Problematic BTK Calcium? You're Gonna Love the Sound of This.

PREDICTABLY SAFE
Safely modify calcium while significantly reducing the risk of complications to make procedures more predictable and efficient.

DISTINCTLY INTUITIVE
Simplify the treatment of calcium from the very first case via a unique MOA on an intuitive platform.

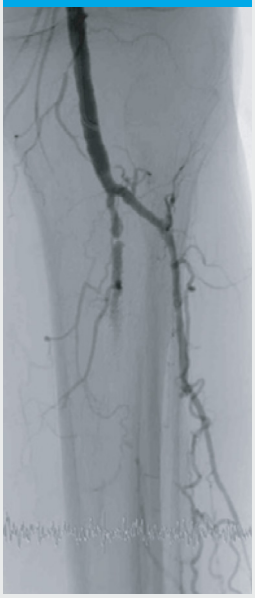
CONSISTENTLY EFFECTIVE
Proven to achieve a low residual stenosis across multiple vessel beds by disrupting superficial and deep calcium.

Effective in Both Intimal and Medial Calcium

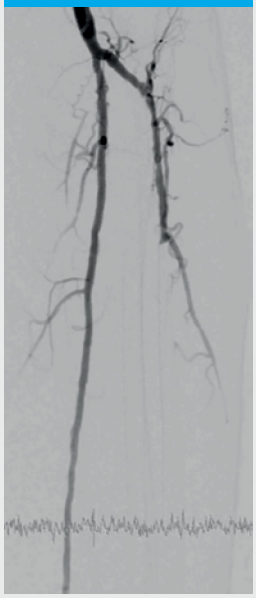
IVL is effective at fracturing superficial and deep calcium in the vessel wall.

OCCLUDED POSTERIOR TIBIAL ARTERY

Diagnostic Angiogram Post IVL



Final Angiogram Post IVL

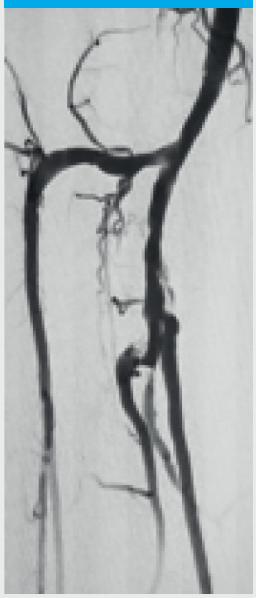


Courtesy of Prof. Patrice Mwipatayi

CALCIFIED ANTERIOR AND POSTERIOR TIBIAL ARTERY BIFURCATION

Diagnostic Angiogram

Final Angiogram Post IVL

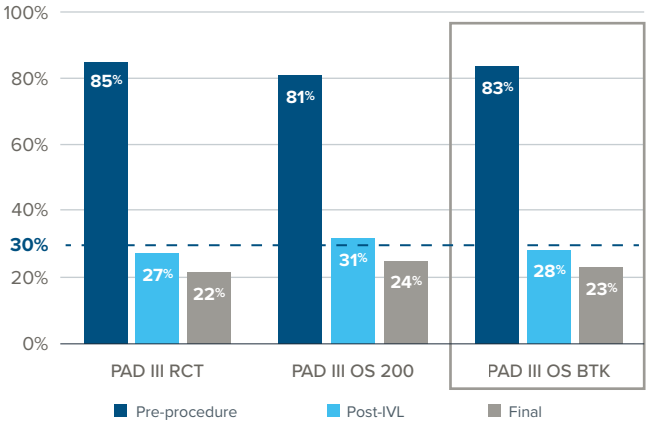


Courtesy of Dr Roger Gammon

PAD III OS Interim Analysis: IVL Treatment of Calcified Infrapopliteal Arteries

Disrupt PAD III OS BTK outcomes add to the IVL body of evidence, confirming the consistent safety and effectiveness of IVL across multiple vessel beds.

Diameter Stenosis (Core-Lab)



1. Adams et al., JEVT, 2020;27(3):473-480. **2.** Data presented by G. Adams, LINC 2021

Final Angiographic Complications (Core-Lab)

	PAD III RCT	PAD III OS 200[1]	PAD III OS BTK[2]
N	153	200	96
Vessels	SFA/Pop	Iliac, CFA,SFA/ Pop, BTK	Infrapopliteal
Dissection (Type D-F)	0%	1.1%	0%
Perforation	0%	0.5%†	0%
Embolization	0%	0%	0%
Thrombus	0%	0%	0%
No reflow	0%	0%	0%
Abrupt closure	0%	0%	0%

†Following DCB inflation; unrelated to IVL

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

IVL Generator

CATALOG NUMBER: **IVLGCCD**

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 Connector Cable

CATALOG NUMBER: **IVLCC**

IVL CATHETER SPECS

Catalog Number	Diameter (mm)	Length (mm)	Emitters	Pulses/ Cycle	Cycles	Guidewire (in)	Sheath Compat.	Working Length (cm)	GTIN
S4IVLK2540	2.5	40	4	20	8	0.014	5F	135	00195451000317
S4IVLK3040	3.0	40	4	20	8	0.014	5F	135	00195451000324
S4IVLK3540	3.5	40	4	20	8	0.014	5F	135	00195451000331
S4IVLK4040	4.0	40	4	20	8	0.014	5F	135	00195451000348

Discover how you can treat calcium more effectively with the Peripheral Intravascular Lithotripsy (IVL) System. Visit shockwavemedical.com for more information.

SAFETY INFORMATION: In the United States: Rx Only • Indication for Use – The Shockwave Medical Intravascular Lithotripsy 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 thinners • 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 • Please contact your local Shockwave representative for specific country availability and refer to the Shockwave S4 instructions for use containing important safety information.