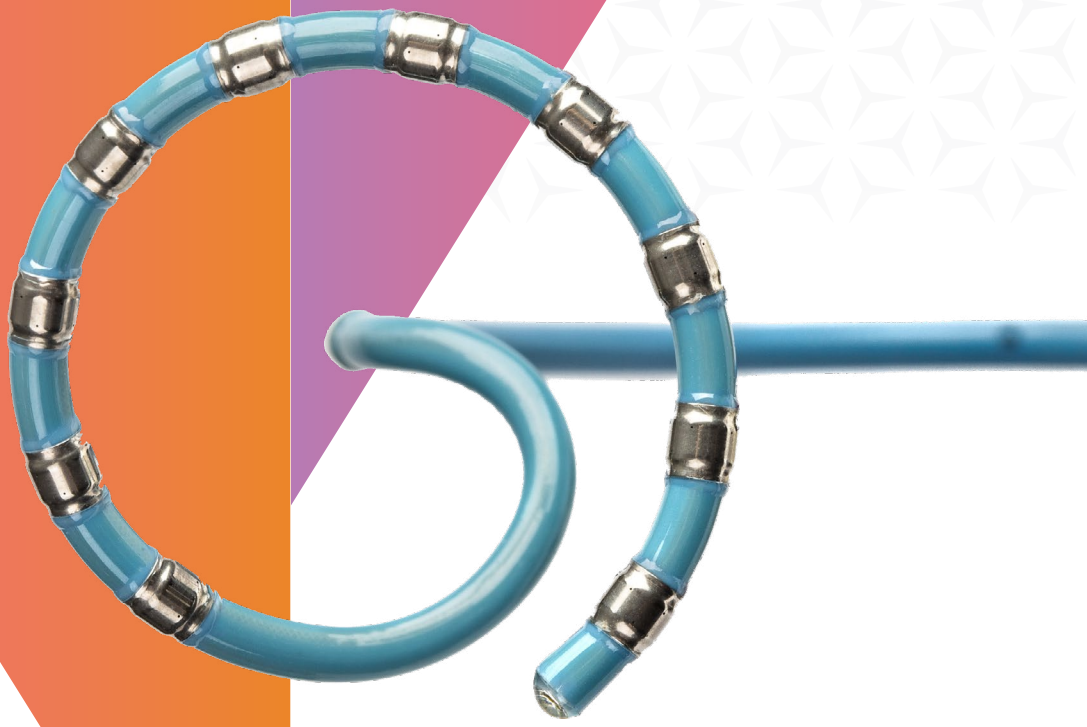
VARIPULSE™
Platform

The Value of the Pulsed Field Ablation VARIPULSE™ Platform



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INTRODUCTION

Pulsed field ablation (PFA) is a new, minimally thermal, ablative technique that shows promise in treating atrial fibrillation (AF). PFA represents a new approach to treating AF, utilizing a controlled electric field to ablate and treat cardiac tissue through a process called irreversible electroporation (IRE).[18] Due to its tissue selectivity, IRE offers the potential to reduce the risk of damage to surrounding tissues including esophageal, pulmonary vein, and phrenic nerve injury.[18]

This value brief summarizes clinical findings from recent studies on the safety and effectiveness of the CARTO™ integrated VARIPULSE™ Platform in treating paroxysmal AF.

VARIPULSE™ PFA Catheter

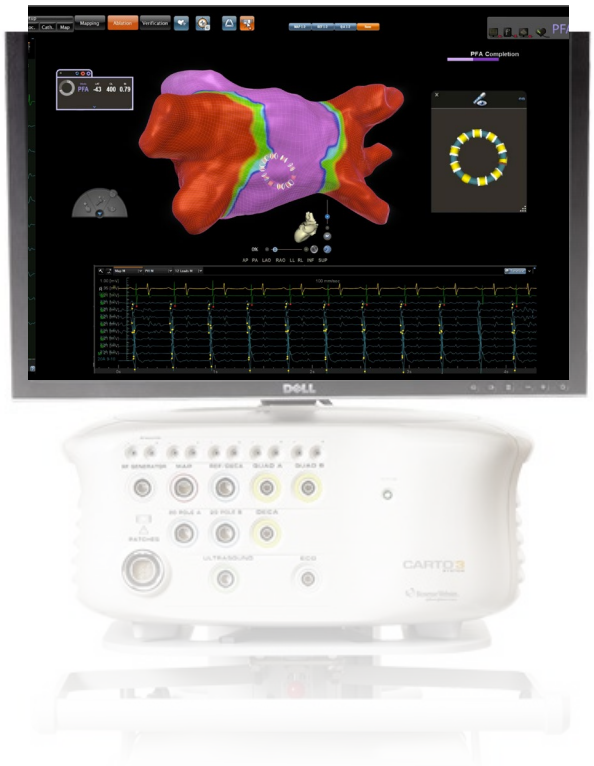
The VARIPULSE™ Catheter utilizes bipolar and biphasic PFA to accurately and efficiently create durable lesions while also simplifying the workflow, and reducing the risk of thermal injuries during catheter ablation procedures. The operator can choose to deliver therapy through all electrodes or select specific ones for more flexibility in treatment location and application efficiency.

