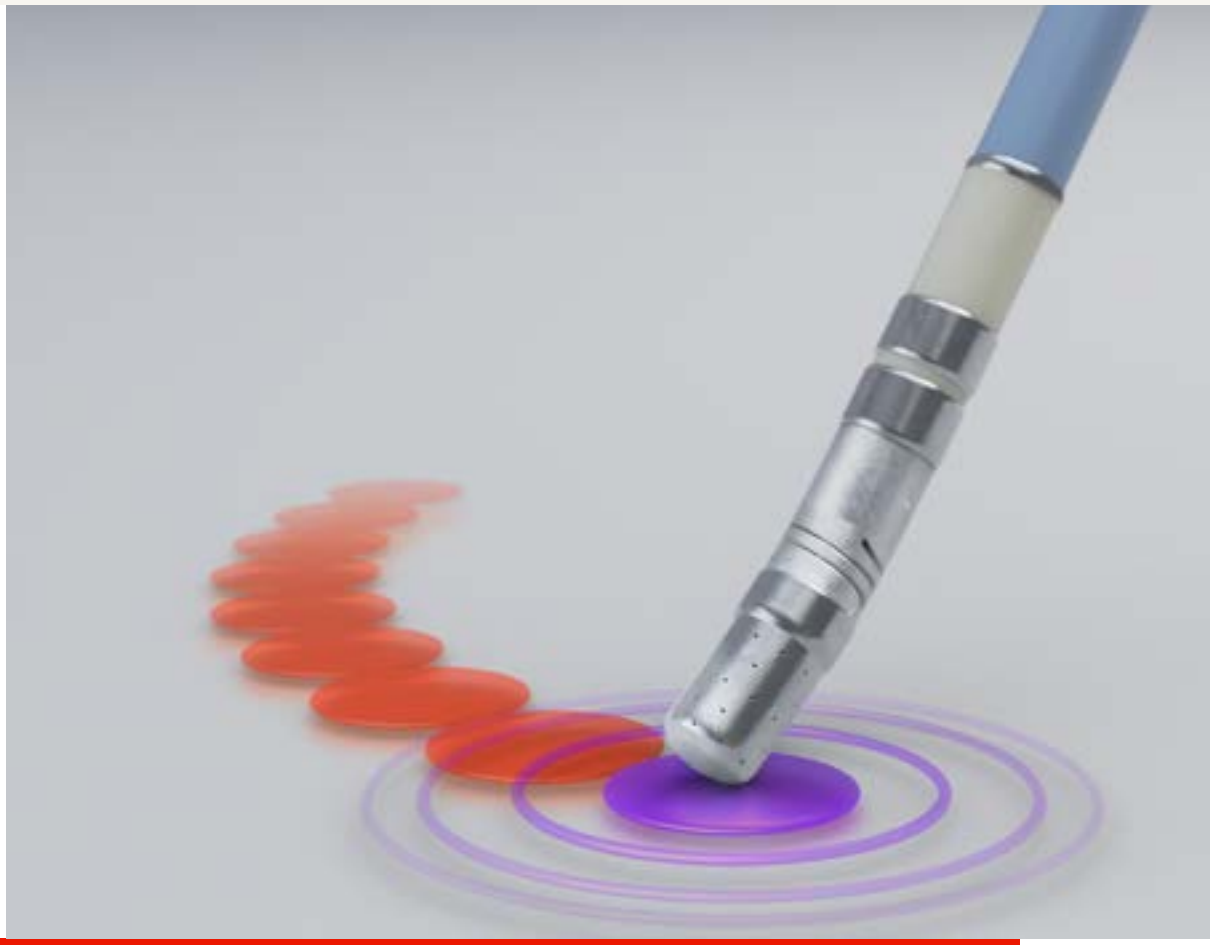
Dual Energy THERMOCOOL SMARTTOUCH™ SF Platform

