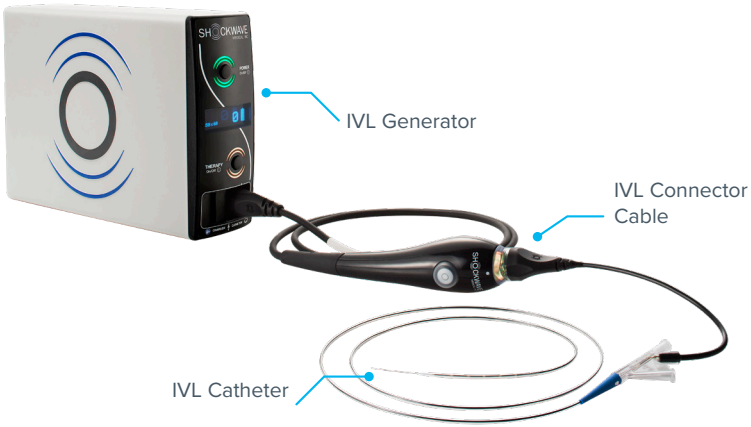
SHOCKWAVE MEDICAL INC

DISRUPT CALCIUM. REDEFINE THERAPY.

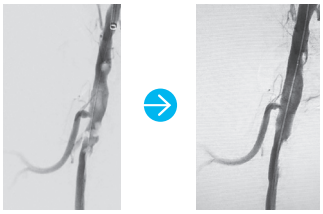
Peripheral Intravascular Lithotripsy (IVL) System

Localized Lithotripsy for Vascular Calcium

Shockwave Medical's Peripheral Intravascular Lithotripsy (IVL) System includes IVL catheters, a connector cable, and a generator. These are familiar tools for interventionalists, making the technology inherently familiar, easy to learn, adopt, and use on a day-to-day basis.



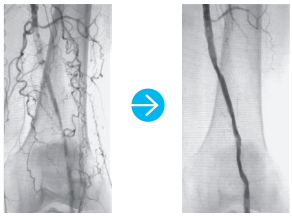
Common Femoral Artery



Pre-Assessment Angiogram | **Final Angiogram (Post IVL)**

Images courtesy of Bill Miller, MD

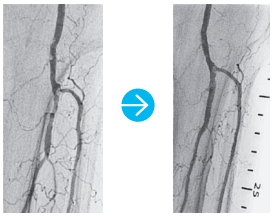
Femoropopliteal Artery



Pre-Assessment Angiogram | **Final Angiogram (Post IVL)**

Images courtesy of Marianne Brodmann, MD

Below-The-Knee



Pre-Assessment Angiogram | **Final Angiogram (Post IVL)**

Images courtesy of Thomas Zeller, MD

IVL technology selectively and effectively modifies intimal and medial calcium while minimizing injury due to its unique mechanism of action.

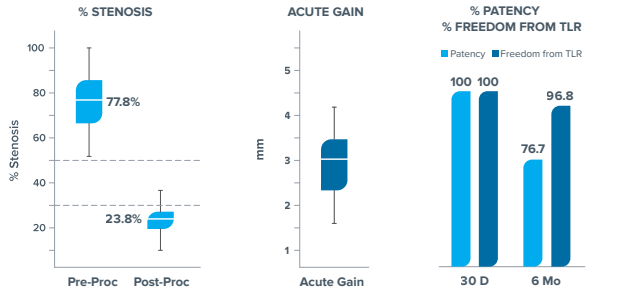
DISRUPT PAD clinical program studied the safety and effectiveness of the Shockwave Medical Intravascular Lithotripsy (IVL) System in the treatment of calcified, stenotic peripheral arteries, 95 patients with SFA/Popliteal disease were treated with 99% of lesions classified as moderate or severely calcified.

DISRUPT PAD STUDY: SAFETY RESULTS

MAJOR ADVERSE EVENTS	30 days N=95	6 mo N=93
Target limb emergency surgical revascularization	0%	0%
Target limb major amputation	0%	0%
Thrombus or distal emboli with treatment	0%	0%
Perforations and dissections (≥D) with treatment	1.1% (1)	1.1% (1)

- No procedural complications related to perforations, abrupt closure, slow/no reflow, thrombosis or distal embolization
- 1% of procedures required provisional stent placement due to one grade D dissection

DISRUPT PAD STUDY: EFFECTIVNESS RESULTS



- 100% successful crossing with limited adjunctive balloon required
- 24% residual stenosis and 3.0mm acute gain

IVL GENERATOR AND CONNECTOR CABLE SPECS

Power	110-240 VAC; 50-60Hz; Single Phase, 15A service
Size	11" (28.0 cm) high x 6" (15.2 cm) wide x 11.5" (29.2 cm) deep
Weight	15 pounds (6.8 kg)
Output	Proprietary pulse delivery system. Output voltage 3000 volts peak, pulse frequency 1Hz
Mobility	Product is designed to be mounted to a stable mobile or stationary IV pole. An IV pole with five casters located in a circular pattern with a diameter of at least 23 inches (58 cm), such as the I.V. League Ventilator Stat-Stand™ model 1059 (or equivalent) is recommended.

IVLGCC
IVL Generator and Connector Cable Kit

Length	5 ft (1.53m)
Compatibility	Connector Cable has a male key designed on the proximal end to connect to the generator and a different female key designed to connect to the Catheter.
Operation	Lithotripsy pulsing is activated by pushing a button on the Connector Cable.
Use	Re-usable

IVLCC
IVL Connector Cable

IVL CATHETER SPECS

CATALOG NUMBER	DIAMETER (mm)	LENGTH (mm)	GUIDEWIRE COMPATIBILITY (in)	SHEATH COMPATIBILITY	WORKING LENGTH (cm)	PULSES (max)
M5IVL3560	3.5	60	0.014	6F	110	**300**
M5IVL4060	4	60	0.014	6F	110	**300**
M5IVL4560	4.5	60	0.014	6F	110	**300**
M5IVL5060	5	60	0.014	6F	110	**300**
M5IVL5560	5.5	60	0.014	6F	110	**300**
M5IVL6060	6	60	0.014	6F	110	**300**
M5IVL6560	6.5	60	0.014	7F	110	**300**
M5IVL7060	7	60	0.014	7F	110	**300**

Discover how you can treat calcium more effectively with the Peripheral Intravascular Lithotripsy (IVL) System.

Visit shockwavemedical.com or call 877-77-LITHO (877-775-4846) for more information.

Caution—Federal law (USA) restricts this device to sale by or on the order of a physician.
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 0.014 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