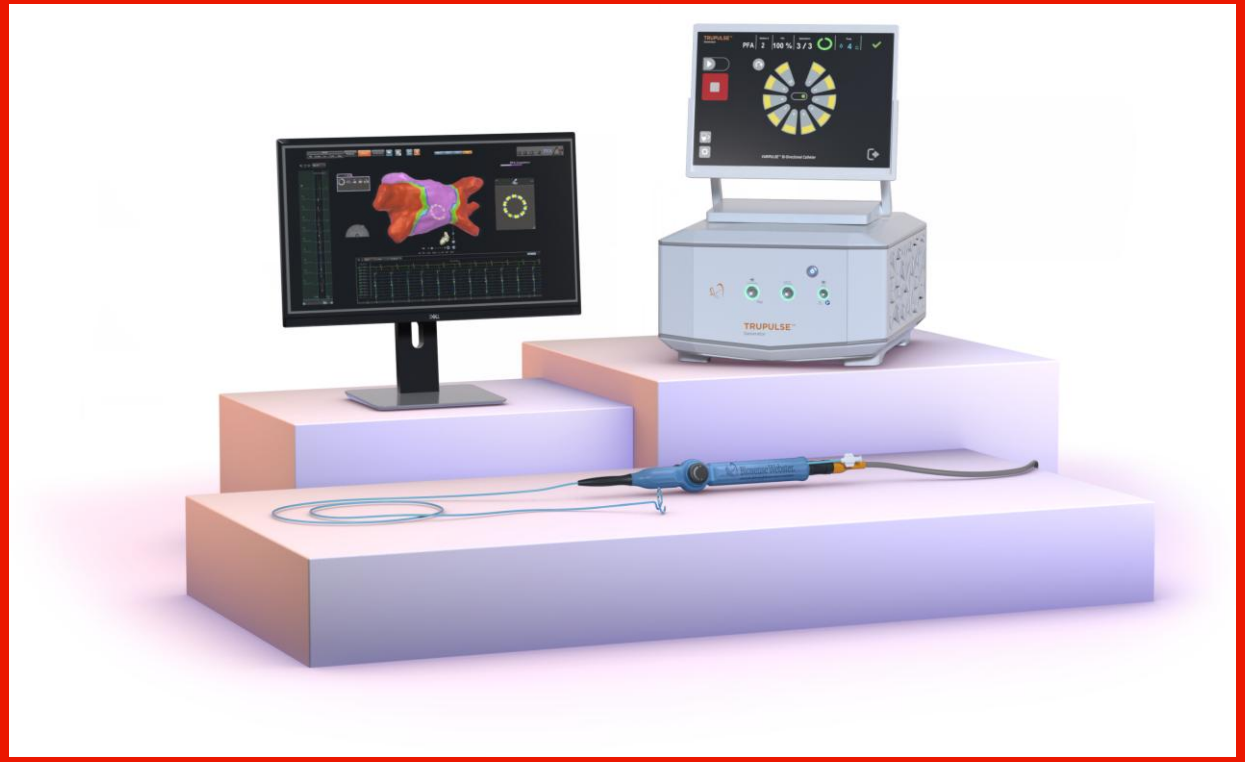
VARIPULSE

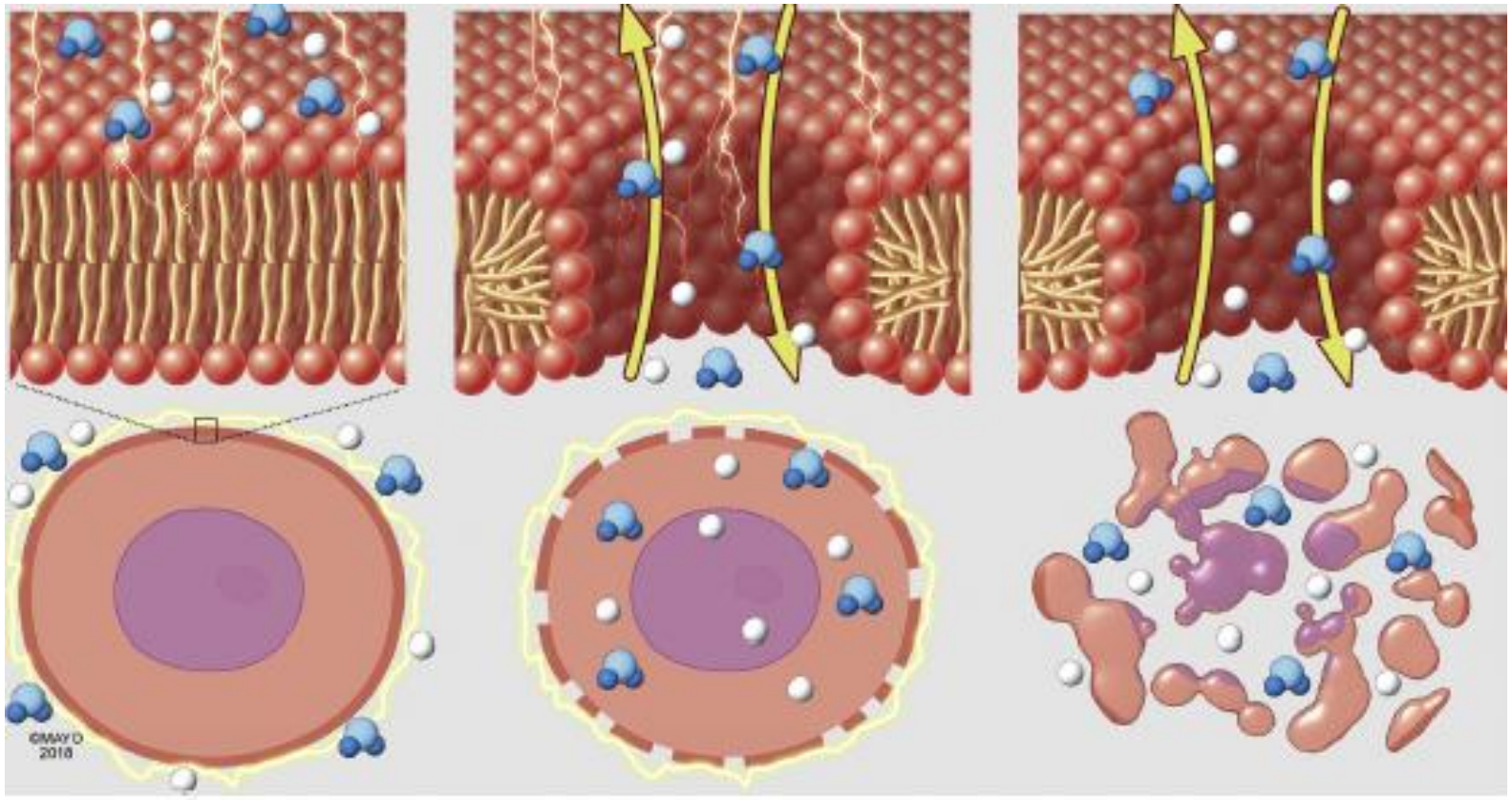


Abubakarr Bah
Subtitle or speaker info
Date
Location
Document status

Johnson&Johnson
MedTech

Electrophysiology

Mechanism of Pulsed Field Ablation (PFA)



Pulsed field ablation refers to application of intermittent, high-intensity electric fields for short periods of time (micro- or nanoseconds).

