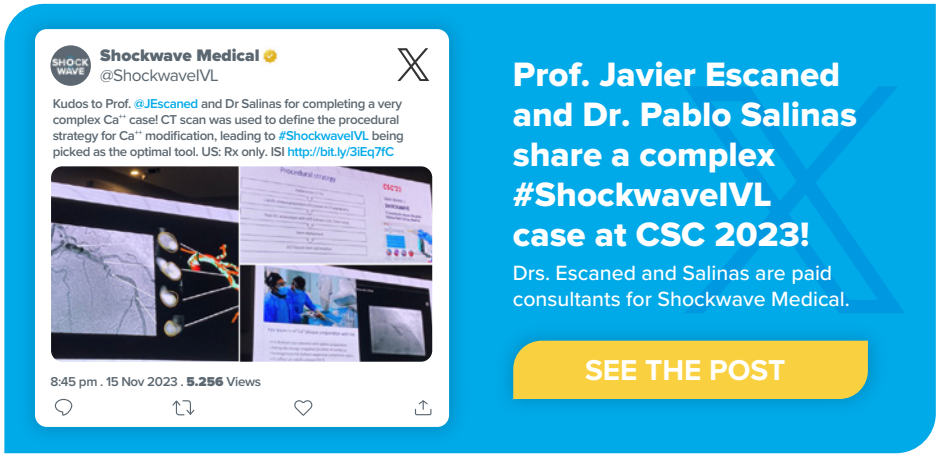
SHOCKWAVE MEDICAL

PulsePoint
Quarterly Newsletter

Q4 '23: FINISHING THE YEAR WITH A SPARK

What a fantastic finish!
From launching the new 120-pulse Shockwave C^{2+} catheter in the U.S. to establishing a new Category I CPT® Add-on Code for Coronary IVL, Q4 was filled with wave-making moments and positive momentum.

One highlight was the release of sex-specific outcomes data for both Coronary and Peripheral IVL from the DISRUPT PAD III, DISRUPT CAD III and CAD IV studies. Additionally, the DISRUPT PAD III study provided important data supporting the practice of sizing up by 10% for Peripheral IVL. Look back at a few of our most noteworthy Q4 accomplishments and get excited about what's coming in 2024 in the latest issue of the PulsePoint Newsletter.



Prof. Javier Escaned and Dr. Pablo Salinas share a complex #ShockwaveIVL case at CSC 2023!

Drs. Escaned and Salinas are paid consultants for Shockwave Medical.

SEE THE POST

PUBLICATIONS

JOURNAL OF VASCULAR SURGERY

Sex-Specific Analysis of Intravascular Lithotripsy for Peripheral Artery Disease from the DISRUPT PAD III Observational Study

Dr. Lansky, *et al.*

Read More >

CARDIOVASCULAR INTERVENTIONS

Impact of Calcium Eccentricity on the Safety and Effectiveness of Coronary Intravascular Lithotripsy: Pooled Analysis From the DISRUPT CAD Studies

Dr. Ali, *et al.*

Read More >

JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS

Sex-Specific 1-Year Outcomes in Coronary Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Lesions: A Patient-Level Pooled Analysis of the DISRUPT CAD III and CAD IV Studies

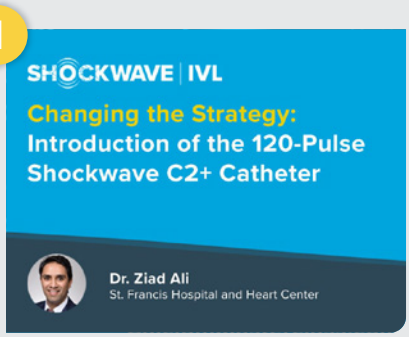
Dr. Lansky, *et al.*

Read More >

20 4s² Catalyst Calcium 40.078

Top 3 Catalyst Blogs from Q4

1



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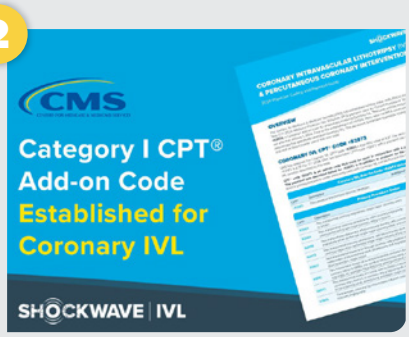

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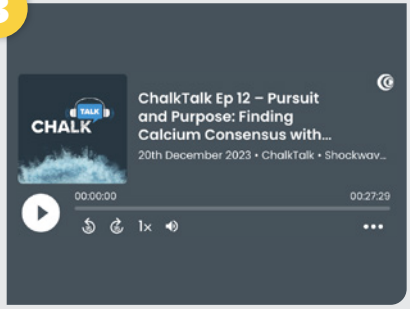
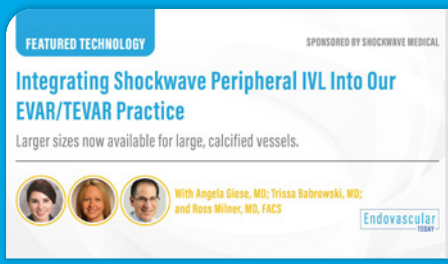


SHOCKWAVE MEDICAL

PHYSICIAN PERSPECTIVES ON IVL



Integrating Shockwave Peripheral IVL Into Our EVAR/TEVAR Practice

In the recent Endovascular Today article, Dr. Ross Milner uncovers his tips to effectively treat calcified CIAs with Shockwave IVL before an EVAR and Dr. Milner shares how he was able to successfully treat endovascularly.

Read Now >

Size for Success: Peripheral IVL Sizing for Optimal Results

In this short, three-part video series, Dr. Eric Secemsky and Dr. Michael Siah discuss appropriate peripheral intravascular lithotripsy sizing – the what, why, and how – for optimal clinical results.

Watch Now >

Shockwave C²⁺ Physician Perspectives: Dr. Darshan Doshi

In this physician perspective video, Dr. Darshan Doshi breaks down how the additional pulses of Shockwave C²⁺ can optimize treatment of nodular calcium.

Watch Now >

SHOCKWAVE IN THE NEWS

New Shockwave Coronary IVL Publications Confirm Safety and Efficacy Across Multiple Calcium Morphologies

Read More >

Centers for Medicare & Medicaid Services Establishes New Category I CPT® Add-On Code for Coronary IVL

Read More >

New Shockwave Coronary IVL Publication Shows Similar Outcomes in Women And Men

Read More >

FEATURED VIDEOS

WATCH THE VIDEOS >

UPCOMING EVENTS

CRT

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

March 9 - 12

Register Now >

SIR

Join us at SIR, attend the Shockwave Lunch Symposium on Tuesday March 26, 2024 (12:00 - 1:00pm) and visit the booth!

March 23 - 28

Register Now >

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.

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 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" (M5, M5+, S4) 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

Please contact your local Shockwave representative for specific country availability.

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.

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