SHOCKWAVE | C²⁺

ON THE +PLUS SIDE.

+ PULSES
Additional pulses needed for **eccentric** and **nodular** calcium along the treatment lesion

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

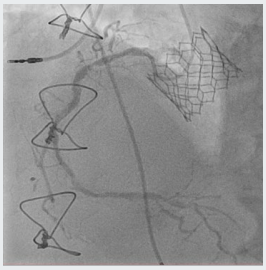
+ PRACTICALITY
A **sterile sleeve** for the connector cable is **now packaged with each catheter**

Shockwave C²⁺: More Energy Where it Counts

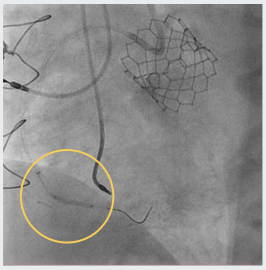
Shockwave C²⁺ keeps things safe, simple and efficient within longer calcified lesions

Case Courtesy of Dr. Nikos Werner

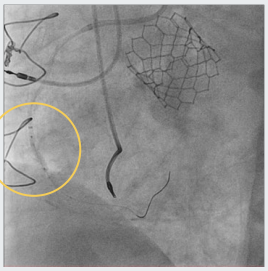
Krankenhaus der Barmherzigen Brüder
Trier, Germany

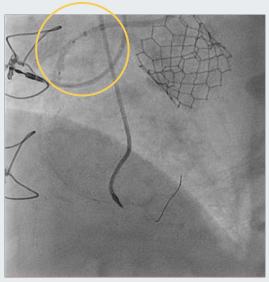


Baseline

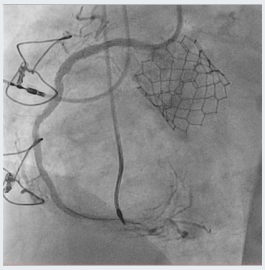


Guide extension-facilitated delivery of IVL





120 pulses delivered distally to proximally with single 3.0mm Shockwave C²⁺ catheter treating ~100mm of the lesion

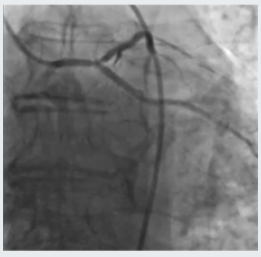


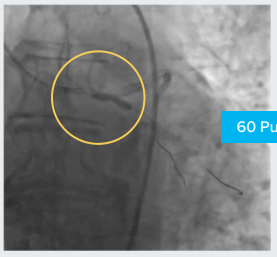
Final result after DES

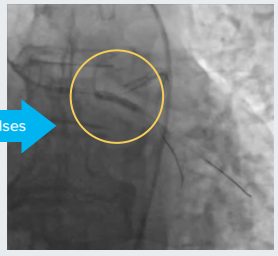
Shockwave C²⁺ demonstrates efficacy and efficiency within bifurcated, eccentric lesions

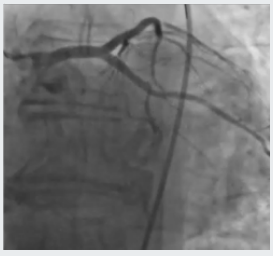
Case Courtesy of Dr. Peter O'Kane

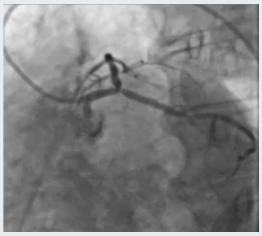
Royal Bournemouth Hospital
Bournemouth, UK



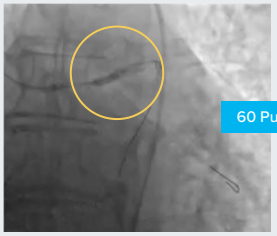


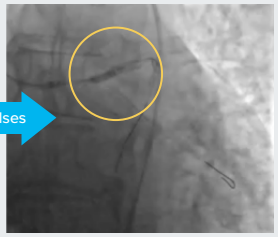




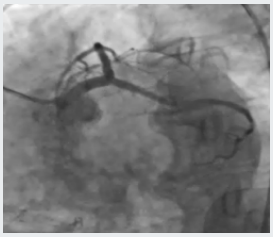


Baseline





Single 3.5mm Shockwave C²⁺ catheter delivers 120 pulses for vessel preparation within LCX and LAD



Final result after stenting via Culotte technique with 3.5x15mm Synergy and 3.5x24mm Megatron

IVL GENERATOR AND CONNECTOR CABLE SPECS

Power	90-240VAC; 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	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
(FOR **U.S. CUSTOMERS**)

IVLGCCD
(FOR **NON-U.S. CUSTOMERS**)

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

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
C2KIVL2512	120	Included in Kit	2.5	12	0.014"	5F	138	.044 max	*C2KIVL2512*	00195451000423
C2KIVL3012	120	Included in Kit	3.0	12	0.014"	5F	138	.045 max	*C2KIVL3012*	00195451000430
C2KIVL3512	120	Included in Kit	3.5	12	0.014"	5F	138	.045 max	*C2KIVL3512*	00195451000447
C2KIVL4012	120	Included in Kit	4.0	12	0.014"	5F	138	.047 max	*C2KIVL4012*	00195451000454

* 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 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.