This results in formation of pores in the cell membranes. Pore formation leads to permeabilization.

Higher-strength electric fields cause dramatic changes in membrane permeability, which leads to cell death--**Irreversible Electroporation (IRE).**
(number of channels & size)

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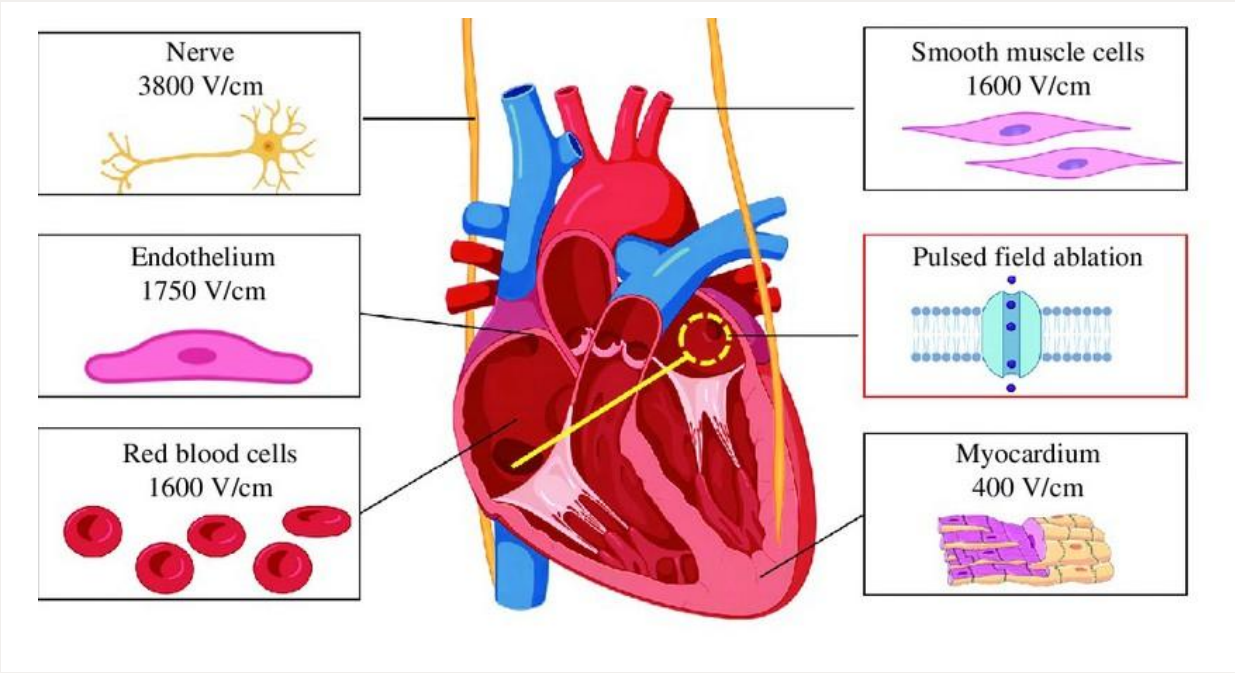
Maor, et al. "Pulsed electric fields for cardiac ablation and beyond: A state-of-the-art review." Heart Rhythm Journal. https://doi.org/10.1016/j.hrthm.2019.01.012

Can EP benefit from this technology?

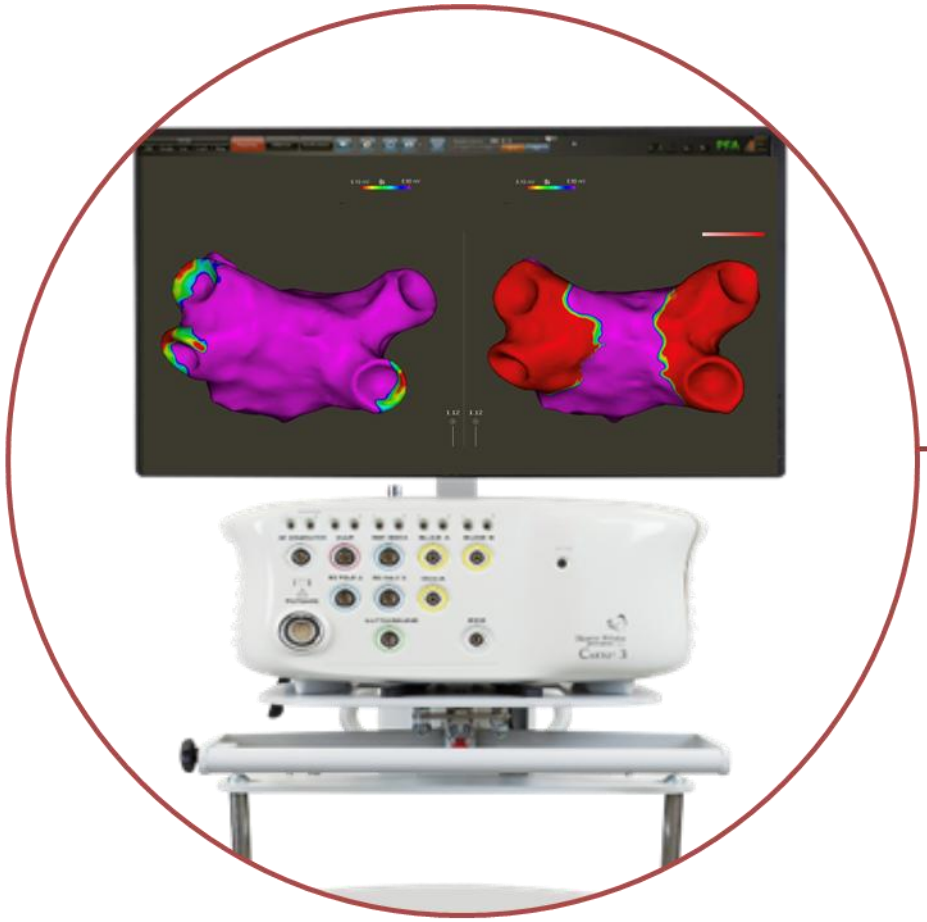
Tissue type	Electroporation threshold (V/ cm)	Reference
Nerve	3800	Li et al. PLOS One 2011
Vascular smooth muscle	1750	Maor et al, PLOS One 2009 (abstract)
Red blood cells	1600	Bao et al, Interg Biol 2010
Liver	700	Sano et al, Biomed Engineering Online, 2010
Kidney	600	Neal et al, IEEE Trans Biomed Eng, 2015
Pancreas	500	Arena et al, Biophys J, 2012
Myocardium	400	Kaminska et al, Gen Physiol Biophys, 2012



