# SHOCKWAVE | C²⁺ Set-up Guide


## Prepare the IVL Generator


### 1. Power On
Press power button.
The light will turn green.


### 2. Detach Cable
Detach charger cable from the IVL Generator and confirm charge.

### 3. Cover Cable with Sterile Sleeve
Make sure connector cable is encased in a sterile sleeve. For more information, please reference instructional video on **shockwavemedical.com**.

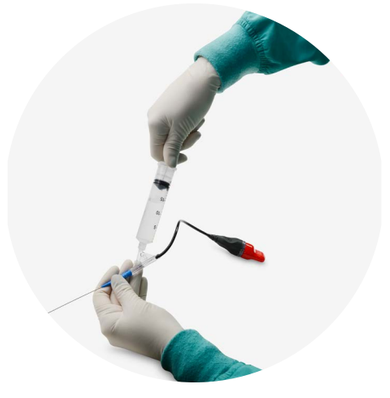

### 4. Attach Connector Cable
Slide the connector door to the left and insert the proximal end of the connector.

## Prepare and Insert the IVL Catheter

| Diameter (mm) | 2.5 | 3.0 | 3.5 | 4.0 |
|---|---|---|---|---|
| Max Crossing Profile (in) | .044 | .045 | .045 | .047 |
| Length (mm) | 12 | | | |
| Max Pulse Count | 120 | | | |
| Guidewire Compatibility (in) | 0.014” | | | |
| Guide Catheter Compatibility | 5F | | | |
| Working Length (cm) | 138 | | | |

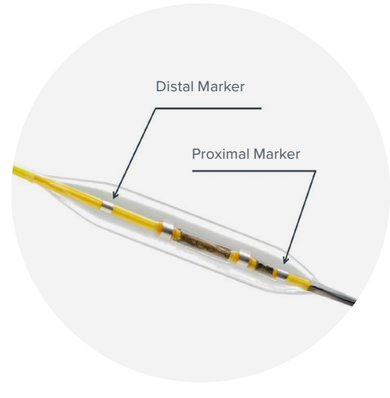
### 1. Size Appropriately
Size catheter 1:1 with intended stent size to ensure apposition and optimal energy transfer.

### 2. Remove Catheter
Remove catheter from sterile packaging, tray, loop and protective sheath.



### 3. Prepare Balloon
Use standard balloon prep with 50/50 saline contrast mixture. Pull vacuum at least three times to ensure air is completely removed.

### 4. Connect Catheter
Connect proximal end of IVL Catheter to connector cable in sterile cable sleeve.




### 5. Advance & Position
Advance the IVL Catheter over .014” guidewire and position using standard technique.

## Deliver IVL Therapy

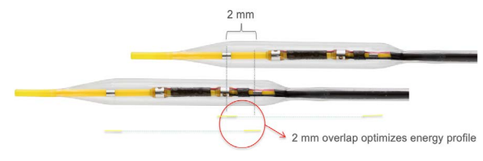
### 1. Inflate Balloon
Inflate to 4 atm and confirm no air is in the catheter.


### 2. Activate
Press “Therapy” button to enable delivery of pulses - light will turn from orange to green on generator and connector cable; to disable, press “Therapy” button again.

**Do not exceed 80 pulses within a 12 mm segment**

### 3. Delivery Pulses
Press and hold connector cable button to pulse; audible clicks and flashing LED confirm therapy delivery; do not exceed 80 pulses in 12 mm segment.

### 4. Expand to Nominal
Expand to RVD at 6 atm and deflate.




### 5. Reposition Catheter
Reposition catheter periodically between pulse cycles; overlap catheter by 2 mm when repositioning.

## IVL Troubleshooting

### Generator Error 88
(Most Commonly Associated with Air in Catheter)

1. Power off generator
2. Check catheter & connector cable connections
   a. Ensure sterlie sleeve is not interfering
   b. Ensure generator connector door is not preventing the cable from being fully inserted
3. Purge and re-prep the balloon
   a. Use syringe to purge air from catheter with negative pulls 2-3X
   b. Use syringe with 50/50 saline-contrast mix to top off catheter port
   c. Remove air from indeflator through vertical expression of air
   d. Connect to hub and purge with multiple-backs
4. Power on generator
5. Press therapy button when ready
6. Resume pulse delivery
7. If the error condition persists, replace the catheter


### Generator Error 87
(Most Commonly Associated with Data Transmission Error)

1. Power off generator
2. Check catheter & connector cable connections
   a. Ensure sterlie sleeve is not interfering
   b. Ensure generator connector door is not preventing the cable from being fully inserted
3. Power on generator
4. Press therapy button when ready
5. Resume pulse delivery
6. If error condition persists, replace the catheter


### Benign, Intermittent Ventricular Capture and/or Artifact May Be Observed on ECG

If patient heart rate is <60 bpm, IVL’s pressure waves may lead to pacing as it will be the fastest pacer (for 10 seconds during delivery of pulses).

No electricity leaves the IVL catheter – the temporary capture is caused by the IVL catheter’s release of mechanical energy in close proximity to myocardium.

41% of patients within Shockwave’s pivotal study experienced IVL-induced capture. IVL capture did not result in sustained ventricular arrhythmias and was not associated with adverse events[1].

If patient’s blood pressure drops simultaneously, cease delivery of pulses and allow time for patient to tolerate therapy.


**1.** Hill, J. M., Kereiakes, D. J., Shlofmitz, R. A., Klein, A. J., Riley, R. F., Price, M. J., . . . Stone, G. W. (2020). Intravascular lithotripsy for treatment of severely calcified coronary artery disease. Journal of the American College of Cardiology, 76(22), 2635-2646. doi:10.1016/j.jacc.2020.09.603

**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**

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C²⁺ coronary catheter instructions for use containing important safety information.