

Coronary Intravascular Lithotripsy (IVL) YOUR SOUND CALCIUM STRATEGY.

SHOCKWAVE | C²



MINIMIZE TRAUMA

Minimize trauma to soft tissue by safely selecting and fracturing intimal and medial calcium

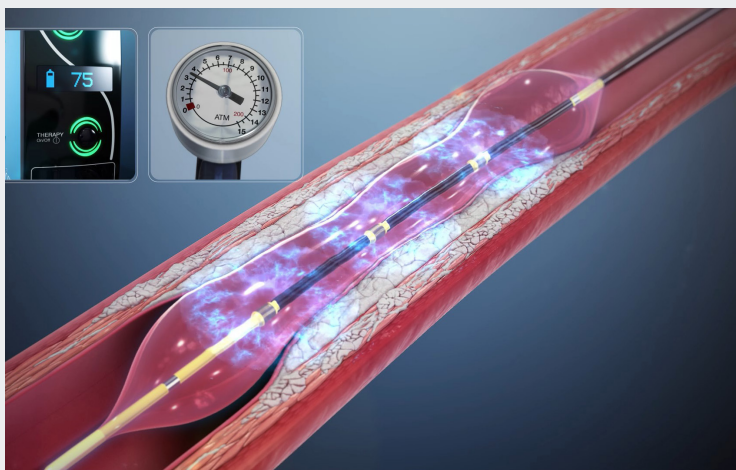
OPTIMIZE OUTCOMES

Optimize stent delivery, expansion and apposition while reducing risk of perforation and cost escalation

SIMPLIFY PROCEDURES

Simple and intuitive system that makes complex calcified coronary procedures more predictable

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**.

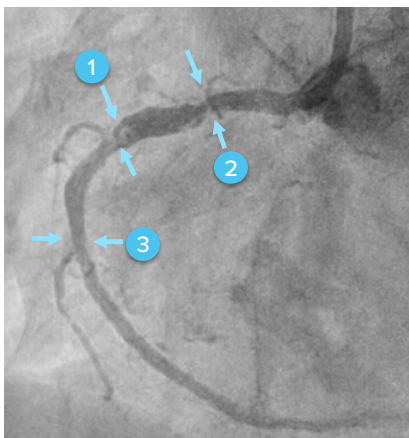
The sonic pressure waves travel through the coronary tissue, while reflecting off and cracking calcium with an effective pressure of **~50 atm**. The emitters along the length of the device create a **localized field effect** within the vessel to fracture both **intimal and medial** calcium.

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.

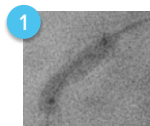
IVL-in-Action: Multi-Lesion RCA

SUMMARY: Multi-lesion RCA; Couldn't advance guidewire to distal lesion despite predilation; advanced 3.5mm IVL catheter as far as possible **(1)**; delivered one cycle (10 pulses) and vessel opened; pulled back to the ostium **(2)** and vessel opened after one cycle (10 pulses); advanced to distal lesion **(3)** and vessel opened after one cycle (10 pulses); easily delivered 80mm of DES.

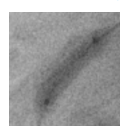
Baseline



IVL @ 0 Pulses (4atms)



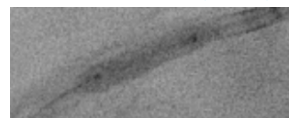
IVL @ 10 Pulses (4atms)



IVL @ 0 Pulses (4atms)



IVL @ 10 Pulses (4atms)



IVL @ 0 Pulses (4atms)



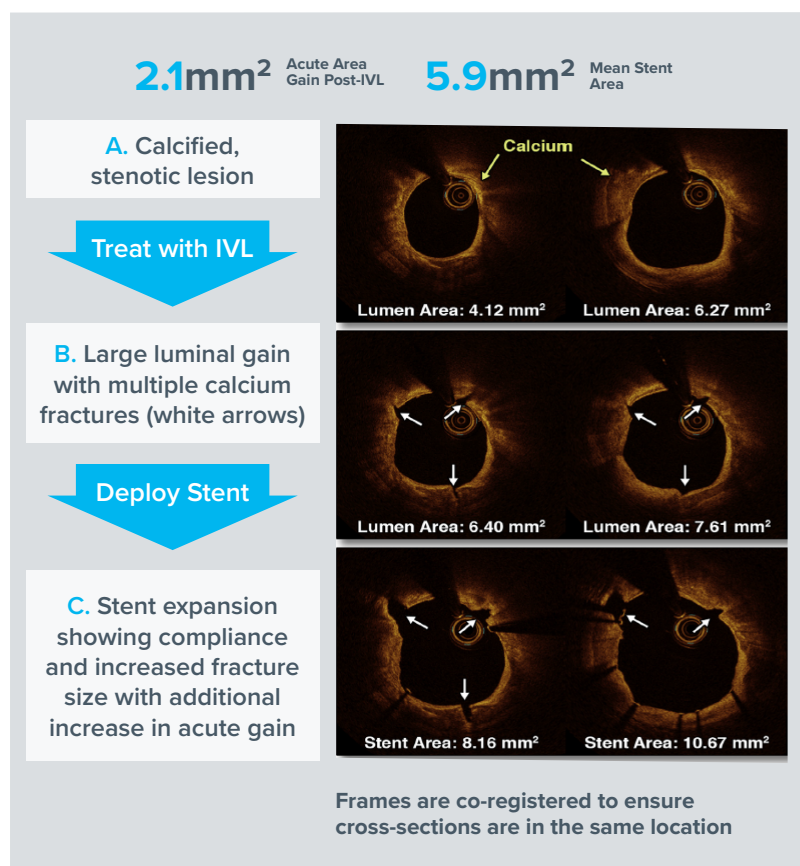
IVL @ 10 Pulses (4atms)



Post-Stent



Coronary IVL MOA Established by OCT in DISRUPT CAD I



DISRUPT CAD II Verifies Strong Safety & Performance of IVL

Objective: A post-market study to assess the safety and performance of the Coronary IVL System with more patients in more centers

Primary Safety Endpoint: In-hospital MACE (Cardiac death, MI or TVR)

Secondary Performance Endpoints: Clinical and Angiographic Success

120

Patients At 15 Sites

94%

Severe Ca++

100%

IVL & Stent Delivery

0%

Major Dissections

0%

Perforations

0%

Slow/No Reflow

5.8%

MACE (non-q-wave MI)

1.7mm²

Acute Gain

8%

Residual Stenosis

IVL GENERATOR AND CONNECTOR CABLE SPECS

Power	90-240 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	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
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 Generator

CATALOG NUMBER:
IVLGCCD



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	.043
C2IVL3012	3.0	12	80	0.014"	6F	138	.044
C2IVL3512	3.5	12	80	0.014"	6F	138	.044
C2IVL4012	4.0	12	80	0.014"	6F	138	.046

Visit ShockwaveC2.com or email info@shockwavemedical.com for more information.

Shockwave C2 Coronary IVL catheters are commercially available in certain countries outside the U.S. Please contact your local Shockwave representative for specific country availability. The Shockwave C2 Coronary IVL catheters are indicated for lithotripsy-enhanced, low-pressure balloon dilatation of calcified, stenotic de novo coronary arteries prior to stenting. For the full IFU containing important safety information please visit: <https://shockwavemedical.com/clinicians/international/coronary/shockwave-c2/>