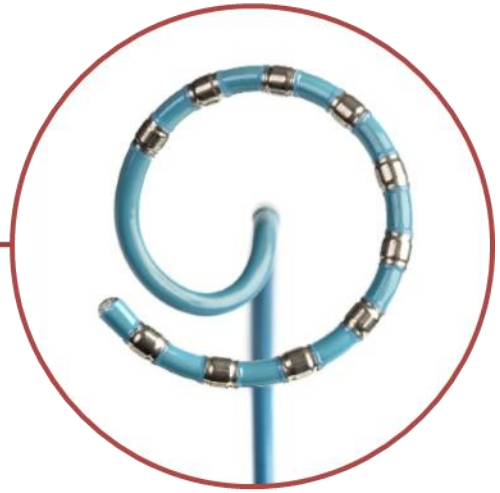
Guo F, Wang J, Zhou L, Wang Y, Jiang H, Yu L. Advances in the Application of Pulsed Field Ablation for Arrhythmia Treatment. Cardiovascular Innovations and Applications. 2023;8(1). doi:https://doi.org/10.15212/cvia.2023.0019

VARIPULSE Platform

TRUPULSE™
Generator



VARIPULSE™
Catheter



TRUPULSE™ Generator

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Electrophysiology

The Power of the TRUPULSE™ Generator

The Power of the TRUPULSE™ Generator

Technical features

- 10 independent HW channels capable of powering each pair
- Automatic PFA catheter identification (dedicated sequence)
- Operating impedance range 100-300 Ohms
- Advanced self testing and troubleshooting capabilities
- Accurate impedance measurement circuits
- Simple touch screen interface for generator interaction

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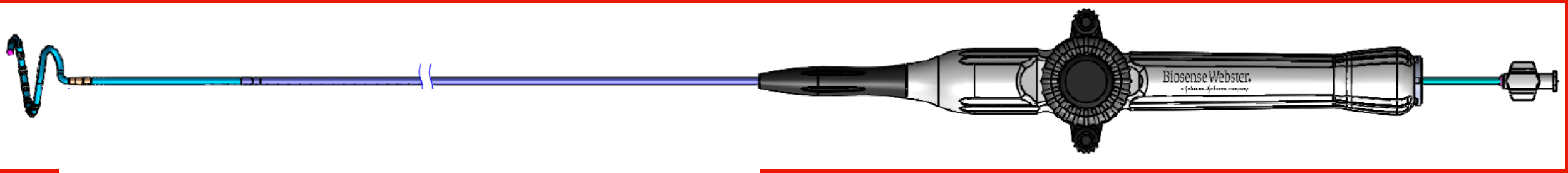
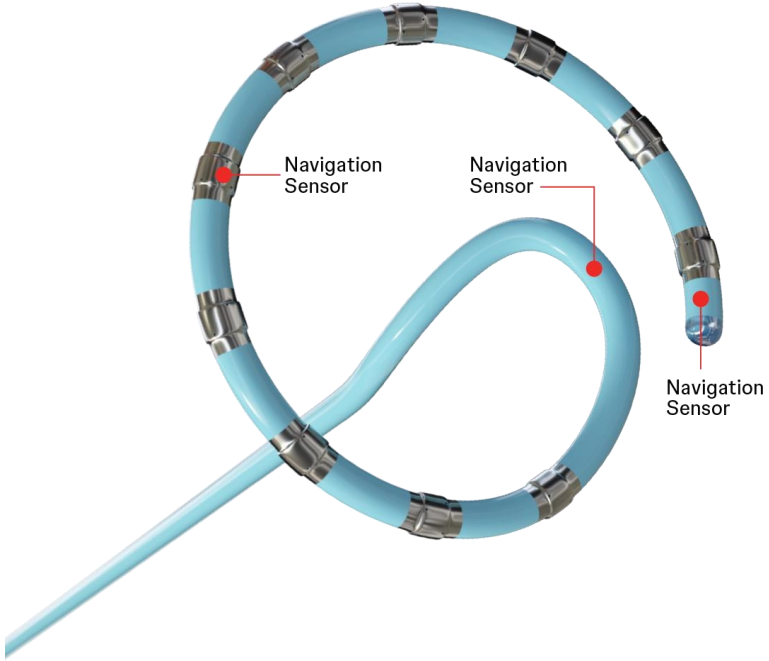
Electrophysiology

VARIPULSE™ Catheter



VARIPULSE™ Catheter

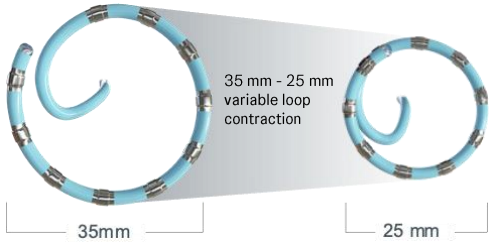
Designed to adapt in the moment



Designed for Mapping Integration

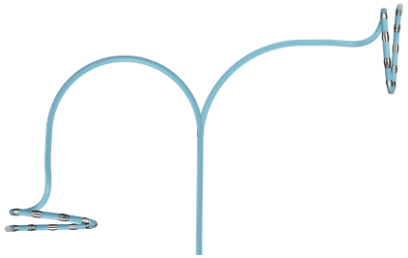
3 Single Axis Sensor locations for accurate visualization on the CARTO™ 3 System.

1. VARIPULSE CATHETER, BI-DIRECTIONAL. D-1412-00; Page 8. 2.CARTO™ 3 System with PFA Support for VARIPULSE™ Catheter Instructions for Use and Release Notes.UG-5440-018H (00A). May 2024;Page 1, Overview, Paragraphs 1 and 2



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.



