

PulsePoint

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

Q2'21: Not Time for a Summer Holiday Yet!

As some regions of the world begin to embrace their first vacations in over a year, Shockwave was still hard at work in Q2 '21, with notable milestones including JACC:CI publishing a trio of peer-reviewed publications, the U.S. granting pass-through reimbursement for Coronary IVL in

outpatient procedures, the launch of our first education series - [CalciumMasterclass.com](https://www.calciummasterclass.com), and last but not least, announcing that we now offer direct sales for customers in the UK! See all the highlights of the quarter below. Time flies when you are cracking calcium!



SHOCKWAVE IVL
New IVL Trilogy in JACC Interventions
Hear the Highlights

Keith D. Dawkins, M.D.
Chief Medical Officer
Shockwave Medical

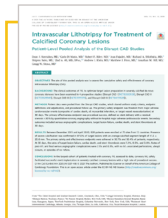
New IVL Trilogy in JACC Interventions – Hear the Highlights

[WATCH THE VIDEO](#)

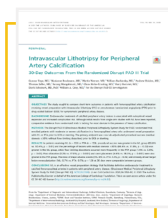
NEW IVL PUBLICATIONS



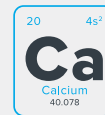
JACC: Cardiovascular Interventions
Dr. Ziad A. Ali
Principles of Intravascular Lithotripsy for Calcific Plaque Modification
[Read More >](#)



JACC: Cardiovascular Interventions
Dr. Gregg W. Stone
Intravascular Lithotripsy for Treatment of Calcified Coronary Lesions: Patient-Level Pooled Analysis of the Disrupt CAD Studies
[Read More >](#)




JACC: Cardiovascular Interventions
Dr. William A. Gray
Intravascular Lithotripsy for Peripheral Artery Calcification: 30-Day Outcomes From the Randomized Disrupt PAD III Trial
[Read More >](#)



Catalyst

Top 3 Blog Posts from Q2


1 SHOCKWAVE IVL
Sound Science Yields Vessel Compliance: Dr. Ziad Ali Explains the Unique Mechanism of Action (MOA) of IVL



2 **CALCIUM MASTERCLASS**
SHOCKWAVE IVL OPTIMA
CalciumMasterclass.com



3 SHOCKWAVE IVL
A Patient-level Pooled Analysis of the Disrupt CAD I, II, III and IV Studies: Q&A with Dr. Robert Riley



Dr. Robert Riley
Director, Complex Coronary Therapeutics Program,
The Christ Hospital Health System

TOP 3 CONGRESS & DATA PRESENTATION HIGHLIGHTS

SHOCKWAVE IVL
CRT21 Live Case: IVL in Coronary Nodules
 Hayder Hashim, MD
 Interventional Cardiologist
 Medstar Washington Hospital Center
CRT21 Virtual

CRT 2021
 CRT21 Live Case: IVL in Coronary Nodules
[Watch Now >](#)

euroPCR
 18-20 May 2021
Crack Back Into the IVL Content at EuroPCR 2021
[Watch the Symposia](#)
 SHOCKWAVE IVL

EuroPCR 2021
 Crack Back Into the IVL Content at EuroPCR 2021
[Watch Now >](#)

From Data to Daily Practice
 Simplifying Calcium Treatment with Intravascular Lithotripsy (IVL)
 Andrew Holden, MD
 Linyu Kumbhani, MD
 Christopher Miller, MD

Charing Cross 2021 Symposium
 From Data to Daily Practice: Simplifying Calcium Treatment with Shockwave IVL by Prof. Andrew Holden
[Watch Now >](#)

SHOCKWAVE IN THE NEWS

- CMS Grants Transitional Pass-Through (TPT) Payment for Shockwave's Coronary IVL
[Read More >](#)
- Publications Validate Clinical Safety and Efficacy of Shockwave Intravascular Lithotripsy
[Read More >](#)
- CMS Proposes Additional Payment for Shockwave's Coronary IVL in Hospital Inpatient Cases
[Read More >](#)

TUNE IN FOR THE CALCIUM MASTERCLASS SERIES!

Calcium Masterclass
 Calcium education can't be accomplished in a tweet. Just like treating calcium, sometimes you have to go deep.
 Welcome to your new destination for holistic calcium education: a comprehensive collection of the world's best calcium experts having live dialogue, debate and case-sharing while revealing new M-character calcium curriculum developed in partnership with Optima Education.
37 Masters. 10 Classes. 5 Live Cases. 14 Modules. Explore the Calcium Masterclass series!
calciummasterclass.com

UPCOMING NEWS

CLASS 9 (LIVE CASE) - LARGE VESSEL BIFURCATIONS- FOCUS ON BEST PRACTICES
FACULTY
 JAMES C SPRATT, CLAUDIA COSGROVE, SIMON WALSH, KAMBIS MASHAYEKHI AND COLM HANRATTY
 28 DAYS 18 HOURS 34 MINS

Class 9 (Live Case) - Large Vessel Bifurcations: Focus on Best Practices
[Register Now >](#)

CRF TVT
 THE STRUCTURAL HEART SUMMIT
JULY 20-22, 2021
 46th Person Experience! Broadcast LIVE from Orlando, Florida
 7/20/2021

Keeping it Femoral with Intravascular Lithotripsy
[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:

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 M⁵ and Shockwave S⁴ instructions for use containing important safety information.