

Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System (Important Safety Information for U.S.)

Rx Only

Indication 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 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.

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