Peripheral Intravascular Lithotripsy (IVL) System

**SHOCKWAVE M5**

**Intravascular Lithotripsy (IVL) for Safe and Effective Treatment of Vascular Calcium**

**MINIMIZE TRAUMA | OPTIMIZE OUTCOMES | SIMPLIFY PROCEDURES**

**Broad Applications in Calcified Peripheral Arteries**

- **Common Femoral Disease**
  *Enable Endovascular CFA Treatment*
  - Pre-Treatment Angiogram
  - Final Angiogram (Post IVL + DCB)
  
  Images courtesy of Bill Miller, MD

- **Femoropopliteal Disease**
  *Safe and Effective Vessel Prep or Treatment*
  - Pre-Treatment Angiogram
  - Final Angiogram (Post IVL)
  
  Images courtesy of Marianne Brodmann, MD

- **Symptomatic Iliac Disease**
  *Preservation of Future Treatment Options*
  - Pre-Treatment Angiogram
  - Final Angiogram (Post IVL)
  
  Images courtesy of Patricia Furey, MD

- **TAVI, TEVAR & EVAR Access**
  *Facilitate Delivery of Large-Bore Devices*
  - Pre-Treatment Angiogram
  - Final Angiogram (Post IVL & 23Fr TEVAR)
  
  Images courtesy of David Caparrelli, MD
Peripheral Intravascular Lithotripsy (IVL) System

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
- **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 Generator
CATALOG NUMBER: IVLGCCD

IVL Connector Cable
CATALOG NUMBER: IVLCC

M5 CATHETER SPECS

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*Products are equivalent; either Catalog Number may be used when ordering and either product may be received.

STERILE SLEEVE

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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 anti-coagulant 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