

BE LARGE & IN CHARGE

Purpose-built to address challenging calcium in large vessels

LARGE VESSEL TREATMENT

8.0, 9.0, 10.0 & 12.0mm diameter sizes

CONSISTENT HIGH ENERGY Compact emitter design

FOCUSED TREATMENT 30mm balloon length

SUPPORT YOU NEED .018" guidewire

ULTRA-LOW PRESSURE IVL therapy at 2-4 atm

CALCIFIED BILATERAL ILIACS

Pre-Treatment Angiogram



Bilateral calcified iliacs measuring 11.0 x 11.5mm

Case Courtesy of Dr. JD Corl

IVL Treatment





Shockwave L⁶ 12.0mm x 30mm, 150 pulses each side



IVL provided effective calcium modification to allow for appropriately-sized & fully expanded stents



PRE-TAVR ACCESS

Pre-Treatment Angiogram



25mm calcified focal ostial lesion

Case Courtesy of Dr. Samer Garas

IVL Treatment

Post-IVL Treatment Angiogram



Shockwave L⁶ 9.0mm x 30mm, 300 pulses



IVL successfully changed vessel compliance for valve delivery

SHOCKWAVE L⁶ PERIPHERAL IVL CATHETER SPECIFICATIONS

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)	Sheath Compatibility	Catheter Working Length (cm)	Pulses /Cycle	Cycles	Pulses (Max)	Balloon Crossing Profile (in)
L6IVL080030	8.0	30	7F	110	30	10	300	0.087
L6IVL090030	9.0	30	7F	110	30	10	300	0.089
L6IVL100030	10.0	30	8F	110	30	10	300	0.093
L6IVL120030	12.0	30	8F	110	30	10	300	0.095

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 or cerebral vasculature.

Contraindications: Do not use if unable to pass 0.018" 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.

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events.

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