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NEWS RELEASE

Johnson & Johnson Unveils Results from the VARIPURE Substudy of SECURE, a Real-World Study on VARIPULSE™ Platform, at 2025 European Society of Cardiology (ESC) Congress

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VARIPURE demonstrated strong safety outcomes with no incidence of stroke and 99.7% acute effectiveness of the VARIPULSE™ Platform in nearly 800 enrolled patients[i]

IRVINE, Calif., Sept. 2, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) -- Johnson & Johnson MedTech, a global leader in cardiac arrhythmia treatment, today announced acute safety and effectiveness results from the VARIPURE substudy of SECURE, evaluating the VARIPULSE™ Platform in pulsed field ablation (PFA) procedures for atrial fibrillation (AF). The real-world data, presented at the 2025 European Society of Cardiology (ESC) Congress in Madrid, demonstrated a strong safety profile, high acute effectiveness and procedural efficiency within the 791 patients included in this analysis: notably, a 0.6% primary adverse rate with no strokes was reported along with 99.7% acute PVI and high adherence to the recommended ablation workflow.[i]

VARIPURE, a SECURE substudy, is a prospective, observational, post-market study conducted across 20 European centers, including 62 operators, that evaluated acute safety, effectiveness, and procedural characteristics of index AF ablations performed with the VARIPULSE™ Platform.[i] The VARIPULSE™ Platform consists of the VARIPULSE™ Catheter and TRUPULSE™ Generator, which seamlessly integrates with the CARTO™ 3 System and enables an efficient and reproducible workflow that enhances treatment and optimizes outcomes for AF.[ii,iii,iv]

"An overall 0.6 percent primary adverse event rate with no strokes, coronary spasm, or other PFA-related complications demonstrates a favorable safety profile when using the VARIPULSE™ Platform. These outcomes, observed in nearly 800 patients across varying procedural workflows, demonstrate the platform's consistent

application and adaptability in this study. By delivering a 99.7 percent acute PVI rate alongside seamless integration into diverse procedural workflows, this study reinforces our ability to deliver durable lesion sets, giving electrophysiologists the confidence to adopt PFA widely and safely[i]," said Alexandre Almorad[1], M.D., Cardiac Electrophysiologist, Director of the Arrhythmia Unit at Brussels University Hospital St Pierre and at the Brussels Heart Rhythm Management Center, the study presenting author.

The consistency and scale of these results reinforce PFA as a transformative option for AF care, illustrating how the VARIPULSE™ Platform's safety, efficacy, and reproducibility are already reshaping everyday clinical practice.

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[1] Dr. Almorad serves as a consultant for Johnson & Johnson but was not compensated for this announcement

In addition to VARIPURE, Johnson & Johnson MedTech recently highlighted at Kansas City HRS new real-world evidence regarding the VARIPULSE™ Platform from the company funded REAL AF Registry—a collaboration across 70 sites in the US and Canada. The REAL AF analysis included 200 diverse clinical profiles under different workflows using the VARIPULSE™ Platform, with nearly 80% of these procedures completed with the 30mL irrigation flow rate. No strokes, deaths, or device-related hospitalizations were reported, and only one minor event occurred that was deemed procedure-, not device-related.[v]

"Johnson & Johnson MedTech is committed to advancing the real-world evidence base for VARIPULSE™, generating robust clinical data to demonstrate its safety and efficacy across diverse patient populations," said Jennifer Currin, Ph.D., Vice President, Scientific Affairs, Electrophysiology, Johnson & Johnson MedTech. "Through growing registries and collaborative studies with electrophysiologists in everyday practice settings, we're building the clinical foundation that empowers physicians to optimize patient outcomes and establish a new standard of care in cardiac ablation."

Johnson & Johnson MedTech will continue collaborating with the clinical community to expand real-world evidence around the VARIPULSE™ Platform and accelerate patient-centered innovation in atrial fibrillation care.

About the VARIPURE Study

VARIPURE, a substudy of SECURE, is a prospective, observational, multicenter postmarket follow-up study in Europe, Middle East, and Africa 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 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 regarding the VARIPULSE™ 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: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges and uncertainties inherent in product research and development,

including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including 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** 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 supplied with this device for indications, contraindications, side effects, warnings and precautions.

This press release reports the use of VARIPULSE™ Catheter with 30mL/Min irrigation flow rate. In EU, the approval of this workflow is in review, it is not CE marked and not approved for use. Refer to the IFU applicable for your country for approved flow rate.

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[i] Almorad A, Sebag FS, Brix Kronborg M, et al. Acute safety, effectiveness and procedural workflow for the pulsed field ablation variable loop circular catheter in AF procedures: a prospective, multicenter, post-market clinical trial. Presented at: European Society of Cardiology (ESC) Congress; September 1, 2025; Madrid, Spain.

[ii] Di Biase L, Marazzato J, Gomez T, et al. Application Repetition and Electrode-Tissue-Contact Results in Deeper Lesions Using a Pulsed-Field Ablation Circular Variable Loop Catheter. Europace. Published online August 16, 2024. Page 3, paragraph 2, Results Section

[iii] Duytschaever M, De Potter T, Grimaldi M, et al. Paroxysmal Atrial Fibrillation Ablation Using a Novel Variable-Loop Biphasic Pulsed Field Ablation Catheter Integrated With a 3-Dimensional Mapping System: 1-Year Outcomes of the Multicenter inspIRE Study. Circ Arrhythm Electrophysiol. 2023 Mar;16(3):e011780. Page 5, Column 1, paragraph 1

[iv] 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. Published online September 11, 2024. doi: 10.1161/CIRCULATIONAHA.124.070333.Page 5, paragraph 2, Procedural Data Section

[v] Porterfield C, Krishnan K, Saleem M, Steckman D, Ebinger M, Gampa A, et al. Real-world safety profile of a multi-electrode variable loop pulsed-field ablation catheter. Presented at: Kansas City Heart Rhythm Symposium 2025; August 16 2025; Overland Park (Kansas City), KS.

Media Contacts:

Erin Farley

Efarley1@its.jnj.com

Majo Echeverria

MEchever@its.jnj.com

Investor Relations:

Sandra Easton

investor-relations@its.jnj.com

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