**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.  
www.shockwavemedical.com