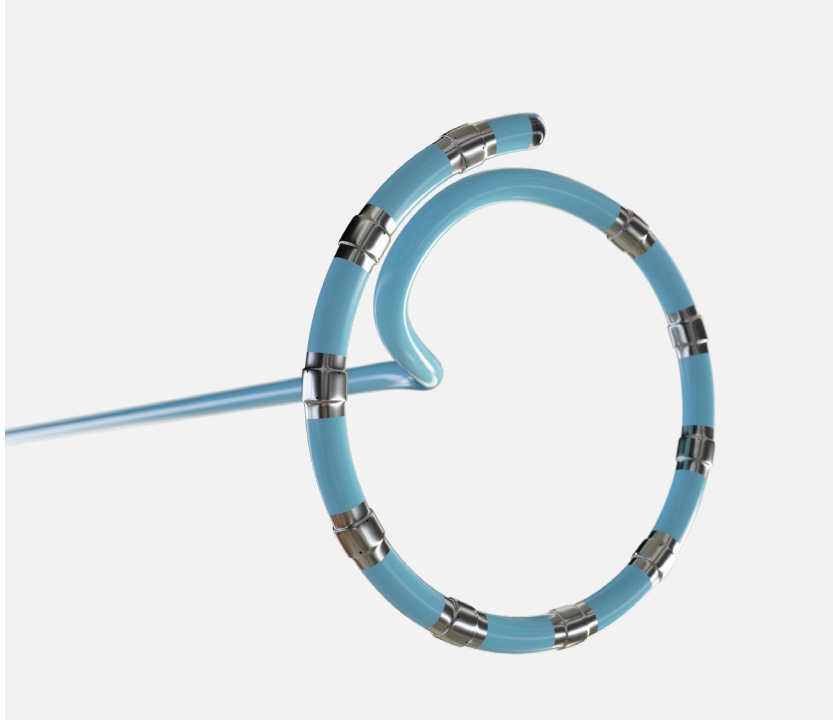
Varipulse™ Platform

Best Innovative Device-Technology of the Year



Emanuele Merola
Marketing Manager

Giovanna Barbara Serena Perrotta
New Technology Manager

April 2025

Johnson&Johnson
MedTech

Life Science Excellence Awards

Contents

1. Rationale
2. Description
3. Results
4. Why Varipulse™ is considered Innovative

Italian Marketing Team Members

Emanuele Merola
Marketing Manager

Chiara Pintor
Product Manager

Valeria Violante
New Technology Development Manager

Giovanna Perrotta
New Technology Manager

Atrial Fibrillation
Key numbers

2% [1]

of population in Italy is affected by Atrial Fibrillation (AF), with prevalence rates increasing in individuals over **65**.

120k [1]

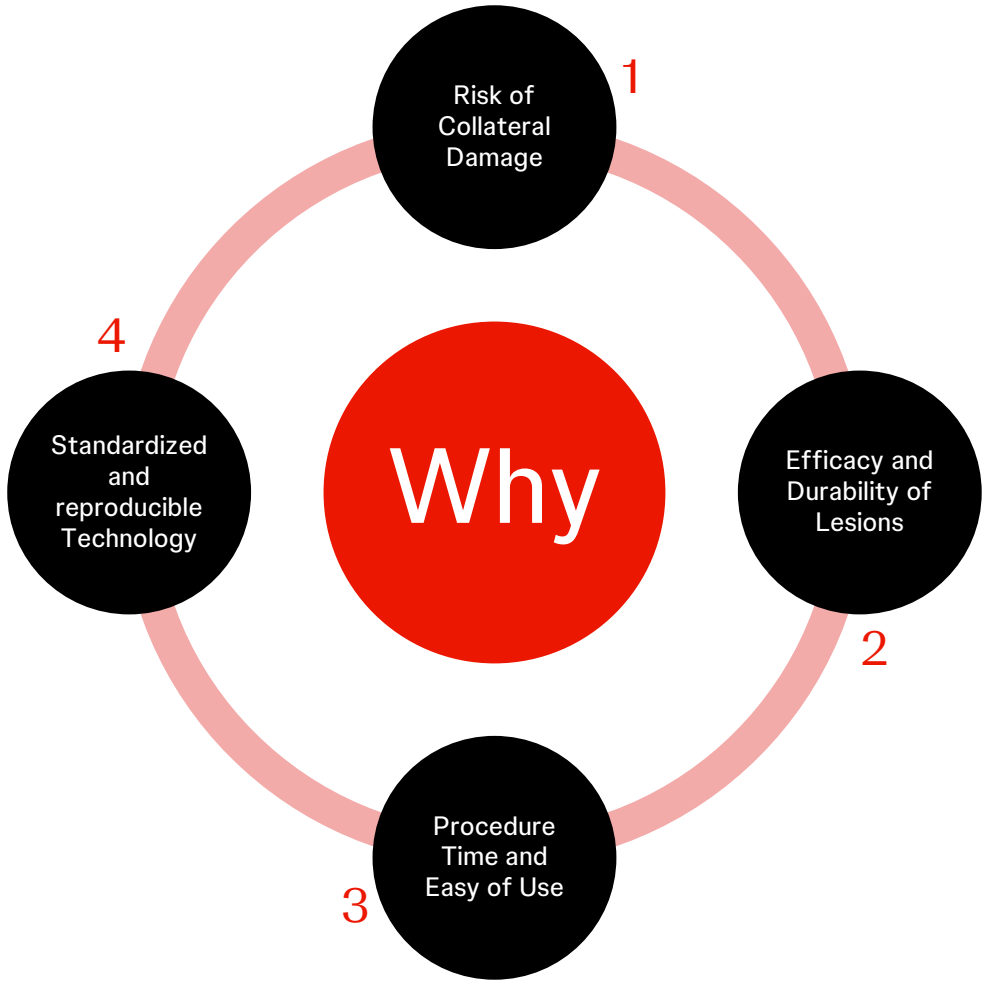
every year new cases of Atrial Fibrillation are diagnosed in Italy, with numbers on the rise **due to an improved screening methods**.

3,5% [2]

of patients with Atrial Fibrillation are **treated with catheter ablation**

Unmet needs [3,4,5]

Atrial Fibrillation Ablation



1 Risk of Collateral Damage

Radiofrequency (RF) and Cryoablation destroy tissue through thermal conduction, increasing the risk of damage to surrounding structures:

- Esophagus → risk of atrio-esophageal fistula
- Phrenic nerves → potential diaphragmatic paralysis
- Coronary vessels → vascular damage, leading to ischemia
- Atrial wall → risk of pulmonary vein stenosis

2 Efficacy and Durability of Lesions

Rf and Cryoablation lesions may be incomplete due to:

- Variability in tissue resistance (e.g., epicardial fat)
- Poor catheter-tissue contact

3 Procedure Time and Easy of Use

RF and Cryoablation requires:

- Precise catheter movements to ensure lesion continuity
- Constant temperature and contact monitoring
- Prolonged application time for each mapping point

4 Standardized and reproducible Technology

For atrial fibrillation ablation:

- RF outcomes highly depend on operator expertise
- Pulsed Field Ablation (PFA) enables a more standardized approach, less reliant on individual skill levels

Market

Atrial Fibrillation Ablation

Actual Contest

Atrial Fibrillation Ablation Market

- **Market Growth**: Atrial fibrillation is the most common cardiac arrhythmia, with a rising prevalence due to an aging population.
- **Rising Demand for Safe and Effective Solutions**: AF treatment is increasingly shifting toward less invasive technologies that reduce risks and procedure times while improving long-term efficacy.

