Johnson&Johnson MedTech | Cardiovascular

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FOR IMMEDIATE RELEASE

Johnson & Johnson MedTech Announces CE Mark Approval for Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter

The Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter offers electrophysiologists the ability to switch between radiofrequency and pulsed field energy in a single, fully integrated catheter

CE Mark supported by the SmartfIRE study on the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter for the treatment of paroxysmal atrial fibrillation (AFib)

Additional milestones announced include complete enrollment of the SmartPulse and PulseSmart trials

Irvine, CA – January 10, 2025 – Johnson & Johnson MedTech, a global leader in cardiac arrhythmia treatment, today announced European CE mark approval of the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter for the treatment of cardiac arrhythmias. The Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter is an irrigated, contact-force sensing catheter powered by the TRUPULSE™ Generator, and is fully integrated with the CARTO™ 3 System for electro-anatomical mapping and for tag indexing[1]. The company expects TRUPULSE™ Generator hardware compatibility in the first half of 2025. When fully approved, the platform will provide electrophysiologists with the ability to switch between radiofrequency (RF) and pulsed field (PF) energy in the same catheter they know and trust. The Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter is not currently approved in the United States. The Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter is designed on the same platform as the radiofrequency THERMOCOOL SMARTTOUCH™ SF Catheter – the most commonly used catheter in the world today, with many years of physician experience.

“As the number of people with AFib grows around the world, physicians are looking for integrated and flexible tools to help deliver safe, effective and efficient cardiac ablation procedures,” said Tom De Potter, M.D., Head of Electrophysiology and Associate Director of the Heart Center, OLV Hospital, Aalst, Belgium.[i] “Both PF and RF energy have important advantages in clinical practice. With the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter, having the ability to easily switch between RF and PF energy provides the flexibility to customize treatment depending on the patient anatomy and clinical need, enabling electrophysiologists to perform more targeted ablation procedures which could lead to improved outcomes for patients.”

[1] The CARTO VISITAG™ Module provides access to data collected during the application of energy. The Tag Index values should not be used to guide energy delivery.

The safety and efficacy of the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter was investigated in the SmartfIRE clinical trial.[2] Early results from the study, published in April 2024, showed that the use of the catheter led to a 100% acute success rate, with first-pass isolation achieved in 96.8% of veins.[3]*

“Based on our collaboration with electrophysiologists around the world, we know that each AFib procedure is different; having both RF and PF energy through one device will allow physicians to personalize each procedure based on patient anatomy and clinical need and offer a point-by-point workflow that many of our customers prefer,” said Jasmina Brooks, President, Electrophysiology, Johnson & Johnson MedTech. “The Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter offers the benefit of both energy modes in one familiar device. We are pleased to bring forward this innovation to enable electrophysiologists to deliver safe and effective procedures for patients in Europe impacted by AFib.”

Additional Studies Underway

In addition to receiving European CE Mark approval, the company is making strides to bring the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter to other regions of the world.

- The company has completed enrollment in the SmartPulse clinical trial – a prospective, single arm, multi-center clinical study of 250 patients with paroxysmal atrial fibrillation (PAF) across 27 sites in the United States to evaluate the safety and effectiveness of the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter.
- The PulseSmart clinical trial, evaluating the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter in Australia and Canada, has also completed enrollment. This trial enrolled 136 patients with drug-refractory PAF across 7 sites.

“The ability to deliver both PF and RF energy via the same catheter simplifies the workflow for ablation procedures and enables personalized treatment,” said Dr. Dhanunjaya (DJ) Lakkireddy, Executive Medical Director, Kansas City Heart Rhythm Institute, who took part in the SmartPulse clinical trial.[2] “In addition, the integration of the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter with the CARTO™ 3 System can enable real-time catheter visualization and feedback on contact force measurements and tag indexes, which are important factors for durable lesion formation.”

“The SmartPulse and PulseSmart studies are part of a broad set of PFA clinical trials and diverse research initiatives that Johnson & Johnson MedTech is undertaking to generate the evidence necessary to guide informed treatment decisions, optimize clinical use, and ultimately enhance AFib treatment outcomes,” said Jennifer Currin, Ph.D., Vice President, Scientific Affairs at Johnson & Johnson MedTech.

Catheter ablation is a minimally invasive procedure performed by an electrophysiologist to treat heart rhythm disorders, including AFib, by interrupting irregular electrical pathways in the heart.[4] Catheter ablation can be more than four times more effective than antiarrhythmic drugs alone in preventing recurrent arrhythmia in AFib patients.[ii,5]

In addition to the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter, Johnson & Johnson MedTech is committed to offering a portfolio of products designed to work seamlessly together for optimal efficiency and

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*n=137

[2] ClinicalTrials.gov. Safety and Effectiveness Evaluation of the THERMOCOOL SMARTTOUCH™ SF Catheter with the TRUPULSE™ Generator for treatment of Paroxysmal Atrial Fibrillation (PAF) (SmartfIRE). “https://clinicaltrials.gov/ct2/show/NCT05752487.

[3] Mattias Duytschaever, 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

[4] British Heart Foundation. Catheter Ablation. Available at: https://www.bhf.org.uk. Last accessed: January 2024.

[5] Joglar, J, et al. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2024 Jan, 83 (1) 109–279.

compatibility in the treatment of cardiac arrhythmias. This includes the VARIPULSE™ Platform, which received CE Mark in February 2024 and U.S. FDA approval in November 2024. The company is also investigating the OMNYPULSE™ Catheter – a large tip, focal PFA catheter; the OMNYPULSE™ Catheter is not approved in any region of the world.

About the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter
The Dual Energy THERMOCOOL SMARTTOUCH™ SF Platform consists of the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter[ii] – an irrigated, contact-force sensing catheter – and the TRUPULSE™ Generator, providing both RF and PF energy to the catheter through the toggling of the two energy sources on the generator monitor.[2] The catheter and the generator are fully integrated with the world's leading CARTO™ 3 System, enabling live 3D mapping and advanced visualization during ablation procedures.[ii] The Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter is the first dual energy pulsed field ablation (PFA) / radiofrequency (RF) ablation catheter integrated with a PF and RF tag index.

About the SmartfIRE Study
SmartfIRE is an open-label interventional study evaluating the safety and efficacy of the investigational Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter with the TRUPULSE™ Generator, in the treatment of paroxysmal atrial fibrillation. The study enrolled 149 adult patients in Europe with drug refractory paroxysmal AFib, identified as candidates for catheter ablation, who received (PF) or (RF) catheter ablation using the Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter and TRUPULSE™ generator during their cardiac ablation procedure. The study includes patients experiencing recurrent symptomatic atrial fibrillation following at least one antiarrhythmic drug (AAD; class I to IV), or patients who can either not tolerate AAD or for whom AAD is contraindicated.

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, circular 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 and connect on LinkedIn and X, formerly Twitter.

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 cardiovascular, orthopaedics, surgery and vision solutions at https://thenext.jnjmedtech.com. Biosense Webster, Inc. is a Johnson & Johnson MedTech company.

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 Dual Energy THERMOCOOL SMARTTOUCH™ SF Catheter. 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: uncertainty of regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of healthcare products and services; and trends toward healthcare cost

containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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 sec.gov, 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.

[i] AZ Sint-Jan Brugge Oostende AV entered into a clinical trial agreement with Johnson & Johnson Medical NV/SA for its participation in the SmartfIRE Clinical Trial. Dr. Mattias Duytschaever serves as a study investigator and was not compensated for his contributions to this announcement

[ii] Results reported after 9 months for patients with paroxysmal AFib who had failed 1 antiarrhythmic medication in randomized trial.