

Johnson & Johnson Reports First Real-World VARIPULSE Pro Platform Data and 12-Month OMNYPULSE Platform Outcomes for Atrial Fibrillation Treatment at APHRS 2026

2026-10-22

VARIPURE findings reported 100% acute procedural success with the VARIPULSE Pro Platform, 0.4% primary adverse event rate and a mean ablation time of 17.9 minutesⁱ

Omny-IRE data showed 82.5% of patients treated with the investigational OMNYPULSE Platform¹ remained free from documented atrial arrhythmia recurrence at 12 months under stringent monitoringⁱⁱ

IRVINE, Calif.--(BUSINESS WIRE)-- Johnson & Johnson (NYSE: JNJ) today announced new data from the late-breaking VARIPURE and Omny-IRE studies presented at the Asia Pacific Heart Rhythm Society (APHRS) 2026 Annual Meeting in Busan, South Korea. Both studies were published simultaneously in **Europace** and **Heart Rhythm**, respectively.

VARIPULSE Pro Platform. Not approved in the U.S.

"The data presented at APHRS demonstrate the progress we

are making across our pulsed field ablation (PFA) pipeline and portfolio," said Gregory Michaud, M.D., Chief Medical and Scientific Officer, Electrophysiology, Johnson & Johnson. "The acute safety and efficiency results from VARIPULSE Pro and 12-month outcomes with the investigational OMNYPULSE Platform strengthen the clinical evidence supporting our differentiated technologies as we work to advance atrial fibrillation care for physicians and patients."

VARIPURE: First multicenter experience with the VARIPULSE Pro Platform

VARIPURE evaluated 225 patients treated across 19 centers in Europe, representing a diverse population of

paroxysmal (65.8%) and persistent (34.2%) atrial fibrillation (AF) patients.ⁱ The VARIPULSE Pro Platform introduced a new 3.8-second ablation pulse sequence and is currently available in Europe, Japan and other APAC and LATAM markets. It is not currently approved in the United States.

Key highlights from the late-breaking study include:

- Effectiveness and safety results: enrolled patients had 100% acute procedural success. Study data also shows one primary adverse event (0.4%) that was resolved without sequelae, and zero reported stroke, coronary spasm, acute kidney injury, or death.ⁱ
- Workflow evaluation: Mean ablation duration of 17.9 minutes, and single-catheter mapping and ablation used in 88.9% of cases.ⁱ

“The VARIPURE study provides the first real-world data for VARIPULSE Pro,” said Leon Iden, M.D.², Head of the Electrophysiology Department, Herzzentrum Bad Segeberg, Germany. “The findings on safety, acute procedural success and catheter versatility, together with conveniently short ablation duration, highlight the potential to streamline PFA procedures and help physicians deliver efficient, consistent care across a broad range of patients with atrial fibrillation.”ⁱ

Omny-IRE: 12-month outcomes with the investigational OMNYPULSE Platform

Omny-IRE evaluated 136 patients with symptomatic paroxysmal atrial fibrillation treated across 13 European centers.ⁱⁱ The investigational OMNYPULSE Platform features a large-tip focal PFA catheter with contact-force sensing.

Key findings from the late-breaking study include:

- Study effectiveness results: 82.5% freedom from documented atrial fibrillation, atrial flutter (AFL) or atrial tachycardia (AT) recurrence at 12 months with stringent monitoring; and 90.1% with standard-of-care monitoring.ⁱⁱ
- Safety results: 2.9% adverse event rate. Notably, all safety events were resolved.ⁱⁱ
- Quality-of-life and healthcare utilization results: 25.5-point mean improvement in the Atrial Fibrillation Effect on Quality-of-Life (AFEQT) score, alongside reductions in antiarrhythmic medication use and cardiovascular-related hospitalizations.ⁱⁱ

“For physicians evaluating new PFA technologies, sustained effectiveness at 12 months is a key measure of whether strong acute results translate into meaningful outcomes over time,” said Tom De Potter, M.D.³, Head of Electrophysiology and Associate Director of the Heart Center, OLV Hospital, Aalst, Belgium. “The Omny-IRE findings are encouraging because they extend beyond meeting the effectiveness and safety endpoints or collecting quality of life and healthcare utilization dataⁱⁱ, helping us better understand what treatment with the investigational

OMNYPULSE Platform could mean for both physicians and patients.”

Poster presentation: Comparative outcomes with CARTO 3 System and EnSite⁴ mapping system

CARTO 3 System is the foundation of Johnson & Johnson's integrated electrophysiology ecosystem, connecting technologies across access, imaging, mapping, ablation and clinical support designed to enable differentiated workflows that help physicians treat patients more efficiently, precisely and confidently.^{iii,iv,v}

A new 12-month analysis of the Premier Database, which included data from more than 1,000 hospitals, showed that use of the CARTO 3 System was associated with lower long-term AF-related acute-care utilization compared with EnSite. Patients treated with EnSite had a 31% higher risk of AF/AFL/AT-related inpatient readmissions or emergency room visits.^{vi}

Together, the APHRS 2026 findings provide real-world and multicenter clinical evidence from more than 350 patients across two distinct PFA platforms.^{i,ii} Alongside new comparative data for the CARTO 3 Systemⁱⁱⁱ, the results strengthen the evidence supporting Johnson & Johnson's differentiated electrophysiology portfolio and pipeline of PFA technologies, and their potential to enable efficient, consistent AF care.

