

# SHOCKWAVE | C<sup>2+</sup> 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
Length (mm)	12			
Max Pulse Count	120			
Guidewire Compatibility (in)	0.014"			
Guide Catheter Compatibility	5F			
Working Length (cm)	138			
Max Crossing Profile (in)	.044	.045	.045	.047



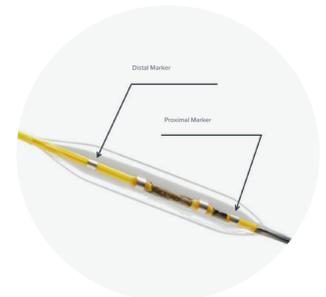
**1. Size Appropriately**  
Select catheter 1:1 with intended stent size to ensure apposition & optimal energy transfer.



**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.



**3. Delivery Pulses**  
Press and hold connector cable button to pulse; audible clicks and flashing LED confirm therapy delivery; don't exceed 80 pulses in 12 mm segment.



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



**5. Reposition Catheter**  
Deliver at least 20 pulses in each 12 mm segment; deliver pulses until desired luminal gain is achieved under angiography; Overlap by 2 mm when repositioning catheter to treat another segment.

Do not exceed 80 pulses within a 12 mm segment

## IVL Troubleshooting

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

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



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

- Power off generator
- Check catheter & connector cable connections
  - Ensure sterile sleeve is not interfering
  - Ensure generator connector door is not preventing the cable from being fully inserted
- Power on generator
- Press therapy button when ready
- Resume pulse delivery
- 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<sup>1</sup>.

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