

EMPOWER CAD

REAL-WORLD DATA EMPOWERS: Benefits of IVL-first* Strategy Confirmed in Females

First Female All-comers Study with an IVL-first* Approach in Patients with Calcified Coronary Artery Disease (CAD)

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WHAT

Real-world clinical evidence associated with coronary Intravascular Lithotripsy (Shockwave IVL). A prospective, multi-center, single-arm, all-female, all-comers study.

WHY

Underdiagnosed. Underrepresented. Underwhelming outcomes.^{1,2,3} Coronary artery disease in female patients has historically been under investigated in the clinical setting. Women present later with a unique set of symptoms, challenging anatomy, and typically have worse procedural outcomes with calcium modification modalities.

TRIAL DESIGN

EMPOWER CAD assessed an IVL-first* strategy in a real-world cohort, of women with calcified coronary artery disease.

399

Patients

45

Global Sites

99%

Severe Calcification

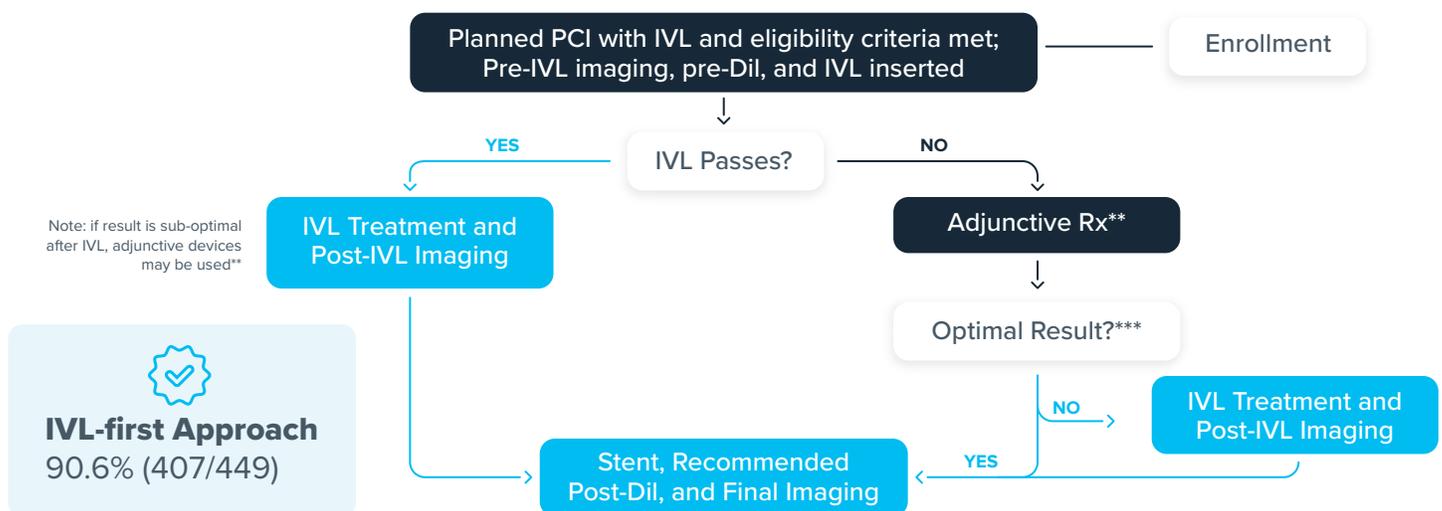
26%

Acute Coronary Syndrome

37%

Bifurcation and Trifurcation Lesions

IVL-FIRST STRATEGY^{4*}



*IVL-first strategy: the utilization of a non-compliant balloon first, and subsequently if the lesion was found to need additional therapy, and Shockwave IVL could pass, it was the front-line calcium modification tool used. Additional tools were used only if needed after VL at the operator's discretion.

**NC Balloon, atherectomy or cutting/scoring balloon

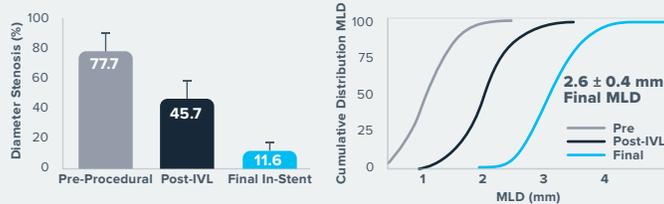
***Optimal result = adequate balloon expansion by visual estimate per investigator

PRIMARY EFFECTIVENESS ENDPOINT

Procedure success defined as stent delivery with a residual in-stent stenosis ≤30% in all target lesions (core laboratory assessed) and without in-hospital TLF (CEC adjudicated).

