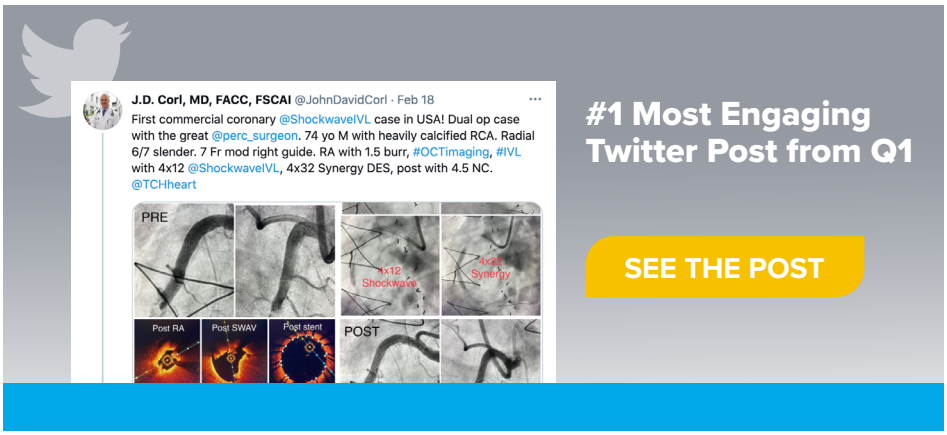
SHOCKWAVE | IVL PREDICTABLY SAFE | DISTINCTLY INTUITIVE | CONSISTENTLY EFFECTIVE

PulsePoint

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

Q1'21: Time to Get Cracking in The USA!

Wow, the first three months of the year have been wild! First, the U.S. FDA approval for Coronary IVL, which means lots of new cardiologists trying IVL for the first time, and then rounded out with a new JV in China. But the excitement didn't stop there, check out some of our notable news and milestones from the quarter!



NEW IVL PUBLICATIONS

Clinical Research in Cardiology

Safety and Effectiveness of Coronary Intravascular Lithotripsy in Eccentric Calcified Coronary Lesions

Dr. Holger M. Nef

Read More >

Cardiovascular Business

Breaking Through: Have Severely Calcified Lesions Met Their Match?

Read More >

Circulation: Cardiovascular Interventions

Calcium Modification Techniques in Complex Percutaneous Coronary Intervention

Dr. Kalpa De Silva

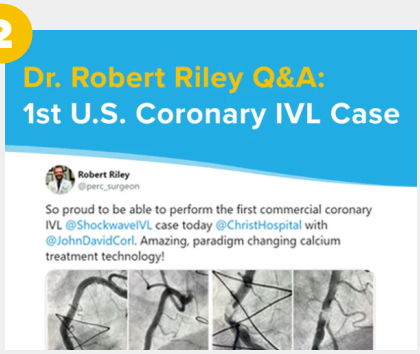
Read More >

Catalyst

Top 3 Blog Posts from Q1

1

2



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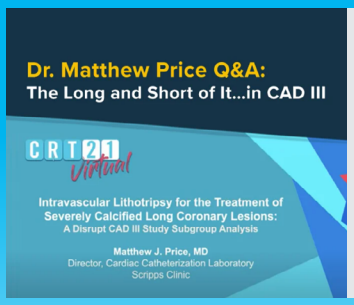
CONGRESS & DATA PRESENTATION HIGHLIGHTS



Dr. Matthew Price Q&A

IVL for the Treatment of Severely Calcified Long Coronary Lesions with Dr. Matthew Price at CRT21

Watch Now >

Disrupt Pad III

Consistently Effective: CFA Outcomes Fit The Pattern - Dr. Nicolas Shammas

Watch Now >

PCR Webinars

The Impact of DISRUPT CAD III Data on Clinical Practice – PCR Roundtable Webinar

Watch Now >

SHOCKWAVE IN THE NEWS

Shockwave Intravascular Lithotripsy FDA Approved to Treat Advanced Heart Disease

Read More >

Shockwave Announces Joint Venture in China

Read More >

Shockwave Provides Update on U.S. Launch of Coronary IVL System

Read More >

#1 FEATURED VIDEO IN Q1

DISRUPT PAD III OS Below-The-Knee Interim Results Presented by Dr. George Adams

Watch Video >

UPCOMING NEWS

Don't miss ACC 2021: Disrupt CAD Pooled Data ~700 IVL Patients Treated in CAD I, II, III & IV

Register Now >

NCVH
New Cardiovascular Horizons

Screen fatigue yet? Attend NCVH in NOLA in-person! Crack it yourself at our booth. June 1-4th

Register Now >

Important Safety Information

CORONARY ISI:

Rx only

Indications for Use—The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave 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 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.