Johnson&Johnson
MedTech

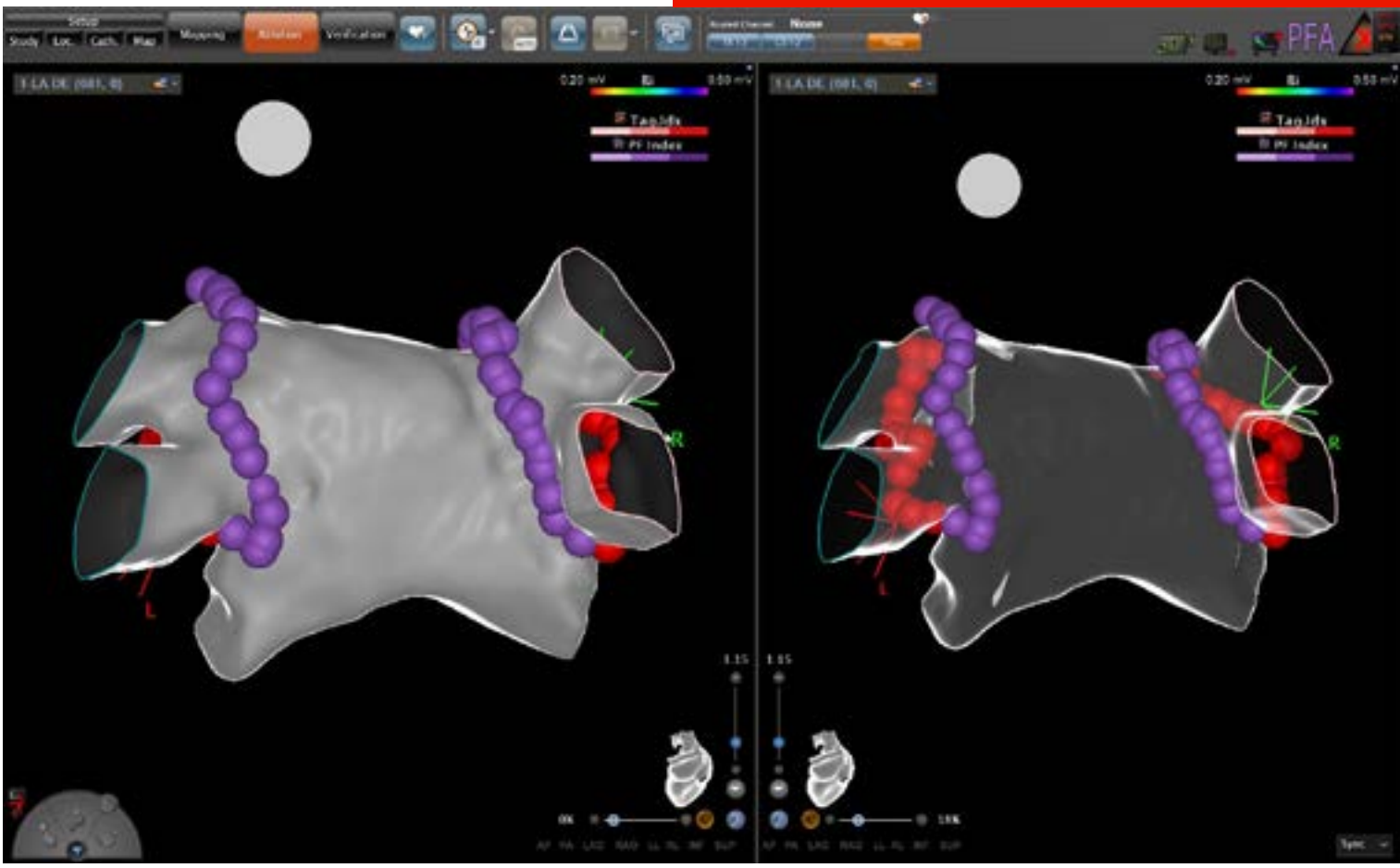


The THERMOCOOL SMARTTOUCH™ SF Catheter, a globally trusted catheter with extensive clinical validation, has treated over a million patients worldwide. By integrating pulsed field ablation energy, the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter offers flexibility with both RF and PF energy in a single procedure.

Choose your energy.[1]

Customize your care.[1]

The ability to choose your energy modality provides flexibility to treat each patient individually and deliver the specific energy required for every case.[1]



TRUPULSE™ Generator with Connection Interface Unit

Choose your energy.[1]

Powered by the TRUPULSE™ Generator, you can confidently select the appropriate energy modality for each part of the procedure, delivering personalized care while ensuring the safety of critical areas.[1]

Enabled by the TRUPULSE™ Connection Interface Unit

- Integration with CARTO™ 3 System presents physicians with contact force measurement and PF index*[4]
- Streamlined connection point for Johnson & Johnson MedTech's electrophysiology catheters
- Deliver a unique uni-polar, bi-phasic pulse sequence specifically tailored for the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter design, and bi-polar, bi-phasic pulse sequence for the VARIPULSE™ Catheter[1]

The dual energy mode provides the advantage of quickly switching between both energy modes during the ablation procedure.[2]

*The CARTO VISITAG™ Module provides access to data collected during the application of energy.
•The Tag Index values should not be used to guide energy delivery.