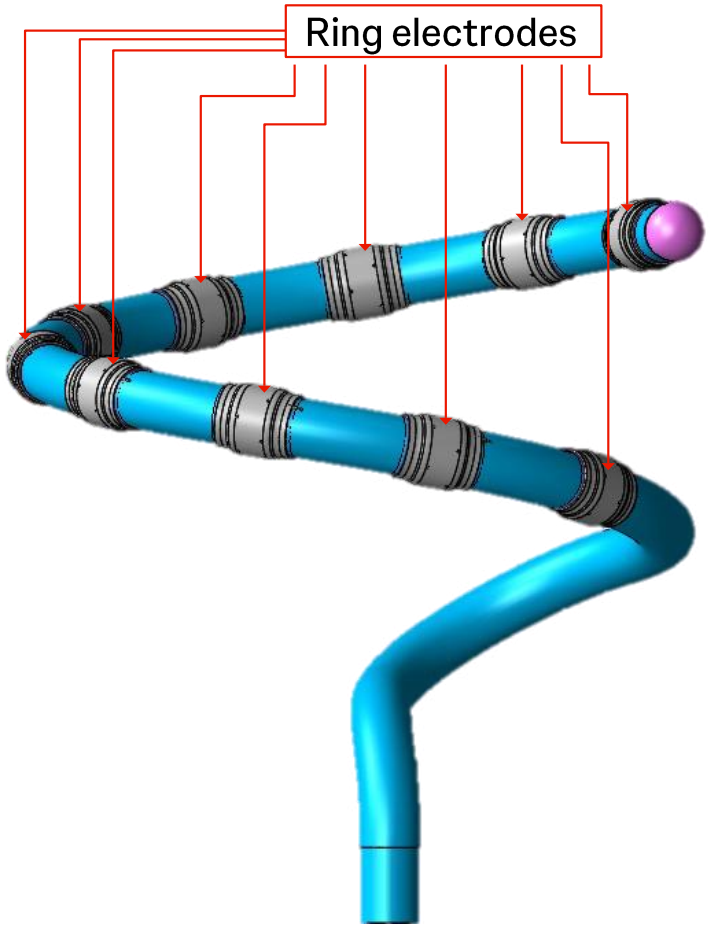
The VARIPULSE™ Catheter is built on a bi-directional, 8 Fr platform compatible with the CARTO VIZIGO™ Bi-Directional Sheath or similar 8.5 F inner lumen sheath.

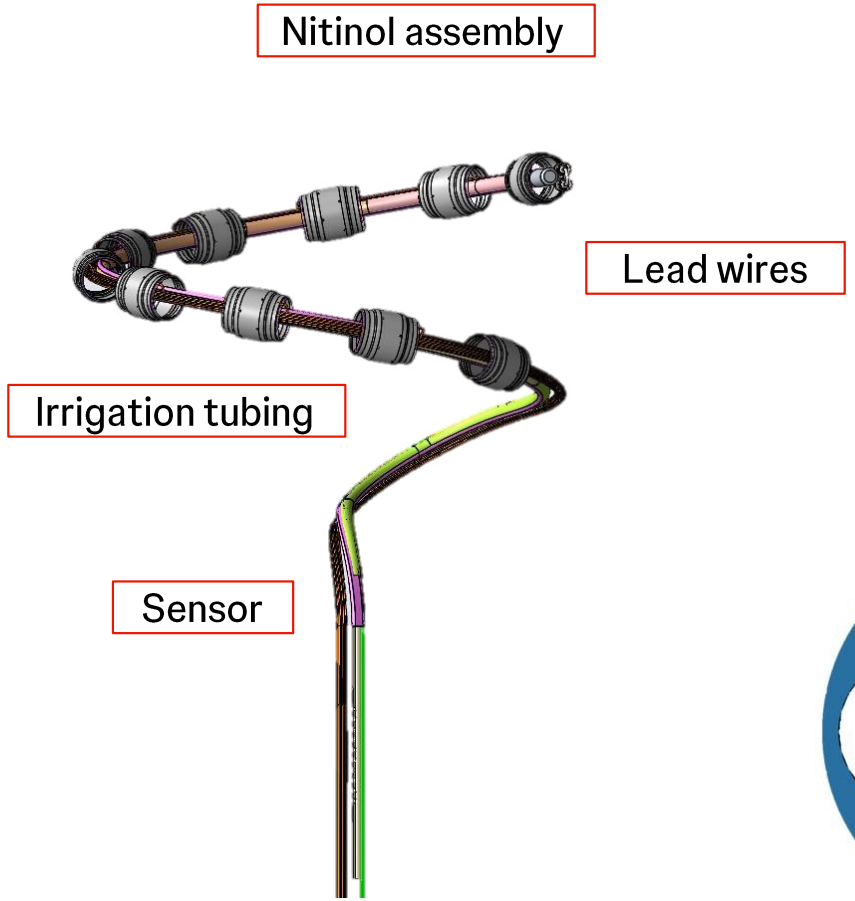
1. CRTM-0653 Rev L, Page 4, Row 26, Column 4.
2. CARTO 3 SYSTEM WITH PFA SUPPORT FOR VARIPULSE™ CATHETER. Instructions for Use and Release Notes. UG-5440-018H (00A); Page 14, "Catheter Visualization" sentence

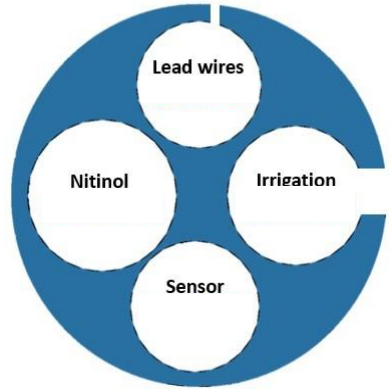
Electrophysiology
J&J MedTech

Nair DG, Gomez T, De Potter T. VARIPULSE: A step-by-step guide to pulmonary vein isolation. J. Cardiovasc Electrophysiol. 2024;35(9):1817-1827. doi:10.1111/jce.16366

