

SHOCKWAVE | M⁵

Intravascular Lithotripsy (IVL) for Safe and Effective Treatment of Vascular Calcium



MINIMIZE TRAUMA | OPTIMIZE OUTCOMES | SIMPLIFY PROCEDURES

Broad Applications in Calcified Peripheral Arteries

Common Femoral Disease

Enable Endovascular CFA Treatment



**Pre-Treatment
Angiogram**

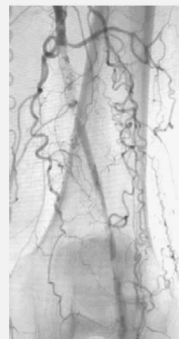


**Final Angiogram
(Post IVL + DCB)**

Images courtesy of Bill Miller, MD

Femoropopliteal Disease

Safe and Effective Vessel Prep or Treatment



**Pre-Treatment
Angiogram**



**Final Angiogram
(Post IVL)**

Images courtesy of Marianne Brodmann, MD

Symptomatic Iliac Disease

Preservation of Future Treatment Options



**Pre-Treatment
Angiogram**



**Final Angiogram
(Post IVL)**

Images courtesy of Patricia Furey, MD

TAVI, TEVAR & EVAR Access

Facilitate Delivery of Large-Bore Devices



**Pre-Treatment
Angiogram**



**Final Angiogram
(Post IVL & 23Fr TEVAR)**

Images courtesy of David Caparelli, MD



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 an IV pole
Length	5 ft (1.53m)
Compatibility	Proprietary male key distally designed to connect only to catheter.
Operation	Lithotripsy pulsing is activated by pushing a button on the Connector Cable.
Use	Re-usable



IVL Generator

CATALOG NUMBER:
IVLGCCD


IVL Connector Cable

CATALOG NUMBER:
IVLCC

M5 CATHETER SPECS

M5 Branding*	Catalog Number Original Branding*	Diameter (MM)	Length (MM)	Sheath Compatibility	Working Length	Pulses/ Cycle	Cycles	Pulses (Max)	Crossing Profile
M5IVL3560	M732LPBC3560DX1	3.5	60	6F	110	30	10	300	.054
M5IVL4060	M732LPBC4060DX1	4.0	60	6F	110	30	10	300	.057
M5IVL4560	M732LPBC4560DX1	4.5	60	6F	110	30	10	300	.058
M5IVL5060	M732LPBC5060DX1	5.0	60	6F	110	30	10	300	.062
M5IVL5560	M732LPBC5560DX1	5.5	60	6F	110	30	10	300	.064
M5IVL6060	M732LPBC6060DX1	6.0	60	6F	110	30	10	300	.066
M5IVL6560	M732LPBC6560DX1	6.5	60	7F	110	30	10	300	.068
M5IVL7060	M732LPBC7060DX1	7.0	60	7F	110	30	10	300	.073

*Products are equivalent; either Catalog Number may be used when ordering and either product may be received.

STERILE SLEEVE

Catalog Number	Length (CM)	Length (IN)	Description	Quantity
706932	13 x 244	5 x 96	Tear Tip Camera Cover	10

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