SHOCKWAVE | C²⁺

ON THE +PLUS SIDE.

+ PULSES
Additional pulses to treat **longer lesions with diffuse calcium, eccentric and nodular calcium**

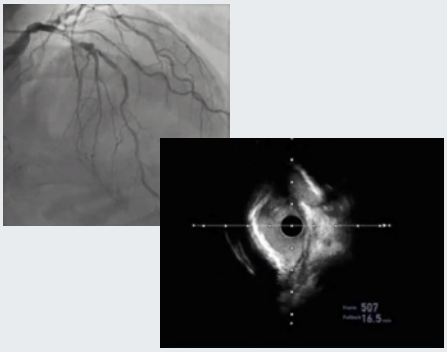
+ EFFICIENCY
Single-cather modification of **longer calcified lesions**

+ PRACTICALITY
A **sterile sleeve** for the connector cable is **now packaged with each catheter**

Shockwave C²⁺ – MORE ENERGY WHERE IT COUNTS

Additional pulses to treat longer lesions with diffuse calcium

Baseline

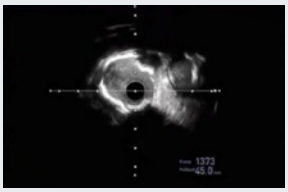


Baseline angiogram and IVUS demonstrate a long, severely calcified lesion with mixed calcium morphologies.

IVL-Therapy with Shockwave C²⁺

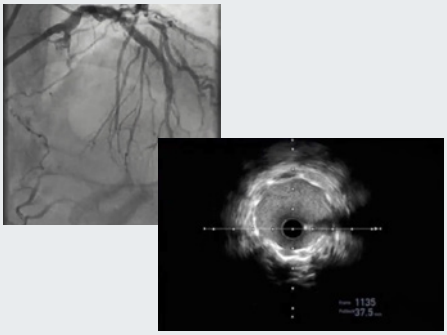
Shockwave C²⁺ IVL Therapy

Post-IVL NC Balloon Expansion



120 pulses delivered distally to proximally with a 3.0 mm Shockwave C²⁺ catheter. Post IVL NC balloon demonstrates full balloon expansion. Post IVL and NC IVUS demonstrates calcium fracture.

Final Result

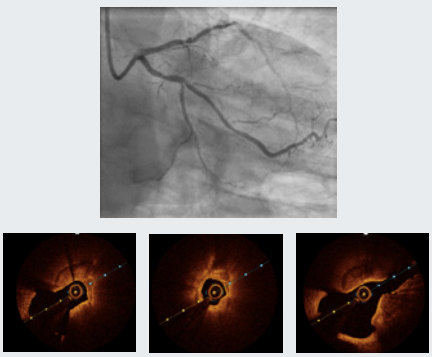


3.0x32 mm and 3.5x38 mm DES stents placed distally and proximally respectively. Post stent IVUS image demonstrates well apposed stent & impressive angiographic result.

Case Courtesy of Drs. Claudia Cosgrove and Margaret McEntegart

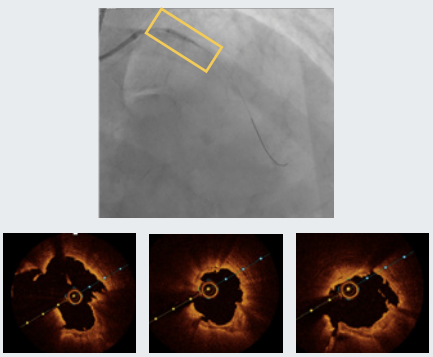
Additional pulses to treat eccentric and nodular calcium

Baseline



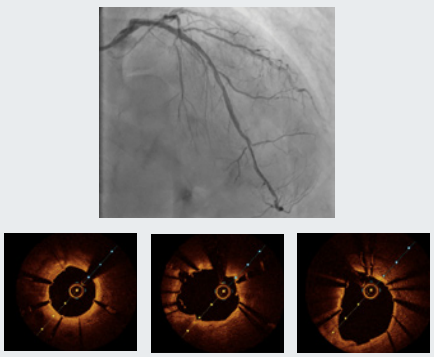
Baseline angiogram and OCT demonstrates mixed calcium morphologies along treatment lesion including nodular & eccentric calcium

IVL-Therapy with Shockwave C²⁺



IVL pulses delivered along treatment lesion with 2.5 mm Shockwave C²⁺. Post IVL OCT demonstrates calcium fracture across calcium morphologies.

Final Result



2.75x24 mm DES implanted and optimized via 3.0 & 3.5 mm NC balloon. Post stent OCT demonstrates a well opposed and expanded stent with min expansion 98% and MSA 5.86mm²

Case Courtesy of Dr. Angela McInerney

IVL GENERATOR AND CONNECTOR CABLE SPECS

Power	90-240VAC; 50-60Hz; Single Phase, 15A service
Size	7.9” (20.1 cm) high x 2.9” (7.4 cm) wide x 11.1” (28.2 cm) deep
Weight	6 pounds (2.7 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:
IVLGCCDX

Length	5 ft (1.52m)
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

SHOCKWAVE C²⁺ CATHETER SPECS

Catalog Number	Pulses (Max*)	Sterile Sleeve	Diameter (mm)	Length (mm)	Guidewire Compat. (in)	Guide Catheter Compat.	Working Length (cm)	Crossing Profile Range (in)	Barcode	GTIN
C2PIVL2512	120	Included in Kit	2.5	12	0.014”	5Fr	138	.044 max	*C2PIVL2512*	00195451000003
C2PIVL3012	120	Included in Kit	3.0	12	0.014”	5Fr	138	.045 max	*C2PIVL3012*	00195451000010
C2PIVL3512	120	Included in Kit	3.5	12	0.014”	5Fr	138	.045 max	*C2PIVL3512*	00195451000027
C2PIVL4012	120	Included in Kit	4.0	12	0.014”	5Fr	138	.047 max	*C2PIVL4012*	00195451000034

* Do not exceed 80 pulses in a 12 mm segment

Visit ShockwaveIVL.com for more information.

Coronary Safety Information

In the United States: 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 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 indications, contraindications, warnings, precautions and adverse events. www.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.