The catheter's unique design allows for easy manipulation and contact anywhere in the left atrial (LA) chamber, while its full integration with the CARTO™ 3 System enables accurate navigation without the need for fluoroscopy, making it easier to place the catheter precisely within the 3D chamber for optimal therapy delivery.

CARTO Integration

The VARIPULSE™ Platform provides a holistic PFA experience with the CARTO™ System integration, allowing physicians to adapt their AF procedure approach with patient-centric therapy.

The VARIPULSE™ Platform enables precise energy delivery and identification of gaps to complete PVI efficiently, providing physicians with the confidence of the accurate CARTO™ Ecosystem they know.



EXCELLENT SAFETY

In clinical trials, VARIPULSE™ Catheter has demonstrated a very favorable safety profile with no device-related adverse events reported.[3,6,9*]

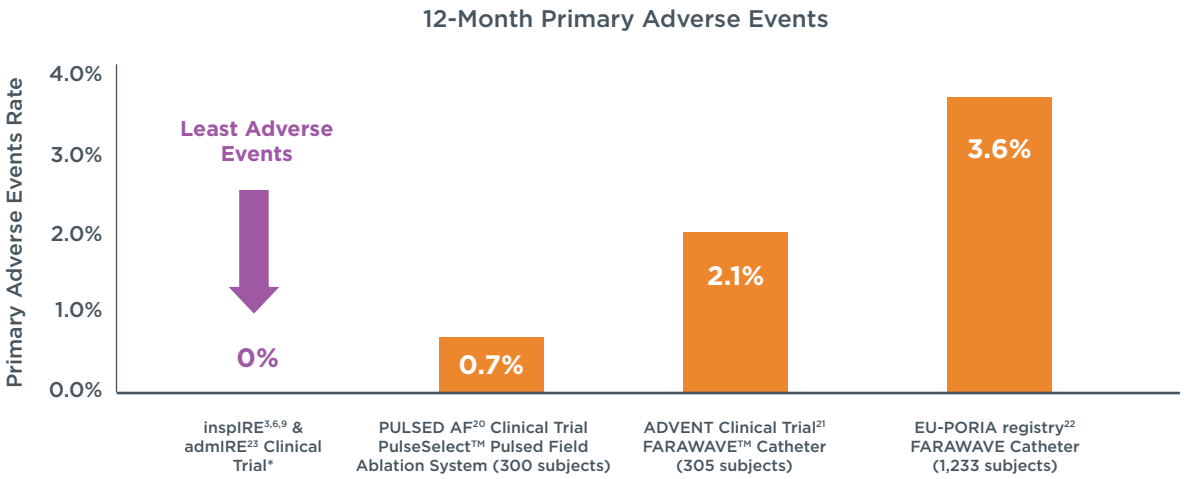
*Based on results from the InspIRE trial with 226 subjects.

PRIMARY ADVERSE EVENTS

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, thromboembolism, TIA, or myocardial infarction.[3,6,9,23]

OVERALL LOW SAFETY EVENT RATE

The EU-PORIA registry (FARAWAVE™ Catheter) reported that the overall safety event rate for ablation with PFA was 3.6%, with 45 events reported in 1,233 subjects after 12 months. This event rate is consistent with those previously reported for real-world experiences with thermal ablation modalities.[22]



*inspIRE 226 subjects; admIRE clinical trial pilot phase 21 subjects

No statistical analysis performed for comparison
Primary Adverse Events for all studies include: death, atrioesophageal fistula, myocardial infarction, cardiac tamponade/perforation, stroke/ cerebrovascular accident/ transient ischemic attack, phrenic nerve injury/ diaphragmatic paralysis, major vascular access complication/ bleeding, PV stenosis.

