Johnson & Johnson MedTech | Cardiovascular

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FOR IMMEDIATE RELEASE

Johnson & Johnson Launches Landmark Head-to-Head Pulsed Field Ablation Trial in Persistent Atrial Fibrillation

The PERSIGMA randomized control trial will deliver comparative evidence on the safety and effectiveness of the investigational VARIPULSE Pro and FARAPULSE[1] platforms

Irvine, CA – April 24, 2026 – Johnson & Johnson today announced the initiation of the PERSIGMA randomized controlled trial (RCT), one of the first randomized studies evaluating competitive pulsed field ablation (PFA) technologies. In this rapidly advancing field, there is an increasing need for head-to-head data that provides insights on how different technologies influence outcomes in practice. PERSIGMA RCT reflects a deliberate step forward to generate clear, comparative evidence and bring greater rigor to how PFA technologies are evaluated.

Up to 466 participants across 50 sites will be randomly assigned to receive treatment with either VARIPULSE Pro Platform -the next-generation pulse sequence PFA- or the control FARAPULSE PFA platform[1] in patients with persistent atrial fibrillation (AFib). VARIPULSE Pro received CE mark in March, and is not yet approved in the U.S. The study's primary endpoints include safety, evaluated by the occurrence of primary adverse events, and effectiveness, defined by freedom from arrhythmia recurrences during the evaluation period of 60 days after the procedure.

Johnson & Johnson is committed to continuously evolving its PFA portfolio. The VARIPULSE Pro Platform is integrated with the CARTO System, a connected ecosystem that brings together imaging, mapping, and therapy. This evolution is driven through multigenerational innovative launches, including optimized irrigation rates and enhanced pulse sequences to further improve procedural efficiency and patient outcomes[i,ii,iii,iv]. It seeks to build on the platform's proven precision[v,vi] and safety profile[vii] supported by VARIPURE 12-month interim results, presented at the 2026 EHRA Congress[viii]. Additional real-world data will be presented during HRS 2026[ix,x,xi].

"Having this head-to-head study to compare pulsed field ablation technologies is extremely important for the electrophysiology community since it will help us better understand how they perform relative to one another and make more informed treatment decisions in daily practice", said Devi Nair[2], M.D., FHRS, Director of Cardiac Electrophysiology & Research, St. Bernard's Medical Center & Arrhythmia Research Group, Jonesboro, Arkansas, and Co-National Study Principal Investigator of the PERSIGMA trial.

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[1] Trademarks listed are the property of their respective owners

[2] Dr. Nair served as a study investigator and as a consultant for Johnson & Johnson. Dr. Nair was not compensated for this authorship contribution.

At Heart Rhythm 2026 Congress in Chicago, IL, Dr. Devi Nair will feature one of the first cases from the PERSIGMA RCT trial during the Rhythm Theatre presentations on Friday April 24th, offering an early look at procedural experience with the study protocol and PFA technology.

“PERSIGMA marks an exciting next phase in PFA research—moving the field forward with the rigorous, head-to-head evidence we need in persistent atrial fibrillation,” said Andrea Natale[3], M.D, F.A.C.C., F.H.R.S., F.E.S.C. Executive Medical Director, Texas Cardiac Arrhythmia Institute at St. David's Medical Center and Co-National Study Principal Investigator of the PERSIGMA trial. “As we broaden evaluation of PFA technology into more complex patient populations, studies like this are essential to helping physicians understand performance, refine procedural strategies, and ultimately improve outcomes for patients living with AFib.”

Atrial fibrillation is the most common sustained cardiac arrhythmia and remains a significant public health challenge. It is a progressive disease that becomes more complex to treat over time. It often begins as paroxysmal atrial fibrillation with intermittent episodes that terminate spontaneously, and can advance to persistent atrial fibrillation, in which episodes last longer than seven days and typically require medical intervention to restore normal heart rhythm[xii].

“Pulsed field ablation has advanced rapidly but not all technologies perform the same, and physicians make decisions without direct comparative data,” said Gregory Michaud, M.D., Chief Medical and Scientific Officer, Electrophysiology, Johnson & Johnson. “We are confident in our PFA technology, our innovation pipeline and in the strength of our integrated portfolio. With PERSIGMA RCT, we are raising the bar to better understand how different PFA technologies perform in patients with persistent AFib and expand the indication to a broader patient population.”

With PERSIGMA RCT, the company will continue to grow the body of research supporting its electrophysiology portfolio to strengthen the evidence base for PFA and help improve outcomes for patients living with atrial fibrillation.

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 J&J MedTech electrophysiology.

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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 VARIPULSE Pro. 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: 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, 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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