

Johnson & Johnson Launches Next-Generation Shockwave™ C2 Aero Fly Coronary IVL Catheter, Cutting IVL Treatment Time in Half

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- Next-generation intravascular lithotripsy (IVL) catheter delivers pulses at 2 Hz, improving efficiency in calcium modification treatment of coronary artery disease¹
- Faster pulsing reduces duration patients may experience procedure-induced ischemic time²
- Shockwave C2 Aero Fly builds on the best-in-class features of Shockwave C2 Aero, featuring leading deliverability, crossability and repositioning capabilities³

SANTA CLARA, Calif.--(BUSINESS WIRE)-- Johnson & Johnson (NYSE: JNJ) announced today the U.S. launch of its Shockwave C2 Aero Fly Coronary IVL Catheter designed to treat a broad range of calcified coronary artery lesions in half the time as previous coronary IVL devices.¹ Leveraging Shockwave IVL's differentiated mechanism of action, and building on improvements delivered in the Shockwave C2 Aero platform, this next-generation coronary IVL catheter delivers pulses at double the speed and decreases pause time between pulsing cycles by half, while maintaining the safety and effectiveness of prior-generation catheters.^{1,3,4}

The Shockwave™ C2 Aero Fly Coronary IVL Catheter delivers pulses at 2 Hz, cutting IVL treatment time in half.

"Shockwave C2 Aero Fly is built for the future of coronary interventions, where physicians

need proven technologies that can help them move faster without compromising safety or confidence in challenging calcified cases," said Mike Lang, Worldwide President, Circulatory Restoration, MedTech, Johnson & Johnson. "As the pioneer and leader of the category, Johnson & Johnson is giving physicians and patients an increasingly efficient, predictable platform designed to meet the growing demands of complex coronary care."

Built to Meet Growing Cath Lab Demand

Coronary artery disease (CAD) is the leading cause of death globally, affecting an estimated 315 million people worldwide and approximately 1 in 20 adults over the age of 20 in the U.S.^{5,6,7} With the prevalence of cardiovascular diseases expected to rise and coronary interventions among hospitals' highest-volume procedures, efficiency is critical to ensure cardiac catheterization laboratories and physicians can manage growing procedural volumes.^{8,9}

"In the cath lab, every second matters, especially as we see more complex cases and higher procedure volumes," said Hector Tamez Aguilar, M.D., Interventional Cardiologist at Piedmont Healthcare in Atlanta, Georgia.¹⁰ "By delivering pulses twice as fast and decreasing pause time between cycles, Shockwave C2 Aero Fly enables faster workflows, helping physicians treat calcified coronary disease more efficiently while meeting the growing pace and demand of cath labs."

Designed to Treat Calcified Coronary Disease More Efficiently

Shockwave C2 Aero Fly enables physicians to treat complex calcified coronary disease faster while enhancing the patient treatment experience through:

- Faster pulsing: Pulses are delivered at 2 Hz to cut treatment time in half, 115 seconds versus 230 seconds with previous generations of IVL.¹
- Shorter pause time: Pause time between pulsing cycles is cut to five seconds, shortening wait times between cycles by 50%.¹
- Reduced patient ischemic time: Lowered balloon inflation time minimizes temporary procedure-related blood flow blockage and patient ischemic symptoms, such as chest pain.²
- Leading deliverability, crossability and repositioning capabilities: Builds on Shockwave C2 Aero's best-in-class features.³

"During IVL treatment, balloon inflation temporarily blocks blood flow, and that time matters for patient care," said Karim Al-Azizi, M.D., Medical Director, Structural Heart Program and Cardiac Catheterization Laboratories at Baylor Scott & White Health, Plano, Texas.¹¹ "Shockwave C2 Aero Fly raises the bar for coronary interventions by making procedures easier for physicians and less strenuous for patients. Its shorter balloon inflation and pause time reduce ischemic time and related symptoms for patients, enabling better, quicker and more streamlined care."

Shockwave C2 Aero Fly is now available in the U.S. The next-generation coronary IVL technology will be featured in the Circulatory Restoration booth from Johnson & Johnson MedTech at TCT 2026, which is taking place in San Diego, California from October 31-November 3, 2026.

Cardiovascular Solutions from Johnson & Johnson

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 and peripheral 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 information on circulatory restoration, visit our **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 cardiovascular, orthopaedics, surgery and vision solutions at <https://www.jnjmedtech.com/en-US/>. Follow us at **@JNJMedTech** and on **LinkedIn**. Shockwave Medical, Inc. is a Johnson & Johnson company.

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 Shockwave C2 Aero Fly Coronary IVL Catheter. 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.

- ¹ As compared to Shockwave C2+/Shockwave C2 Aero. Treatment time includes pulsing time and pause time. Pause time may vary by patient need.
- ² A shorter inflation time exposes the patient to less ischemic time compared to prior Shockwave devices.
- ³ Compared to Shockwave C2+ in simulated use bench testing. Based on feedback from physicians who participated in the Limited Market Release Survey. Bench testing not necessarily being indicative of clinical outcomes.
- ⁴ Davies RE, Shlofmitz RA, Kim M, et al. Safety and Effectiveness of a Novel 2Hz Coronary IVL System: The Disrupt CAD Duo IDE Study. JACC Cardiovasc Interv. 2026 Mar 7;S1936-8798(26)00777-6. doi: 10.1016/j.jcin.2026.02.018.
- ⁵ Centers for Disease Control and Prevention. About Coronary Artery Disease (CAD). <https://www.cdc.gov/heart-disease/about/coronary-artery-disease.html>. Last Accessed: March 24, 2025.
- ⁶ Centers for Disease Control and Prevention. Heart Disease Facts. <https://www.cdc.gov/heart-disease/data-research/facts-stats/index.html>. Last Accessed: March 24, 2025.
- ⁷ JACC: <https://www.jacc.org/doi/10.1016/S0735-1097%2824%2904310-9>
- ⁸ T S Vijfinkel, B Nikookar, J Constandse, B H W Hendriks, M Van Der Elst, J J Van Den Dobbelsteen, Medical Process Engineering, Time is muscle: measuring workflow and procedure duration in the catheterization laboratory, European Heart Journal, Volume 44, Issue Supplement_2, November 2023. https://academic.oup.com/eurheartj/article/44/Supplement_2/ehad655.2947/7390764
- ⁹ Bruckel J, Lee A, Boudoulas KD. Strategies for Cost-Effective Care in the Cath Lab. Society for Cardiovascular Angiography & Interventions. Published March 16, 2023. Accessed August 7, 2026. <https://www.scai.org/quality-improvement-tools/qi-tips/strategies-cost-effective-care-cath-lab>
- ¹⁰ Dr. Hector Tamez Aguilar is a paid consultant for Shockwave Medical. He has not been compensated in connection with this press release.
- ¹¹ Dr. Karim Al-Azizi is a paid consultant for Shockwave Medical. He has not been compensated in connection with this press release.

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