

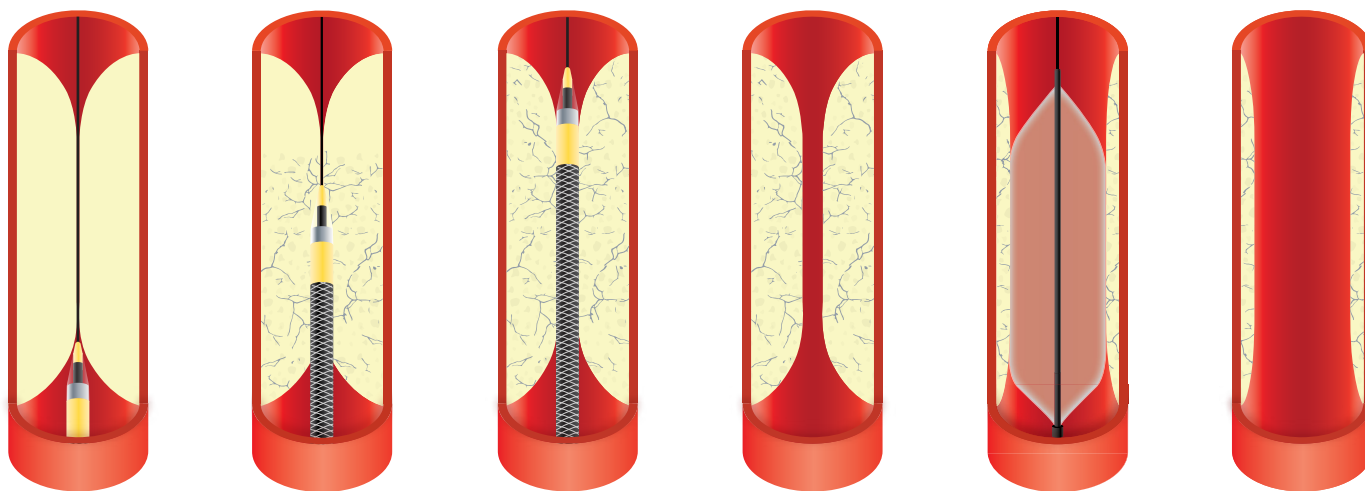
LEAD THE CHARGE

Peripheral IVL Redefined to Modify & Cross Calcified Occlusive Disease

- First-of-its-kind Forward IVL Platform transforms treatment of difficult-to-cross lesions
- Single distal emitter delivers energy and cracks calcium beyond the tip
- Proven safety and efficacy profile consistent with Balloon IVL Platform



SHOCKWAVE JAVELIN PERIPHERAL MODIFIES AS IT CROSSES



Shockwave Javelin delivered to the lesion

Shockwave Javelin modifies calcium spherically, including beyond the tip

Shockwave Javelin crosses lesion

Small lumen created + calcium modified throughout

Facilitates definitive therapy of choice (PTA pictured above)

Larger lumen created

Internal testing shows a spherical sonic output from distal emitter consistent with previous Shockwave balloon-based IVL emitters, with sonic output extending beyond the tip of the catheter.

SHOCKWAVE JAVELIN CATHETER SPECIFICATIONS

Catalog Number	Tip Entry Profile (in)	Crossing Profile (mm)	Sheath Compatibility (Fr.)	Guidewire Compatibility (in)	Catheter Working Length (cm)	Pulses/Cycle	Cycles	Pulse (Max)
JVNPIVLF	0.025	1.5	5	0.014	150	10	12	120

PERIPHERAL SAFETY INFORMATION

Shockwave Javelin

In the United States: Rx only.

Indications for Use— The Shockwave Medical IVL System with the Shockwave Javelin Peripheral IVL Catheter is intended for lithotripsy-enabled modification and crossing of calcified lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries, prior to final treatment. Not for use in the coronary, carotid, cerebral, or pulmonary vasculature.

Contraindications— Do not use if unable to pass 0.014" (0.36mm) guidewire across the treatment site—Not intended for treatment of in-stent restenosis or in coronary, carotid, cerebral or pulmonary 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— Avoid applying acoustic pressure pulses while IVL window is not filled with sterile saline—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.

Shockwave S4, Shockwave M5, Shockwave M5+, Shockwave E8, and Shockwave L6

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, infra-popliteal, and renal arteries. Not for use in the coronary, carotid or cerebral vasculature.

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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