SHOCKWAVE | E8

ABOVE AND BEYOND FOR BELOW THE KNEE

Versatile Sizes
2.5 - 6.0 mm Diameter Sizes

Longer Treatment Zone
400 Pulses at 2Hz

Ultra-Low Pressures
IVL Therapy at 2 - 4 atm

Longer Catheter Shaft
150 cm Catheter Length

Treats Long Lesions Efficiently

400 pulses at 2Hz pulsing speed allow for efficient treatment of over 30 cm lesions

Provides Extended Reach Below-the-Knee

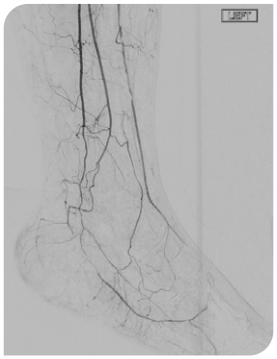
150 cm working length allows for the treatment of difficult to reach lesions

Enables Access Options with Sheath Compatibility

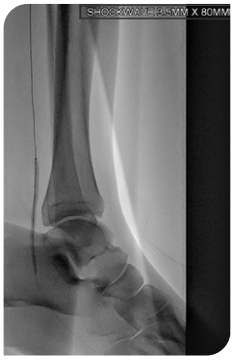
The 5 Fr. and 6 Fr. compatibility enables the use of access sites such as pedal and radial

SHOCKWAVE™ E8 FOR THE TREATMENT OF THE POSTERIOR TIBIAL AND LATERAL PLANTAR ARTERIES IN A PATIENT WITH DIABETIC FOOT DISEASE

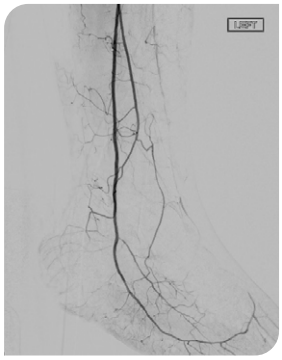
55-year-old old male patient with insulin-dependent diabetes. Gangrene of left 2nd and 3rd toes. Absent foot pulses, popliteal pulse palpable. Planned for hybrid procedure: amputation of both toes and revascularisation.
Past medical history: hypertension, hyperlipidaemia. Currently unable to work due to CLTI.



Baseline angiograms showing normal inflow/outflow, but narrowed distal PT and heavily stenosed lateral plantar arteries. **IVUS confirming significant stenosis of the distal PT and lateral plantar arteries**.



10 cycles of 3.5 mm Shockwave E8 delivered in distal posterior tibial artery and proximal lateral plantar arch.



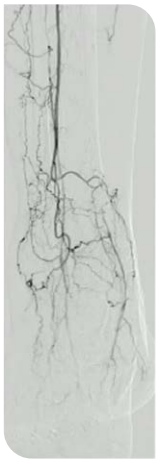
Final foot angiograms showing widely patent distal PT and lateral plantar arteries with excellent digital blood supply to 2nd and 3rd toes targeted for amputation. Foot pulses present following the case

Case courtesy of DR Ash PATEL – GUY'S & ST THOMAS' NHS FOUNDATION TRUST, London

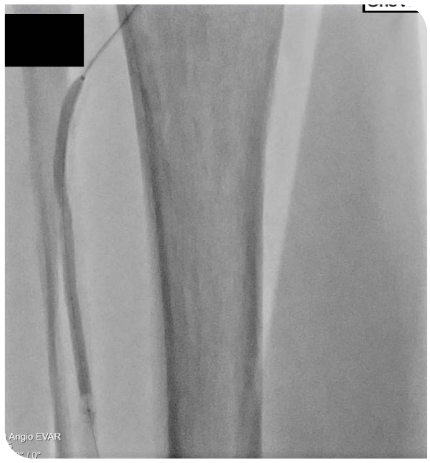
SHOCKWAVE E8 FOR THE TREATMENT OF A LONG ANTERIOR TIBIAL OCCLUSION

83-year-old male patient. Rutherford VI. Ischemic ulcers of 1st and 2nd toe with presence of gangrene in 5th toe and permanent rest pain. Renal insufficiency stage IV, insulin dependant diabetes and arterial hypertension.

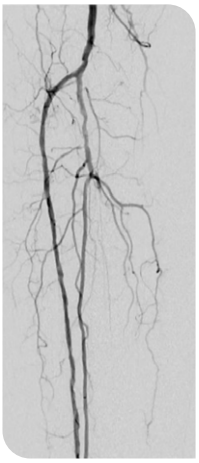
Baseline Angio showing diffuse Anterior Tibial disease



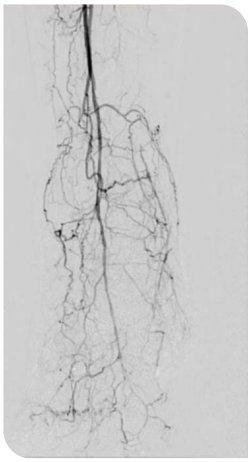
AP view shows no plantar arch or flow to metersals arteries and no pedal pulse present



Patient was treated with 3.5 mm Shockwave E8 catheter. The image shows 3rd cycle with Shockwave E8



400 pulses of Shockwave E8 delivered along ATA and < 10% residual stenosis across the lesion length



Final angio shows direct flow to metersal arteries and palpable pulses with resolution of rest pain. 5th toe amputation was completed post procedure with triphasic signals in foot following DUS assessment

Case courtesy of Dr Arne SCHWINDT – St. Franziskus Hospital, Münster

SHOCKWAVE E8 IVL CATHETER SPECIFICATIONS

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)	Sheath Compatibility (Fr.)	Catheter Working Length (cm)	Pulses/ Cycle	Cycles	Pulses (Max)	Balloon Crossing Profile (in)
E8IVL025080	2.5	80	5	150	40	10	400	.050
E8IVL030080	3.0	80	5	150	40	10	400	.051
E8IVL035080	3.5	80	5	150	40	10	400	.053
E8IVL040080	4.0	80	5	150	40	10	400	.055
E8IVL050080	5.0	80	6	150	40	10	400	.061
E8IVL060080	6.0	80	6	150	40	10	400	.066

Peripheral Safety Information

Peripheral IVL Important Safety Information

In the United States: Rx only. 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, and infra-popliteal 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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