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Shockwave Medical Expands U.S. Peripheral IVL Portfolio with Enhanced Catheter

Shockwave E⁸ Augments IVL's Capabilities for Physicians Treating Peripheral Arterial Disease
Above and Below the Knee

SANTA CLARA, CA, September 16, 2024 – Shockwave Medical, Inc., part of Johnson & Johnson MedTech* and a global leader in the field of circulatory restoration, announced the full U.S. launch of the Shockwave E⁸ Peripheral IVL Catheter, following clearance by the U.S. Food and Drug Administration (FDA). The Shockwave E⁸ catheter is designed to optimize the treatment of patients with calcified femoro-popliteal and below-the-knee peripheral artery disease (PAD), including patients with complex chronic limb-threatening ischemia (CLTI).

PAD affects more than eight million people aged 40 and older in the United States. People suffering from PAD have not only impaired quality of life but also increased risk of heart attack or stroke. CLTI is the most advanced and serious form of PAD, impacting nearly 2 million patients in the U.S. It is associated with 40% major amputations at 1 year, and a 50% mortality rate at 5 years, worse than most forms of cancer.

"Shockwave's newest peripheral catheter offers significant improvements that will help physicians refine their treatment algorithm and better support challenging patients with heavily calcified disease," said Venita Chandra[†], M.D., Vascular Surgeon and Clinical Associate Professor, Division of Vascular Surgery, Stanford Health Care. "The catheter's ability to treat long lesions and its extended reach enable safe and effective treatment of some of our most difficult-to-treat patients, including those with CLTI, a complicated and severe disease state with a high mortality rate."

With four hundred pulses delivered twice per second, and eight emitters across an 80cm balloon, Shockwave E⁸ can treat longer lesions more efficiently. With an increased catheter working length of 150cm, physicians can extend their IVL treatment to reach below-the-knee and very distal lesions. Combined with Shockwave L⁶, Shockwave M⁵⁺, and Shockwave S⁴ IVL catheters, the addition of Shockwave E⁸ offers physicians a complete IVL portfolio to treat challenging calcified lesions across the entire peripheral anatomy.

"Shockwave E⁸ represents our commitment to physician-guided innovation while maintaining the simplicity and effectiveness of our IVL technology," said Isaac Zacharias, President, Shockwave Medical. "We have received very positive physician feedback on Shockwave E⁸ and look forward to establishing it as our new workhorse peripheral IVL catheter for physicians addressing challenging calcium above and below the knee."

About Shockwave Medical

Shockwave Medical, 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 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



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more at www.shockwavemedical.com.

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.

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 Shockwave E⁸ 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 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 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 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.

- * Comprising the surgery, orthopaedics, vision, and cardiovascular businesses within Johnson & Johnson's MedTech segment.
- [†] Dr. Chandra is a paid consultant for Shockwave Medical. She has not been compensated in connection with this press release.
- ¹ https://www.nhlbi.nih.gov/health/peripheral-artery-disease
- ² https://www.cdc.gov/heart-disease/about/peripheral-arterial-disease.html
- ³ https://www.ahajournals.org/doi/full/10.1161/CIRCOUTCOMES.120.007539