Loop Tip Components & Assembly Process





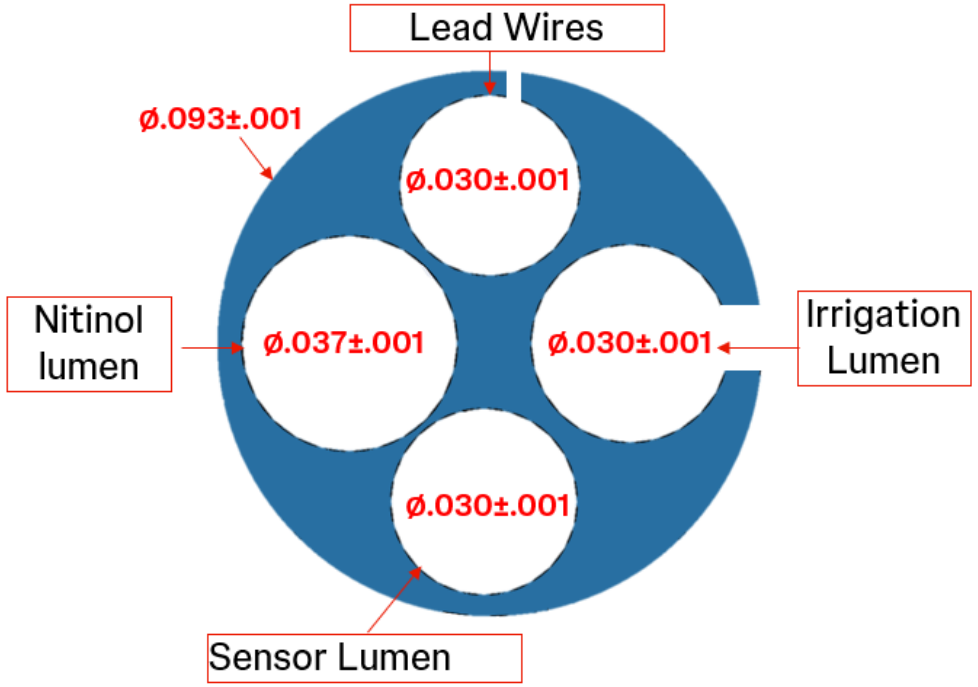


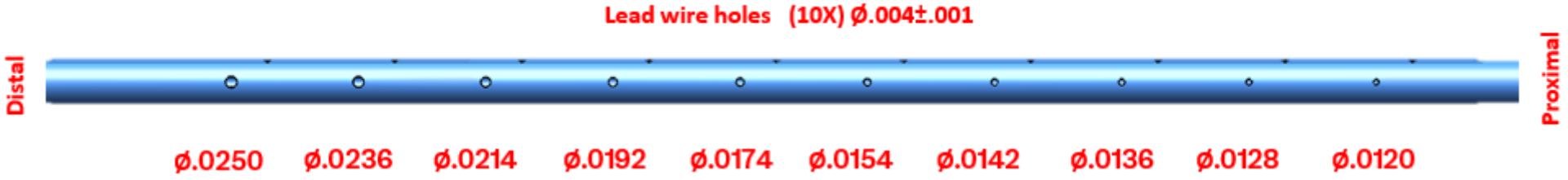
Video presentation/speech VARIPULSETM Catheter and TRUPULSETM Generator Overview; Tzachi Levy; Director of R&D, JNJ MedTech EP, VARIPULSE Platform integration Lead Nov. 13, 2024

Loop Lumen

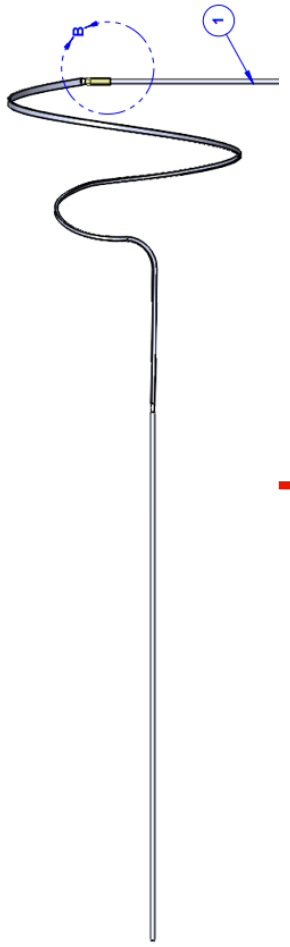
M-5794-25

- Material: PELLETHANE 2363-55D (75% 1%), BARIUM SULFATE 4518 (24% 1%)
- Quad-lumen: 4 internal lumens
- 10 variable holes along the length connecting to internal irrigation lumen
- 10 equal holes (.004”±.001) along the length connecting to internal lead wire lumen.

