



**MINIMIZE TRAUMA**

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

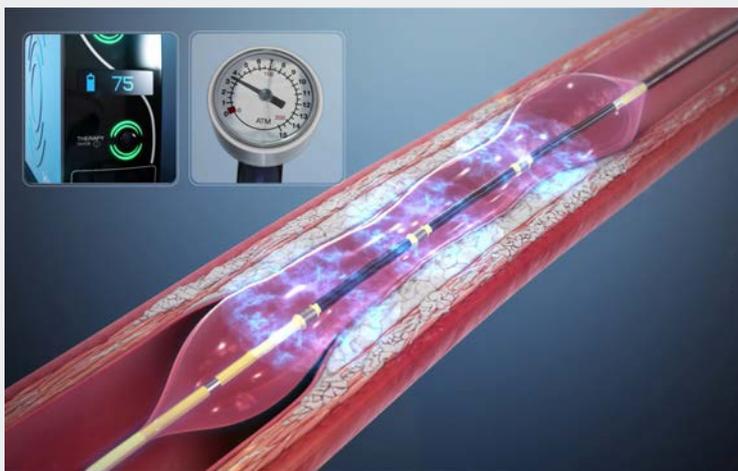
**OPTIMIZE OUTCOMES**

Optimize stent delivery, expansion and apposition while reducing complications 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**



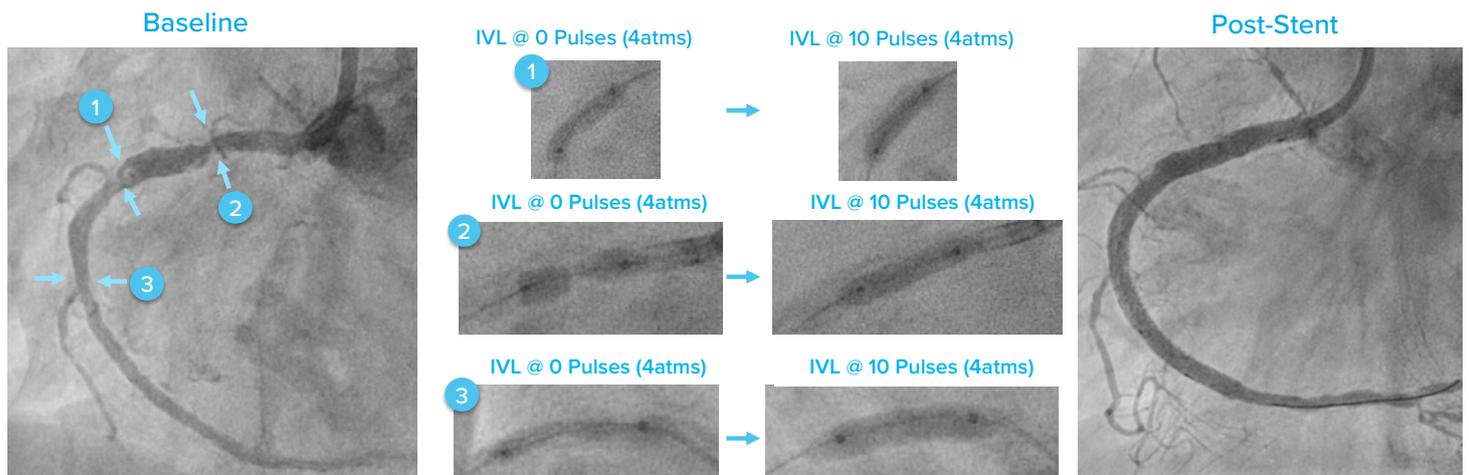
After inflating the integrated balloon to 4-atm, a small spark at the emitters vaporizes the saline-contrast solution and creates a bubble which rapidly expands and collapses within the balloon; this expanding and collapsing bubble creates a **short burst of sonic pressure waves**.

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 guideliner 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.



# Compelling Performance in DISRUPT CAD I<sup>1</sup>

100% of pts had moderate/severe CAC

Outcomes	Results
<b>30-Day Freedom from MACE<sup>2</sup></b> Death N=0; QWMI N=0; NQWMI <sup>3</sup> N=3; TVR N=0	95%
<b>Dissections<sup>4</sup> (D/E/F)</b>	3.3% <sup>5</sup> / 0.0%/0.0%
<b>Perforation<sup>4</sup></b>	0%
<b>Abrupt Closure<sup>4</sup></b>	0%
<b>Slow flow<sup>4</sup></b>	0%
<b>No reflow<sup>4</sup></b>	0%
<b>Stent Delivery</b>	100%

<sup>1</sup>CAD I assessed the safety and performance of IVL in 60 subjects across 7 sites with moderate/severely calcified, de novo coronary lesions RVD 2.5–4.0 mm, stenosis ≥50%, lesion length ≤ 32 mm.

<sup>2</sup>CEC adjudicated

<sup>3</sup>NQMI defined as 3 upper limit

<sup>4</sup>Core Lab adjudicated

<sup>5</sup>3.3% resolved with planned stent implantation

**2.1mm<sup>2</sup>** Acute Area Gain Post-IVL

**5.9mm<sup>2</sup>** Mean Stent Area

**A. Calcified, stenotic lesion**

Treat with IVL

**B. Large luminal gain with multiple calcium fractures (white arrows)**

Deploy Stent

**C. Stent expansion showing compliance and increased fracture size with additional increase in acute gain**

The images show three stages of treatment: A. Pre-IVL calcified stenotic lesion with Lumen Area: 4.12 mm<sup>2</sup> and Lumen Area: 6.27 mm<sup>2</sup>. B. Post-IVL large luminal gain with multiple calcium fractures (white arrows) with Lumen Area: 6.40 mm<sup>2</sup> and Lumen Area: 7.61 mm<sup>2</sup>. C. Post-stent deployment showing compliance and increased fracture size with additional increase in acute gain with Stent Area: 8.16 mm<sup>2</sup> and Stent Area: 10.67 mm<sup>2</sup>.

Frames are co-registered to ensure cross-sections are in the same location

## IVL GENERATOR AND CONNECTOR CABLE SPECS

<b>Power</b>	110-240 VAC; 50-60Hz; Single Phase, 15A service
<b>Size</b>	11" (28.0 cm) high x 6" (15.2 cm) wide x 11.5" (29.2 cm) deep
<b>Weight</b>	15 pounds (6.8 kg)
<b>Output</b>	Proprietary pulse delivery system. Output voltage 3000 volts peak, pulse frequency 1Hz
<b>Mobility</b>	Product is designed to be mounted to an IV pole
<b>Length</b>	5 ft (1.53m)
<b>Compatibility</b>	Proprietary male key distally designed to connect only to catheter.
<b>Operation</b>	Lithotripsy pulsing is activated by pushing a button on the Connector Cable.
<b>Use</b>	Re-usable



IVL Generator

CATALOG NUMBER:  
**IVLGCC**



IVL Connector Cable

CATALOG NUMBER:  
**IVLCC**

## IVL CATHETER SPECS



Diameter (mm)	Length (mm)	Max Pulse Count	Guidewire Compatibility (in)	Guide Catheter Compatibility	Working Length (cm)	Crossing Profile Range* (in)
2.5	12	80	0.014"	6F	138	0.044 +/- 0.002
3.0						
3.5						
4.0						

\*0.043" max. for 2.5mm, 0.044" max. for 3.0-3.5mm and 0.046" max. for 4.0mm

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