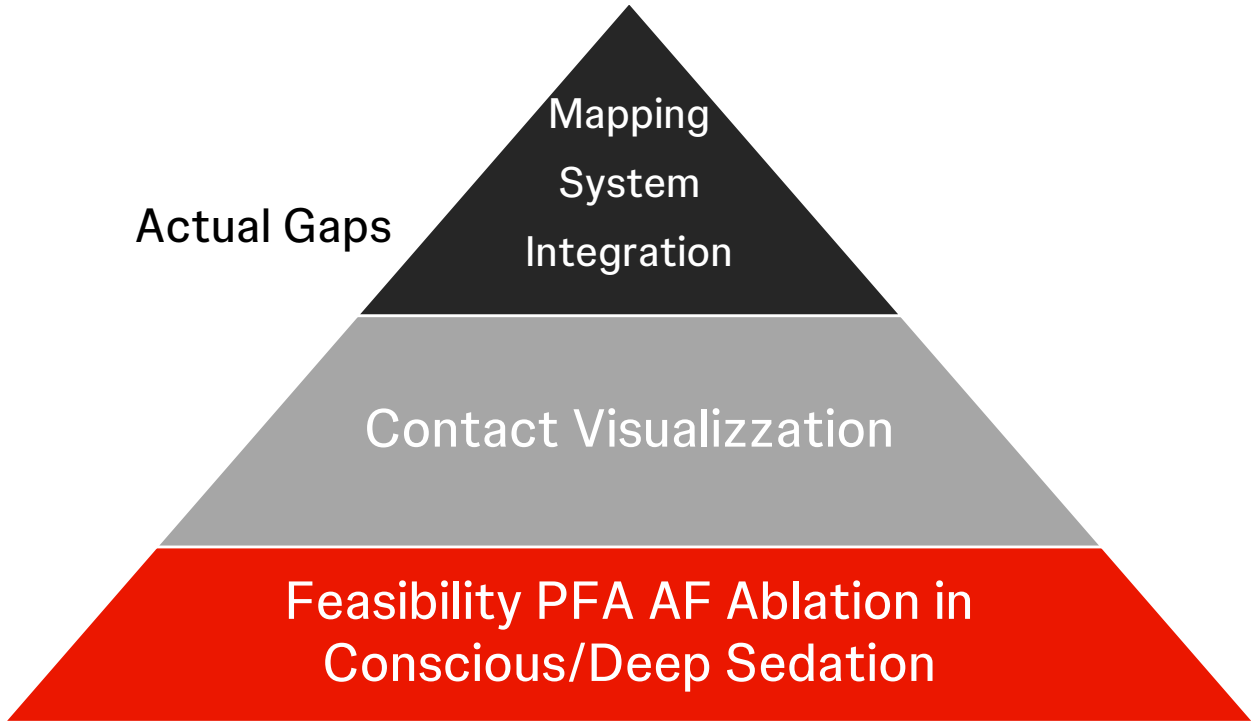
Evolution of Ablation Technologies

- **Radiofrequency (RF) Ablation**: The gold standard but associated with risks of collateral tissue damage and variability in lesion quality.
- **Cryoablation**: Limitations in terms of flexibility and the risk of phrenic nerve injury.
- **Laser and Ultrasound**: Used in some centers but less widespread compared to RF and cryoablation.

Emerging key Competitors in the PFA Segment

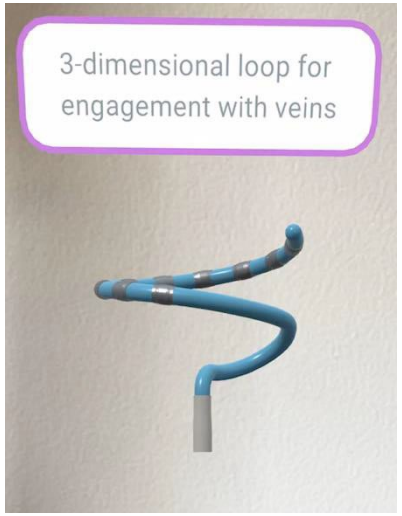
- Medtronic
- Boston Scientific
- Abbott

"Varipulse™ Strategic Positioning"



VARIPULSE™ Platform: Catheter

Designed to adapt in the Moment



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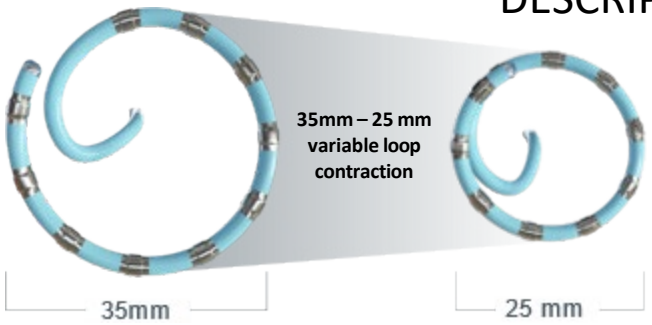
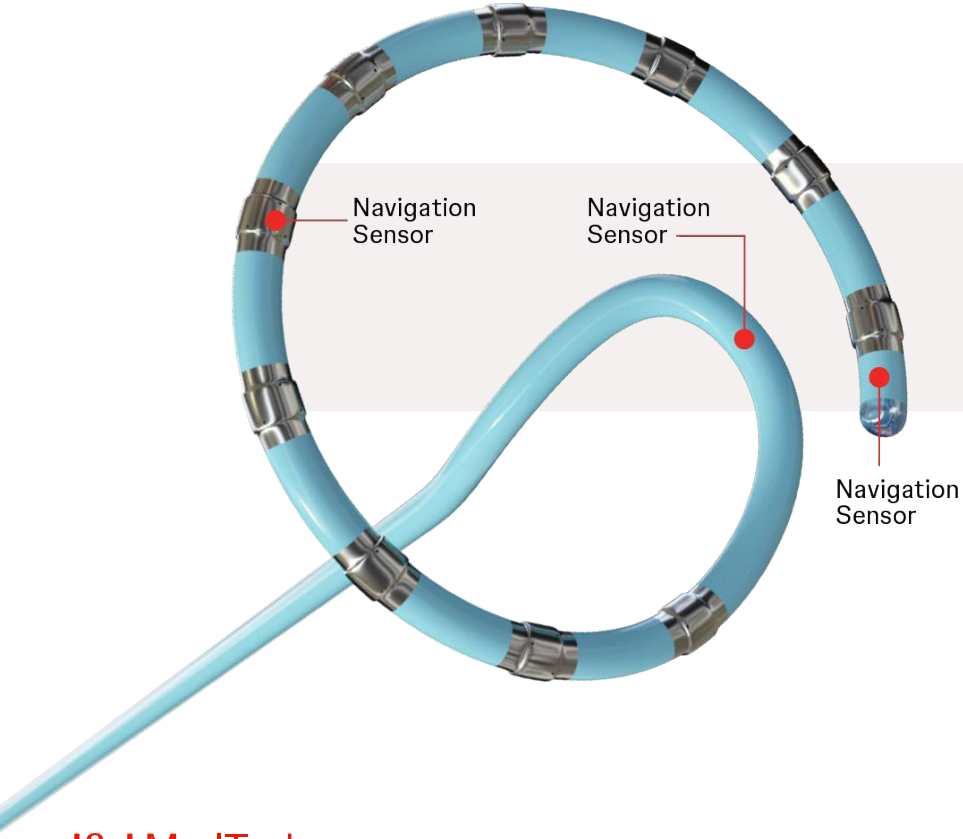


