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NEWS RELEASE

Johnson & Johnson Presents Early Outcomes from the OMNY-AF Pilot Study at 2026 AF Symposium

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OMNY-AF pilot study reports 90% 12-month freedom from AFib with zero procedure-related adverse events[i]

Additional data presented further reinforces the favorable and consistent safety and efficiency profile of the VARIPULSE platform[ii,iii,iv,v]

IRVINE, Calif.--(BUSINESS WIRE)-- Johnson & Johnson today announced 12-month pilot-phase data from the OMNY-AF study, evaluating the investigational OMNYPULSE Platform for the treatment of symptomatic paroxysmal atrial fibrillation (AFib), during the 31st Annual AF Symposium in Boston. Initial results for 12-month outcomes across the 30-patient pilot cohort show investigators achieved 100% acute procedural success with no procedure-associated adverse events, while 56.7% of cases were performed with zero fluoroscopy and 90% of patients achieved primary effectiveness at 12 months.[i]

OMNY-AF is a prospective, single-arm, multi-center clinical trial conducted across more than 40 sites in the U.S. and Australia.[vi] The study pairs the OMNYPULSE Catheter, a 12 mm large-tip focal catheter featuring contact-force sensing and bipolar, biphasic pulse delivery with the TRUPULSE Generator. This integrated design combines precise mapping, controlled energy delivery and live feedback through the PF index on the CARTO 3 System.[vii] The OMNYPULSE Platform is not currently approved in any region of the world.

“The 12-month data provide encouraging early evidence on the OMNY-AF study with promising safety outcomes – no procedure-related adverse events or MRI-detected cerebral lesions – across eight centers in the pilot phase[i]. In my cases during the ongoing OMNY-AF trial, the seamless integration of advanced mapping, ultrasound, and PF Index with contact force were valuable for precise and efficient pulsed field energy delivery,” said Dinesh Sharma,

M.D.[1], Section Head of Cardiac Electrophysiology at the Naples Heart Institute, the study presenting author.

Alongside the OMNY-AF data, Johnson & Johnson is highlighting new findings related to the VARIPULSE Platform. Data presented by Andrea Natale, M.D.[2], and simultaneously published in **JACC Clin Electrophysiology**, by Moussa Mansour, M.D.[3] examined the incidence of neurovascular events following the workflow enhancements and the introduction of an optimized irrigation flow rate. Notably, the platform sustained a low neurovascular event rate of 0.22% in 6,811 patients after implementation of both workflow enhancements and the updated irrigation rate.[ii]

Additional VARIPULSE Platform data presented at AF Symposium adds to the growing body of evidence underscoring the platform's consistent and favorable safety profile across a range of clinical and real-world settings, including:

- VARISURE Safety survey data presented by Christopher Porterfield, M.D.[4]: Early results from this physician survey on 850 procedures indicated low complication rates with a 1.9% rate of primary adverse events, a 0.2% incidence of neurovascular events and no reported cases of coronary spasm or death. Same-day discharge was achieved in 87.9% of patients. [iii]
- REAL AF registry analysis presented by Mohammad-Ali Jazayeri, M.D.[5]: Results from the REAL AF registry showed excellent acute safety outcomes of the VARIPULSE Catheter, with a low overall acute safety event rate of 0.5% with no neurovascular events, high rates of same-day discharge and no observed differences in safety outcomes across AFib classifications. [iv]
- Irrigation Flow Optimization research presented by Fengwei Zou, M.D.[6]: Preclinical data demonstrated parity between the 4 mL/min and 30 mL/min irrigation rates in microbubble generation, hemolysis and lesion depth when using the VARIPULSE Catheter, while confirming that higher irrigation significantly reduced electrode surface heating. [v]

"These data reinforce confidence in the consistency of safety outcomes observed across Johnson & Johnson's electrophysiology portfolio. As a relatively new energy modality, pulse field ablation technologies should be individually evaluated for safety and reproducibility in atrial fibrillation ablation," said Gregory Michaud, M.D., Chief Medical and Scientific Officer, Electrophysiology, MedTech, Johnson & Johnson. "As pulsed field ablation continues to evolve, rigorous evidence generation and transparent data sharing will be essential to advancing the science and enabling the next wave of innovation with this technology."

Johnson & Johnson remains committed to evidence-driven innovation that advances patient care and informs clinical decision-making across its electrophysiology portfolio. These efforts are supported by the CARTO 3 System, the world's leading cardiac mapping system[7].

