SHOCKWAVE | IVL PREDICTABLY SAFE | DISTINCTLY INTUITIVE | CONSISTENTLY EFFECTIVE

PulsePoint

Shockwave Quarterly Newsletter to Keep Your Finger on the Pulse of IVL News, Trends, & Evidence

Q4 '22: Ending 2022 in a Big Way

2022 was another big year for Shockwave and Q4 was no exception! On Twitter, the first Shockwave L^6 cases were posted by physicians who participated in its limited release and it was great to see their excitement for our new large-vessel peripheral IVL catheter launching soon in the U.S.! At VIVA '22, Dr. Ehrin Armstrong presented the final 1,373 patient cohort data from the Disrupt PAD III Observational Study; this larger patient data set reinforces the predictability of Shockwave IVL and its ability to consistently modify calcium across vessel beds, challenging lesions and complex patients. Additionally, international calcium experts shared their real-world experiences with the safety and efficacy of Coronary IVL across different calcium morphologies, including concentric, eccentric and nodular calcium. Check out that and more in the new PulsePoint Newsletter!

#1 Most Engaging Twitter Post from Q4

SEE THE POST

NEW IVL PUBLICATIONS

Cardiology in Review

Intravascular Lithotripsy in Peripheral Artery Disease

Dr. Carlos E Vazquez Sosa, et al.

Read More >

Cardiovascular Revascularization Medicine

Efficacy and safety of intravascular lithotripsy versus rotational atherectomy in balloon-crossable heavily calcified coronary lesions

Dr. Mohamed A.A.Mousa, et al.

Read More >

Catheterization & Cardiovascular Interventions

Long-term outcomes following intravascular lithotripsy (IVL) for calcified coronary lesions: A Real-World Multicenter European Study

Dr. Sandeep Basavarajaiah, et al.

Read More >

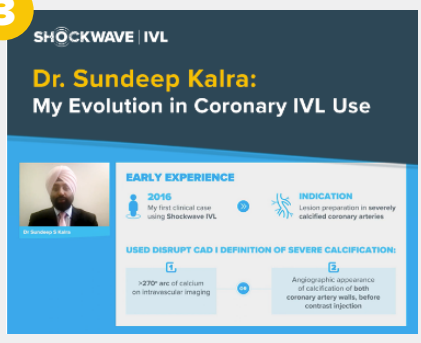
Catalyst

Top 3 Catalyst Posts from Q4

1

2

3

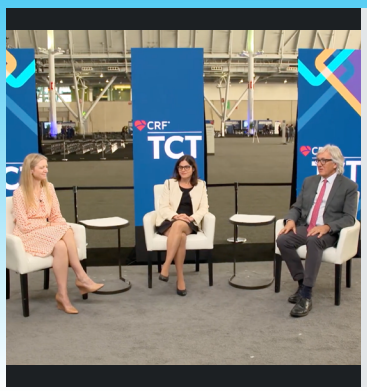


PHYSICIAN PERSPECTIVES ON IVL

Does Sex Impact Outcomes in Disrupt PAD III?

Dr. Misty Humphries reviews the sex specific analysis from the Disrupt PAD III Observational Study while at VIVA 2022. Because females often present with more difficult characteristics for endovascular therapy, this analysis of 1,373 patients aimed to illustrate that IVL can safely and effectively modify calcium regardless of gender.

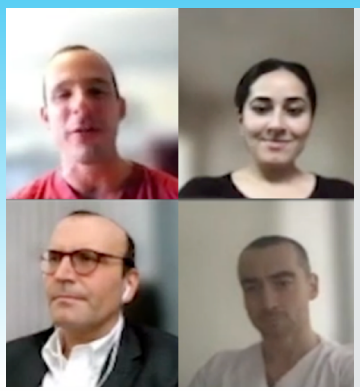
Watch Now >



Does Calcium Morphology Matter? Coronary IVL Real World Experience from Europe

In this webcast recorded at TCT 2022, Prof. Javier Escaned and Dr. Nieves Gonzalo from Clinico San Carlos Madrid, and Dr. Angela McInerney, from University Hospital Galway, share their experience with IVL and the results from their most recent studies.

Watch Now >



Vascupedia Shockweek Day 2: Changing Parameters in CLTI Treatment

In session 2 of Shockweek on Vascupedia, Dr. Elias Noory treats multiple highly calcified femoropopliteal lesions with IVL. During the session, our expert panel of Drs Lorenzo Patrone, Enrique Alejandre Lafont, Bella Huasen and Thanos Saratzis discuss how IVL can overcome the pitfalls of CLTI treatment by changing vessel compliance to reduce procedural complications.

Watch Now >

SHOCKWAVE IN THE NEWS

Shockwave Agrees to Acquire Neovasc

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Shockwave Confirms Consistent Outcomes for IVL in the Largest Prospective “Real World” Study of Patients with Heavily Calcified Peripheral Arterial Disease

Read More >

Germany Welcomes in the New Year with New Reimbursement in 2023

Read More >

FEATURED VIDEO

Vascupedia Shockweek Day 1: Tackling Calcium in Large Vessels

Watch the Video >

UPCOMING NEWS

EuroPCR 2023

MAY 16 - 19, 2023

Register Now >

SCAI 2023

MAY 18 - 20, 2023

Register Now >

Important Safety Information

CORONARY ISI:

Rx only

Indications for Use—The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave 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 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 non-emergency coronary artery bypass surgery-Emergency or non-emergency 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.
https://shockwavemedical.com/IFU

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C² instructions for use containing important safety information.

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.

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave M⁵, Shockwave M⁵⁺, Shockwave S⁴, and Shockwave L⁶ instructions for use containing important safety information.

www.shockwavemedical.com