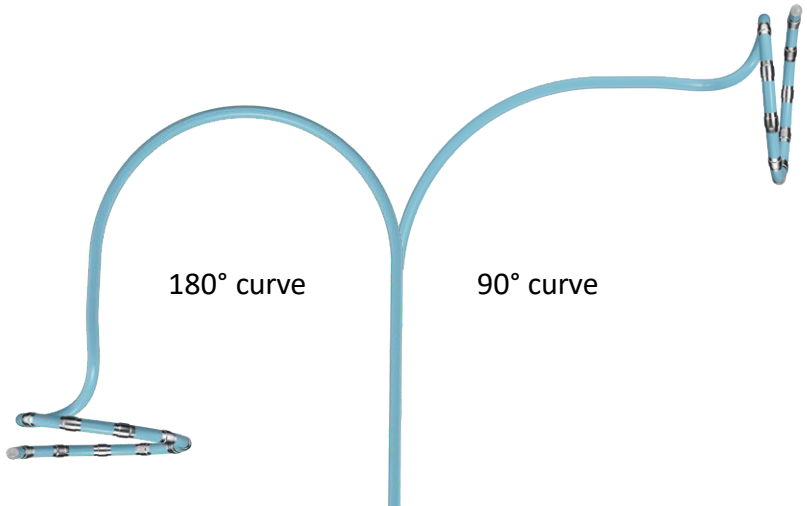
Ten irrigated 3mm electrodes spaced 7mm center-to-center that electro-anatomically map, emit pulsed field for ablation, and allow pacing per electrode.

Corkscrew shaped variable loop size adjusts to fit the patient's anatomy.



Designed for Mapping Integration

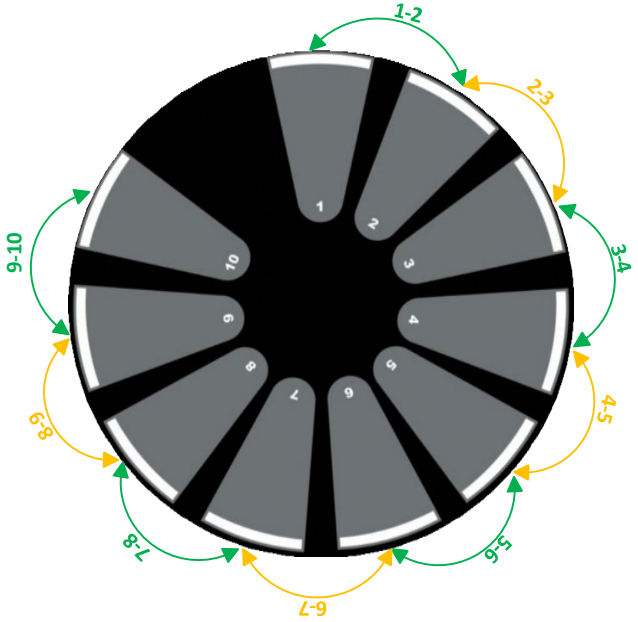
3 Single Axis Sensor locations for accurate visualization on the CARTO™ System.



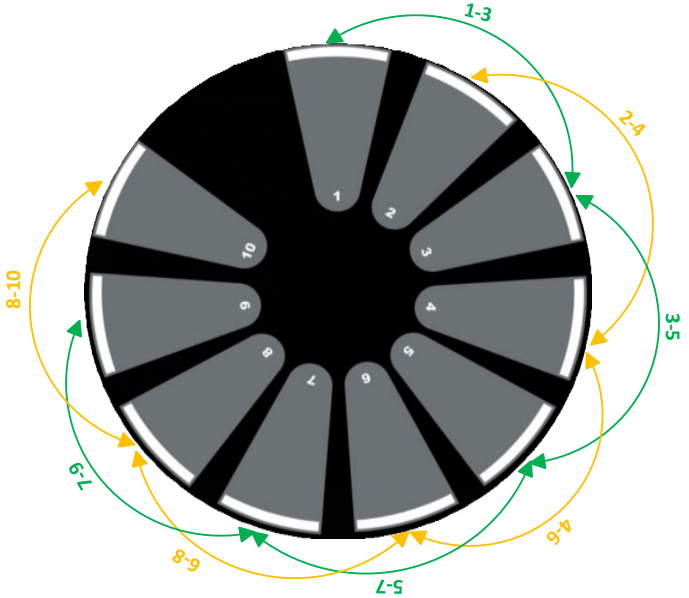
The VARIPULSE™ Catheter is built on a bi-directional, 8 Fr platform compatible with the CARTO VIZIGO™ Sheath or similar 8.5 F inner lumen sheath.

VARIPULSE™ Platform: Catheter Ablation Sequence

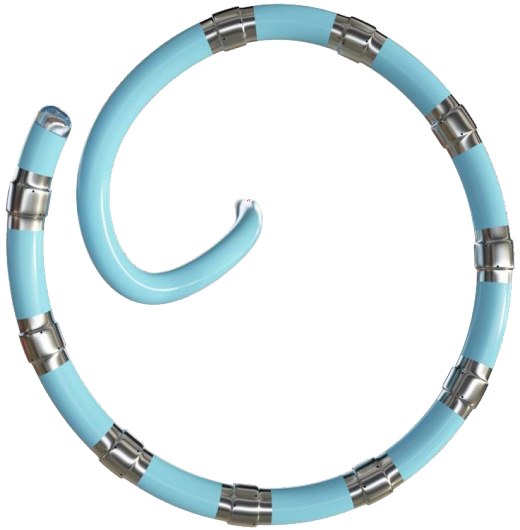
DESCRIPTION



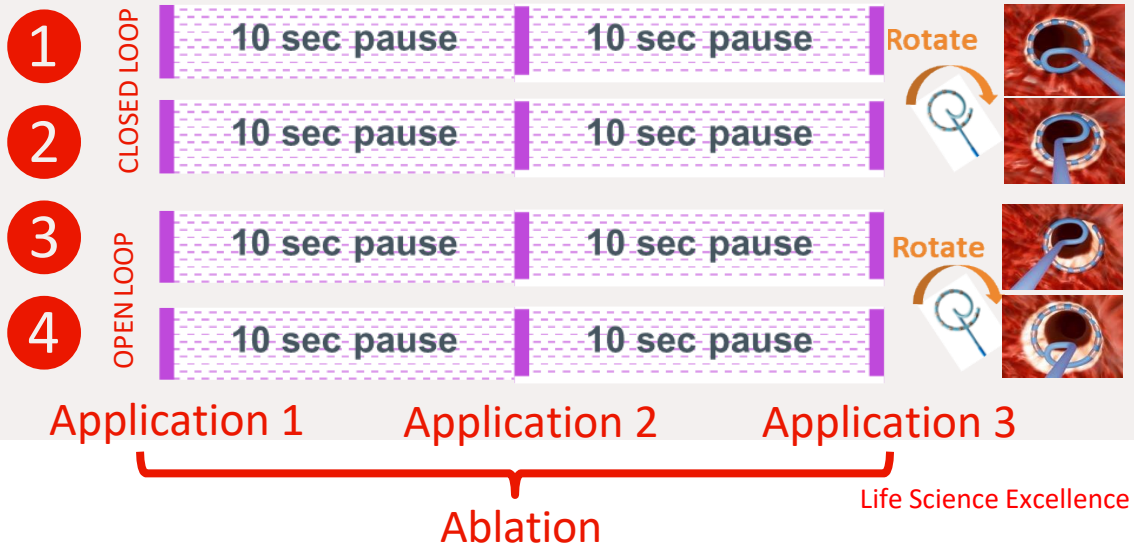
ADJACENT electrodes pairs



ALTERNATE electrodes pairs



- Bipolar & Biphasic sequence with 1800V output
- Pulse train duration is < 250 mSec
- 1 Ablation = 3 applications
- 10 Seconds between applications
- No energy between electrodes 1 and 10



