Johnson&Johnson MedTech | Cardiovascular

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FOR IMMEDIATE RELEASE

Shockwave Medical Launches Novel Forward Intravascular Lithotripsy Platform in U.S. to Transform Treatment of Difficult-to-Cross Calcified Lesions

Now available in the U.S., the Shockwave Javelin Peripheral Intravascular Lithotripsy Catheter safely modifies and crosses occlusive or extremely narrowed calcific peripheral artery disease

SANTA CLARA, Calif. – March 4, 2025 – Today, Shockwave Medical, Inc., part of Johnson & Johnson MedTech and a global leader in the field of circulatory restoration, announced the U.S. launch of its Shockwave Javelin Peripheral IVL Catheter, a novel intravascular lithotripsy (IVL) platform designed to modify calcium and cross extremely narrowed vessels in patients with peripheral artery disease (PAD). The first-of-its-kind forward IVL platform has a similar safety and efficacy profile of legacy Shockwave IVL catheters and bolsters the company's market-leading IVL portfolio.

PAD is the narrowing or blockage of the vessels that carry blood from the heart to the legs, reducing blood flow and affecting more than eight million people aged 40 and older in the U.S.[1,2] People suffering from PAD have impaired quality of life and increased risk of heart attack or stroke.[1] Chronic limb-threatening ischemia (CLTI) is the most advanced and serious form of PAD, impacting nearly two million patients in the U.S. It is associated with 40% major amputations at one year and a 50% mortality rate at five years, worse than most forms of cancer.[3]

"Physicians have faced significant challenges in tackling complex calcific lesions in narrowed peripheral vessels, and there is a growing need for more effective crossing and treatment tools," said JD Corl, M.D., FACC, FSCAI, Medical Director of the PAD/CLI Program at The Lindner Center for Research and Education at The Christ Hospital.† "With proven safety and effectiveness similar to existing IVL devices, Shockwave's new IVL platform will bring a transformative approach to our peripheral practices, enabling us to make cases more efficient and optimize outcomes for our patients living with PAD, especially those with more complex CLTI."

The forward IVL platform is designed to modify calcium and cross calcified occlusive disease or extremely narrowed lesions where a wire will cross but devices might not. Shockwave Javelin has a working length of 150 centimeters and features a single distal emitter that creates up to 120 shockwave pulses. Each shockwave pulse creates a spherical energy field that extends beyond the tip of the catheter. This novel design delivers lithotripsy closer to calcium than the balloon-based platform. Despite the challenging nature of the calcified lesions studied, the clinical outcomes from the FORWARD PAD IDE trial demonstrated that Shockwave Javelin has a similar safety and effectiveness profile to balloon-based Shockwave IVL catheters.

“As the pioneer of IVL technology, our goal is to continue to deliver innovations that address the unmet needs of the physicians that we serve,” said Nick West, M.D., Chief Medical Officer, Shockwave Medical. “By listening to and leveraging their valuable insights, we developed our transformational forward IVL platform with the unique capability to both modify calcium and cross extremely narrowed vessels. We are proud to be leading the charge in offering endovascular interventionalists more flexibility to address critical treatment needs and potentially reduce the risks associated with CLTI for their patients.”

Combined with Shockwave E8, Shockwave L6, Shockwave M5+, and Shockwave S4 IVL catheters, the addition of the Shockwave Javelin Peripheral IVL catheter offers physicians a comprehensive IVL portfolio to treat challenging calcified lesions above and below the knee across the entire peripheral anatomy.

About Shockwave Medical
Shockwave Medical Inc., part of Johnson & Johnson MedTech, is a leader in the development and commercialization of innovative products that are transforming the treatment of cardiovascular disease. Its first-of-its-kind Intravascular Lithotripsy (IVL) technology has transformed the treatment of atherosclerotic cardiovascular disease by safely using sonic pressure waves to disrupt challenging calcified plaque, resulting in significantly improved patient outcomes. Its Reducer technology, which is under clinical investigation in the United States and is CE Marked in the European Union and the United Kingdom, is designed to provide relief to the millions of patients worldwide suffering from refractory angina by redistributing blood flow within the heart. Learn more at www.shockwavemedical.com.

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.

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. Follow us at @JNJMedTech and on LinkedIn. Shockwave Medical, Inc. is part of Johnson & Johnson MedTech.

Cautions Concerning Forward-Looking Statements
This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995. 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 Shockwave Medical, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; 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 health care 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 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. Neither Shockwave Medical, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.as a result of new information or future events or developments.

† Dr. Corl is a paid consultant for Shockwave Medical. He has not been compensated in connection with this press release.

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[1] https://www.cdc.gov/heart-disease/about/peripheral-arterial-disease.html

[2] https://www.nhlbi.nih.gov/health/peripheral-artery-disease

[3] https://www.ahajournals.org/doi/full/10.1161/CIRCOUTCOMES.120.007539