Dual Energy
THERMOCOOL SMARTTOUCH™ SF Catheter

Customize your care.[1]

The Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter builds on the proven foundation of the THERMOCOOL SMARTTOUCH™ SF Catheter, a globally trusted device that has treated over a million patients worldwide.

Integrating pulsed field ablation energy into this established platform

- Offers the ability to adapt in the moment, providing treatment options with the benefits of a single catheter equipped with both RF and PF energy
- Enables flexibility to customize treatment depending on the patient anatomy and clinical need with 3.5mm focal tip catheter
- Provide operators with enhanced procedural flexibility on a familiar catheter platform[3]

12M effectiveness

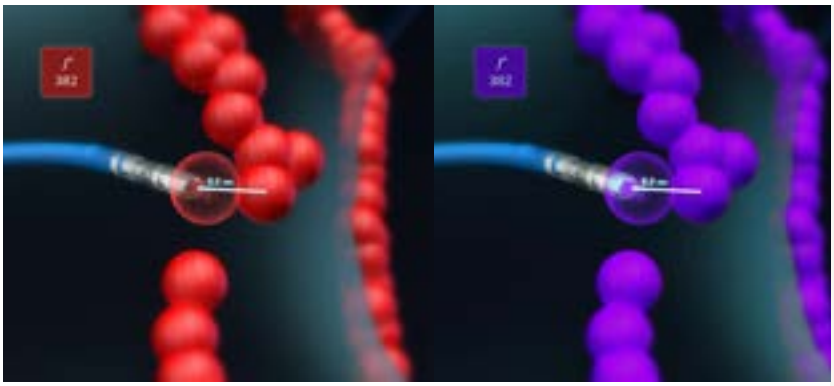
87% with the adherence to recommended ablation workflow SmartfIRE (n=47)

Notably high safety using PF energy

0 esophageal injuries (0 out of 31, or 0%). No coronary artery spasms or phrenic nerve damage (n=137)[3]

Power. Contact Force. PF Index.

The Dual Energy THERMOCOOL SMARTTOUCH™ SF Platform integrates seamlessly with VISITAG SURPOINT™ PF Index and is designed for precision and performance.

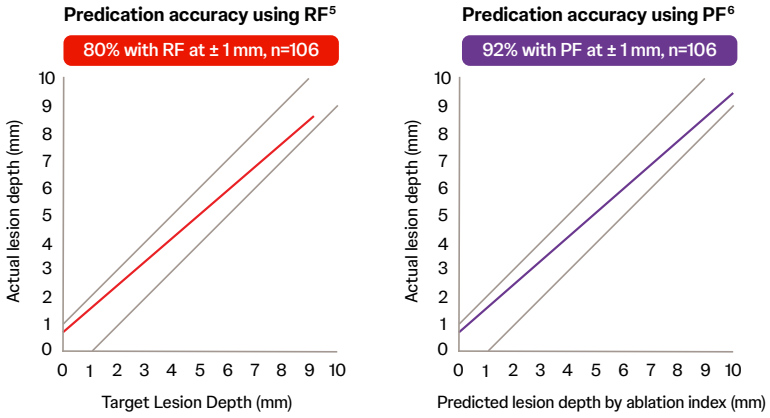


Index guided reproducibility

The **VISITAG SURPOINT™ PF Index** was developed and validated based on its correlation with contact force and PF applications, highlighting the importance of contact force in focal PF ablation.

Its purpose is to standardize reproducible ablation strategies using PF energy comparable to the established VISITAG SURPOINT™ Module Tag Index.*[4]

*The CARTO VISITAG™ Module provides access to data collected during the application of energy. The Tag Index values should not be used to guide energy delivery.

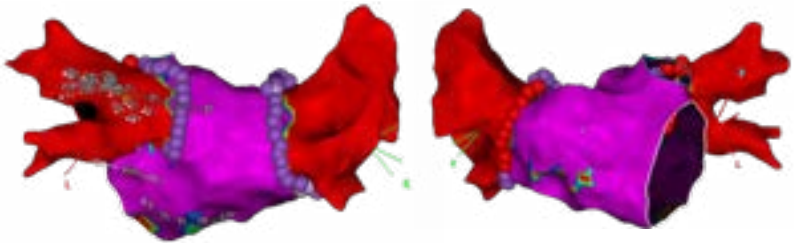


Preclinically validated accuracy

Pre-clinical studies demonstrated that the VISITAG SURPOINT™ PF Index provides lesion prediction accuracy comparable to the Surpoint Tag Index used in RF ablations.

