

BE LARGE & IN CHARGE

Purpose-built to Address
Challenging Calcium in Large Vessels

LARGE VESSEL TREATMENT

8.0, 9.0, 10.0 & 12.0 mm diameter sizes

CONSISTENT HIGH ENERGY

Compact emitter design

FOCUSED TREATMENT

30 mm balloon length

SUPPORT YOU NEED

.018" guidewire

ULTRA-LOW PRESSURE

IVL therapy at 2-4 atm



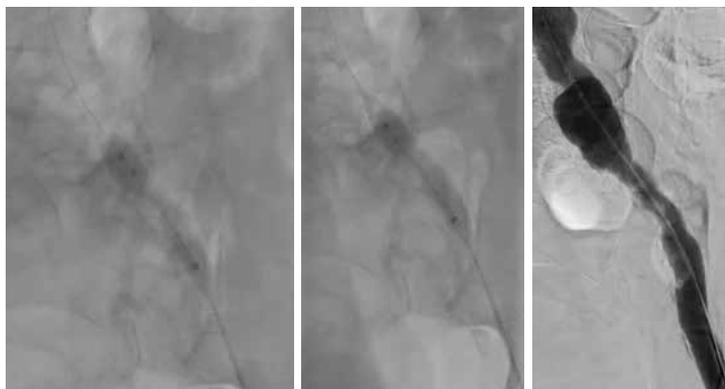
CALCIFIED EXTERNAL ILIAC

Pre-Treatment Angio



Severe life-limiting claudication.
Hemodynamically significant
90% stenosis of EIA.

IVL Treatment Angio



Shockwave L6 9.0mm; 300 pulses delivered;
<15% residual stenosis

Final Angio



Low residual stenosis
with improvement
from monophasic
to triphasic flow.

PRESERVING THE ILIAC BIFURCATION

Pre-Treatment Angio



CLTI patient with severe rest pain caused by bilateral iliac and CFA disease

IVL Treatment Angio



Common Femoral Endarterectomy and patch plasties followed by bilateral 10.0 mm Shockwave L6

Stent Deployment



8x79 VBX stents

Final Angio



Completion angio following stent deployment showed no residual stenosis, and rest pain resolved.

Case courtesy of Dr. Nair and Dr. Patel

SHOCKWAVE L6 PERIPHERAL IVL CATHETER SPECIFICATIONS

Catalog Number	Diameter (mm)	Length (mm)	Sheath Compatibility	Working Length (cm)	Pulses/Cycle	Cycle	Pulses (Max)	Crossing Profile (in)
L6IVL080030	8.0	30	7 F	110	30	10	300	.086
L6IVL090030	9.0	30	7 F	110	30	10	300	.087
L6IVL100030	10.0	30	8 F	110	30	10	300	.091
L6IVL120030	12.0	30	8 F	110	30	10	300	.093

Visit www.shockwavemedical.com for more 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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