SHOCKWAVE JAVELIN PERIPHERAL

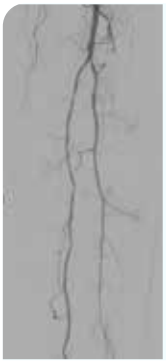
LEAD THE CHARGE

Cross by modifying to deliver further treatment

- First-of-its-kind Forward IVL Platform transforms treatment of difficult-to-cross lesions
- Single distal emitter delivers energy and cracks calcium beyond the tip
- Proven safety and efficacy profile consistent with Balloon IVL Platform[1, 2, 3, 4]

SHOCKWAVE™ JAVELIN FOR THE TREATMENT OF A LONG ANTERIOR TIBIAL ARTERY OCCLUSIVE LESION

83-year-old male patient with type 2 diabetes, dyslipidemia and hypertension. He is suffering from Rutherford category 5 PAD and is presenting a heel ulcer.



Baseline angio shows a total occlusion of the anterior tibial artery, with a diffuse lesion of 30 cm length.

ABI pre procedure: 0.30.

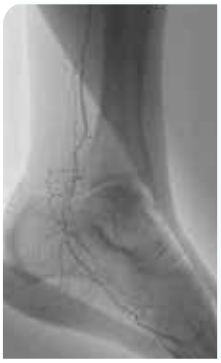
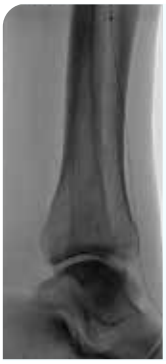


Image shows poor distal run-off at the dorsalis pedis artery.

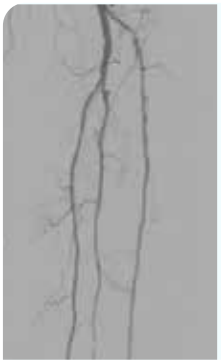
After crossing with a 0.014 guidewire, 2.0mm PTA balloon couldn't cross at the origin of the ATA.

Shockwave Javelin Peripheral was used to cross the occlusion by modifying the calcium.



120 pulses were delivered along the proximal and medial segment of the ATA.

Shockwave Javelin Peripheral allowed to modify calcium along the lesion, enabling effective treatment with 2.5mm PTA balloon.



Final angio shows restored flow of the anterior tibial artery.

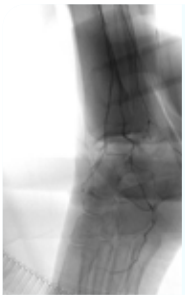
ABI post procedure: 0.75.

Foot angio shows direct flow from the anterior tibial artery into the dorsalis pedis.

Case courtesy of Dr Maria Antonella Ruffino – Ticino Vascular Center, Lugano.
Dr. Ruffino is a paid Shockwave Medical consultant.

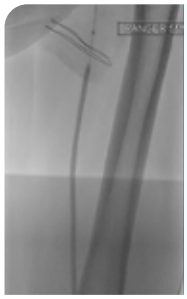
SHOCKWAVE JAVELIN FOR BELOW THE ANKLE REVASCULARIZATION IN A PATIENT WITH CLTI

71-year-old female patient, smoker and with hypertension. The patient presents left hallux gangrene and severe rest pain. Rutherford category 5 PAD. No previous treatments.

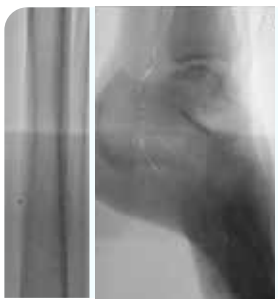


Baseline angio shows occluded lateral plantar and dorsalis pedis arteries.

ABI pre-procedure: 0.4.

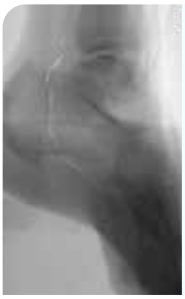


SFA and Popliteal artery presenting some fibrotic plaque were treated with 5.0mm POBA and DCB to improve flow.

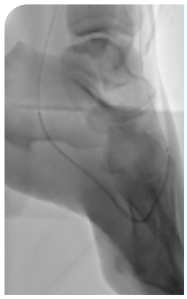


The lesion was wire crossable but not device crossable (IVUS did not cross).

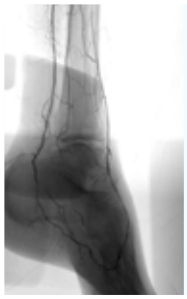
Shockwave Javelin Peripheral was advanced via the posterior tibial artery and through the common plantar artery.



120 pulses of Shockwave Javelin Peripheral delivered across the occluded lateral plantar and dorsalis pedis arteries.



