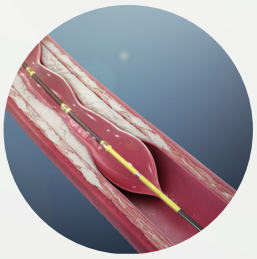
SHOCKWAVE | IVL

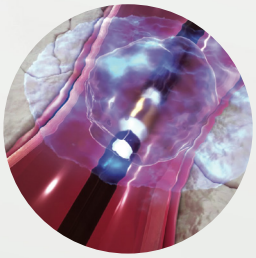
PREDICTABLY SAFE | DISTINCTLY INTUITIVE | CONSISTENTLY EFFECTIVE

Your Sound Calcium Strategy.

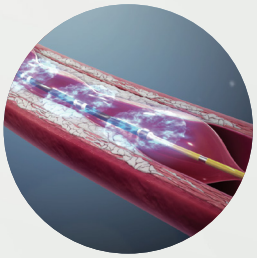
Unique Mechanism of Action
to Disrupt Calcium



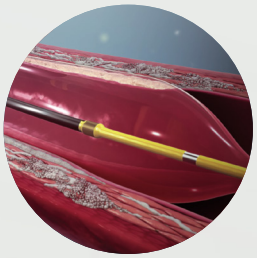
The IVL catheter is delivered across a calcified lesion over an 0.014” wire and the integrated balloon is expanded to 4atm to facilitate efficient energy transfer



An electrical discharge from the emitters vaporizes the fluid within the balloon, creating a rapidly expanding & collapsing bubble that generates sonic pressure waves



The waves create a localized field effect that travels through soft arterial tissue, selectively cracking superficial and deep calcium within the vessel wall



After calcium modification, the integrated balloon may subsequently be used to dilate the lesion at low pressure in order to maximize luminal gain prior to stent placement

48mm
Calcium Length

0.96mm
Average Max Calcium Thickness

98%
IVL Crossing & Therapy Delivery

2.1%
Severe Dissections Post-IVL

0%
Abrupt Closure Post-IVL

99%
Stent Delivery

102%
Stent Expansion

6.5mm^2
MSA

11.9%
Residual Stenosis

1.7mm
Acute Gain

Hill J., Kereiakes D., et al. Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease. J Am Coll Cardiol. 2020 Dec, 76 (22) 2635–2646.

Intravascular Lithotripsy System

for Cardiovascular Calcium

IVL Generator

- Portable and rechargeable
- No external connections
- Quick & easy setup with no settings

IVL Connector Cable

- Simple magnetic connections
- Push-button activated

SHOCKWAVE | C² IVL Catheter

- Standard interventional technique
- Rapid exhange system
- 0.014" guidewire of choice

Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease

Jonathan M. Hill, MD,[a,b] Dean J. Kereiakes, MD,[b,c] Richard A. Shlofmitz, MD,[c] Andrew J. Klein, MD,[d] Robert P. Riley, MD,[e] Matthew J. Price, MD,[f] Howard C. Herrmann, MD,[g] William Buchbinder, MD,[h] Ron Waksman, MD,[i] Gregg W. Stone, MD,[j] on behalf of the Disrupt CAD III Investigators

ABSTRACT

BACKGROUND Coronary calcification hinders stent delivery and expansion and is associated with adverse outcomes. Intravascular lithotripsy (IVL) delivers acoustic pressure waves to modify calcium, enhancing vessel compliance and optimizing stent deployment.

OBJECTIVES The purpose of this study was to assess the safety and effectiveness of IVL in severely calcified de novo coronary lesions.

METHODS Disrupt CAD III (NCT03595176) was a prospective, single-arm multicenter study designed for regulatory approval of coronary IVL. The primary safety endpoint was freedom from major adverse cardiovascular events (cardiac death, myocardial infarction, or target vessel revascularization) at 30 days. The primary effectiveness endpoint was procedural success. Both endpoints were compared with a pre-specified performance goal (PG). The mechanism of calcium modification was assessed in an optical coherence tomography (OCT) substudy.