4 Steps to Create PVI

VARIPULSE™ Platform: TRUPULSE™ Generator

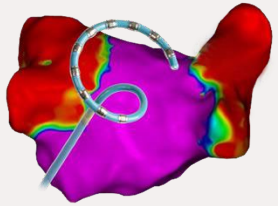
DESCRIPTION

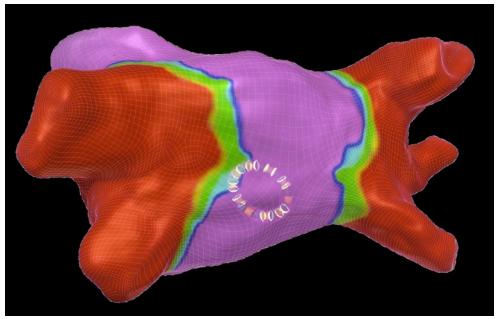
- Simple TRUPULSE ™ Generator User Interface
- Highly automated and streamlined
- Easily toggle electrodes, ablation on, and other functionalities
- Clear communication of parameters during ablation

VARIPULSE™ Platform: CARTO™ 3 System V8

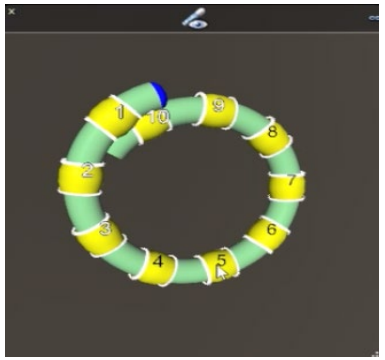
DESCRIPTION

***Integrated by design*, the VARIPULSE™Platform delivers these key differentiators as an integrated PFA mapping system**



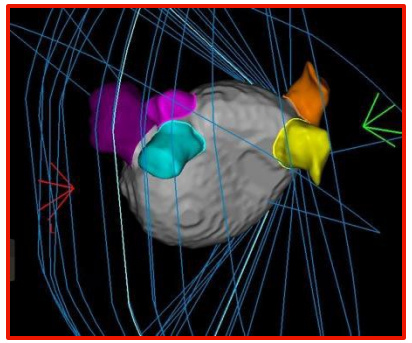


Integrated mapping and accurate visualization of the VARIPULSE™ Catheter in the CARTO™3 System



Tissue Proximity Indication (TPI) on the VARIPULSE™Catheter electrodes for optimal ablation delivery

CARTO VISITAG™ Module precisely showing where energy is delivered and helps to identify potential gaps



CARTOSOUND™FAM and ICE integration enabling a Zero Fluoro workflow, including automatic creation of the LA anatomy

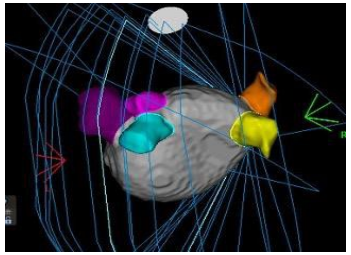
VARIPULSE™ Platform

DESCRIPTION

VARIPULSE™ Ablation Workflow with CARTO™ 3 System V8

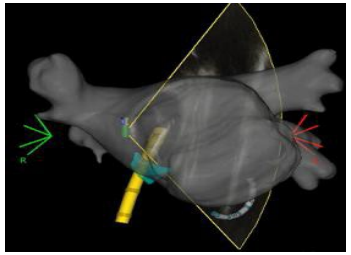
1 **Create Anatomy**

Create the left atrium (LA) map using **CARTOSOUND™ FAM** and/or Advanced Diagnostic of Physician's choosing.



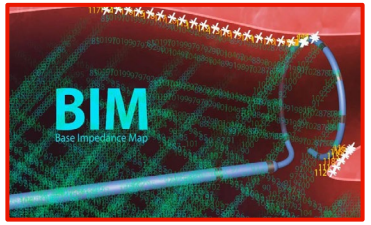
2 **Transseptal**

Use the 8.5 Fr **VIZIGO® Sheath** for transseptal puncture.



3 **TPI Calibration**

Calibrate TPI as the **VARIPULSE™ Catheter** is placed in the LA.

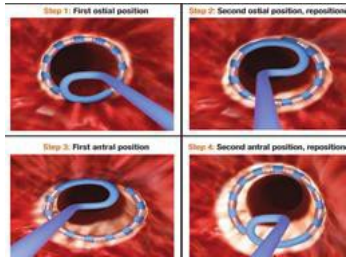


4 **Catheter Positioning**

Utilize TPI for catheter positioning in the Pulmonary Veins (PV), to confirm **Tissue Proximity (CARTO™ 3 V8 Feature)** on several electrodes.

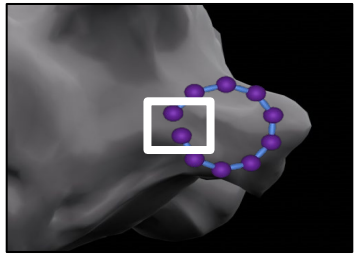
5 **Pulmonary Veins Isolation (PVI) Ablation**

Perform PVI with 4 ablations per vein, repositioning the **VARIPULSE™ Catheter** between each ablation.



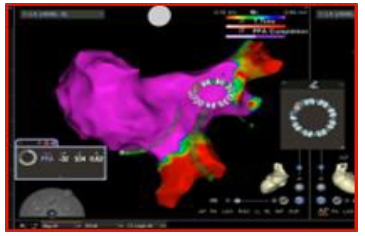
6 **Gap Checks**

Use **VISITAG** features on **CARTO™3 System** to identify potential gaps.