92% with PF at ± 1.0mm PF Index prediction accuracy[†7]

[†]Statement is based on a single center study. Value is based off of preclinical data.



Recommended PVI workflow
- Interlesion distance: ≤6 mm Tag Size: 3mm
- Ablation index: ≥400 posteriorly and 550 anteriorly
- PF at posterior/inferior and RF at anterior/ridge/carina

Clinically demonstrated success

The SmartfIRE study demonstrated the long-term effectiveness for the treatment of PAF.

72% with 12-month freedom from recurrence with stringent monitoring[8]

87% effectiveness with high adherence to recommended ablation workflow[8]

149 patients enrolled between February and June 2023.

Consistent workflow. Trusted experience.

Integrated with the familiar CARTO™ 3 ecosystem you know and trust to optimize your day

The workflow you choose matters.
When you use a system you trust, you can focus on what's important: delivering exceptional patient care.

The Dual Energy THERMOCOOL SMARTTOUCH™ SF platform offers flexibility and control, providing a consistent workflow that supports reliable, reproducible focal ablation outcomes in every procedure.

High PVI durability

87% durable PVI after 3M remap (n=30)

Conscious sedation compatibility

15% of patients successfully undergoing the procedure under conscious sedation (n=20)[3]

Minimal fluoro exposure

<1 one minute of fluoroscopy time during ablation achieved*[3]

*When used with CARTO™ 3 System and ultrasound.

Always verify catheter tip location using common clinical practice for real-time verification (inspection of IC signals, direct imaging guidance such as fluoroscopy or ultrasound, etc.) and consult the CARTO™ 3 System User Guide regarding recommendations for fluoroscopy use.

Canpolat, U. et al (2020). State of Fluoroless Procedures in Cardiac Electrophysiology Practice. J Innov Cardiac Rhythm Management. 11(3), 4018–4029.
Sommer, P. et al (2018) Safety profile of near-zero fluoroscopy atrial fibrillation ablation with non-fluoroscopic catheter visualization: experience from 1000 consecutive procedures, EP Europace, Volume 20, Issue 12, Pages 1952–1958.

Integrated by design

to elevate your experiences

Our ‘Integrated by Design’ approach goes far beyond a portfolio.[11]

Our suite of products have been designed and engineered to work seamlessly together, ensuring optimal functionality and compatibility.[11]

Ordering information

Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter

Ordering #	Description
D134711	Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter - Unidirectional – D
D134712	Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter - Unidirectional – F
D134713	Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter - Unidirectional – J
D134811	Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter - Bi-directional – DD
D134814	Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter - Bi-directional – FJ
D134815	Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter - Bi-directional – DF

CARTO™ 3 System V8.5

Ordering #	Description
KT5400700	CARTO™ 3 System V8.5 Upgrade Kit
KT5400731	VARIPULSE™ SPx.x. V8.5 Installation Kit
KT5400735	Dual Energy STSF SPx.x V8.5 Inst. Kit
KT5400725	VISITAG SURPOINT™ DUAL EN. SP V8.5KT
KT5400750	LAM Module V8.5 Kit
KT5400755	CARTO ELEVATE™ Module V8.5 Kit
KT5400780	CARTOSOUND™ FAM Module V8.5 Kit
KT5400720	VISITAG SURPOINT™ V8.5 KIT
KT5400790	SOUNDSTAR CRYSTAL™ SP V8.5 Kit

TRUPULSE™ Generator with Connection Interface Unit

Ordering #	Description
TRUPULSE Generator	TRUPULSE™ Core system kit
D141701	TRUPULSE™ Generator Kit
D143201	TRUPULSE™ Remote Monitor Kit
CW098015F	TRUPULSE™ and nGEN™ Generators to CARTO™ 3 System Workstation Adapter
Connection Interface Unit (CIU)	**Connection Interface Units Core Kit**
M5831217	TRUPULSE™ Connection Interface Unit (CIU) Kit
M5831188	CIU Integrated Cart
M5831282	CIU Cart Single Monitor Arm
M5831283	CIU Cart Dual monitor Arm
M724001	TRUPULSE™ CIU Software Upgrade Kit
M5831245	Recording System Kit

Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter

1. Mattias Duytschaever, Gediminas Račkauskas, Tom De Potter, et al. Dual energy for pulmonary vein isolation using dual-energy focal ablation technology integrated with a three-dimensional mapping system: SmartfIRE 3-month results. EP Europace, Volume 26, Issue 5, May 2024, euae088, https://doi.org/10.1093/europace/euae088.

