PulsePoint

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

Q1'22: Starting the Year **Off with Pulses Racing!**

Shockwave made tremendous waves across the globe this quarter. To start, Shockwave was recognized by Fast Company as one of the World's Most Innovative Companies for 2022, which was an incredible honor. You can listen to Shockwave's CEO, Doug Godshall, discuss how innovation is uniquely fostered here at Shockwave in our latest Chalktalk podcast. JSCAI released several publications regarding Shockwave data such as

the Expert Consensus on Sex-Specific Considerations, Disrupt CAD III 1yr Data, and the Disrupt CAD Pooled Gender Analysis. We also had an exciting end to the quarter with the release of the <u>new Shockwave M⁵⁺</u> IVL catheter! Now available globally, please connect with your local rep to learn more about how life on the plus side can help optimize your treatment of patients with calcified PAD.





Read More >

Dr. Alexandra Lansky

Dr. Dean J. Kereiakes

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SHOCKWAVE IVL

PHYSICIAN PERSPECTIVES ON IVL

SHOCKWAVE IVL

Expanding the Boundaries of Transfemoral Access in TAVI



Expanding the Boundaries of Transfemoral Access in TAVI

Dr. Sam Dawkins, Dr. Ole De Backer, and Prof. Carlo Di Mario discuss how IVL has expanded the boundaries of TF TAVI by safely changing vessel compliance and allowing controlled luminal expansion.

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sно̂скwave ıv∟ <u>(Cath Lab Digest</u> IVL in Hospitals with

Dr. B. Clay Sizemore Cardiovascular Consultants of South Georg Thomassille. GA

No Surgical Backup

IVL in Hospitals with No Surgical Backup with Dr. B. Clay Sizemore

In the Calcium Corner atricle, Dr. B. Clay Sizemore speaks about his experience with Coronary IVL in a no-surgical-backup hospital.

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FEATURED VIDEO

4

Featured Shockwave IVL Topics with Experts

This Calcium IVLeague video playlist features various calcium experts discussing a range of Shockwave IVL topics.

Watch Now >

NOWLED

Genders and Over Time

Watch the Video >

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PCR Webinar: The Consistency of Coronary IVL Across Calcium Types,

SHOCKWAVE IN THE NEWS



Shockwave Medical Announces Global Launch of New Peripheral Intravascular Lithotripsy Catheter

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Shockwave Medical Named to Fast Company's "Most Innovative Company" List

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The Economics of Shockwave with Dr. Margaret McEntegart

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UPCOMING NEWS

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EuroPCR 2022 MAY 17-20, 2022

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2022 Scientific Atlanta Sessions SCAI 2022 Scientific Sessions

MAY 19 - 22, 2022 | ATLANTA

SCAI 2022 Scientific Sessions MAY 19-22, 2022

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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 lithotripsyenabled, 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 M^5 , Shockwave M^{5+} , and Shockwave S^4 instructions for use containing important safety information.

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SHOCKWAVE | IVL