SHOCKWAVE MEDICAL

PulsePoint

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

SPARKING MOMENTS IN Q2

Over the past three months, Shockwave continued to ride a big wave of momentum with new product launches, inclusions in new journal articles, a pulse-racing presence at EuroPCR and more.

The launch of Shockwave L^6 Peripheral IVL Catheter in the U.S. came with physician-led case reviews, Q&As and more valuable content that demonstrate the big impact it can make in large peripheral vessels.

We also turned up the heat at **EuroPCR** in Paris, where we showcased live cases, hosted an engaging symposium and participated in PCR TV interviews - all while focusing heavily on the **European launch of our Shockwave C^{2+}** Coronary IVL Catheter, which includes 50% more pulses than the original Shockwave C^2.

Dive right in and catch the wave of excitement in the latest issue of the PulsePoint newsletter!

WANT TO SEE MORE IVL CASES?

Check out our new case-focused Instagram account, **@ShockwaveMedical!**
Follow us and tag us with your best IVL cases. **#LetsGetCracking**

First patient enrolled in EMPOWER CAD
by Dr. Margaret McEntegart

SEE THE POST

NEW IVL PUBLICATIONS

JACC: CARDIOVASCULAR INTERVENTIONS

Safety and Effectiveness of Coronary Intravascular Lithotripsy for Treatment of Calcified Nodules

Dr. Ali, *et al.*

Read More >

THE AMERICAN JOURNAL OF CARDIOLOGY

Coronary Lithotripsy as Elective or Bail-Out Strategy After Rotational Atherectomy in the Rota-Shock Registry

Dr. Sardella, *et al.*

Read More >

JACC: CARDIOVASCULAR INTERVENTIONS

The Effect of Intravascular Lithotripsy on Cardiac Implantable Electronic Device Function

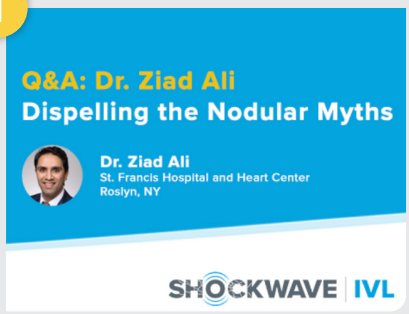
Dr. Montero-Cabezas, *et al.*

Read More >

20 4s^2
Catalyst
Calcium
40.078

Top 3 Catalyst Blogs from Q2

1



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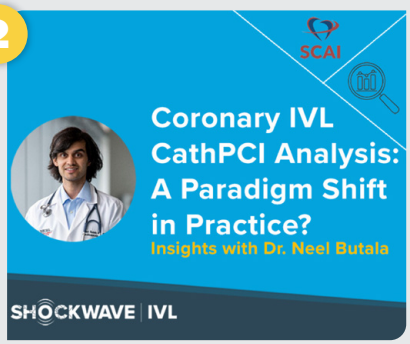

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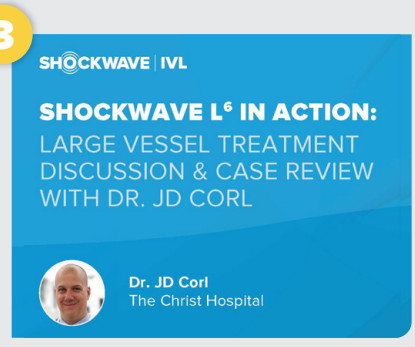


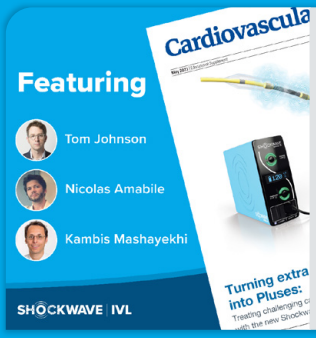
SHOCKWAVE MEDICAL

PHYSICIAN PERSPECTIVES ON IVL

EuroPCR 2023: What a Blast!

Three sponsored sessions, two featured live cases, one interview on PCR TV and many, many invaluable conversations at our booth. Thank you to all of you who attended for making this our best EuroPCR so far!

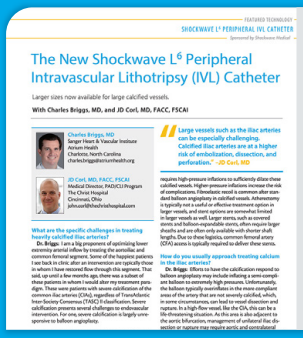
Watch Now >



Turning Extra Pulses Into Pluses

This set of articles has a fresh perspective on today's management of coronary calcium. It includes a deep dive into the use of Intravascular Lithotripsy for treating calcified nodules, and early experience with the new Shockwave C^{2+} coronary catheter.

Read More >



The New Shockwave L^6 Peripheral Intravascular Lithotripsy (IVL) Catheter

Check out the Q&A with Drs Charles Briggs and JD Corl.

Read More >

SHOCKWAVE IN THE NEWS

Shockwave Medical Launches New Coronary IVL Catheter Internationally and Enrolls First Patient in All-Female EMPOWER Study

Read More >

Shockwave Medical Completes Acquisition of Neovasc

Read More >

Vascular News: Adding 8–12mm diameter devices to the Shockwave Peripheral Intravascular Lithotripsy toolkit

Read More >

FEATURED VIDEO: Shockwave L^6 Case Review

WATCH THE VIDEO >

UPCOMING EVENTS

CIRSE 2023
September 9-13 | Copenhagen, Denmark

CIRSE

Join us at CIRSE and come check out the Shockwave IVL booth!

September 9 - 13, 2023.

Register Now >

CRF
TCT
OCTOBER 23–26, 2023
MOSCONE CENTER
SAN FRANCISCO, CA

TCT 2023

Join us at TCT, check out the Shockwave symposium and stop by the booth.

October 23 - 26, 2023.

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 warnings, precautions and adverse events. www.shockwavemedical.com/IFU.

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C^2 and 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 S^4, Shockwave M^5, Shockwave M^{5+} and Shockwave L^6 instructions for use containing important safety information.

NEOVASC REDUCER ISI:

Intended for physicians in countries with Reducer commercially available. 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

Caution: In the United States, Reducer is an investigational device, limited by United States law to investigational use.