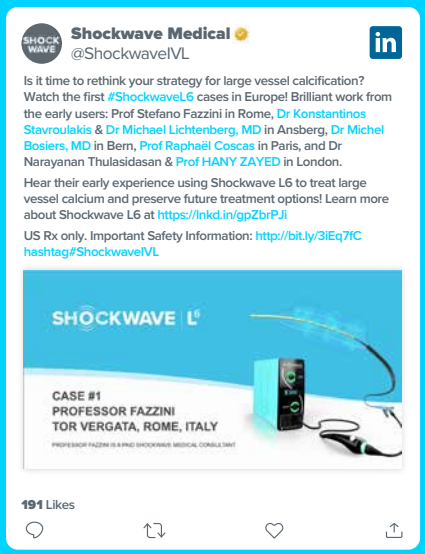
PulsePoint
Quarterly Newsletter

CHECK OUT OUR SHOCK-WORTHY Q3 HIGHLIGHT REEL

As we're halfway through football season in the U.S., let's huddle up — it's time to revisit a few difference-making moments from Q3 that are helping physicians score big gains for their patients. Shockwave E8 went above and beyond with a successful U.S. launch that is already extending physicians' ability to crack complex peripheral calcium above and below the knee. Meanwhile, Shockwave L6 sprinted into the cath labs nationwide with game-changing updates that enable 2x faster pulsing to crack iliac calcium more efficiently.

Finally, the ROLLERCOASTR-EPIC22 trial results were another impressive showing of the safety of IVL with low rates of severe procedural complications (includes death, perforation, flow-limiting dissection, abrupt vessel closure, ST) — a real-world RCT finding that physicians should find confidence in.[1] Read the latest PulsePoint newsletter to learn more about these and other wave-making Q3 moments.



One of our top-performing posts of the quarter on LinkedIn featuring videos of the first five #ShockwaveL6 cases in Europe.

SEE THE POST

PUBLICATIONS

JOURNAL OF CLINICAL MEDICINE

Intravascular Lithotripsy: Approach to Advanced Calcified Coronary Artery Lesions, Current Understanding, and What Could Possibly Be Studied Next

Dr. Saratzis, et al.

Read More >

JOURNAL OF ENDOVASCULAR THERAPY

Shockwave Intravascular Lithotripsy Use in the Femoro-Popliteal Segment: Considerations From an Expert Pan-European Panel Regarding Best-Care Practice

Dr. Kochiashvili, et al.

Read More >

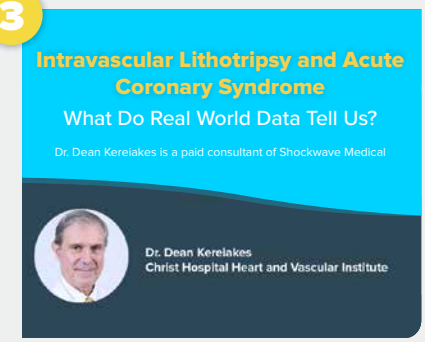
20 4s² Catalyst Calcium 40.078

Top Catalyst Blogs from Q3

1

2

3



1. Jurado-Román et al. REC Interv Cardiol. 2023;5(4):279-286; Jurado, The RollerCoaster-EPIC22 trial, presented at EuroPCR 2024

PHYSICIAN PERSPECTIVES

ROLLERCOASTR-EPIC22 Trial: The Importance of Device Selection

During this year's EuroPCR, Dr Alfonso Jurado-Román presented the results of ROLLERCOASTR-EPIC22.

Read Now >

Q&A: Reducer-I 12-Month Data Q&A with Dr. Verheye

ESC 2024 marked yet another significant milestone for Reducer with new data being presented at the biggest stage of European Cardiology.

Watch Now >

SHOCKWAVE IN THE NEWS

Shockwave Medical Expands U.S. Peripheral IVL Portfolio with Enhanced Catheter
Read More >

FEATURED VIDEOS

Meet Shockwave E8

Reducer-I 12-Month Data Presentation with Dr. Verheye

EuroPCR 2024: Relief for the Unrelievable, the Role of the Reducer for Refractory Angina

WATCH THE VIDEOS >

UPCOMING EVENTS

2024 FELLOWS COURSES

SCAI Fellows

Booth #504
Come check out our symposium and workshops.
- Symposium: Dec. 13: 12:25 – 1:10 PM
- Abiomed Workshop: Dec. 11: 1:45 – 6 PM
- Peripheral Workshop: Dec. 14: 8:30 – 10:30 AM
- Structural Workshop: Dec. 14: 8:30 – 10:30 AM

December 10-15, 2024

Learn More >

iSET

ISET

Come check out our Booth #407 and our Breakfast Symposium:
- Feb. 3, 7:00 – 8:10 AM.

February 2-5, 2025

Register Now >

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

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

SHOCKWAVE MEDICAL