

Shockwave Unveils New Intravascular Lithotripsy Catheter for Calcified Below-the-Knee Peripheral Artery Disease in Europe

Designed Specifically to Address Challenges of Critical Limb Ischemia, the Shockwave S⁴ Catheter Expands the IVL System Portfolio

Fremont, Calif. — April 23, 2018 — Shockwave Medical, a pioneer in the treatment of calcified cardiovascular disease, today announced CE Mark and European commercial availability of the Shockwave S⁴ Peripheral Intravascular Lithotripsy (IVL) Catheter. Shockwave S⁴ is a low-profile catheter specifically designed to access and treat challenging calcified lesions in below-the-knee (BTK) arteries frequently associated with critical limb ischemia (CLI), a serious condition associated with significant morbidity and mortality. Many CLI patients do not respond well to endovascular treatment, especially when calcium is present with blockages reoccurring frequently, often requiring reinterventions or even limb amputation.

Intravascular Lithotripsy is an innovative therapy designed to treat calcified leg artery blockages with lithotripsy - sonic pressure waves historically used to treat patients with kidney stones. The technology minimizes trauma within the artery by delivering pulsatile sonic pressure waves locally that fracture calcium inside the artery wall but pass through surrounding soft vascular tissue in a safe manner.

Shockwave S⁴ complements the existing larger-diameter IVL catheter, which has been available in Europe since 2015 for the treatment of calcified peripheral disease from the iliac arteries down to the knee. Shockwave S⁴ features many design improvements to enhance deliverability in small, distal vessels, including a longer, hydrophilic shaft, a lower crossing and tip profile, smaller lithotripsy emitters and new stronger balloon material.

“The new Shockwave S⁴ IVL catheter has the potential to change the treatment paradigm for our most difficult-to-treat patients – those with CLI,” said Prof Marianne Brodmann, M.D., of the Medical University of Graz. “Acute and long-term outcomes for these patients remain poor, especially for patients with vascular calcification who have a five-fold greater risk of major amputation. Vascular calcium is prevalent in CLI patients and frequently resides deeper in the artery wall, making endovascular treatment more challenging. Intravascular Lithotripsy has the potential to reach and safely treat this deep wall calcium, thereby improving the ability to open these vessels in an effective and predictable manner, while still preserving future treatment options.”

IVL has been demonstrated to be a safe and effective treatment for femoropopliteal arteries in the DISRUPT PAD I and II studies and for infrapopliteal below-the-knee arteries in the DISRUPT BTK study, which demonstrated the feasibility of IVL below-the-knee. Acute performance in a patient population with advanced peripheral artery disease, most suffering from critical limb ischemia, showed low percent residual stenosis (26 percent) and low vascular

complications, including no perforations, distal embolization, reflow complications or abrupt closure and only one grade B dissection. There were no major adverse events including death, myocardial infarction, target limb revascularization or amputation through 30 days.

The Shockwave S⁴ IVL system, similar to other IVL systems, includes a compact, battery-powered generator, a simple and quick hand-held connector cable with a single therapy delivery button and an intuitive catheter, which houses an array of lithotripsy emitters enclosed in an integrated balloon. The catheter is delivered to a lesion similar to standard interventional techniques.

“The treatment of CLI is commonly compounded by the presence of complex medial calcium, deep in the wall of below-the-knee arteries, and clearly remains a significant unmet clinical need based on our customers’ feedback,” said Doug Godshall, CEO of Shockwave Medical. “Representing our commitment to optimizing outcomes and tailoring our IVL therapy for specific use cases across the vasculature, Shockwave S⁴ was designed specifically to address the challenges of CLI. We look forward to introducing this novel technology over the coming months to provide our clinicians with a tool to help them achieve a high degree of luminal gain with minimal complications and greatly simplify these complex CLI procedures.”

Shockwave S⁴ catheters are now commercially available only in Europe and New Zealand. The larger-diameter peripheral Intravascular Lithotripsy catheters are commercially available in both the United States and Europe.

About Shockwave Medical’s Intravascular Lithotripsy System

Shockwave Medical’s IVL System leverages similar principles to urologic lithotripsy, which has been used as a safe and effective treatment for kidney stones for several decades. The generator produces energy that travels through the connector cable and catheter to an array of miniaturized lithotripsy emitters located near the calcified lesion. With the integrated balloon expanded to ultra-low pressure, a small electrical discharge at the emitters vaporizes the fluid within the balloon, creating a rapidly expanding bubble that collapses within microseconds. The bubble’s expansion and collapse generates a series of sonic pressure waves that travel through the fluid-filled balloon and pass through soft vascular tissue, selectively cracking any hardened calcified plaque inside the vessel wall. After the calcium has been fractured, the integrated balloon can be expanded, performing angioplasty safely at low pressures.

The presence of vascular calcium can make endovascular interventions more difficult and lead to complications during the procedure and escalating healthcare costs. Shockwave Medical’s IVL system was designed to minimize trauma to the artery, simplify the endovascular procedure, thereby optimizing outcomes in PAD patients with moderate and severe calcium. To view an animation of the Intravascular Lithotripsy System visit <http://shockwavemedical.com>.

About Shockwave Medical

Shockwave Medical, based in Fremont, Calif., is developing and commercializing innovative intravascular lithotripsy technology for the treatment of calcified peripheral vascular, coronary vascular and heart valve disease. For more information, visit www.shockwavemedical.com.

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