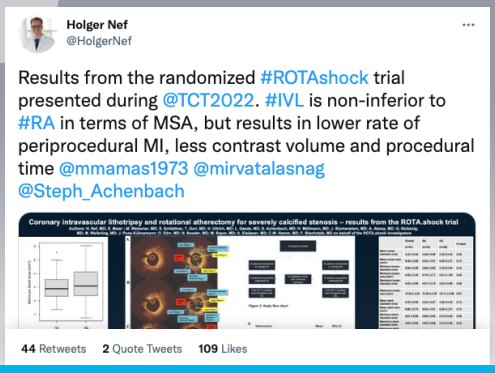
SHOCKWAVE | IVL PREDICTABLY SAFE | DISTINCTLY INTUITIVE | CONSISTENTLY EFFECTIVE

PulsePoint

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

Q3'22: Time to EMPOWER

As October slips into the distance, we find ourselves in the final stretch of the year full of momentum and excitement for the months ahead. Last quarter at TCT 2022, we were proud to announce the first prospective, female-only study of coronary interventions, EMPOWER CAD, which aims to study the effects of coronary IVL in females—a long underrepresented population in published data. Shockwave is thrilled to be partnering with co-principal investigators, Dr. Alexandra Lansky and Dr. Margaret McEntegart, on this momentous research and more details will be shared in 2023. This past quarter also saw leading physicians Dr. Peter Soukas, Dr. Stephan Heo, and Dr. Suzanne J. Baron on *The Catalyst* Blog, with each discussing a range of topics from IVL in CLI patients to guide extension catheter usage and more. Check out the latest publications, register for upcoming conferences and learn more in this new edition of PulsePoint!



#1 Most Engaging Twitter Post from Q3

SEE THE POST

NEW IVL PUBLICATIONS

JSCAI

Intravascular Lithotripsy for Peripheral Artery Calcification: Mid-term Outcomes From the Randomized Disrupt PAD III Trial

Dr. Sahil Parikh & Dr. William Gray

Read More >

Catheterization & Cardiovascular Interventions

Intravascular Lithotripsy in Chronic Total Occlusion Percutaneous Coronary Intervention: Insights From the PROGRESS-CTO Registry

Dr. Emmanouil Brilakis

Read More >

Circulation Reports

Intravascular Lithotripsy for Vessel Preparation in Calcified Coronary Arteries Prior to Stent Placement - Japanese Disrupt CAD IV Study 1-Year Results

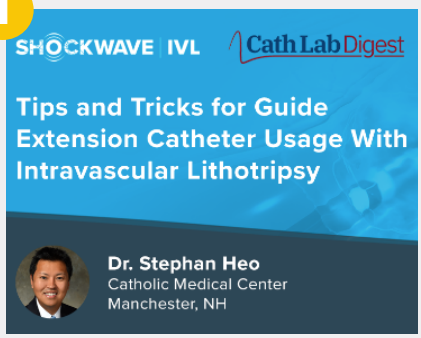
Dr. Shigeru Saito, et al.

Read More >

Catalyst

Top 3 Catalyst Posts from Q3

1



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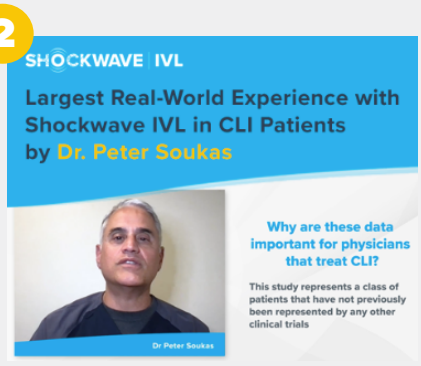

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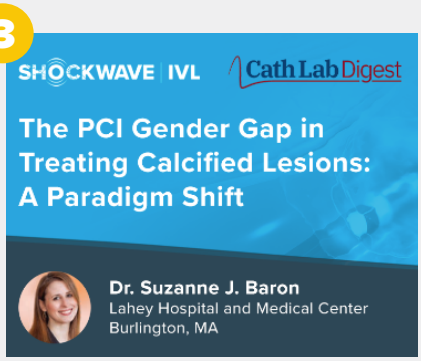
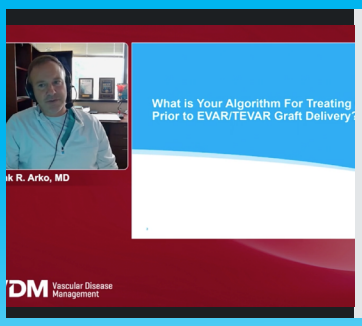


PHYSICIAN PERSPECTIVES ON IVL



Changing Compliance to Change the Game: IVL for Transfemoral EVAR/TEVAR Access

In this interveiw, Frank Arko, MD, Chief of Vascular and Endovascular Surgery at Sanger Heart and Vascular Institute, Atrium Health discusses his use of IVL to maintain transfemoral EVAR/TEVAR access in patients with calcified vessels.

Watch Now >

Shockwave IVL for CLTI Patients at CX22

At Charing Cross 2022, Dr. Thulasidasan shares how Shockwave IVL has improved his treatment for CLTI patients with low complications and increased durability.

Watch Now >

Controversies in Calcium: An Open-Minded Debate on Approaches to Nodular Calcium

In the TCT symposium, leading complex PCI operators and calcium experts share their challenging nodular calcium cases while reviewing the pros and cons of existing calcium modification devices, including current clinical evidence and knowledge gaps.

Watch Now >

SHOCKWAVE IN THE NEWS

Shockwave Medical Initiates All-Female Coronary IVL Study

Read More >

Is IVL equally effective in male and female patients? Shockwave Medical aims to find out with a historic new study.

Read More >

Taking a Pulse Check in Complex Calcified Vessels

Read More >

FEATURED VIDEO

Announcing EMPOWER CAD Video

Watch the Video >

UPCOMING NEWS

THE VIVA FOUNDATION

VIVA 2022

OCTOBER 31 - NOVEMBER 3, 2022

Register Now >

VEITH SYMPOSIUM® Connecting The Vascular Community

VEITH

NOVEMBER 15 - 19, 2022

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:

In the United States: Rx only.

Indications 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 asstated 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 thinner • 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.

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave M⁵, Shockwave M⁵⁺, and Shockwave S⁴ instructions for use containing important safety information.

www.shockwavemedical.com