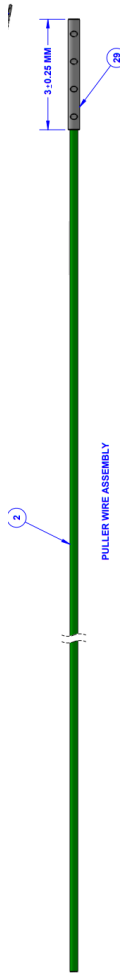




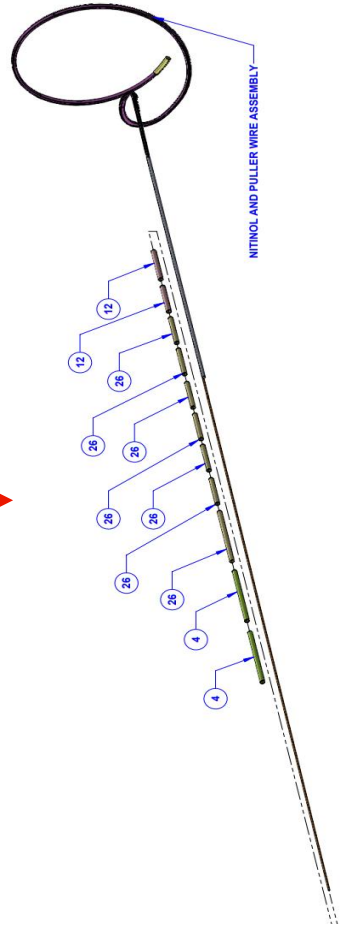
Nitinol & Puller Wire Assembly



Nitinol Wire

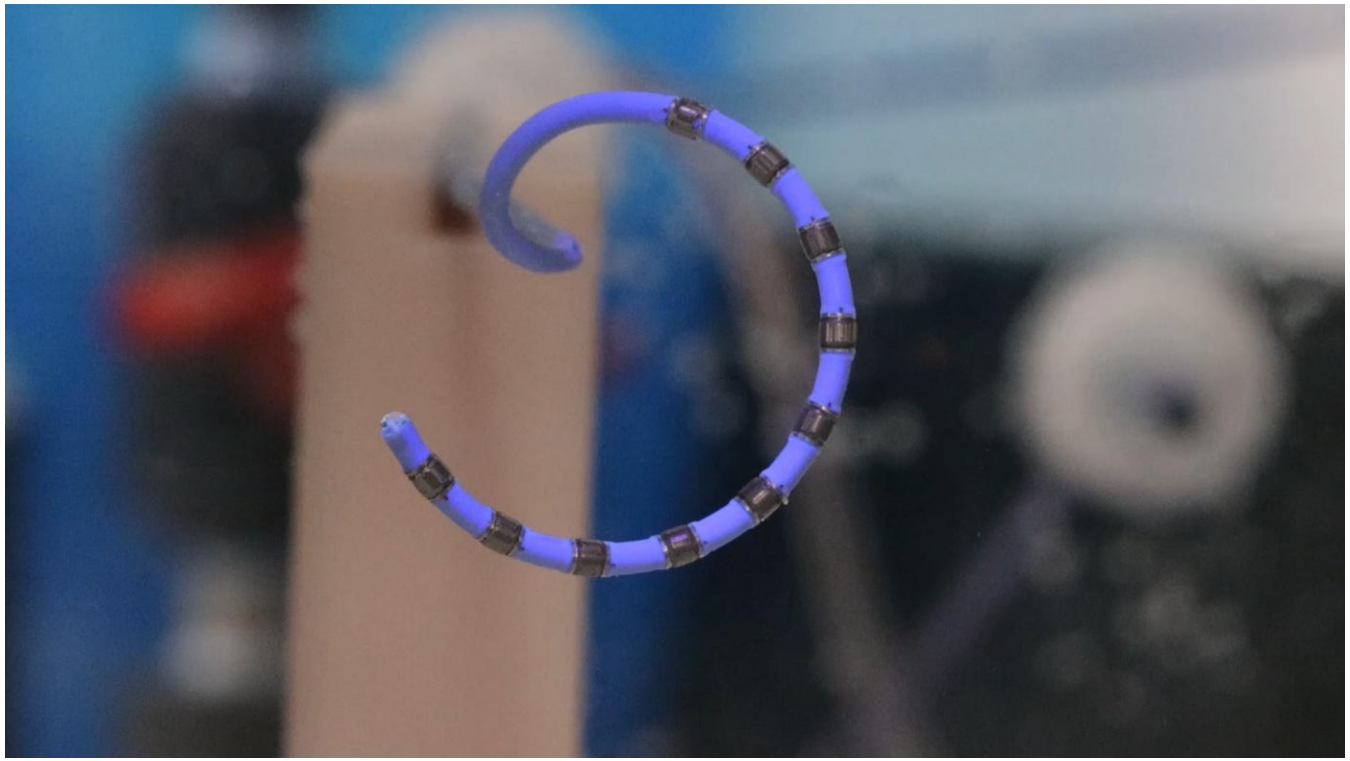


Puller Wire with Ferrule



Nitinol Wire with polyimide tubes

Loop Lumen Assembly: Irrigation

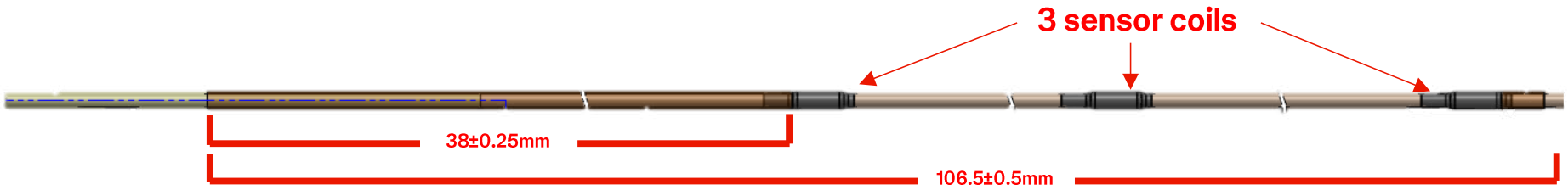


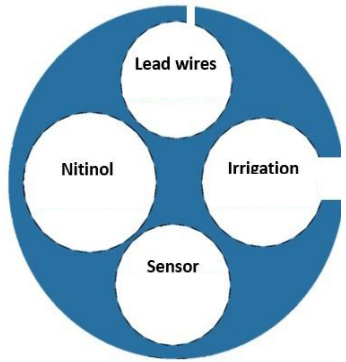
Varipulse catheter irrigation

Ring Electrodes Shape

- Platinum/Iridium electrode with 10 irrigation holes around circumference
- Each is welded to a copper wire
- Adhered to loop lumen with PU adhesive
- Shaped to optimized energy delivery while irrigating

Sensor & Sensor Prep





Loop Contraction

- Loop range is about 25mm-35mm
- Knob allows user to contract loop

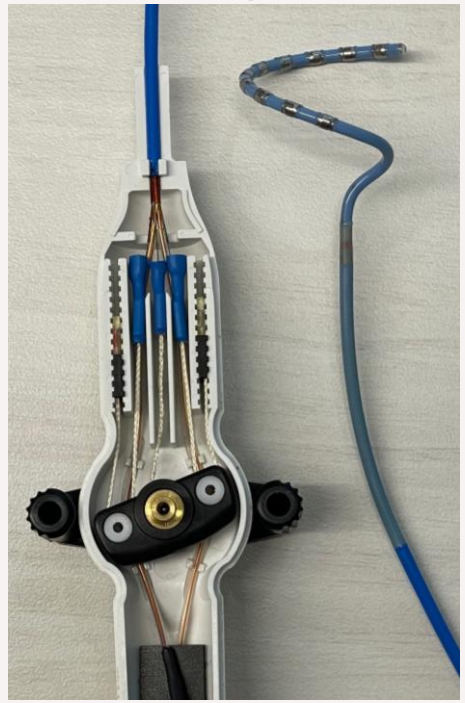
Uncontracted

Contracted

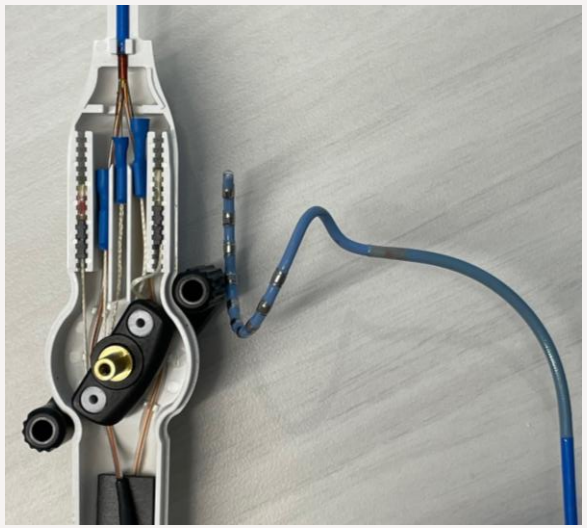
Deflection

- Deflection is from 90 degrees to 180 degrees
- Rocker allows user to deflect catheter

