translumina
LIMITLESS POSSIBILITIES

SHOCKWAVE C²+

ON THE PLUS SIDE

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

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

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

Coronary IVL Clinical Program

	Disrupt CAD I	Disrupt CAD I I	Disrupt CAD III	Disrupt CAD IV	Disrupt CAD Pooled
Publication	Circulation	Circulation	JACC	Circulation	JACC
Study design	Single arm, safety and feasibility	Single arm, post-market, safety and effectiveness	Single arm, IDE, safety and effectiveness	Single arm, pre-market safety and effectiveness	Individual patient-data (IPD) pooled analysis of the Disrupt CAD I-IV studies
Patients / Sites	60 / 7	120 / 15	384 / 47	64 / 8	628 / 72
OCT Sub-study (N)	28	57	106	71	262
Severe Calcification	100%	94.20%	100%	100%	97%
IVL EFFECTIVENESS					
Procedural Success	95%	94%	92.40%	93.80%	92.40%
Stent Delivery	100%	100%	99.20%	100%	99.50%
Acute Lumen Gain (mm)	1.7 mm	1.7 mm	1.7 mm	1.7 mm	1.7 mm
Final Residual Stenosis	12%	7.80%	11.90%	9.90%	12.10%
IVL SAFETY					
Final Severe Dissections	0%	0%	0.30%	0%	0.20%
Final Perforations	0%	0%	0.30%	0%	0.20%
Final Abrupt Closure	0%	0%	0.30%	0%	0.20%
Final Slow Flow/No Reflow	0%	0%	0%	0%	0%
In-Hospital MACE	5.00%	5.80%	7.00%	6.30%	6.50%

- Disrupt CAD trials across **72 sites** in **628** severely calcified patients.
- **Consistently effective** outcomes with excellent lumen gain (1.7mm) and stent expansion (residual stenosis 12%)
- **Predictably safe** with almost zero risk of severe dissections & Perforations.

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SHOCKWAVE C2+

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)
C2KIVL2512	120	Included in Kit	2.5	12	0.014”	5F	138	.044 max
C2KIVL3012	120	Included in Kit	3.0	12	0.014”	5F	138	.045 max
C2KIVL3512	120	Included in Kit	3.5	12	0.014”	5F	138	.045 max
C2KIVL4012	120	Included in Kit	4.0	12	0.014”	5F	138	.047 max

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