

+ FASTER

Increase efficiency with half the cycle time

+ FURTHER

Broaden access options with an increased catheter working length of 135cm

+ LARGER

Optimally treat larger diameter vessels with an 8.0 mm size



+ LARGER

Common Femoral Artery Disease

“Shockwave IVL is an excellent endovascular treatment for the CFA, and the 8.0 mm size allowed me to **optimally size** the catheter to the vessel. Shockwave M5+ in 30 minutes and patient goes home same day”.

Images and quote courtesy of Michael Siah, MD

Pre-Treatment Angiogram



Diameter Stenosis = 90%
Lesion Length = 50 mm

IVL Treatment



Shockwave M5+: 8.0 mm x 60 mm,
300 pulses

IVL Treatment



Post-IVL



Diameter Stenosis = 10%

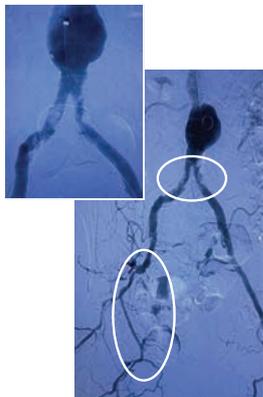
+ FURTHER

Bilateral Iliac Artery Disease

“The extended working length of the M5+ catheter provides us with the **flexibility to treat** from upper extremity access points if a transfemoral approach isn't possible”.

Images and quote courtesy of Stefano Fazzini, MD

Pre-Procedure Angiogram



Right Common Iliac Diameter Stenosis = 90%
Left Common Iliac Diameter Stenosis = 85%
Right External Iliac Diameter Stenosis = 100%

IVL Treatment



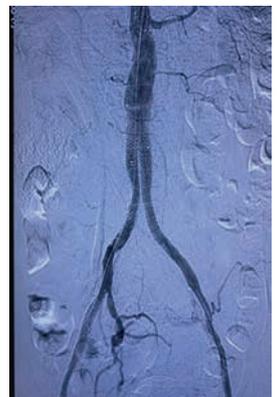
Shockwave M5+: 7.0 mm x 60 mm
Left Common Iliac = 90 pulses

IVL Treatment



Right Common Iliac = 120 pulses
Right External Iliac = 90 pulses

Post-IVL



Right Common Iliac Diameter Stenosis = 15%
Left Common Iliac Diameter Stenosis = 10%
Right External Iliac Diameter Stenosis = 5%

IVL GENERATOR AND CONNECTOR CABLE SPECS

Power	90-240 VAC; 50-60Hz; Single Phase, 15A service	 <p>IVL Generator CATALOG NUMBER: IVLGCCDX</p>
Size	7.9" (20.1 cm) high x 2.9" (7.4 cm) wide x 11.1" (28.2 cm) deep	
Weight	6 pounds (2.7 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	5ft (1.52m)	 <p>IVL Connector Cable CATALOG NUMBER: IVLCC</p>
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	

SHOCKWAVE M5+ CATHETER SPECS

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)	Sheath Compatibility	Catheter Working Length	Pulses/Cycle	Cycles	Pulses (Max)	Balloon Crossing Profile (in)
M5PIVL3560	3.5	60	6F	135	30	10	300	.054
M5PIVL4060	4.0	60	6F	135	30	10	300	.054
M5PIVL4560	4.5	60	6F	135	30	10	300	.057
M5PIVL5060	5.0	60	6F	135	30	10	300	.061
M5PIVL5560	5.5	60	6F	135	30	10	300	.062
M5PIVL6060	6.0	60	6F	135	30	10	300	.065
M5PIVL6560	6.5	60	6F*	135	30	10	300	.066
M5PIVL7060	7.0	60	6F*	135	30	10	300	.068
M5PIVL8060	8.0	60	7F	135	30	10	300	.074

*6F Compatible with Terumo Pinnacle® Destination® Guiding Sheath and Cook Flexor® Ansel Guiding Sheath. Referenced trademarks are trademarks of their respective owners or holders.

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.

Drs. Michael Siah and Stefano Fazzini are paid consultants of Shockwave Medical.

In the United States: Rx Only

Indication 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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