HIGHLY EFFECTIVE

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.[3,6,9,18]

100%
ACUTE SUCCESS

In prospective PFA clinical trials (inspIRE, admIRE, IMPULSE, PEFCAT and PEFCAT II), 100% of patients achieved acute PVI success.[3,6,9,18,23]

82%
CLINICAL SUCCESS

The inspIRE clinical study, using the VARIPULSE™ Catheter reported clinical success of freedom from symptomatic recurrence was 81.7% (95% CI 76.1% - 87.2%)[3]

*Clinical success defined as freedom from documented symptomatic AF/AFL/AT

80%
FREEDOM FROM ARRHYTHMIA RECURRENCE

The inspIRE and admIRE pilot cohort using the VARIPULSE™ Catheter with optimal PFA applications reported 80%* freedom from arrhythmia at 12 months.[23]

*Associated when >12 applications per vein were applied/used

>76%

CLINICAL SUCCESS AT 12 MONTHS

Results from the inspIRE clinical study, using the VARIPULSE™ Catheter indicate clinical success for patients undergoing PFA at 12 months were 76.9%* (95% CI, 63.7%–90.1%) and 78.9% (95% CI, 71.9%–85.9%) for Wave I (n=40) and Wave II (n=186), respectively.[6]

*After a 3-month blanking period; using stringent monitoring

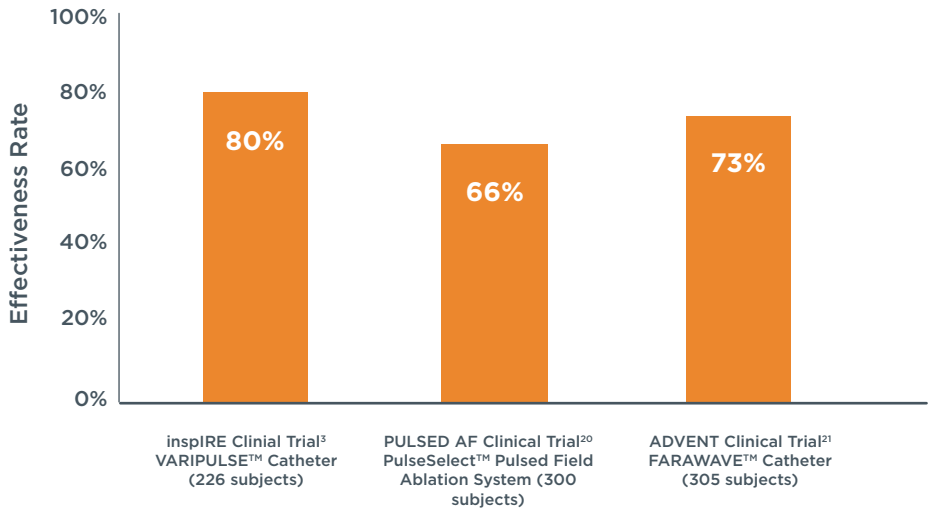
>92%

FREEDOM FROM REPEAT ABLATION AT 12 MONTHS

Results from the inspIRE clinical study, using the VARIPULSE™ Catheter indicated 12-month freedom from repeat ablation was 92.5%* (95% CI, 84.3%–100.0%; Wave I) and 92.3% (95% CI, 87.6%–96.9%); Wave II among patients undergoing PFA.[3,6]

*After a 3-month blanking period

12-Month Primary Effectiveness (including failure modes)



*12-Month effectiveness with optimal PFA applications
No statistical analysis performed for comparison

