SHOCKWAVE | E8

ABOVE AND BEYOND FOR ABOVE AND BELOW

Versatile Sizes
2.5 - 6.0mm Diameter Sizes

Longer Treatment Zone
400 Pulses at 2Hz

Ultra-Low Pressures
IVL Therapy at 2 - 4atm

Longer Catheter Shaft
150cm Catheter Length

Treats Long Lesions Efficiently

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

Provides Extended Reach Below-the-Knee

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

Enables Access Options with Sheath Compatibility

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

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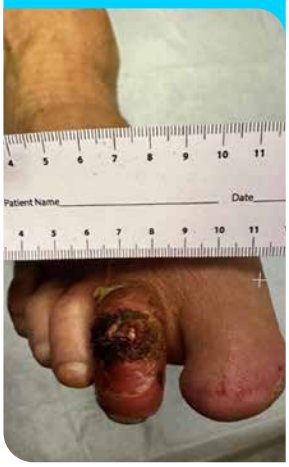
SHOCKWAVE MEDICAL

PATIENT WITH CLTI AND NON-HEALING WOUND

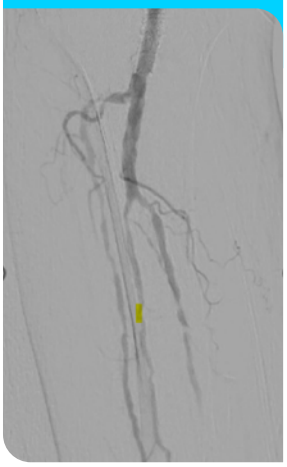
79M with CAD/CHF (EF 30%), AF, prior DVT, and DM2 with a remote history of a right popliteal PTA in 2022 presents with CLTI and right second toe wound s/p amputation by podiatry. Non-invasive studies revealed a toe pressure of 15. Angiogram demonstrated long segment AT occlusive disease and multifocal PT occlusions with heavy calcification. Dr. Siah treated the AT with Shockwave E8 4.0mm balloon using 200 pulses over 3 treatment areas with no pre-dilatation required. The PT was treated with a 3.0mm POBA. Post-procedural toe pressure improved to 85. At 2 month follow-up the toe amputation site is nearly healed with sustained perfusion to the foot on non-invasive studies. Shockwave E8 allows for safe and effective treatment of long-segment tibial occlusive disease, allowing wound healing in a high risk patient with CLTI.

Pre-Amputation



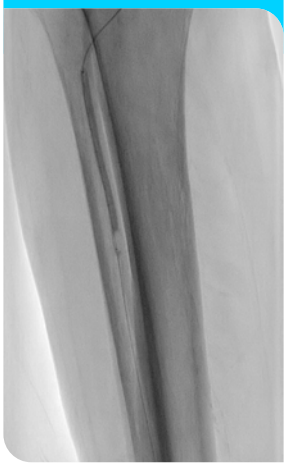
Amputation completed prior to revascularization

Pre-Procedural Angio



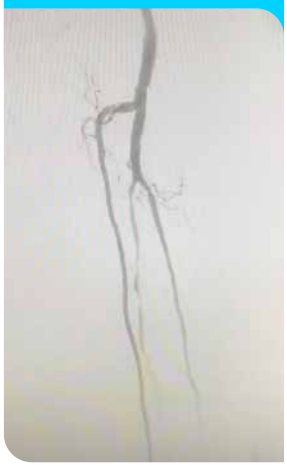
Long segment AT disease, PT disease

Treatment Angio



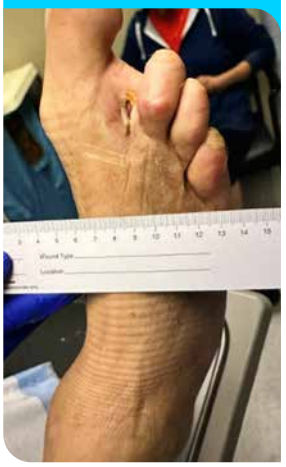
4.0mm Shockwave E8 in AT
200 pulses, 3 treatment areas
3.0mm POBA used in PT

Final Angio



Brisk flow restored

2 Month Follow-Up



Significant wound healing

Case Courtesy of Dr. Michael Siah

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

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, infra-popliteal, and renal arteries. Not for use in the coronary, carotid or cerebral vasculature. **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

Learn more

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