RESULTS Patients (n = 431) were enrolled at 47 sites in 4 countries. The primary safety endpoint of the 30-day freedom from major adverse cardiovascular events was 92.2%; the lower bound of the 95% confidence interval was 89.9%, which exceeded the PG of 84.4% ($p < 0.0001$). The primary effectiveness endpoint of procedural success was 92.4%; the lower bound of the 95% confidence interval was 90.2%, which exceeded the PG of 85.4% ($p < 0.0001$). Mean calcified segment length was 47.9 ± 18.8 mm, calcium angle was 292.5 ± 76.5°, and calcium thickness was 0.96 ± 0.25 mm at the site of maximum calcification. OCT demonstrated multiplane and longitudinal calcium fractures after IVL in 67.4% of lesions. Minimum stent area was 6.5 ± 2.1 mm² and was similar regardless of demonstrable fractures on OCT.

CONCLUSIONS Coronary IVL safely and effectively facilitated stent implantation in severely calcified lesions.

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From the [a]Department of Cardiology, Royal Brompton Hospital, London, United Kingdom; [b]The Christ Hospital and Lindner Research Center, Cincinnati, Ohio; [c]The Heart Center, St. Francis Hospital, Roslyn, New York; [d]Piedmont Heart Interventional Cardiology, Atlanta, Georgia; [e]Division of Cardiovascular Diseases, Scripps Clinic, La Jolla, California; [f]Cardiac Catheterization Laboratories, University of Pennsylvania Medical Center, Philadelphia, Pennsylvania; [g]Heart & Vascular Institute, UPMC Pinnacle Health, Harrisburg, Pennsylvania; [h]Division of Cardiology, MedStar Cardiovascular Research Network, MedStar Washington Hospital Center, Washington, DC; and [i]The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, New York. *Drs. Hill and Kereiakes contributed equally to this work. †Philippe Généreux, MD, served as Guest Associate Editor for this paper. Deepak L. Bhatt, MD, MPH, served as Guest Editor-in-Chief for this paper. The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the JACC author instructions page.

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DISRUPT CAD III

By The Numbers

384
Patients at 47 Sites

100%
Severe Ca++

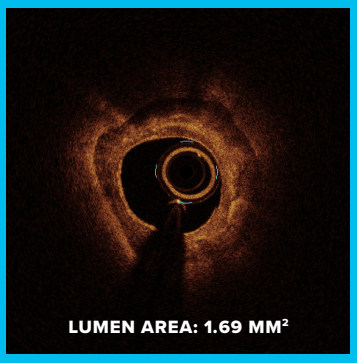
0%
Perforations Post-IVL

0%
No Reflow Post IVL

IVL MOA Under OCT

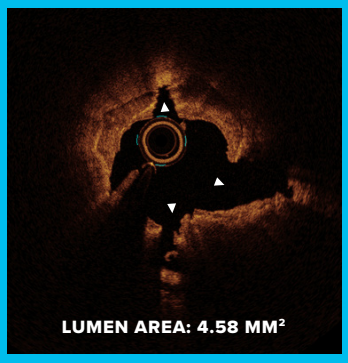
Multi-plane & Longitudinal Calcium Fractures

PRE-PROCEDURE



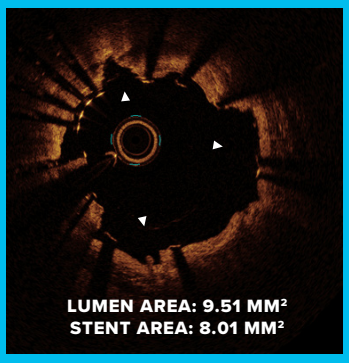
SEVERE CALCIUM DETECTED[1]

POST-IVL



TRANSMURAL CALCIUM FRACTURES[1]

POST-STENT



STENT EXPANDS FRACTURES[1]

PREDICTABLY SAFE

Establish a new standard of care for safe calcium modification by reducing the risk of perforations and other complications to make procedures more predictable and efficient

DISTINCTLY INTUITIVE

Optimally modify calcium from the very first case via a unique mechanism of action in an intuitive platform

CONSISTENTLY EFFECTIVE

Achieve excellent lumen gains and stent expansion consistently despite the calcium morphology – whether superficial or deep, concentric or eccentric, and short or long lesions

Learn more at **ShockwaveIVL.com**

Important Safety Information

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. www.shockwavemedical.com/IFU