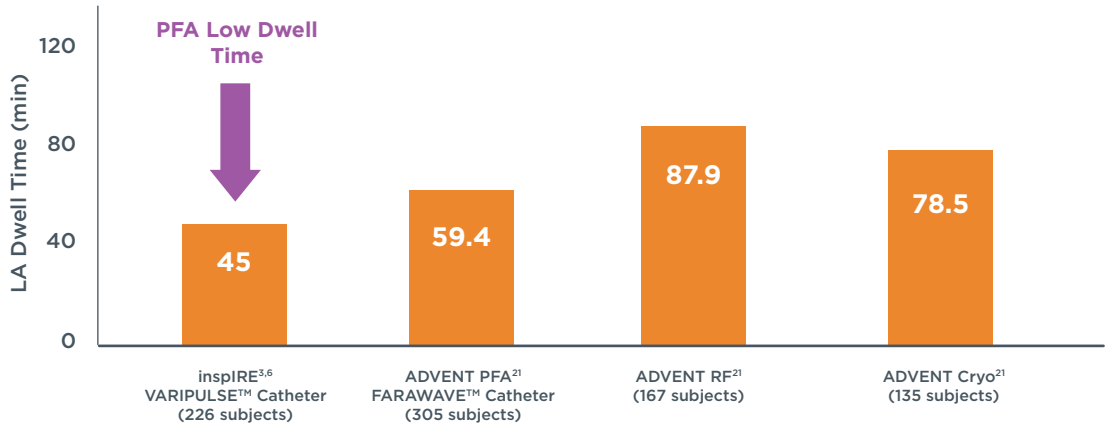
HIGHLY EFFICIENT

Catheter ablation using the PFA system was confirmed to be effective, and appears to have shorter procedure time and catheter dwell time.[6]

27 MIN
PFA TIME

The inspIRE clinical trial using the VARIPULSE™ Catheter reported a mean total transpired PFA time of 26.7 ± 14.0 minutes in PAF patients.[3,6]

Clinical Trial LA Dwell Time Comparison Across Catheter Types



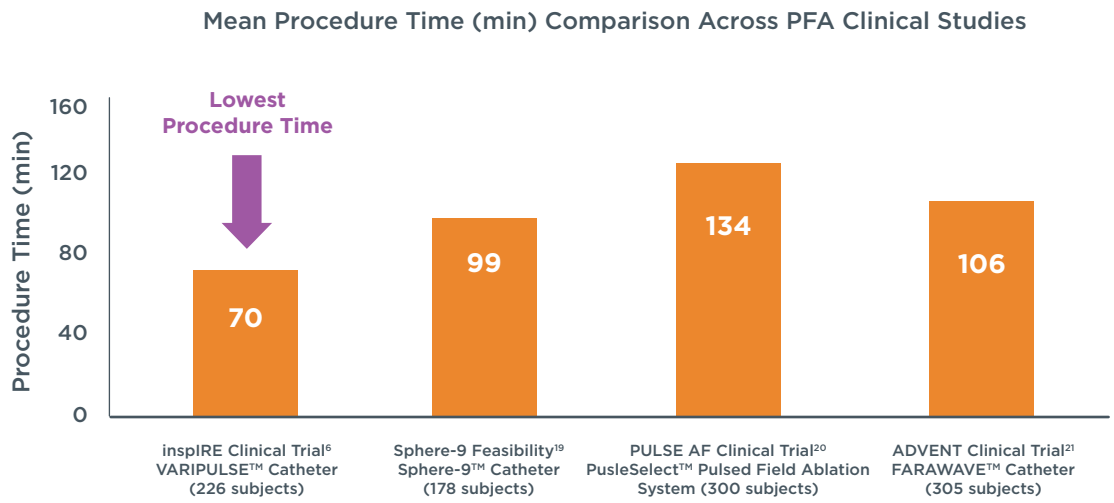
No statistical analysis performed for comparison

70 MIN
MEAN PROCEDURE TIME

In the inspIRE clinical study, using the VARIPULSE™ Catheter, the mean total procedure time reported was 70.1 ± 27.7 minutes.[3]

42%-44%
PROCEDURE TIME REDUCTION

Procedure times for the VARIPULSE™ Platform in the inspIRE trial were 42% faster than Cryo and 44% faster than RF when compared to the ADVENT trial results.[6,21]



