

Johnson & Johnson Announces FDA Approval for the Dual Energy THERMOCOOL SMARTTOUCH SF Platform

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- Dual Energy THERMOCOOL SMARTTOUCH SF Platform brings pulse field and radiofrequency energy together in a single catheter.
- Integrated with the CARTO ecosystem, the platform gives physicians greater versatility to tailor treatment based on patient anatomy and case complexity.ⁱ

IRVINE, Calif.--(BUSINESS WIRE)-- Johnson & Johnson (NYSE: JNJ) today announced that the U.S. Food and Drug Administration (FDA) approved the Dual Energy THERMOCOOL SMARTTOUCH SF Platform (DE STSF), an integrated catheter ablation solution that enables electrophysiologists to deliver both radiofrequency (RF) and pulsed field (PF) energy through a single catheter.ⁱ

Dual Energy THERMOCOOL SMARTTOUCH SF Catheter

"The FDA approval of the Dual Energy THERMOCOOL

SMARTTOUCH SF Platform is another important milestone in what has been an incredible pace of innovation for our business," said Michael Bodner, Company Group Chair, Electrophysiology & Neurovascular, MedTech, Johnson & Johnson. "Our goal has always been to put the best possible technologies into physicians' hands so they can treat increasingly complex cases with confidence. Following a successful introduction in Europe, we're pleased to rapidly expand access to this technology in the U.S. and continue building on the momentum of one of the most active innovation periods in our history."

Built on the THERMOCOOL SMARTTOUCH SF Platform, which has extensive clinical validation and has treated over one million patients in the U.S., the DE STSF Platform brings pulse field capability to a catheter physicians know and

trust.ⁱ

The DE STSF platform is integrated with the CARTO ecosystem, including advanced mapping, imaging and PF Index guidance, helping physicians confidently deliver energy with precise contact force while supporting a predictable procedure and reproducible workflow. The dual energy capability gives physicians the versatility to use RF or PF energy based on patient anatomy and case complexity.ⁱ

"Electrophysiologists need technologies that support different anatomies, substrates, workflows and treatment goals," said Dhanunjaya (DJ) Lakkireddy¹, M.D., FHRS, MBA, Executive Medical Director, The Kansas City Heart Rhythm Institute. "The Dual Energy THERMOCOOL SMARTTOUCH SF Platform gives electrophysiologists the choice to use RF or PF energy based on the needs of each procedure. Having both capabilities integrated in the CARTO system can help us adapt our approach for more complex cases and plan procedures with greater confidence."

Following FDA approval, first U.S. procedures with the DE STSF Platform are expected to begin this summer as Johnson & Johnson initiates a phased commercial rollout.

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 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 Dual Energy THERMOCOOL SMARTTOUCH SF. 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
i Dr. Lakkireddy serves as a consultant for Johnson & Johnson. Dr. Lakkireddy was not compensated for this authorship contribution. Mattias Duytschaever, Gediminas Račkauskas, Tom De Potter, et al. Dual energy for pulmonary vein isolation using dual-energy focal ablation technology integrated with a three-dimensional mapping system: SmartFIRE 3-month results EP Europace, Volume 26, Issue 5, May 2024, euae088, <https://doi.org/10.1093/europace/euae088>

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