SHOCKWAVE | M5+

A VERSATILE CALCIUM-CRACKING TOOL

Expanding Treatment Options for Peripheral Artery Disease Using a Safe, Proven Mechanism of Action

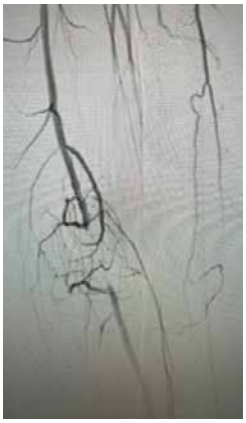
60 MM BALLOON LENGTH

4.0 - 8.0 MM BALLOON DIAMETER SIZES

135 CM WORKING LENGTH

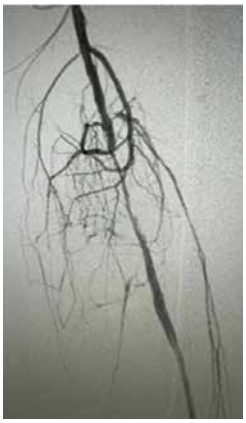
DISTAL SFA OCCLUSIVE DISEASE

Pre-Treatment Angiogram



Pre-treatment Stenosis = **100%**
Lesion Length = **approx. 50mm**

Post-Atherectomy Angiogram



Orbital Atherectomy

IVL Treatment

5.0mm Shockwave™ M5+
240 pulses

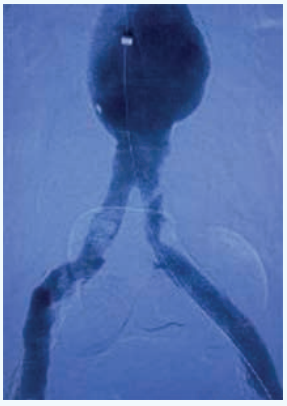
Post-IVL

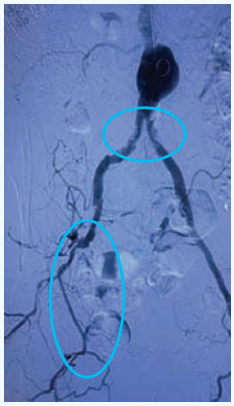
Post-treatment
Stenosis = **10%**

Case courtesy of Nicolas Mouawad, MD

BILATERAL ILIAC ARTERY DISEASE

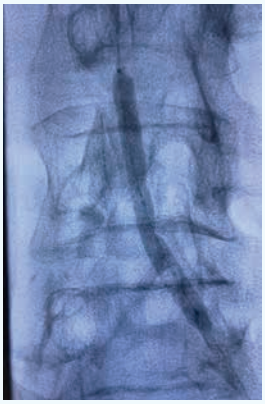
Pre-Treatment Angiogram





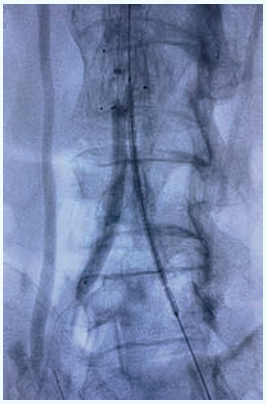
Right Common Iliac Diameter Stenosis = **90%**
Left Common Iliac Diameter Stenosis = **85%**
Right External Iliac Diameter Stenosis = **100%**

IVL Treatment



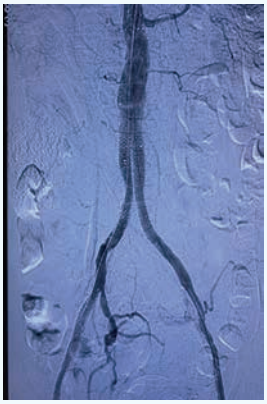
7.0mm Shockwave M5+
Left Common Iliac = **90 pulses**

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%**

Case courtesy of Stefano Fazzini, MD

SHOCKWAVE M5+ PERIPHERAL IVL CATHETER SPECIFICATIONS

Catalog Number	Balloon Diameter (mm)	Balloon Length (mm)	Sheath Compatibility	Catheter Working Length	Pulses/ Cycle	Cycles	Pulses (max)	Balloon Crossing Profile (in)
M5PIVL4060	4.0	60	6F	135	30	10	300	.054
M5PIVL5060	5.0	60	6F	135	30	10	300	.061
M5PIVL6060	6.0	60	6F	135	30	10	300	.065
M5PIVL7060	7.0	60	6Fr*	135	30	10	300	.068
M5PIVL8060	8.0	60	7Fr	135	30	10	300	.074

*6F Compatible with Terumo Pinnacle® Destination® Guiding Sheath and Cook Flexor® Ansel Guiding Sheath.
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Presenting physicians are paid consultants of Shockwave Medical.

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

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