7 **Touch-ups (As Needed)**

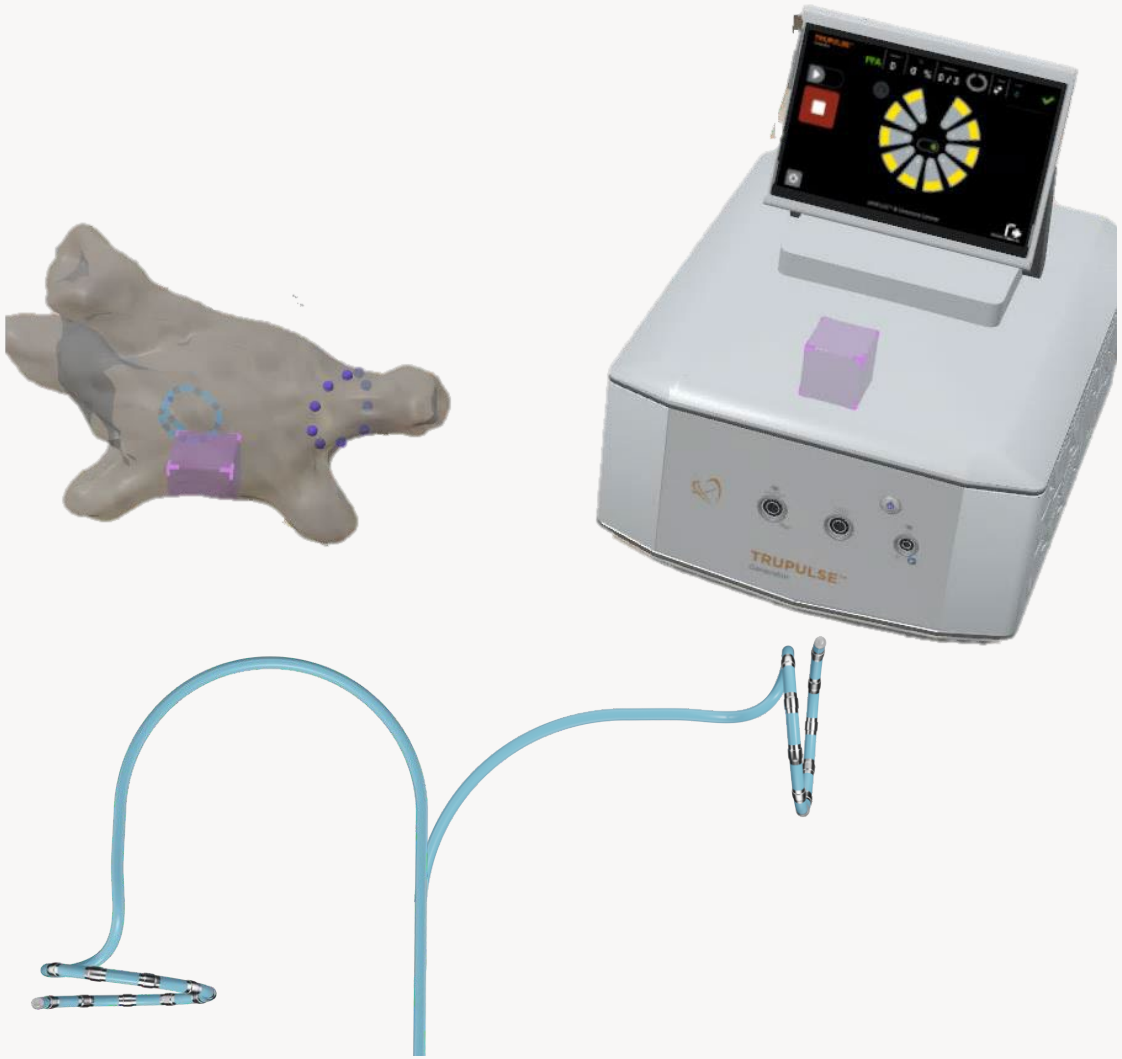
Touch-up with the **VARIPULSE™ Catheter** as needed.



The goal of the procedure is to get a contiguous lesion set around the pulmonary vein.
Important Reminder: Reposition the catheter between ablations

Key Takeaways from VARIPULSE™Platform

DESCRIPTION



Integration is the key:
CARTO™ 3 System visualization for accurate placement of the VARIPULSE™ Catheter and electrodes

Contact Matters:
Enhanced TPI on each electrode visualizing tissue contact and PFA Tags to catalog lesions

Unique recipe:
TRUPULSE™ Generator delivers proprietary high voltage waveform to VARIPULSE™Catheter to allow deep sedation protocol during procedure

VARIPULSE™ Platform

RESULTS

Clinical Impact: admIRE[6] and inspIRE[7,8,9,10]

The inspIRE and admIRE clinical studies, using the VARIPULSE™ Catheter both reported **no device-related primary adverse events (PAEs)** during the procedures at 12 months follow up.

No PV stenosis, esophageal thermal lesions, AE fistula, TIA, myocardial infarction and thromboembolism.

The VARIPULSE™ fully integrated platform with 3D electro-anatomical mapping provides information on electrode-tissue contact, ensuring quality lesion formation resulting in low fluoroscopy time.

Favorable safety profile

admIRE Trial

2.9% primary adverse events*

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

inspIRE Trial

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

7.1 minutes mean fluoroscopy time

When used with CARTO™ 3 System and intracardiac ultrasound.

inspIRE Trial

7.8 minutes mean fluoroscopy time

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

12-month effectiveness demonstrated

admIRE Trial

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

admIRE trial: n=85.

inspIRE Trial

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

31 minutes median PF ablation time

In the admIRE study.

inspIRE Trial

27 minutes mean PF ablation time

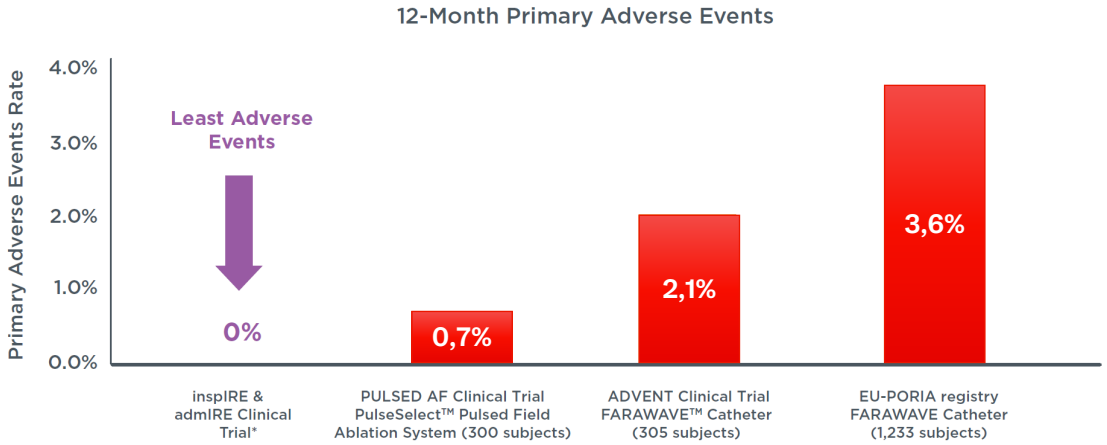
inspIRE trial n=176 with ≥ 4 ablations per vein.

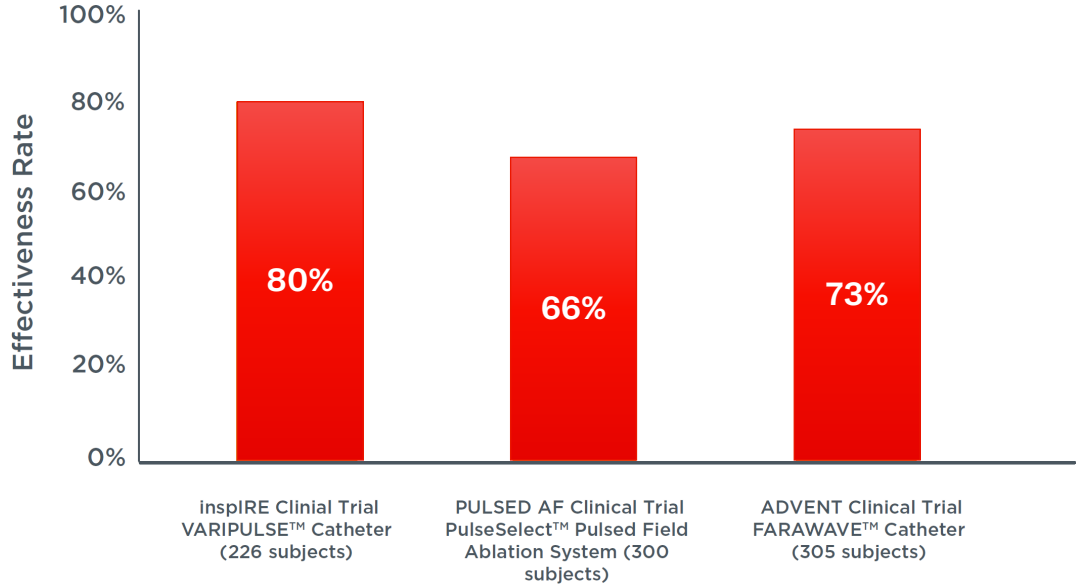
Clinical studies have demonstrated that catheter ablation using PFA is highly effective with high procedure success, the creation of larger lesions when compared to RF ablation and robust freedom from arrythmia at 12 months.