Shockwave Javelin Peripheral allowed to modify calcium along the lesion, enabling final treatment with 2.0 mm PTA balloon.



Final angio shows reconstitution of flow around the foot arch.

ABI post-procedure: 0.8.

Case courtesy of Dr Ashish Patel – St Thomas', London.
Dr. Patel is a paid Shockwave Medical consultant.

SHOCKWAVE JAVELIN CATHETER SPECIFICATIONS

Catalog Number	Tip Entry Profile (in)	Crossing Profile (mm)	Sheath Compatibility (Fr.)	Guidewire Compatibility (in)	Catheter Working Length (cm)	Pulses/ Cycle	Cycles	Pulse (Max)
JVNPIVLF	0.025	1.5	5	0.014	150	10	12	120

[1]Internal testing shows a spherical sonic output from distal emitter consistent with previous Shockwave balloon-based IVL emitters.

1: Corl JD, Clair D, Mwipatayi P, et al. FORWARD PAD IDE/Feasibility Studies: Primary Endpoint Analysis of a Novel Non- Balloon-Based Peripheral IVL Catheter. JACC: Cardiovascular Interventions. Published online November 4, 2024. doi:10.1016/j.jcin.2024.10.035; **2:** Corl J, VIVA Late Breaking Clinical Trial 2024; **3:** Tepe, Gunnar et al. Intravascular Lithotripsy for Peripheral Artery Calcification: Mid-term Outcomes From the Randomized Disrupt PAD III Trial. Journal of the Society for Cardiovascular Angiography & Interventions, Volume 1, Issue 4, 100341. July-August, 2022; **4:** Armstrong EJ, Adams G, Soukas PA, et al. Intravascular Lithotripsy for Peripheral Artery Calcification: 30-Day Outcomes From the Disrupt PAD III Observational Study. Journal of Endovascular Therapy. 2024;0(0). doi:10.1177/15266028241283716.

PERIPHERAL SAFETY INFORMATION

Shockwave Javelin

Indications for Use— The Shockwave Medical IVL System with the Javelin Peripheral IVL Catheter is intended for lithotripsy-enabled modification and crossing of calcified lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries, prior to final treatment. This device is not intended for use in coronary, carotid, or cerebrovascular arteries. Additionally, not for use in pulmonary vasculature in the US and New Zealand. **Contraindications—** Do not use if unable to pass 0.014" (0.36mm) guidewire across the treatment site-Not intended for treatment of in-stent restenosis or in coronary, carotid, cerebral or pulmonary arteries. **Warnings—** Only to be used by physicians who are familiar with interventional vascular procedures—Physicians must be trained prior to use of the device— Use the generator in accordance with recommended settings as stated in the Operator's Manual. **Precautions—** Avoid applying acoustic pressure pulses while IVL window is not filled with sterile saline—Appropriate anticoagulant therapy should be administered by the physician—Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology. **Adverse effects–** Possible adverse effects consistent with standard angioplasty include–Access site complications –Allergy to contrast or blood thinner–Arterial bypass surgery—Bleeding complications— Death—Fracture of guidewire or device—Hypertension/Hypotension—Infection/sepsis—Placement of a stent—renal failure—Shock/pulmonary edema—target vessel stenosis or occlusion—Vascular complications. Risks unique to the device and its use—Allergy to catheter material(s)— Device malfunction or failure.

Shockwave S4, Shockwave M5, Shockwave M5+, Shockwave E8, and Shockwave L6

Indications for Use— The Shockwave Medical Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary, carotid or cerebral vasculature. Peripheral IVL is also indicated for use in renal arteries in certain jurisdictions, including the United States. Please reference Instructions For Use for country specific information. **Contraindications—**Do not use if unable to pass 0.014" (M5, M5+, S4, E8) or 0.018" (L6) guidewire across the lesion-Not intended for treatment of in-stent restenosis or in coronary, carotid, or cerebrovascular arteries. **Warnings—** Only to be used by physicians who are familiar with interventional vascular procedures—Physicians must be trained prior to use of the device—Use the generator in accordance with recommended settings as stated in the Operator's Manual. **Precautions—** Use only the recommended balloon inflation medium—Appropriate anticoagulant therapy should be administered by the physician—Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology. **Adverse effects–** Possible adverse effects consistent with standard angioplasty include–Access site complications–Allergy to contrast or blood thinner–Arterial bypass surgery—Bleeding complications—Death— Fracture of guidewire or device—Hypertension/Hypotension—Infection/sepsis—Placement of a stent—renal failure—Shock/pulmonary edema—target vessel stenosis or occlusion—Vascular complications. Risks unique to the device and its use—Allergy to catheter material(s)— Device malfunction or failure—Excess heat at target site.

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events. www.shockwavemedical.com/ifu
Please contact your local Shockwave representative for specific country availability.

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