SHOCKWAVE MEDICAL

PulsePoint
Quarterly Newsletter

Q3 '23: FANTASTIC FIRSTS, SHOCK-WORTHY RESULTS

From the first U.S. Shockwave C²⁺ case to the unveiling of the 2023 TopShock finalists, this past quarter had a lively pulse all its own.

In other news, we're very excited to share the impressive results from the two-year DISRUPT CAD III study of IVL for Treatment of Severely Calcified Coronary Arteries.

For our international customers, there was an excellent poster session presented during ESC Congress that featured three presentations on our Coronary Sinus Reducer. We also launched a series of real-world application videos from VAM 2023 that highlight Shockwave L⁶ and the benefits of using it to tackle calcium in large vessels.

Dive head first into the latest PulsePoint Newsletter to learn more about the big waves made in Q3!

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 U.S. Shockwave C²⁺ Case
by Drs. Richard Shlofmitz & Allen Jeremias.

SEE THE POST

PUBLICATIONS

JOURNAL OF CRITICAL LIMB ISCHEMIA

Safe and Effective Treatment of Below-the-Knee Calcium in CLI Patients

Dr. Sameh Sayfo

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JOURNAL OF VASCULAR AND INTERVENTIONAL RADIOLOGY

Treatment of Challenging Below-The-Knee Calcium

Dr. Michael Meuse

Read More >

JACC: CARDIOVASCULAR INTERVENTIONS

Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Arteries: 2-Year Results — Disrupt CAD III Study

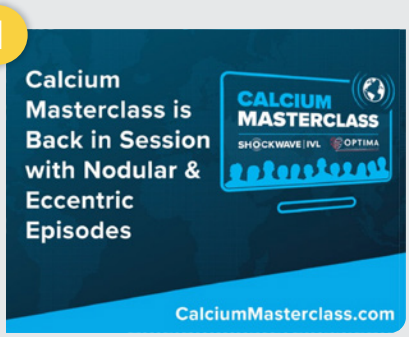
Dr. Kereiakes, *et al.*

Read More >

20 4s² Catalyst Calcium 40.078

Top 3 Catalyst Blogs from Q3

1



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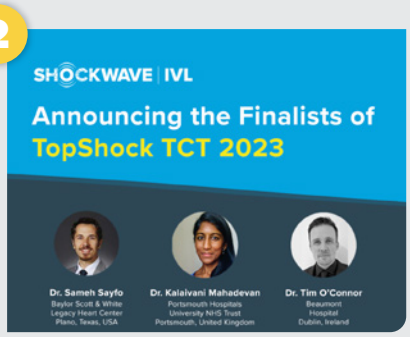

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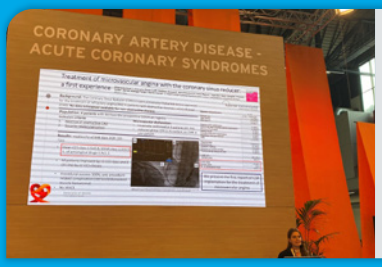
PHYSICIAN PERSPECTIVES



Coronary Sinus Reducer at ESC Congress

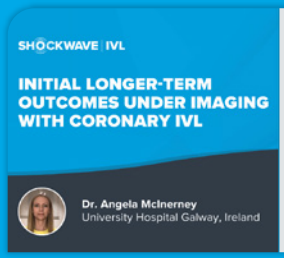
To our international customers: Excellent poster session during ESC Congress featuring three presentations on the Coronary Sinus. Thank you, Drs. Eleonora Gnan, Panagiotis Theofilis, Kevin Cheng and research partners for furthering our knowledge to help patients suffering from refractory angina.

Read More >

Dr. Raj Pyne Case Review: Popliteal CTO in CLI Patient

In this video, Dr. Raj Pyne provides a detailed case review treating a popliteal CTO in a patient with Critical Limb Ischemia.

Watch Now >



Initial Longer-Term Outcomes Under Imaging with Coronary IVL

In the Q&A, Dr. Angela McInerney explains the new study that dives into mid-term angiographic and intracoronary imaging results post IVL usage, showing durable results with preserved stent parameters following IVL.

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SHOCKWAVE IN THE NEWS

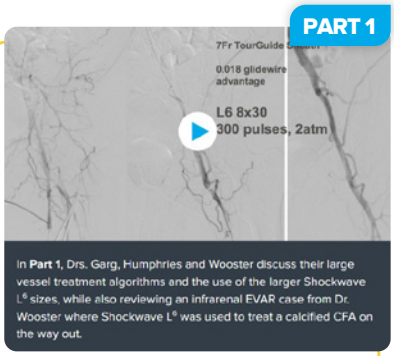
Centers For Medicare & Medicaid Services Creates New Hospital Inpatient Payment for Coronary Intravascular Lithotripsy

Read More >

Shockwave Medical Introduces Enhanced Coronary IVL Catheter in the United States

Read More >

SHOCKWAVE L^6 IN REAL-WORLD APPLICATIONS



In **Part 1**, Drs. Garg, Humphries and Wooster discuss their large vessel treatment algorithms and the use of the larger Shockwave L^6 sizes, while also reviewing an infrarenal EVAR case from Dr. Wooster where Shockwave L^6 was used to treat a calcified CFA on the way out.

In **Part 2**, the physicians expand their conversation to the entire Shockwave IVL peripheral portfolio and review a case from Dr. Humphries where Shockwave L^6 was used to effectively modify a calcific iliac artery in order to place a sheath for a successful physician-modified endograft delivery.

WATCH THE VIDEOS >

UPCOMING EVENTS

VEITH SYMPOSIUM®
Connecting The Vascular Communit

VEITH

Join us at VEITH, check out the Shockwave symposium and stop by the booth!

November 14 - 18, 2023.

Register Now >

SCAI
Society for Cardiovascular Angiography & Interventions

SCAI Fall Fellows

Join us at SCAI Fall Fellows and come check out the Shockwave IVL booth!

December 1 - 5, 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:

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

The Reducer is subject of Investigational testing and is being studied in the COSIRA-II trial in Canada.

The Reducer is commercially available in certain countries outside the U.S. and Canada. 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