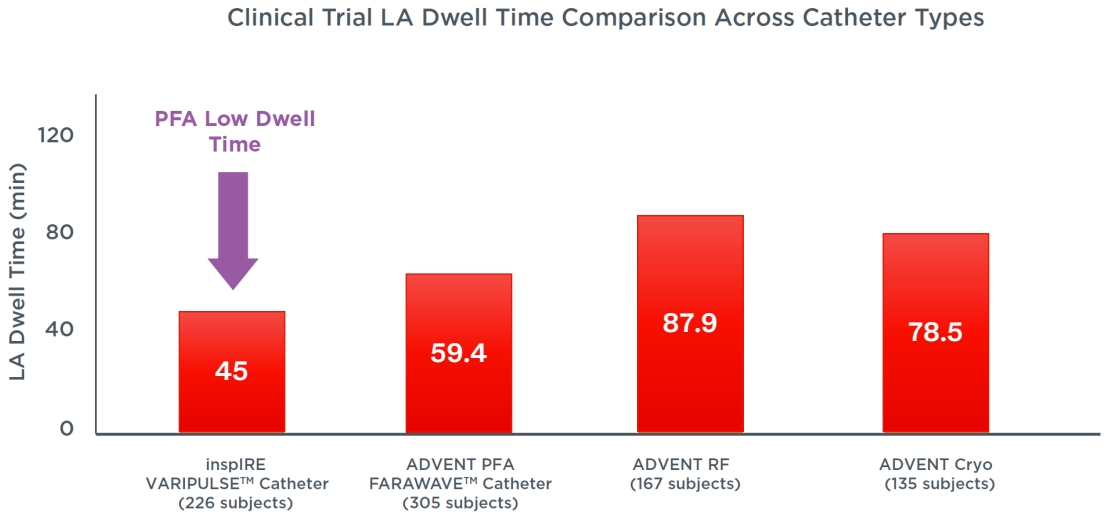
Catheter ablation using the PFA system was confirmed to be effective and appears to have shorter procedure time and catheter dwell time.

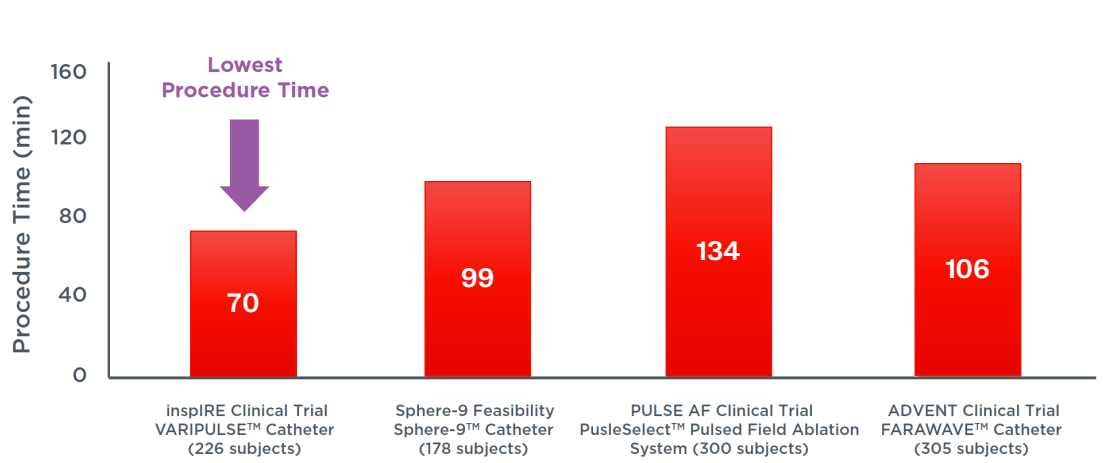
Clinical Evidence:[11,12,13]

Safety, Effectiveness and Efficiency Overview VS main clinical evidence from competitive technology





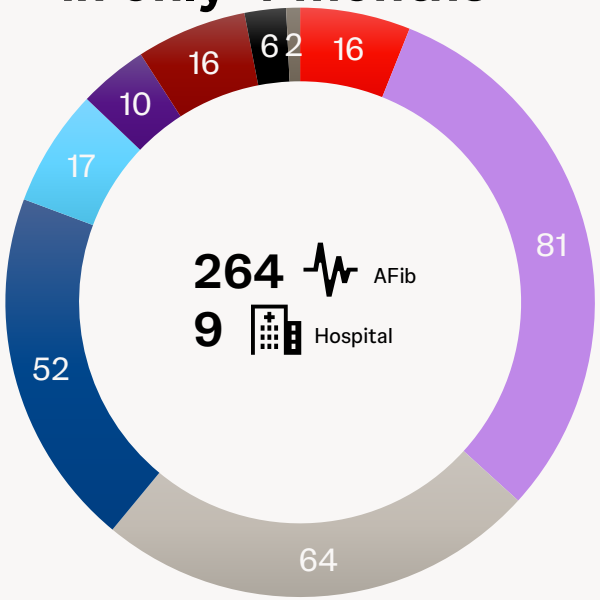




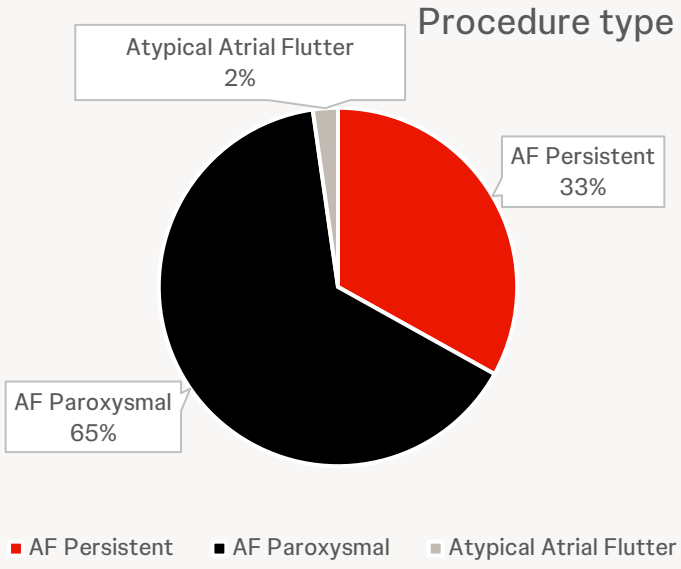
Early Italian Experience 2024

RESULTS

Activated centers and procedures in only 4 months



- Miulli
- Ospedale Ancona
- Niguarda
- Ospedale Piacenza
- Ospedale Sassari
- San Donato
- Cardiologico Monzino
- Mediterranea
- Ospedale Bolzano



70 minutes	Average Skin to skin
33.2 minutes	Average Dwell time
26.1 minutes	PF Ablation time
96%	First pass Isolation
7.5 minutes	Mean fluoroscopy time
23.6	Average PF Sessions

Varipulse™ Launch at AIAC National Congress

4	Key Opinion Leader
>70	Expert electrophysiologists

Key messages

- ✓ Integration for Effectiveness
- ✓ Versatility in Treatment
- ✓ Learning Curve & Efficiency
- ✓ Revolutionizing Workflow

Integration is the key

Near-zero fluoroscopy workflow for pulmonary vein isolation in atrial fibrillation using a variable loop, 3D-integrated circular PFA catheter (Varipulse™): initial single-center experience with the first 35 patients.[14] Journal of Interventional Cardiac Electrophysiology. 2025

Borlich M, et al.

