



SHOCKWAVE | S⁴

IVL Optimized for Challenging Calcified Below-the-Knee Disease

MINIMIZE TRAUMA

Minimize trauma to soft tissue by safely selecting and fracturing intimal and medial calcium

OPTIMIZE OUTCOMES

Optimize luminal gain consistently and preserve future treatment options while reducing complications

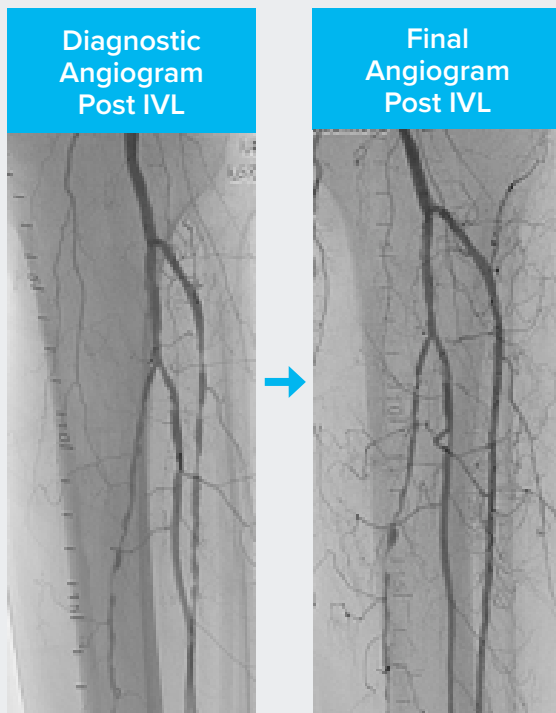
SIMPLIFY PROCEDURES

Simple and intuitive system that makes complex calcified below-the-knee procedures more predictable

Effective in Both Intimal and Medial Calcium

IVL is effective in fracturing calcium throughout the vascular wall, producing high acute gain with minimal complications

CALCIFIED POSTERIOR TIBIAL ARTERY

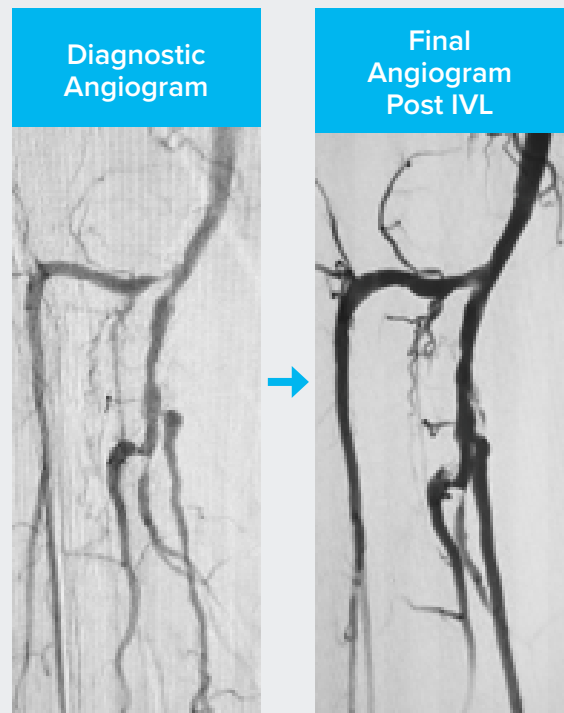


65% Stenosis

21% Residual
1.6mm Acute Gain

Courtesy of Prof. Andrew Holden

CALCIFIED ANTERIOR AND POSTERIOR TIBIAL ARTERY BIFURCATION



Previous PT & AT
Intervention 30d ago

24% Residual
Stenosis

Courtesy of Dr. Roger Gammon



High Lumen Gain with Minimal Complications Below-the-Knee

Low residual stenosis with no angiographic complications in moderate/severely calcified CLI patients

		DISRUPT PAD I 95 subjects, 8 sites	DISRUPT BTK 20 subjects, 21 lesions, 3 sites
Patients Included	Vessels	Femoral/Popliteal Arteries	Tibial/Peroneal Arteries
	Intermittent Claudication	98.9% (94)	20.0% (4)
	Critical Limb Ischemia	1.1% (1)	80.0% (16)
Safety	Dissections	1% (1) Grade D or greater	0 Grade D or greater
	Embolization	0 Embolic Events	0 Embolic Events
	Perforations, abrupt closure, slow/no reflow or thrombosis	0 Complications	0 Complications
Effectiveness	Residual Stenosis	23.8%	26.2%
	Acute Gain	2.9mm	1.5mm
Follow-Up	30 days	100% Freedom from TLR 100% Patency	100% Freedom from TLR 0% MAE (death, amp. or MI)

IVL CATHETER SPECS

CATALOG #	Diameter (mm)	Length (mm)	Emitters	Pulses/Cycle	Cycles	Guidewire (in)	Sheath Compat.	Working Length (cm)
S4IVL3540	3.5	40	4	20	8	0.014	5F	135
S4IVL4040	4.0	40	4	20	8	0.014	5F	135

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