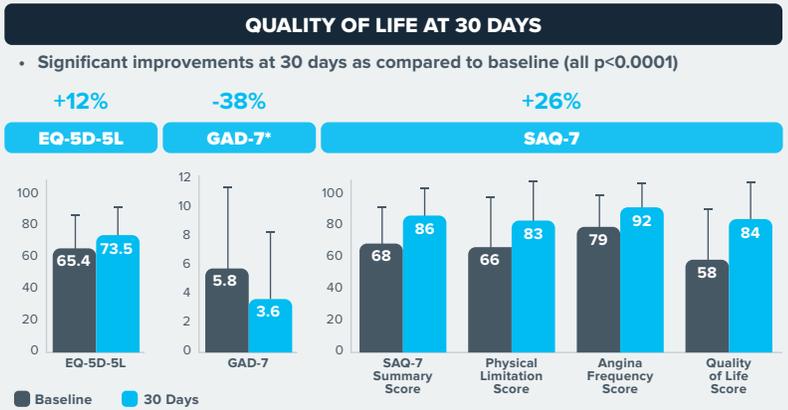
IVL proved to be an effective calcium modification strategy in an all-comers female population

EFFECTIVENESS ENDPOINTS	
Procedural Success	87.4% (341/390)
Stent Delivered	98.5% (384/390)*
≤ 30% Residual Stenosis	98.5% (384/390)
Without In Hospital TLF	89.2% (348/390)



*Data on file

Quality of life at 30 days showed significant improvements as compared to baseline



*Data on file

PRIMARY SAFETY ENDPOINT

Target lesion failure (TLF) defined as a composite of cardiac death, myocardial infarction (per fourth universal definition) attributable to target vessel (TV-MI), or ischemia-driven target lesion revascularization (ID-TLR) at 30 days.

In a real-world female patient population with challenging calcium IVL had strong safety outcomes

Parameter	Rate
Target Lesion Failure within 30-days	11.6% (46/397)
Cardiac Death	1.0% (4/397)
MI	10.6% (42/397)
Peri-procedural MI (<48hrs)	9.6% (38/397)
Spontaneous MI (>48hrs)	1.5% (6/397)
ID-TLR	1.3% (5/397)

- Protocol required systematic biomarker collection in all patients
- MI rate reflective of complex patient population
- Majority of MIs were biomarker elevation alone without clinical symptoms

SCAI definition used for periprocedural MI. The Fourth Universal definition (Type 4a) used for spontaneous MI beyond discharge.

ANGIOGRAPHIC COMPLICATIONS		
• EMPOWER CAD had 233 lesions with available angiography for post-IVL angiographic complication analysis.		
Parameter	Post-IVL (N=233)	Final (N=419)
Serious Angiographic Complications	2.6% (6/233)	0.2% (1/420)
Dissection (Type D to F)	2.6% (6/233)	0.0% (0/420)
Perforation	0.0% (0/233)	0.2% (1/420)
Abrupt Closure	0.0% (0/233)	0.0% (0/420)
Slow Flow	0.0% (0/233)	0.0% (0/420)
No-reflow	0.0% (0/233)	0.0% (0/420)



CONFIRMED: An IVL-first* strategy has proven to be safe and effective in a complex, female patient population.

REFERENCES

- Lansky, Alexandra et al. SCAI Expert Consensus Statement on Sex-Specific Considerations in Myocardial Revascularization. Journal of the Society for Cardiovascular Angiography & Interventions. 2022; 100016; 2. Shaw, Leslee et al., Sex differences in calcified plaque and long-term cardiovascular mortality: observations from the CAC Consortium, European Heart Journal. 2018; 101093; 3. Ford, Thomas et al., Sex differences in procedural and clinical outcomes following rotational atherectomy, Catheterization & Cardiovascular Interventions, 2019; 101002; 4. M. McEntegart et al. Women with Calcified Coronary Arteries Treated With Intravascular Lithotripsy. Presented at EuroPCR 2025. May 20, 2025; 5. McEntegart et al., JSCAI 2026.

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 IVL pulses may potentially interfere with certain implanted electrical devices (e.g., ventricular support systems). **Cautions—** Shockwave C2 and Shockwave C2+ should not be re-inserted once they are pulled out of the patient's body. Shockwave C2 Aero may be re-inserted up to 3 times in the same patient when used in accordance with the IFU. **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(s) 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. © 2026 Shockwave Medical, Inc. All rights reserved. SPL 76018 Rev. B.