



SHOCKWAVE | S<sup>4</sup>

## 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

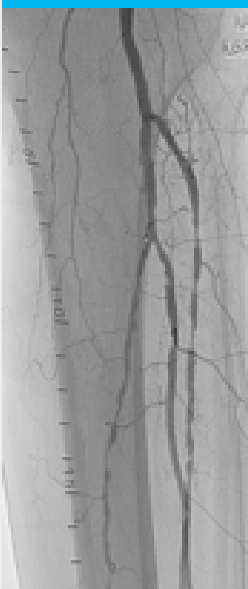
Simple and intuitive system that makes complex calcified below-the-knee procedures more predictable

## Effective in Both Intimal and Medial Calcium

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

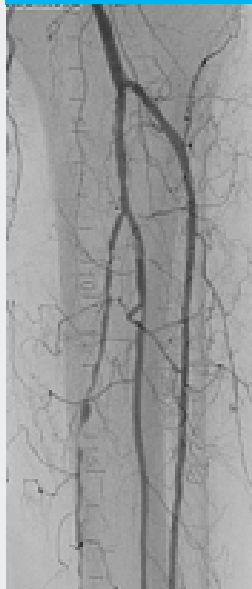
### CALCIFIED POSTERIOR TIBIAL ARTERY

Diagnostic  
Angiogram  
Post IVL



65% Stenosis

Final  
Angiogram  
Post IVL

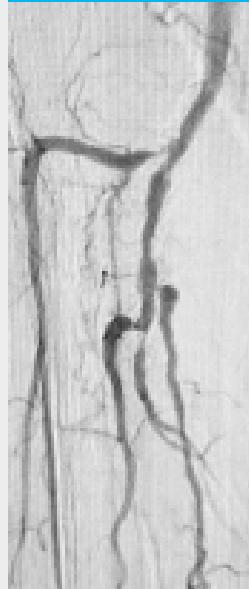


21% Residual  
1.6mm Acute Gain

*Courtesy of Prof. Andrew Holden*

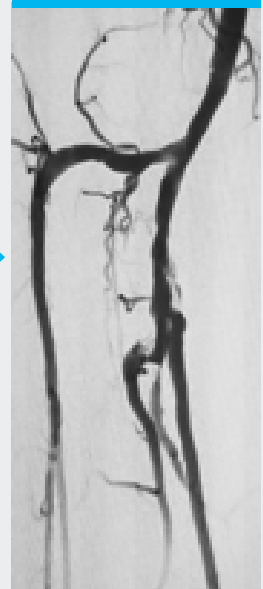
### CALCIFIED ANTERIOR AND POSTERIOR TIBIAL ARTERY BIFURCATION

Diagnostic  
Angiogram



Previous PT & AT  
Intervention 30d ago

Final  
Angiogram  
Post IVL



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 GENERATOR AND CONNECTOR CABLE SPECS

<b>Power</b>	110-240 VAC; 50-60Hz; Single Phase, 15A service	 <p>IVL Generator CATALOG NUMBER: <b>IVLGCC</b></p>
<b>Size</b>	11" (28.0 cm) high x 6" (15.2 cm) wide x 11.5" (29.2 cm) deep	
<b>Weight</b>	15 pounds (6.8 kg)	
<b>Output</b>	Proprietary pulse delivery system. Output voltage 3000 volts peak, pulse frequency 1Hz	
<b>Mobility</b>	Product is designed to be mounted to a stable mobile or stationary IV pole. An IV pole with five casters located in a circular pattern with a diameter of at least 23 inches (58 cm), such as the I.V. League Ventilator Stat-Stand™ model 1059 (or equivalent) is recommended.	 <p>IVL Connector Cable CATALOG NUMBER: <b>IVLCC</b></p>
<b>Length</b>	5 ft (1.53m)	
<b>Compatibility</b>	Connector Cable has a male key designed on the proximal designed to connect to the Catheter.	
<b>Operation</b>	Lithotripsy pulsing is activated by pushing a button on the Connector Cable.	
<b>Connector Cable</b>	Use Re-usable	

### IVL CATHETER SPECS

CATALOG #	Diameter (mm)	Length (mm)	Emitters	Pulses/ Cycle	Cycles	Guidewire (in)	Sheath Compat.	Working Length (cm)
S4IVL2540	2.5	40	4	20	8	0.014	5F	135
S4IVL3040	3.0	40	4	20	8	0.014	5F	135
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.

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