Objective

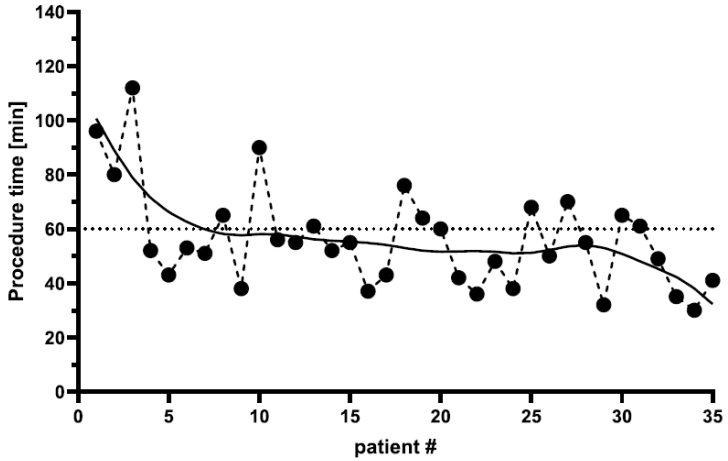
Assess the procedural characteristics, safety, and acute efficacy of pulmonary vein isolation (PVI) using the VARIPULSE™ PFA catheter in patients with AF, while specifically evaluating a near-zero fluoroscopy workflow to minimize radiation exposure during the procedure.

Take Home Messages

"The VARIPULSE™ Pulsed Field Ablation system enables efficient, nearly fluoroscopy-free atrial fibrillation ablation"

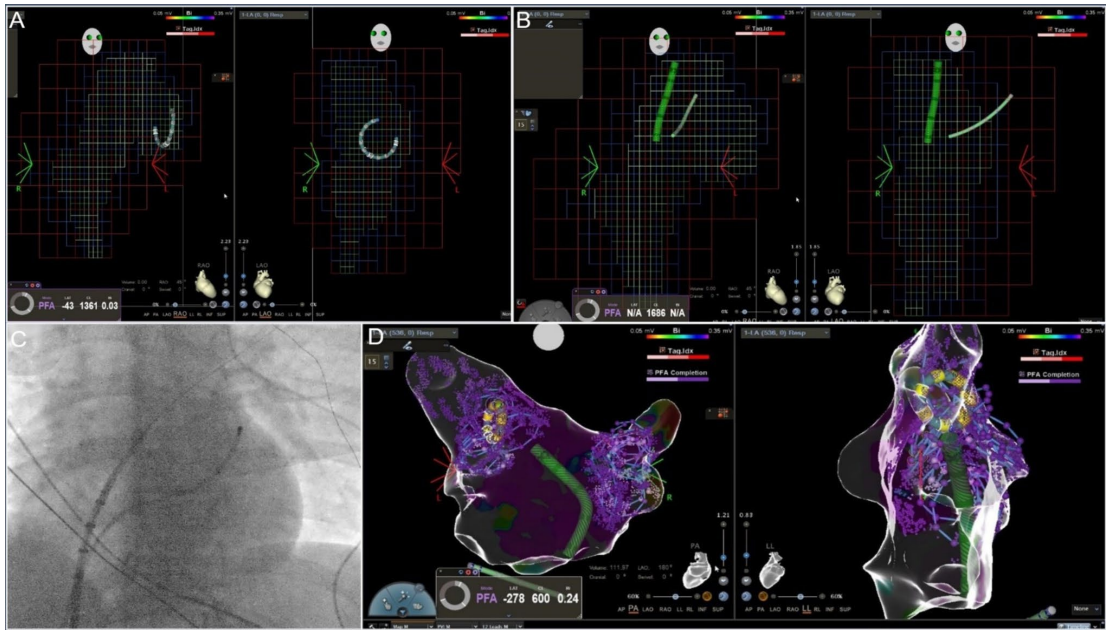
It achieved effective pulmonary vein isolation (PVI) with minimal radiation exposure and no major complications

Martin Borlich, MD



Results

- ✓ Median fluoroscopy time was 0.8 min
- ✓ Total median procedure time 53 min
- ✓ Median LA dwell time 38 min
- ✓ Median fluoroscopy dose 20.4 µGym2
- ✓ Pulmonary vein isolation was achieved in 100% of cases



Contact Matters

Clinical Importance of Tissue Proximity Indication During Pulsed Field Ablation for Atrial Fibrillation: Insights from Initial Experience.[15] Heart Rhythm. 2025

Okumura Y, et al.

Yasuo Okumura, MD

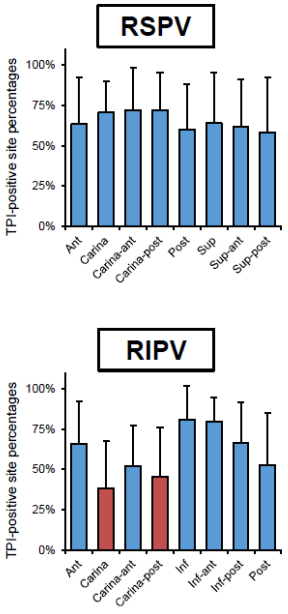
Consistent TPI-based contact during PFA was strongly associated with distinct chronic transmural lesions, emphasizing the of tissue contact in optimizing circumferential lesion formation with circular PFA catheters.

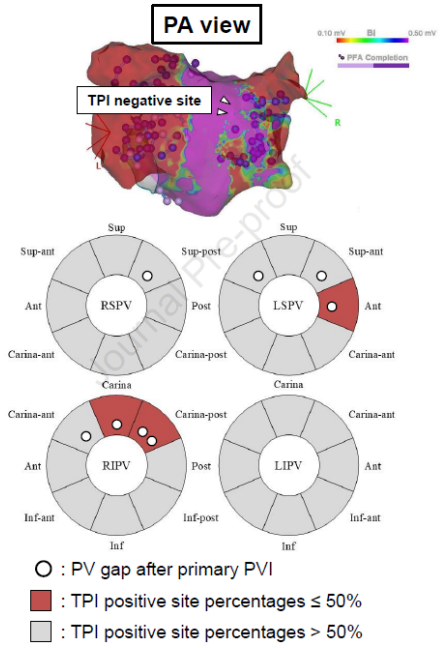
Take Home Messages

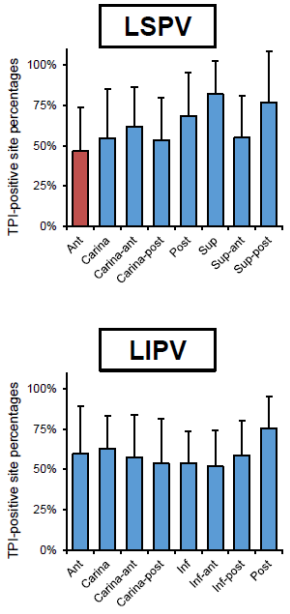
"Critical role of optimizing TPI-based tissue contact to ensure the formation of effective, distinct transmural lesions, particularly in areas with a thickened left atrial wall."

