SHOCKWAVE | C²

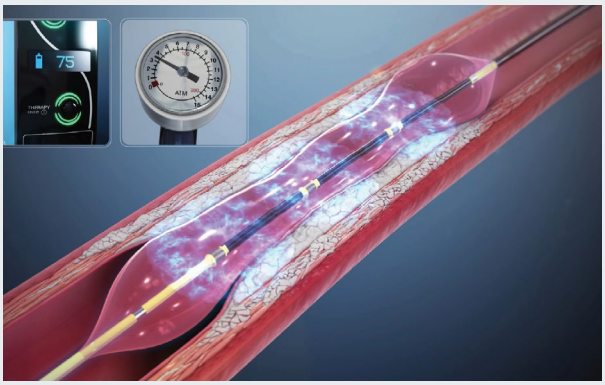
Coronary Intravascular Lithotripsy (IVL)
LET'S GET CRACKING.

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

IVL Uses Sonic Pressure Waves To Crack Calcium In Situ



After inflating the integrated balloon to 4-atm, a small spark at the emitters vaporizes the saline-contrast solution and creates a bubble which rapidly expands and collapses within the balloon; this expanding and collapsing bubble creates a **short burst of sonic pressure waves.**

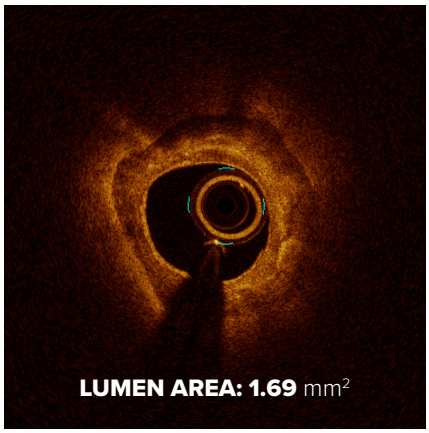
The sonic pressure waves travel through the coronary tissue, while reflecting off and cracking calcium with an effective pressure of **~50 atm.** The emitters along the length of the device create a **localized field effect** within the vessel to fracture both **superficial and deep** calcium.

The integrated balloon plays a unique role; its apposition to the vessel wall **facilitates efficient energy transfer** during IVL, after which, it is used to dilate the lesion to maximize lumen gain.

IVL MOA Under OCT

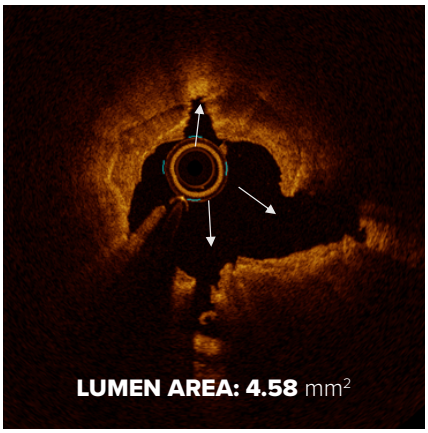
Multi-plane & Longitudinal Calcium Fractures

PRE-PROCEDURE



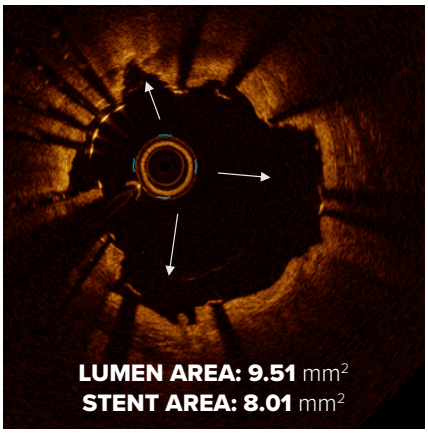
Severe Calcium Detected[1]

POST-IVL



Transmural Calcium Fracture[1]

POST-STENT



Stent Expands Fractures[1]

DISRUPT CAD III Verifies Strong Safety and Effectiveness of IVL in U.S. Patients

384
Patients at 47 Sites

100%
Severe Ca++

47.9*mm*
Calcium Length

98%
IVL Crossing & Therapy Delivery

99%
Stent Delivery

102%
Stent Expansion

Coronary IVL Associated with Low Rates of Angiographic Complications

Core Lab Analysis	Immediately Post-IVL	Final
Any serious angiographic complication	2.6%	0.5%
Severe dissection (Type D-F)	2.1%	0.3%
Perforation	0.0%	0.3%
Abrupt closure	0.0%	0.3%
Slow flow	0.6%	0.0%
No-reflow	0.0%	0.0%

IVL GENERATOR AND CONNECTOR CABLE SPECS

Power	110-240 VAC; 50-60Hz; Single Phase, 15A service
Size	11" (28.0 cm) high x 6" (15.2 cm) wide x 11.5" (29.2 cm) deep
Weight	15 pounds (6.8 kg)
Output	Proprietary pulse delivery system. Output voltage 3000 volts peak, pulse frequency 1Hz
Mobility	Product is designed to be mounted to an IV pole

IVL Generator

CATALOG NUMBER:
IVLGCCD

Length	5 ft (1.53m)
Compatibility	Proprietary male key distally designed to connect only to catheter
Operation	Lithotripsy pulsing is activated by pushing a button on the Connector Cable.
Use	Re-usable

IVL Connector Cable

CATALOG NUMBER:
IVLCC

IVL CATHETER SPECS

Catalog Number	Diameter (MM)	Length (MM)	Max Pulse Count	Guidewire Compat. (IN)	Guide Catheter Compat.	Working Length (CM)	Crossing Profile Range (IN)
C2IVL2512	2.5	12	80	0.014”	6F	138	.044 max
C2IVL3012	3.0	12	80	0.014”	6F	138	.045 max
C2IVL3512	3.5	12	80	0.014”	6F	138	.045 max
C2IVL4012	4.0	12	80	0.014”	6F	138	.047 max

STERILE SLEEVE

Catalog Number	Length (CM)	Length (IN)	Description	Quantity
IVL10CS	13 x 244	5 x 96	Sterile Cable Sleeve	10

Visit ShockwaveIVL.com for more 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

1. Disrupt CAD III Case