SHOCKWAVE MEDICAL

PulsePoint
Quarterly Newsletter

HALFWAY TO ANOTHER SHOCKWORTHY YEAR

Q2 is in the books and it was full of electrifying news, big accomplishments and new beginnings. Of course, a major milestone was the acquisition of Shockwave Medical by Johnson & Johnson MedTech. This new journey is off to a great start and we're excited about how this partnership will help us expand access to our life-changing technologies across the globe.

Updates from the Reducer team for our international physician partners include publishing new data that show positive news for patients suffering from Refractory Angina.* Additionally, our Size for Success training about sizing up for the best Peripheral IVL results is also gaining traction and was featured in several publications. Read the latest PulsePoint Newsletter to learn more about important milestones from Q2!

One of our top-performing posts of the quarter on X featuring Q&A with Rob Riley on SCAI Consensus Statement & Algorithm.

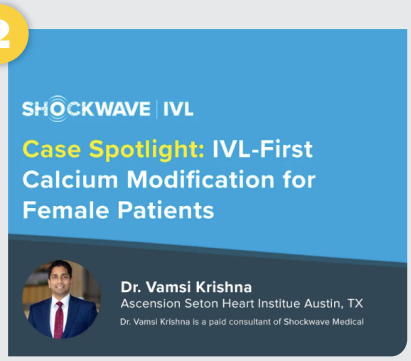
SEE THE POST

20 4s²
Catalyst
Calcium
40.078

Top Catalyst Blogs from Q2

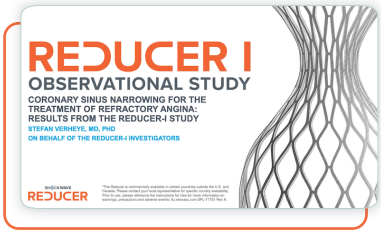
1

2



INTERNATIONAL REDUCER RECAP

REDUCER I CLINICAL DATA PRESENTATION
Watch >



REDUCER 1 CLINICAL DATA Q&A
Watch >

BEYOND THE DATA: ORBITA-COSMIC
Watch >

*In the US and Canada: Investigational Use Only. Prior to use, please reference the Instructions for Use for more information on warnings, precautions and adverse events: ifu.neovasc.com

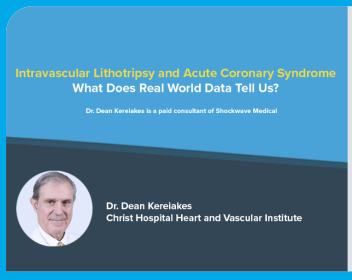
SHOCKWAVE MEDICAL

PHYSICIAN PERSPECTIVES ON IVL

TREATING CALCIFIED BTK DISEASE WITH SHOCKWAVE IVL

Drs. Erik Stilp, Nicolas Mouawad, Elizabeth Genovese and Kumar Madassery discuss their best practices when treating patients with below-the-knee (BTK) disease.

Read Now >



INTRAVASCULAR LITHOTRIPSY AND ACUTE CORONARY SYNDROME: WHAT DOES REAL WORLD DATA TELL US?

In this Q&A, we invited Dr. Dean Kereiakes to share his interpretation of the study's conclusions and the data he presented at SCAI 2024.

Read Now >

SHOCKWAVE IN THE NEWS

Press Release: "Shockwave Reducer Demonstrates Consistent, Positive Results in 'Real-World' Study"

Read More >

Press Release: "Johnson & Johnson to Acquire Shockwave Medical"

Read More >

FEATURED VIDEO

SHOCKWAVE L⁶ IN ACTION: CALCIFIED BILATERAL ILIACS - PRESERVING THE BIFURCATION

Case Review with Dr. JD Corl

WATCH NOW >

UPCOMING EVENTS

CIRSE

Come check out the IVL symposium and stop by our booth at CIRSE!

Sept 14 – 18

Learn More >

TCT

Join us at TCT, check out the Shockwave symposium and stop by the booth!

October 27 – 30

Learn More >

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IVL Important Safety Information

CORONARY ISI:

In the United States: Rx only

Indications for Use— The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C^2 and C^{2+} 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 C^2 and C^{2+} 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.

In the US: Rx Only. Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events. www.shockwavemedical.com/IFU

Please contact your local Shockwave representative for specific country availability.

PERIPHERAL ISI:

In the United States: Rx only.

Indications for Use— The Shockwave Medical IntravascularLithotripsy (IVL) System is intended for lithotripsy-enhancedballoon dilatation of lesions, including calcified lesions, in theperipheral 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, 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. Please contact your local representative for specific country availability.

In the US and Canada: Investigational Use Only. Prior to use, please reference the Instructions for Use for more information on warnings, precautions and adverse events: ifu.neovasc.com