   Dual Energy THERMOCOOL SMARTTOUCH™ SF Bi-Directional Catheter Instruction for Use. M-5276-1122XB.
2. TRUPULSE General User Manual. EML-1417-01-IFU.02-XB0EN. Sept. 13, 2024.
3. Mattias Duytschaever, Gediminas Račkauskas, Tom De Potter, et al. Dual energy for pulmonary vein isolation using dual-energy focal ablation technology integrated with a three-dimensional mapping system: SmartfIRE 3-month results EP Europace, Volume 26, Issue 5, May 2024, euae088, https://doi.org/10.1093/europace/euae088.
4. AB-452672-1 EFFECTS OF ELECTRODE CONTACT FORCE ON LESION SIZE PRODUCED BY PULSED FIELD ABLATION Hiroshi Nakagawa, Salman Farshchi, Jennifer Maffre, Tushar Sharma, Assaf Govari, Christopher Beekler, Andres Altmann, Atsushi Ikeda, Masafumi Sugawara, Ayman A. Hussein, Shady Nakhla, Pasquale Santangeli, Walid I. Saliba, Oussama M. Wazni DOI:https://doi.org/10.1016/j.hrthm.2023.03.394.

   Mattias Duytschaever, Gediminas Račkauskas, Tom De Potter, et al. Dual energy for pulmonary vein isolation using dual-energy focal ablation technology integrated with a three-dimensional mapping system: SmartfIRE 3-month results EP Europace, Volume 26, Issue 5, May 2024, euae088, https://doi.org/10.1093/europace/euae088.

   Hiroshi Nakagawa, MD, PhD, Salman Farshchi-Heydari, MD, et al. Evaluation of Ablation Parameters to Predict Irreversible Lesion Size During Pulsed Field Ablation Circulation: Arrhythmia and Electrophysiology, Volume 17, Number 8 https://www.ahajournals.org/doi/full/10.1161/CIRCEP.124.012814.

   CARTO® 3 System V7.9 with PFA THERMOCOOL SMARTTOUCH® SF Support Instructions for Use and Release Notes..
5. Figures adapted from HRS 2013, Nakagawa H. et all. MP03-4-Prospective Study to Test the ability to create RF lesions at predicted depths of 3,5,7,9 mm using a new formula incorporating contact force, radiofrequency power and application time (Force, Power, Time Index) in the beating Canine Heart.
6. Figures adapted from Nakagawa H. How Deep Can we go with PFA? Measuring Lesion Depth, Presentation at the AF Symposium, Boston, MA, Jan. 2025. Pending formal publication.
7. Taghji P, El Haddad M, Phlips T , et al Evaluation of a strategy aiming to enclose the pulmonary veins with contiguous and optimized radiofrequency lesions in paroxysmal atrial fibrillation. A pilot study. J Am Coll cardiol EP January 01, 2018, 4 (1) 99-108.
8. De Potter T, Scherr D, Pürerfellner H, et al. Safety, effectiveness, and healthcare benefits of a dual energy focal ablation technology to treat paroxysmal atrial fibrillation: SmartfIRE 12-month results. Presented at EHRA 2025; March 31, 2025; Vienna, Austria. Pending formal publication.
9. CARTO™ 3 System V8.1.100 with Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter Support Instructions for Use and Release Notes.

   Philippe Taghji, Philippe Taghji, Mattias Duytschaever, et al. Evaluation of a Strategy Aiming to Enclose the Pulmonary Veins With Contiguous and Optimized Radiofrequency Lesions in Paroxysmal Atrial Fibrillation: A Pilot Study. JACC:Clinical Electrophysiology Volume 4, Issue 1, January 2018, Page 99-108.
10. Dual Energy THERMOCOOL SMARTTOUCH™ SF Bi-Directional Catheter Instruction for Use. M-5276-1122XB.
11. CARTO 3 System Instructions for Use, Software Version 8.1. UG-5400-008H (00A).

    nGEN™ Generator User Manual. EML-1384-02-IFU-00.01A.

    QDOT MICRO™ Bi-Directional Navigation Catheter Instructions for Use. M-5276-829G.

    CARTO™ OCTARAY™ Mapping Catheter with TRUEref™ Technology Instructions for Use. M-5276-1116A.

    OPTRELL™ Mapping Catheter with TRUEref™ Technology Instructions for Use. M-5276-1121A.

    CARTO VIZIGO™ 8.5F BI-DIRECTIONAL GUIDING SHEATH Instructions for Use. M-5276-889.03A.

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

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