About The OMNY-AF Study

The OMNY-AF study is a prospective, single-arm, multi-center study evaluating the clinical safety and effectiveness of the OMNYPULSE Catheter for the treatment of symptomatic paroxysmal AFib. Up to 440 enrolled subjects will undergo an ablation procedure with the OMNYPULSE Platform. The primary safety endpoint in the study is the occurrence of Primary Adverse Events within seven days of the ablation procedure. The primary effectiveness endpoint is freedom from documented (symptomatic and asymptomatic) atrial tachyarrhythmia episodes based on electrocardiographic data and additional failure modes during the effectiveness evaluation period over a 12-month period.

About the VARIPULSE Platform

The VARIPULSE Platform is Johnson & Johnson MedTech's Pulsed Field ablation system. The fully integrated platform includes the VARIPULSE Catheter, TRUPULSE Generator, and CARTO 3 Mapping System VARIPULSE Software. The Platform is now approved for use in the United States, Europe, Asia Pacific, Canada, and Latin America.

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 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 **biosensewebster.com**.

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://thenext.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 Collaborative Outcomes Registry for Evidence in Ventricular Arrhythmias. 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.

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[1]Dr. Sharma served as a study investigator and as a consultant for Johnson & Johnson. Dr. Sharma was not compensated for this authorship contribution.
[2]Dr. Natale served as a study investigator and as a consultant for Johnson & Johnson. Dr. Natale was not compensated for this authorship contribution.
[3]Dr. Mansour served as a study investigator and as a consultant for Johnson & Johnson. Dr. Mansour was not compensated for this authorship contribution.
[4]Dr. Porterfield served as a study investigator and as a consultant for Johnson & Johnson. Dr. Porterfield was not compensated for this authorship contribution.
[5]Dr. Jazayeri served as a study investigator and as a consultant for Johnson & Johnson. Dr. Jazayeri was not compensated for this authorship contribution.
[6]Dr. Zou served as a study investigator and as a consultant for Johnson & Johnson. Dr. Zou was not compensated for this authorship contribution.
[7]J&J MedTech US EP Market Dynamics. Source: DRG Clarivate. Data Latency: 8 weeks. Market Coverage: ~35% US Hospitals.
[i]Weisman D, Khanna R, Maccioni S, Rong Y, Al-Azizi KM. Pulsed field ablation using a large-tip focal catheter with 3D mapping integration: early outcomes from the OMNY-AF single-arm pilot study. Presented at: AFib Symposium; February 6, 2026; Boston, MA.
[ii]Mansour M, Michaud G, Di Biase L, Zei P, Sauer W, Heist K, Nair D, Reddy V, Natale A. Reduced neurovascular events following workflow and irrigation adjustments with a variable loop circular catheter for pulse field ablation. Presented at: AFib Symposium; February 5–7, 2026; Boston, MA.
[iii]Porterfield C, Munjal J, Hushion M, Varley A, Haas P, Quin EM, Rouse C, Krishnan K, Marrouche N. The variable loop circular catheter safety survey (VARISURE): early results. Presented at: AFib Symposium; February 5-7, 2026; Boston, MA.
[iv]Jazayeri M, Khaykin Y, Morales G, Joshi N, Silva J, Hughey A, Steckman D, Osorio J, Zei P, Koplan B, Silverstein J, Ebinger M, Greenberg J, Dominic P, Conti S, Quadros K, Saleem M, Smith M, Gampa A, Porterfield C, Krishnan K. Acute safety profile of variable loop circular catheter pulsed field ablation for paroxysmal and persistent atrial fibrillation in the REAL AF registry. Presented at: AFib Symposium; February 5-7, 2026; Boston, MA.
[v]Zou F, Zhang X, Gomez T, Byun E, Chen Q, Marazzato J, Schiavone M, Mohanty S, La Fazia VM, Motta J, Zamora C, Pandey S, Safren L, Safren Y, Grupposo V, Ynoa D, Lin A, Natale A, Guttenplan N, Di Biase L.Irrigation flow optimization during pulsed field ablation: preclinical insights with a variable loop circular catheter (VLCC). Presented at: AFib Symposium; February 5-7, 2026; Boston, MA.
[vi]A Study of Assessment on Safety and Effectiveness of BWI Pulsed Field Ablation With OMNYPULSE Catheter for the Treatment of Paroxysmal Atrial Fibrillation (PAF) (OMNY-AF). Clinicaltrials.gov. Accessed January 30, 2026.
[vii]Jnjmedtech. OMNYPULSE Bi-Directional Catheter IFU.

Media Contacts:

Erin Farley

Efarley1@its.jnj.com

Majo Echeverria

MEchever@its.jnj.com

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