No statistical analysis performed for comparison

LOW FLUOROSCOPY TIME

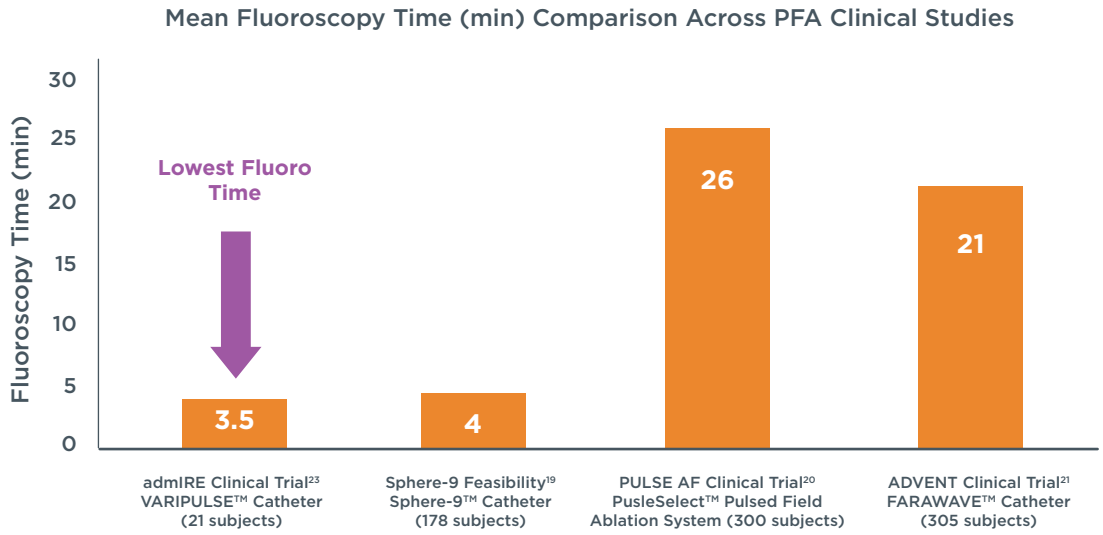
Catheter ablation using a PFA System enhances procedural efficiency by reducing the need for fluoroscopy, thus benefiting physicians and patient.[3,6,9]

3.5 MIN
FLUORO TIME

The initial findings of the admIRE study pilot phase show that the use of the VARIPULSE™ Catheter in combination with a 3D mapping system resulted in efficient and low fluoroscopy procedures, with a median exposure of only 3.5 minutes (ranging from 0 to 14.2 minutes). Moreover, almost half of the procedures (48%) were performed without any fluoroscopy.[23]

LOWER
FLUORO TIME

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



No statistical analysis performed for comparison

OPTIMAL WORKFLOW TIMES

Clinical studies have demonstrated that deep sedation may be used in PFA as an alternative to general anesthesia providing more flexibility for hospital workflow.[7]

DEEP SEDATION MAY BE USED

The inspIRE clinical study, using the VARIPULSE™ Catheter showed that use of the VARIPULSE™ Catheter and its accompanying biphasic pulse for PFA ablation procedures enable deep sedation protocol as an alternative to general anesthesia.[7] In the EU-PORIA registry, only 20% of PFA procedures were performed under general anesthesia, while 80% were performed under deep sedation.[7,22]

Clinical studies have demonstrated that the VARIPULSE™ Platform had a very short learning curve.

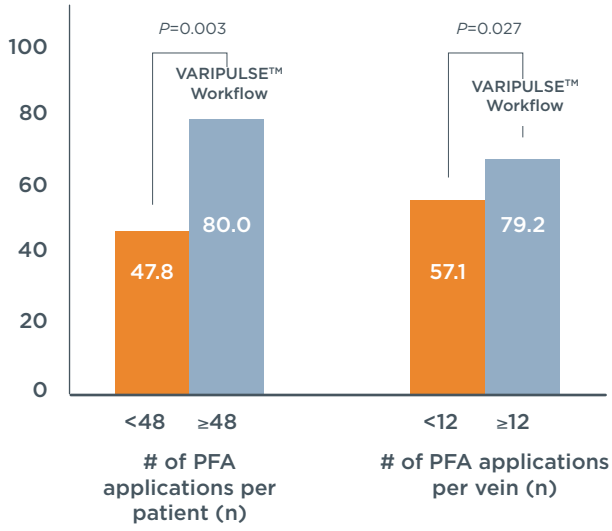
13.6 MIN

REDUCTION LA DWELL TIME

The inspIRE clinical study, using the VARIPULSE™ Catheter reported a very short learning curve resulting in a 13.6 minute reduction in PFA catheter dwell time from the first procedure (Wave 1, N=40).[6]

The VARIPULSE™ Platform uses an optimized workflow to improve procedure effectiveness. Clinical data demonstrates that following the workflow can result in a 50% reduction in the risk of AFib recurrence.[6]

AFib Recurrence is Minimized when VARIPULSE™ Platform Workflow is Utilized[6,25]



The VARIPULSE™ Platform optimized workflow which recommends 48 PFA applications per patient (equivalent to 12 applications per vein). Clinical data has demonstrated that performing less than this requirement doubles the risk of AFib recurrence.[6]

*If isolation is not obtained, additional applications of PF ablation may be needed

KEY TAKEAWAYS

PFA-based PVI procedures using the VARIPULSE™ Platform in treating paroxysmal AF, were shown to demonstrate:

- Excellent safety
- High effectiveness
- Low procedure time and fluoroscopy use
- Minimal recurrence rates

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