About the Omny-IRE Study

Omny-IRE is a pivotal, prospective, multicenter, non-randomized study in Europe and Canada to demonstrate the safety and effectiveness of Johnson & Johnson MedTech's OMNYPULSE Platform, the principal components of which are the OMNYPULSE Catheter and the TRUPULSE Generator. The study is evaluating the system for the treatment of symptomatic paroxysmal atrial fibrillation during standard electrophysiology mapping and ablation procedures while also evaluating the incidence of primary adverse events within seven days post-procedure.

About the VARIPURE Study

VARIPURE, a substudy of SECURE, is a prospective, observational, multicenter postmarket follow-up study in Europe designed to systematically assess the safety and performance of PFA using the VARIPULSE Platform in routine clinical practice. By having patients consent prior to the procedure, ensuring all patient data collection through electronic data capture, implicates a higher level of scientific quality compared to retrospective data collection. This approach includes meticulous monitoring and data cleaning, alongside diligent oversight of safety data collection and review, thereby ensuring the accuracy and integrity of the dataset. This rigorous upfront monitoring is absent in most published data from PFA registries to date.

About Cardiovascular Solutions from Johnson & Johnson MedTech

Across Johnson & Johnson, we are tackling the world's most complex and pervasive health challenges. Through a cardiovascular portfolio that provides healthcare professionals with advanced mapping and navigation,

miniaturized tech, and precise ablation we are addressing conditions with significant unmet needs such as heart failure, coronary and peripheral artery disease, stroke, and atrial fibrillation. We are the global leaders in heart recovery, circulatory restoration, and the treatment of heart rhythm disorders, as well as an emerging leader in neurovascular care, committed to taking on two of the leading causes of death worldwide in heart failure and stroke. For more, visit **this website**.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity. Learn more about our MedTech sector's global scale and deep expertise in surgery, orthopaedics, vision, and cardiovascular solutions at <https://www.jnjmedtech.com/>. Follow us at **@JNJMedTech** and on **LinkedIn**.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to the VARIPULSE Platform and the OMNYPULSE Platform. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and global health care reforms and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com, www.investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Important information: Prior to use, refer to the instructions for use for indications, contraindications, adverse events, warnings and precautions. Caution: US law restricts this device to sale by or on the order of a physician
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- ¹ The OMNYPULSE Catheter is an investigational device and is not approved or available for sale.
² Dr. Iden served as a study investigator and as a consultant for Johnson & Johnson. Dr. Iden was not compensated for this authorship contribution.
³ Dr. De Potter served as a study investigator and as a consultant for Johnson & Johnson. Dr. De Potter was not compensated for this authorship contribution.
⁴ The third party trademarks used herein are the properties of their respective owners.
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ⁱ Iden L, Bessiere F, Almorad A, et al. First multicenter experience with the Seq2 sequence of variable loop circular catheter: insights from VARIPURE. Presented at: Asia Pacific Heart Rhythm Society (APHRS); October 22, 2026; Busan, South Korea.

ⁱⁱ De Potter T, Duytschaever M, Vijgen J, et al. Pulmonary vein isolation with a contact force-sensing large-tip focal pulsed field ablation catheter integrated with 3D mapping to treat paroxysmal atrial fibrillation: OMNY-IRE 12-month results. Presented at: Asia Pacific Heart Rhythm Society (APHRS); October 22, 2026; Busan, South Korea.

ⁱⁱⁱ Reddy VY, Calkins H, Mansour M, et al. Pulsed Field Ablation to Treat Paroxysmal Atrial Fibrillation: Safety and Effectiveness in the AdmIRE Pivotal Trial. *Circulation*. 2024;150(15):1174-1186. doi:10.1161/CIRCULATIONAHA.124.070333

^{iv} Osorio J, Hussein AA, Delaughter MC, et al. Very high-power short-duration, temperature-controlled radiofrequency ablation in paroxysmal atrial fibrillation: the prospective multicenter Q-FICIENCY trial. *JACC Clin Electrophysiol*. 2023;9(4):468-480.

^v Osorio J, Miranda-Arboleda AF, Velasco A, et al. Real-world data of radiofrequency catheter ablation in paroxysmal atrial fibrillation: Short- and long-term clinical outcomes from the prospective multicenter REAL-AF Registry. *Heart Rhythm*. 2024;21(11):2083-2091. doi:10.1016/j.hrthm.2024.04.090

^{vi} Costea AI, Khanna R, Iglesias M, Rong Y, Deshmukh AJ. Differences in long-term hospital readmission among patients with paroxysmal atrial fibrillation undergoing ablation using a non-integrated pulsed field catheter with CARTO 3 versus EnSite electroanatomical mapping system. Presented at: Asia Pacific Heart Rhythm Society (APHRS) 2026 Congress; October 21-24, 2026; Busan, South Korea.

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Source: Johnson & Johnson