# PulsePoint
## Quarterly Newsletter

## CRACKING IN THE NEW YEAR WITH NEW PRODUCTS & DATA

In Q4, Shockwave IVL made big waves at some of our biggest U.S. conferences, revealing eagerly anticipated products and clinical trial milestones.

At this year's TCT, we unvelied Shockwave Javelin to our U.S. customers, our first Peripheral IVL catheter designed for balloon-uncrossable lesions. We were also thrilled that EMPOWER CAD — a landmark Coronary IVL study with all female patients — completed enrollment, with the 400th and final patient enrolled in a live case at TCT by Dr. Margaret McEntegart.

Finally, at VIVA, FORWARD PAD data showcased the first-ever PAD outcomes with Shockwave Javelin while the 30-Day DISRUPT BTK II outcomes showed that patients treated with Peripheral IVL experienced significant quality of life and wound healing improvements with minimal adverse events. Read the latest PulsePoint newsletter to learn more about these and other momentum-building Q4 moments.


**See One of the Top Social Posts from Q4:** The EMPOWER CAD Live Case at TCT Conference

READ THE POST

## PUBLICATIONS

**JOURNAL OF VASCULAR SURGERY**

**Thirty-Day Outcomes from the Disrupt PAD BTK II Study of the Shockwave Intravascular Lithotripsy System for Treatment of Calcified Below-the-Knee Peripheral Arterial Disease**

Dr. Chandra, Dr. Lansky, Dr. Sayfo, et al.

Read More >

**JACC**

**Coronary Sinus Narrowing for Treating Refractory Angina: REDUCER-I Multicenter "Real-World" Observational Study Primary Endpoint Analysis**

Dr. Verheye, et al.

Read More >

**EUROINTERVENTION**

**Outcomes of coronary intravascular lithotripsy for the treatment of calcified nodules: a pooled analysis of the Disrupt CAD studies**

Dr. Ali et al.

Read More >

**JSCAI**

**Equity in Modifying Plaque of Women With Undertreated Calcified Coronary Artery Disease: Design and Rationale of EMPOWER CAD study**

Dr. McEntegart, et al.

Read More >

20 4s² Catalyst Calcium 40.078

## Top Catalyst Blogs from Q4

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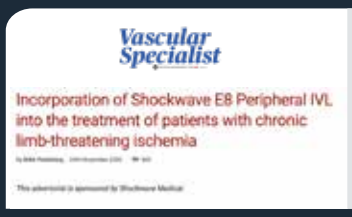
2


3

# PHYSICIAN PERSPECTIVES




**Incorporation of Shockwave E8 Peripheral IVL Into the Treatment of Patients with Chronic Limb-Threatening Ischemia**

Read Now >


**DISRUPT BTK II Acute Outcomes: Physician Perspectives**

Watch Now >

# SHOCKWAVE IN THE NEWS

Shockwave Medical Unveils First Clinical Outcomes of New IVL Platform in Late-Breaking Presentation at VIVA 2024

Read More >

Shockwave Medical Completes Enrollment in EMPOWER CAD, an All-Female Coronary IVL Study

Read More >

Shockwave Medical Further Validates Utility of Intravascular Lithotripsy in Lower Limb Lesions in Late-Breaking Presentation at VIVA 2024

Read More >

## FEATURED VIDEOS


**Furthering the Boundaries of BTK Treatment with Shockwave E8**

Watch Now >


**UK Reducer Day**

Watch Now >

# UPCOMING EVENTS


### CRT

Booth #316

Shockwave Symposia:

- Sunday, March 9th from 12:15–1:15 PM on CRT Center Stage
- Monday, March 10th from 12:30–1:30 PM in Jefferson

March 8 – 11 | Washington, DC

Learn More >


### SCAI

Booth #310

Come check out our lunch symposium!

May 1 – 3 | Washington, DC

Learn More >

# IVL Important Safety Information

## CORONARY ISI:

**Shockwave C2 and Shockwave C2+ Safety Information**

**In the United States: Rx only**

**Indications for Use—** The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2 and C2+ Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

**Contraindications—** The Shockwave C2 and C2+ Coronary IVL System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries.

**Warnings—**Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy.

**Precautions—** Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anticoagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target lesion.

**Potential adverse effects consistent with standard based cardiac interventions include–** Abrupt vessel closure – Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy-Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion-Cardiopulmonary arrest-Cerebrovascular accident (CVA)-Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or nonemergency coronary artery bypass surgery-Emergency or nonemergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention-Hematoma at the vascular access site(s)- Hemorrhage-Hypertension/Hypotension-Infection/sepsis/fever-Myocardial Infarction-Myocardial Ischemia or unstable angina-Pain-Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke Thrombus-Vessel closure, abrupt-Vessel injury requiring surgical repair-Vessel dissection, perforation, rupture, or spasm.

**Risks identified as related to the device and its use:** Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture.

**Prior to use, please reference the Instructions for Use for more information on warnings, precautions and adverse events.** www.shockwavemedical.com/IFU.

## PERIPHERAL ISI:

**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

## JAVELIN PERIPHERAL IVL ISI:

**In the United States: Rx only.**

**Indications for Use—** The Shockwave Medical IVL System with the 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.

**Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events.**
www.shockwavemedical.com/ifu

# Reducer Important Safety Information

## REDUCER ISI:

**Caution:** In the United States, Shockwave Reducer is an investigational device, limited by United States law to investigational use.

The Reducer is subject of Investigational testing and is being studied in the COSIRA-II trial in Canada.

The Reducer is commercially available in certain countries outside the U.S. and Canada.

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events: ifu.neovasc.com

Please contact your local representative for specific country availability.



Johnson&Johnson MedTech

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