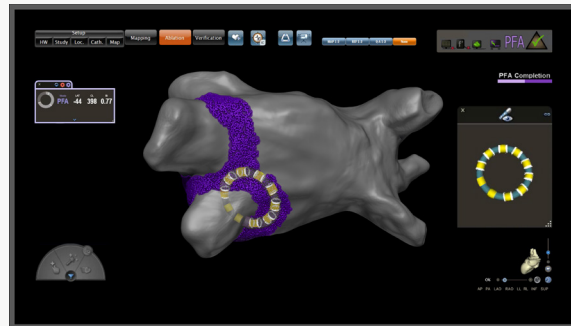


## Tissue proximity indicator



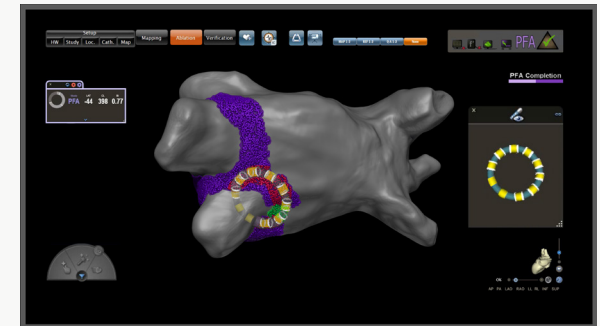
Through pre-clinical studies, Johnson & Johnson MedTech has demonstrated that contact is important to create consistent lesion depth during the ablation.<sup>†</sup> The Tissue Proximity Indicator is designed to visually show the electrodes on the loop that have contact prior, during and after ablation.

## Pulsed field tag coloring



The VARIPULSE™ Software Module provides automatic 3D visual information about application locations during and after ablation. Pulsed Field (PF) tag coloring provides application feedback during the ablation and the TPI filter removes tags that were not in proximity to tissue at the beginning of 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 for initial PVI and identification of gaps when needed, providing physicians with the confidence of an accurate CARTO™ 3 System ecosystem they know.<sup>2</sup>

\* Precise in that it is marked on CARTO™ screen.

† Based on internal benchtop data. TR-0042284.

‡ When used with the CARTO™ 3 System.

# TRUPULSE™ Generator



The TRUPULSE™ Generator delivers a unique bi-polar, bi-phasic pulse sequence specifically tailored for the VARIPULSE™ Catheter design.



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

# Clinically deliver<sup>5</sup>



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.

## Favorable safety profile

admIRE Trial<sup>4</sup>

**2.9%** primary adverse events\*

\*admIRE trial: N=277. Adverse events could include pericarditis, tamponade, TIA/stroke, access complications.

insPIRE Trial<sup>3</sup>

**0%** primary adverse events\*

\*insPIRE trial: n=176 with ≥ 4 ablations per vein. Adverse events could include pericarditis, tamponade, TIA/stroke, access complications.

## Full CARTO™ 3 System integration minimizes fluoroscopy exposure

admIRE Trial<sup>4</sup>

**7.1 minutes** mean fluoroscopy time

When used with CARTO™ 3 System and intracardiac ultrasound.

insPIRE Trial<sup>2</sup>

**7.8 minutes** mean fluoroscopy time

insPIRE trial n=176 with ≥ 4 ablations per vein.

## 12-month effectiveness demonstrated

admIRE Trial<sup>4</sup>

**85%** peak 12-month effectiveness with 73-94 PFA applications\*

admIRE trial: n=85.

insPIRE Trial<sup>3</sup>

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

\*insPIRE trial: n=176 with ≥ 4 ablations per vein.

## Short ablation times

admIRE Trial<sup>4</sup>

**31 minutes** median PF ablation time

In the admIRE study.

insPIRE Trial<sup>2</sup>

**27 minutes** mean PF ablation time

insPIRE trial n=176 with ≥ 4 ablations per vein.



# Ordering information

+ = included in Core System Kit  
o = not included and recommended

VARIPULSE™ Catheter	<b>Ordering #</b>	<b>Product Name Description</b>	
	D141201	VARIPULSE™ Bi-Directional Catheter Multielectrode, variable loop pulsed field ablation catheter	
	D133701	Interface Cable, VARIPULSE™ Catheter to Generator (Orange – Orange)	
TRUPULSE™ Generator System and CARTO™ Software	<b>Ordering #</b>	<b>Irrigation Tubing</b>	
	SAT001	Irrigation Tubing Set	
	<b>Ordering #</b>	<b>Product Name Description</b>	
TRUPULSE™ Generator System and CARTO™ Software	TRUPULSE	TRUPULSE™ Core System Kit, includes:	
	D141702	TRUPULSE™ Generator Kit	+
	D143202	TRUPULSE™ Remote Monitor	+
	CW098015F	TRUPULSE™ and nGEN™ Generators to CARTO™ 3 System Workstation Adapter	+
	KT-5400-600ESA	CARTO™ 3 System V8 Base Upgrade Kit	+
	KT-5400-631E	VARIPULSE™ Service Pack Software	+
TRUPULSE™ Generator System Accessories	<b>Ordering #</b>	<b>Installation Accessories</b>	
	D139702	Irrigation Pump (Same Pump is Compatible with Both TRUPULSE™ System and nGEN™ System)	o
	MA5402330	Ablation Cart	o
	MA5402340	Monitor Arm (Allows Installation of nGEN™ Monitor on Ablation Cart)	o
	M549104SP	Clamp, Pump to IV Pole (Included with Pump)	
TRUPULSE™ Generator System Spare Parts and Accessories	M717701SP	Foot Pedal with Ferrite, 4.9 m	+
	<b>Ordering #</b>	<b>System Interface Cables</b>	
	M589709SP	Cable, USB Communication from Console to Monitor	+
	M581001SP	Cable, Generator to CARTO™ 3 System	+
	M581101SP	Cable, ECG Stimulator, 2 m (6.5 ft)	+
	M589704SP	Ethernet Cable, 10 m (33 ft) (TRUPULSE™ Monitor to CARTO™ Workstation)	+
	M589705SP	Ethernet Cable, 23 m (75 ft) (TRUPULSE™ Monitor to CARTO™ Workstation)	+
	M589710SP	Ethernet Cable, 46 m (150 ft) (TRUPULSE™ Monitor to CARTO™ Workstation)	
	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)	
	<b>Ordering #</b>	<b>System Power Adapters</b>	
	M714601SP	AC Power Cord, Generator Power Supply Unit, 3 m (10 ft)	+
	M5831219SP	Power Supply Cable, Primary Monitor	+
	M5831156SP	Power Supply Cable, Remote Monitor Adapter	+
	M5831149SP	TRUPULSE™ Remote Monitor Power Supply Cable SP	+
	M529723SP	AC Adaptor, Irrigation Pump	o
	M649001SP	AC Power Cord for Irrigation Pump or TRUPULSE™ Remote Monitor, 3 m (10 ft)	+

# 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):eua222.
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.
5. TRUPULSE™ Generator User Manual (Software 2.2.0). EML-1417-01-IFU-B-EN.  
Reddy V, et al. Long-term Safety and Effectiveness After Paroxysmal Atrial Fibrillation Pulsed Field Ablation From the U.S. Multicenter admIRE Study. *Heart Rhythm Society*. Published May 17, 2024.

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.

Caution: US law restricts this device to sale by or on the order of a physician.

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