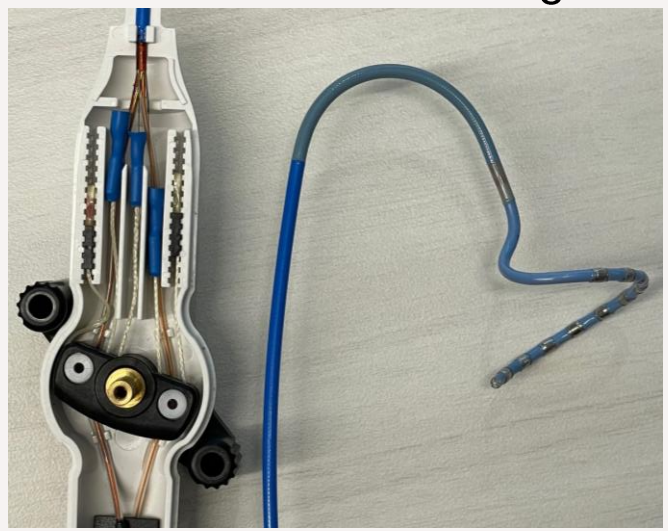
Neutral position



90 degrees



180 degrees



TRUPULSE™ Sequence for VARIPULSE™ Catheter

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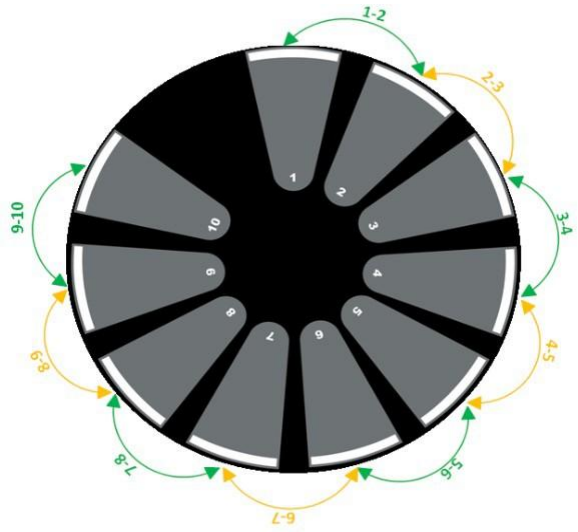
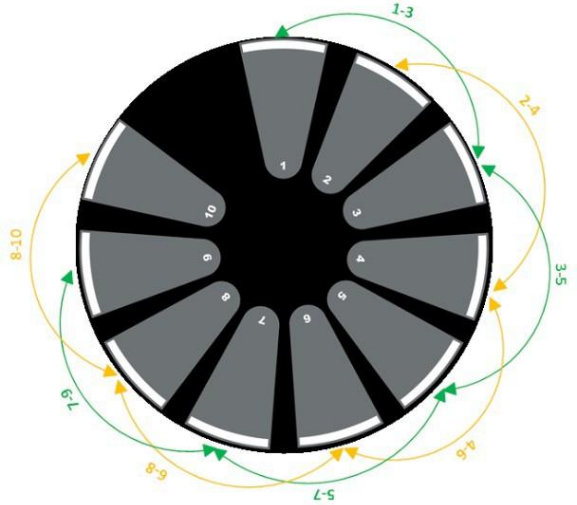
Electrophysiology

HOW IT ALL COMES TOGETHER

- Bipolar & Biphasic sequence with 1800V output
- Pulse train duration is < 250 mSec
- 10 Seconds between applications



ADJACENT electrodes pairs

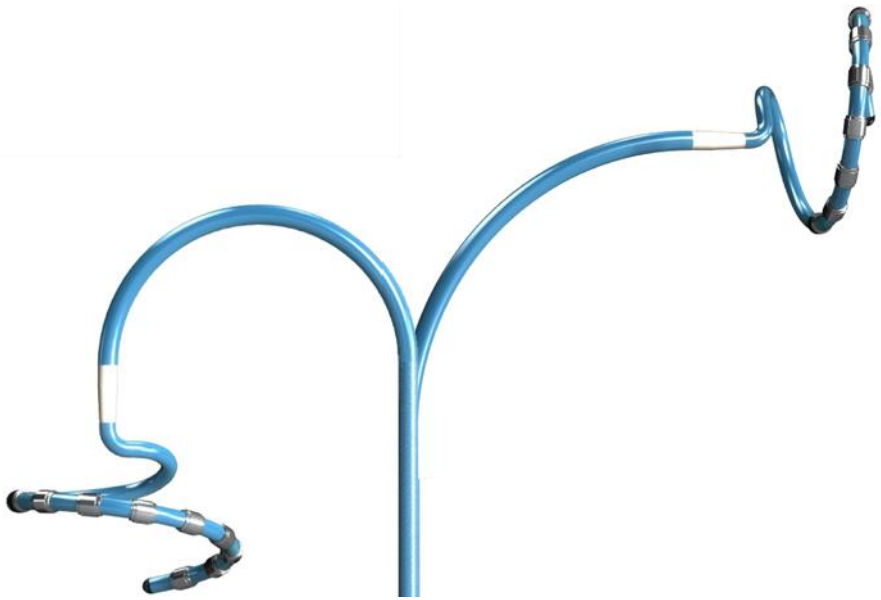


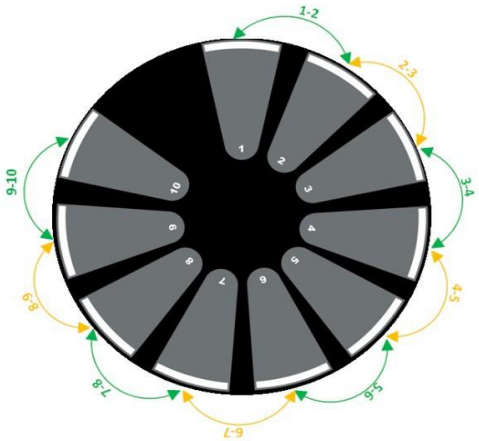
ALTERNATE electrodes pairs

J&J MedTech

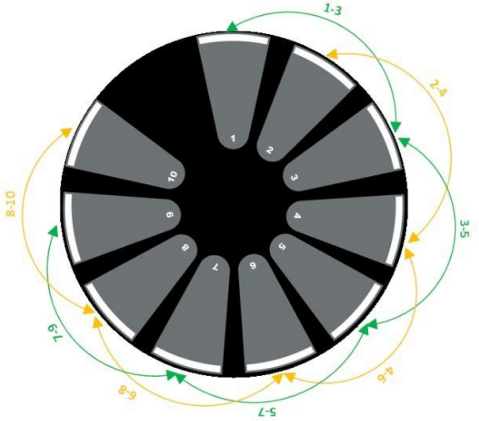
HOW IT ALL COMES TOGETHER

- Bipolar & Biphasic sequence with 1800V output
- Pulse train duration is < 250 mSec
- 10 Seconds between applications

