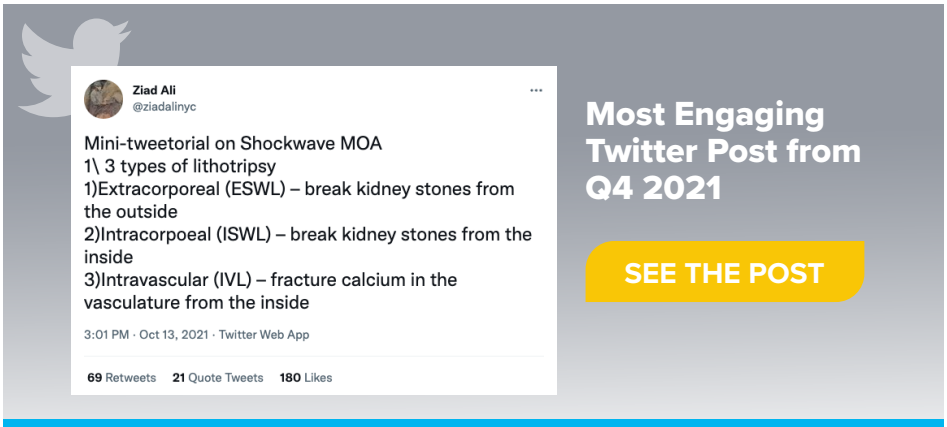
SHOCKWAVE | IVL PREDICTABLY SAFE | DISTINCTLY INTUITIVE | CONSISTENTLY EFFECTIVE

PulsePoint

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

2021: That's A Wrap!

A new year brings new opportunities for Shockwave and we are energized to see what we can accomplish together but before we fully embrace 2022, let's recap of the final quarter of 2021. Between back-to-back conferences, new data analyses from Disrupt CAD Pooled clinical program, and the unveiling of the first 1-year results of Coronary IVL, it's been a busy three months. Then, we received the exciting news that on January 1st, 2022 CMS will increase outpatient reimbursement for Peripheral IVL, above the knee procedures. To wrap up a truly incredible year, we enrolled the first patient in the Disrupt BTK II Study for below the knee lesions. Read the newsletter for all the highlights and stay on the pulse!



Most Engaging Twitter Post from Q4 2021

SEE THE POST

NEW IVL PUBLICATIONS

Journal of Invasive Cardiology

ELCA-Tripsy: Combination of Laser and Lithotripsy for Severely Calcified Lesions

Dr. Raúl Moreno

Read More >

Minerva Cardiology and Angiology

Comparative Study of Costs And Resource Utilisation of Rotational Atherectomy Versus Intravascular Lithotripsy for Percutaneous Coronary Intervention

Dr. Margaret McEntegart

Read More >

EuroIntervention

Peripheral Intravascular Lithotripsy of ILEO-Femoral Arteries to Facilitate Transfemoral TAVI: A Multicentric Prospective Registry

Prof. Carlo Di Mario

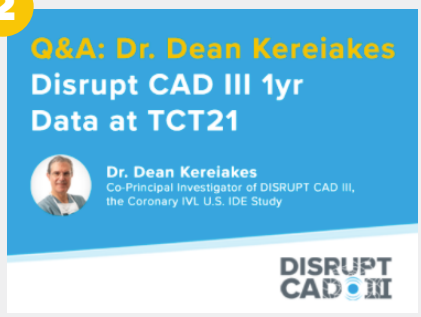
Read More >

Catalyst

Top 3 Catalyst Posts from Q4

1

2



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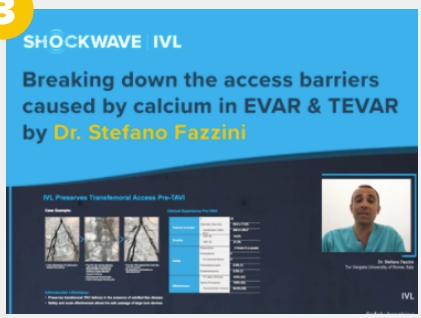
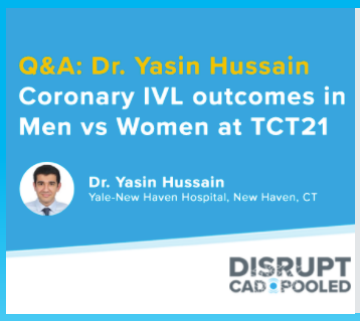


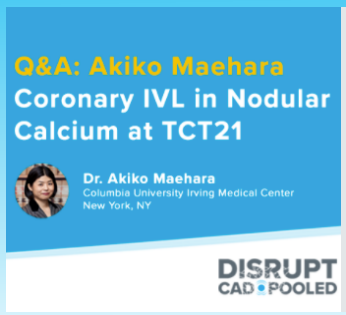
TOP 3 CONGRESS & DATA PRESENTATION HIGHLIGHTS



Gender Equality in Treating Calcium

Explore the Q&A with Dr. Yasin Hussain about the Disrupt CAD Pooled OCT Female vs. Male Analysis presented at TCT 2021.

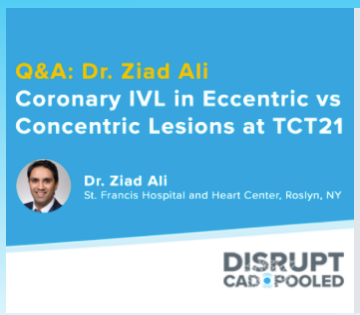
Read More >



Cracking the Nodular Code

Dr. Akiko Maehara explains the Disrupt CAD Pooled OCT Calcific Nodules Analysis presented at TCT 2021 in a Q&A.

Read More >



Applying Shocks in Eccentric v Concentric Rocks

In a Q&A with Dr. Ziad Ali, he discusses the Disrupt CAD Pooled OCT Eccentric vs Concentric Analysis presented at TCT 2021.

Read More >

SHOCKWAVE IN THE NEWS

- Centers For Medicare & Medicaid Services Increases Hospital Outpatient Payment For Peripheral Intravascular Lithotripsy
  Read More >
- Shockwave Medical Unveils First One-Year Results of Coronary Intravascular Lithotripsy
  Read More >
- Shockwave Medical Enrolls First Patient in Disrupt BTK II Study for Long, Calcified, Below the Knee Lesions
  Read More >

FEATURED VIDEO

TCTMD Roundtable featuring Coronary IVL Data from TCT 2021

Watch the Video >

UPCOMING NEWS

CRT 2022

Register Now >

Backtable Podcast Series

Listen to the Podcast Series >

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 C^2 instructions for use containing important safety information.

PERIPHERAL ISI:

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indication 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 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 thinners • 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

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave M^5 and Shockwave S^4 instructions for use containing important safety information.