Objective

Evaluate Clinical Feasibility of Tissue Proximity Indication (TPI) and its relationship with acute Pulmonary Veins (PV) reconnection







Results

- ✓ Primary Pulmonary Veins Isolation Success (PVI) was achieved in 81% patients and 94% Pulmonary Veins (PV)
- ✓ **PV gaps were associated with** higher bipolar voltage and **lower TPI-positive site percentages**
- ✓ The TPI-positive site percentages significantly increased after 7 cases of learning-curve phase

Contact Matters

Application repetition and electrode-tissue-contact results in deeper lesions using a pulsed-field ablation circular variable loop catheter.[16] Europace. 2024

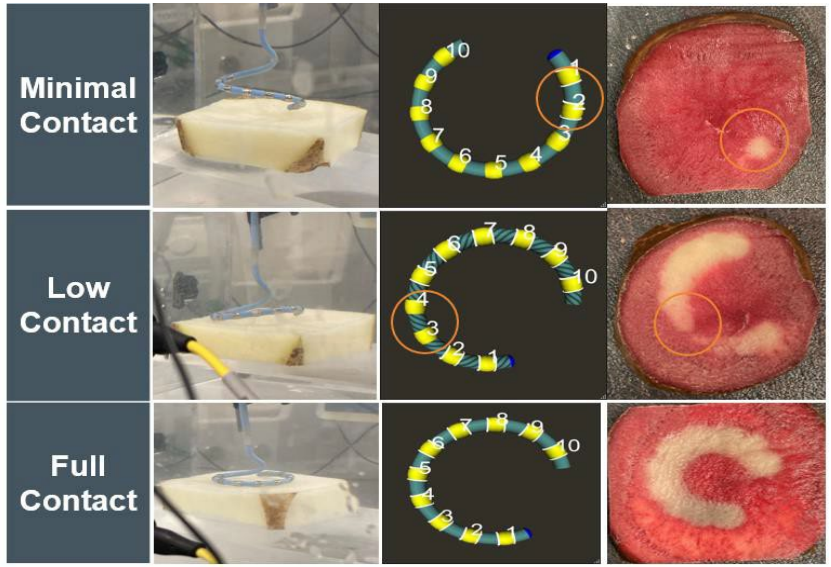
Di Biase L, et al.

Objective

To evaluate the impact of application repetition and catheter-tissue contact on lesion formation during PFA.

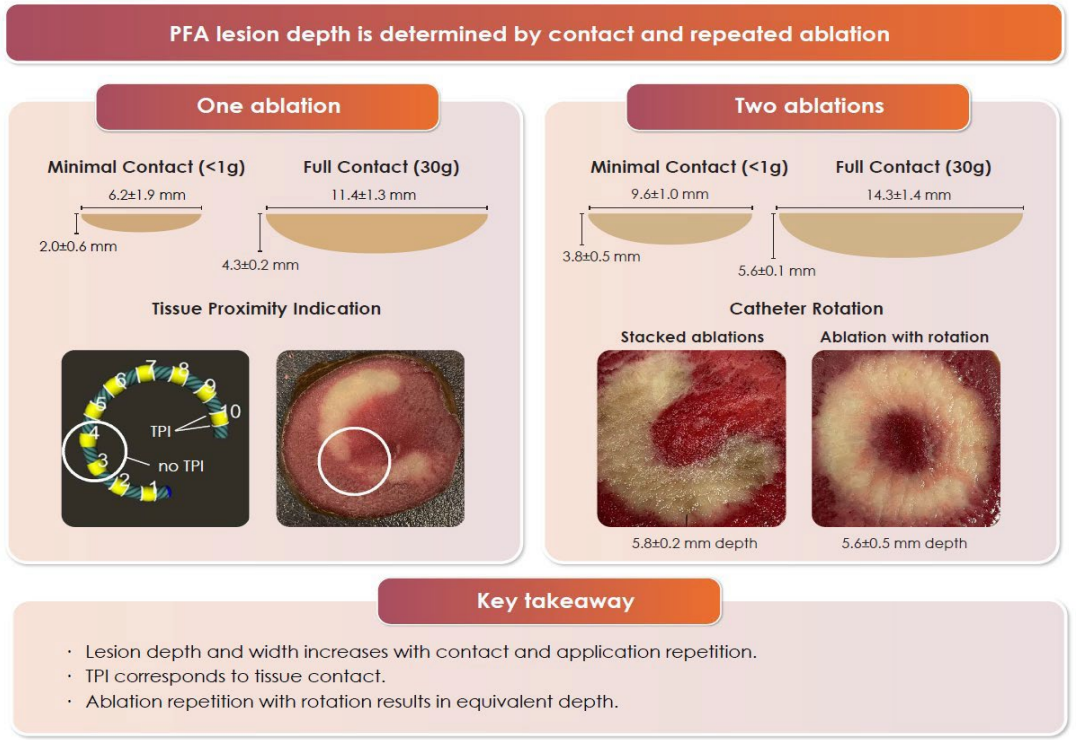
These findings indicate that endpoints for effective PFA are related more to PFA biophysics than to mere EGM attenuation.

Luigi Di Biase, MD



Take Home Messages

"Pulsed-field ablation delivered via a circular catheter showed that both repetition and catheter contact led independently to deeper lesion formation"



Unique Recipe

Deep sedation protocol during atrial fibrillation ablation using a novel variable loop biphasic pulsed field ablation catheter.[10] Europace. 2023

Grimaldi M, et al.

Massimo Grimaldi, MD

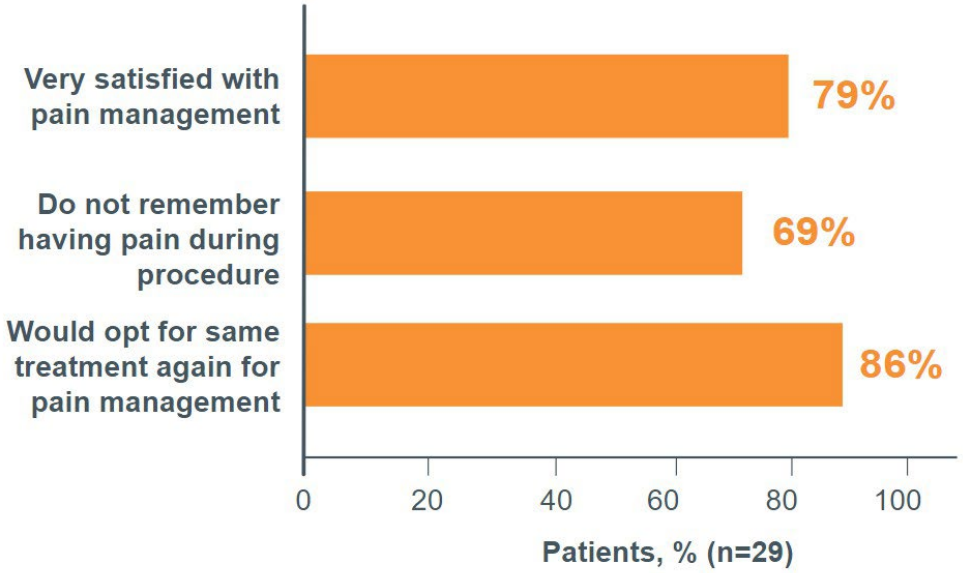
Our deep sedation protocol proved safe and effective, yielding positive patient feedback and adequate sedation scores, making it a viable alternative to general anesthesia.

Take Home Messages

"This study shows deep sedation is safe and effective in pain management during pulsed field ablation for Paroxysmal Atrial Fibrillation"

Objective

To report the data concerning our deep sedation protocol used in 29 participants enrolled in the inspIRE study.



Results

- ✓ The deep sedation protocol was used in all patients; **no procedural complications reported**
- ✓ Anesthetic consultant supervision not required for experienced operator
- ✓ **No muscle contractions** or transient cough were observed
- ✓ **Positive patient feedback** regarding sedation and pain management provided by most participants

Thank you

Available Material

- VARIPULSE Clinical Evidence
- VARIPULSE ODP
- VARIPULSE Platform Brochure
- VARIPULSE Platform Publication List
- VARIPULSE Procedural Workflow Video
- VARIPULSE Value Brief

Johnson&Johnson MedTech

Life Science Excellence Awards

References

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