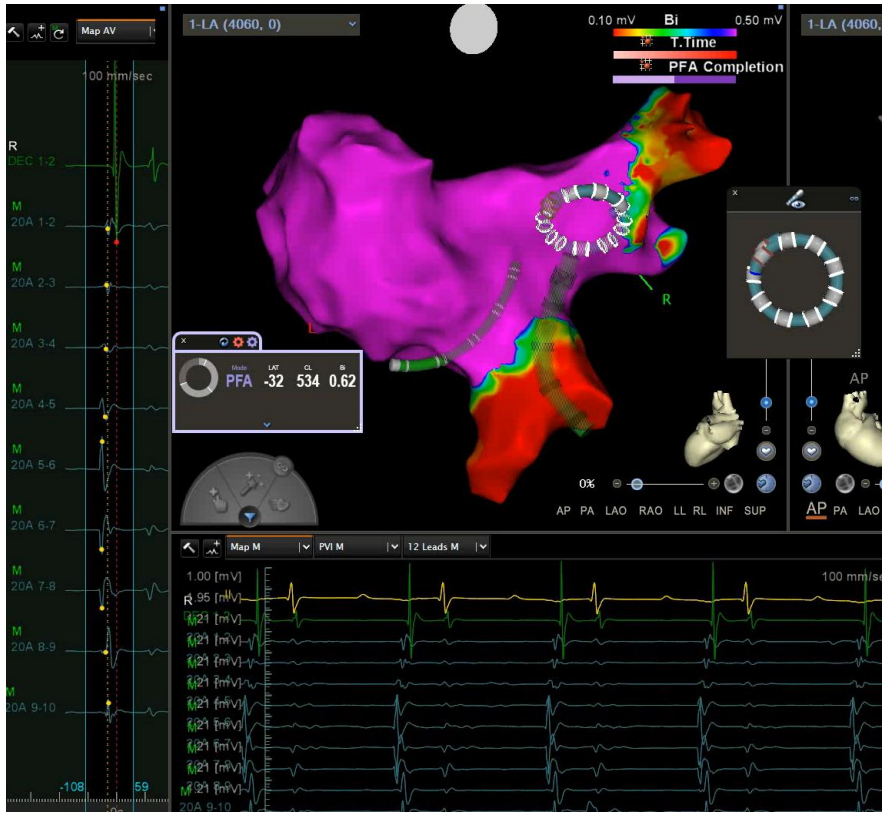




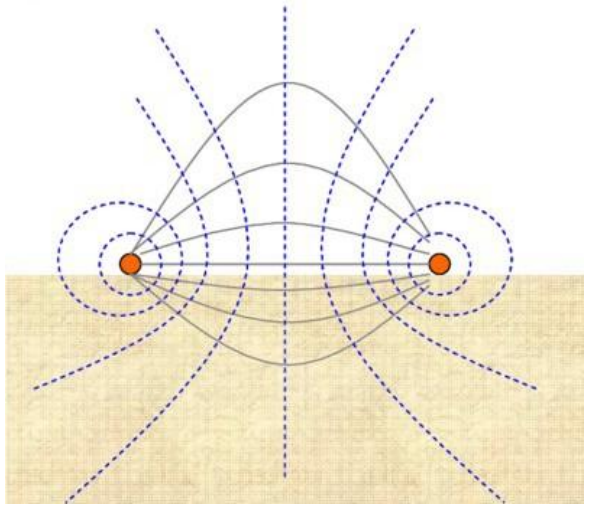
ADJACENT electrodes pairs

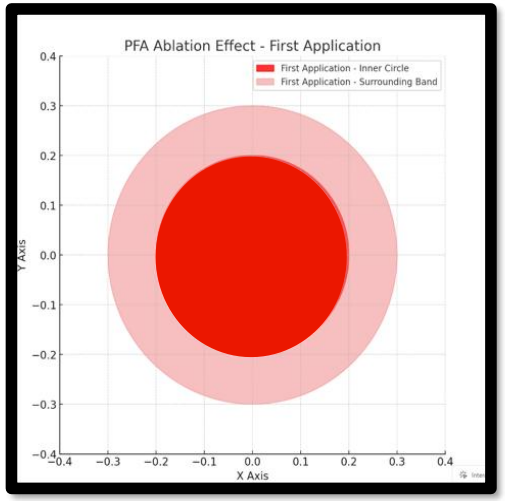


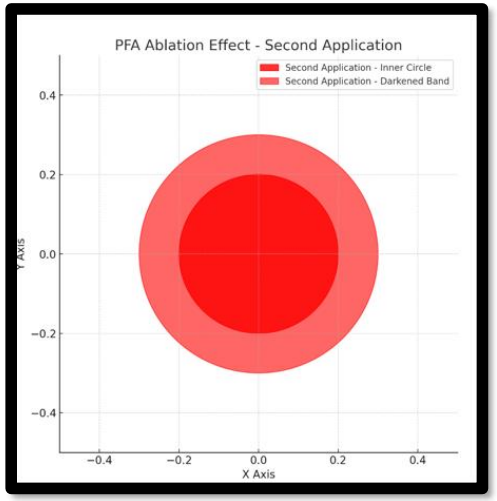
ALTERNATE electrodes pairs

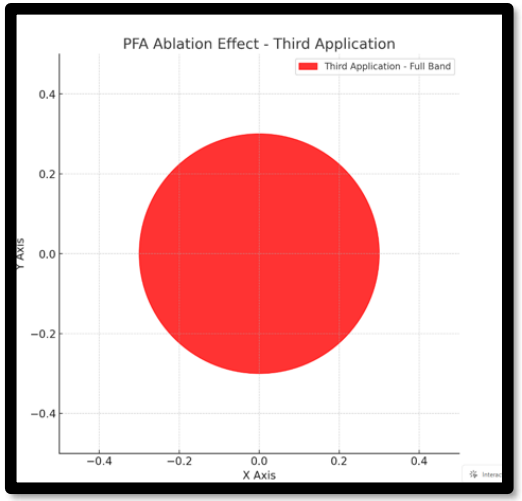


Ablation as an Energy Unit





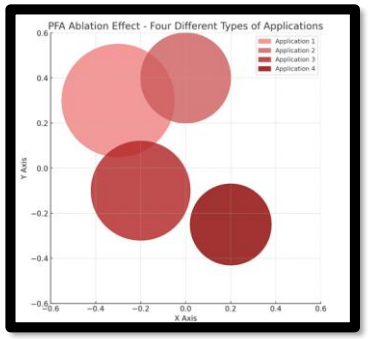




- Field density close to the electrode is homogenous and very effective
- Further away from the electrode is less homogeneous

From our own hypothesis testing, we found that:

- Repetitions can be used for increasing lesion depth without increasing the radius of impact (higher voltage).
- Fix distance between electrodes generates a very predicted reginal impact (vs less controlled catheter shape and distance between electrodes)
- Fixed radius of impact with plateau effect.
- No accumulation effect, Stacking wouldn't work.
- 10 Seconds delay for safety between repetitions



THANK YOU