SHOCKWAVE MEDICAL

PulsePoint
Quarterly Newsletter

NEW YEAR, NEW SPARKS

There's no better way to start a new year than building positive momentum.

Between great developments on coronary reimbursement to positive real-world data for Reducer, 2024 is off to a shock-worthy start.

Another highlight was the continuous enrollment of patients in our EMPOWER CAD Study — the first prospective clinical study in the interventional space completely dedicated to female patients. Our team also created new resources about optimal sizing for Peripheral IVL, as well as put the final touches on our new manufacturing facility in Costa Rica. Read more about our strong start and get excited about what's to come in the latest edition of the PulsePoint Newsletter.

Dr. Neel Butala shares a Tweetorial on the findings of his recent *JSCAI* Publication.

SEE THE POST

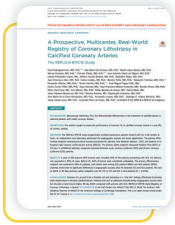
PUBLICATIONS

JOURNAL OF ENDOVASCULAR THERAPY

Intravascular Iliac Artery Lithotripsy to Facilitate Aortic Endograft Delivery: Midterm Results of a Dual-Center Experience

Dr. Fazzini, *et al.*

Read More >



JACC: CARDIOVASCULAR INTERVENTIONS

A Prospective, Multicenter, Real-World Registry of Coronary Lithotripsy in Calcified Coronary Arteries: The REPLICA-EPIC18 Study

Dr. Rodriguez-Leor, *et al.*

Read More >

JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS

SCAI Expert Consensus Statement on the Management of Calcified Coronary Lesions

Dr. Riley, *et al.*

Read More >

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Top 3 Catalyst Blogs from Q1

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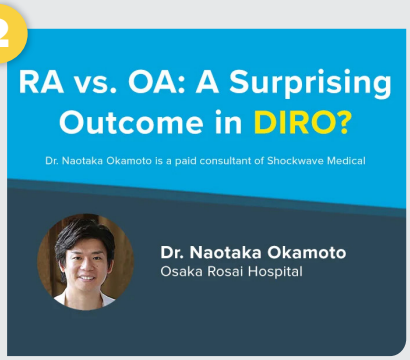

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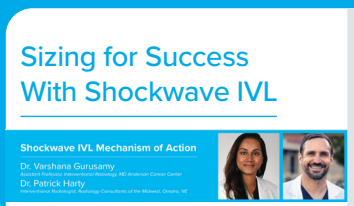
SHOCKWAVE MEDICAL

PHYSICIAN PERSPECTIVES ON IVL

Recently Published in JSCAI

A new publication details an overall increase in the use of calcium modification tools for percutaneous Coronary interventions (PCI) and a rapid uptake in the use of Coronary IVL since the U.S. launch of Shockwave C^2 in early 2021.

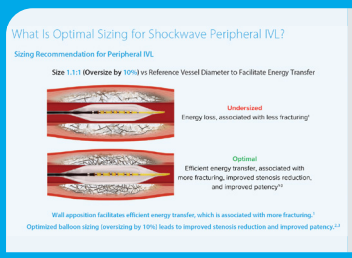
Read Now >



Sizing for Success in JVIR

In the Journal of Vascular and Interventional Radiology, Drs. Patrick Harty and Varshana Gurusamy share their experience oversizing with Peripheral IVL and share two case reviews.

Read Now >



Sizing for Success in EVToday

In this Endovascular Today article, Dr. Sasanka Jayasuriya discusses tips for optimal sizing with Peripheral IVL.

Read Now >

SHOCKWAVE IN THE NEWS

Cath Lab Digest: "A Physician's Perspective on New Permanent Reimbursement Pathways for Coronary Intravascular Lithotripsy"
Read More >

Cath Lab Digest: "New Catheter, New Strategy: An IVL-First Approach to Complex PCI"
Read More >

REDUCER 1 EU: Post-Market Study Demonstrates Consistent, Positive Results for the Shockwave Reducer
Read More >

FEATURED VIDEO

SIZE FOR SUCCESS WITH PERIPHERAL IVL

Interview & Case Review with Dr. Paul Foley

WATCH NOW >

UPCOMING EVENTS

EuroPCR

Check out our training village, Reducer and IVL symposia and stop by the booth!

May 14 - 17

Learn More >

NCVH

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

May 28 - 31

Register Now >

SHOCKWAVE MEDICAL

IVL Important Safety Information

CORONARY ISI:

Shockwave C^2 and Shockwave C^{2+} Safety Information

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:

Shockwave M^{5+}, Shockwave M^5, Shockwave S^4 and Shockwave L^6 Safety Information

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 or cerebral vasculature.

Contraindications— Do not use if unable to pass 0.014″ (M^5, M^{5+}, S^4) or 0.018″ (L^6) 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.

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.

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