SHOCKWAVE MEDICAL INC

Peripheral IVL Case Setup and Execution

Peripheral IVL System Set-up

1. Start

- Press Power Button to turn Generator ON
- The ON indicator will turn green
- The Therapy Status light will turn yellow, indicating that the Generator is ready to activate when ready

Note: If Power Button light turns yellow, please refer to the Generator Manual

2. Confirm

- Confirm Battery capacity via battery symbol
- If the battery symbol is empty, additional charging of the battery is recommended before use

3. Detach

- Detach the Charger Cable from the Generator

4. Slide

- Slide the Connector Door to the left

5. Attach

- Insert the proximal end of the Connector Cable to the Generator

[1]Refer to the Generator Manual for full details and Warnings and Precautions.

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Peripheral IVL Catheter Specs

SHOCKWAVE | M5

Catalog Number		Diameter (MM)	Length (MM)	Sheath Compatibility	Working Length	Pulses/ Cycle	Cycles	Pulses (Max)	Crossing Profile
M5 Branding*	Original Branding*								
M5IVL3560	M732LPBC3560DX1	3.5	60	6F	110	30	10	300	.054
M5IVL4060	M732LPBC4060DX1	4.0	60	6F	110	30	10	300	.057
M5IVL4560	M732LPBC4560DX1	4.5	60	6F	110	30	10	300	.058
M5IVL5060	M732LPBC5060DX1	5.0	60	6F	110	30	10	300	.062
M5IVL5560	M732LPBC5560DX1	5.5	60	6F	110	30	10	300	.064
M5IVL6060	M732LPBC6060DX1	6.0	60	6F	110	30	10	300	.066
M5IVL6560	M732LPBC6560DX1	6.5	60	7F	110	30	10	300	.068
M5IVL7060	M732LPBC7060DX1	7.0	60	7F	110	30	10	300	.073

* Products are equivalent; either Catalog Number may be used when ordering and either product may be received.

Peripheral IVL – Device Prep

1. Remove

- Remove Catheter from sterile packaging
- Remove Catheter from tray and loop
- Remove protective sheath from tip

2. Prepare

- Prepare Balloon using standard technique
- Ensure vacuum is pulled at least twice
- Utilize 1:1 saline/contrast mixture during preparation and use

3. Connect

- Feed Connector Cable through sterile sleeve
- Connect proximal end of Catheter to distal end of Connector Cable

(*Note: image not shown*)

[1]Refer to the Catheter IFU for full details and Warnings and Precautions.

Peripheral IVL – Device Positioning

Advance and Position:

Advance the Catheter over .014” Guidewire to the treatment site and position the Catheter using standard technique

[1]Refer to the Catheter IFU for full details and Warnings and Precautions.

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Peripheral IVL – Device Use

1. Inflate

- Inflate to 4 atm

2. Activate

- Press “Activate” button to arm the Generator – Light will turn from orange to green to indicate “active state” to deliver treatment
- To deactivate the Generator at any time, simply press this button again

Note: If the Therapy Button light turns yellow, please refer to the Generator Manual

3. Deliver

- Press and hold Button on Connector Cable for 10 seconds to deliver energy
- Audible clicks and flashing LED will confirm therapy is being delivered
- Do not exceed 80 pulses in a single segment

Note: Monitor catheter pressure and modulate to maintain at 4 atm as needed

[1]Refer to the Generator Manual for full details and Warnings and Precautions.
[2]Refer to the Catheter IFU for full details and Warnings and Precautions.

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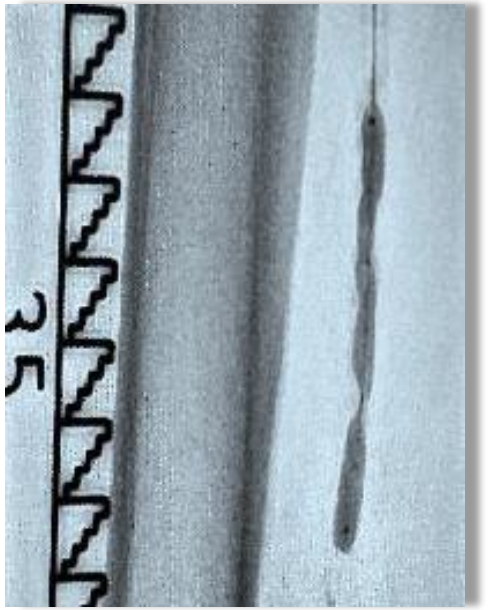
Peripheral IVL – Device Use

4. Expand

- Expand to reference vessel diameter and maintain per standard practice



5. Deflate

- Following treatment, deflate Balloon to re-establish blood flow
- Repeat steps 1 - 4 to complete a single treatment (2 cycles)
- Repeat treatment until desired luminal gain is achieved

Note: When repositioning the Catheter to treat another segment of the same lesion overlap by at least 1cm

[1]Refer to the Generator Manual for full details and Warnings and Precautions.
[2]Refer to the Catheter IFU for full details and Warnings and Precautions.

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Peripheral IVL System Tips & Tricks

Oversize Device 10%

vs. RVD to Facilitate Energy Transfer

Optimal **Undersized**

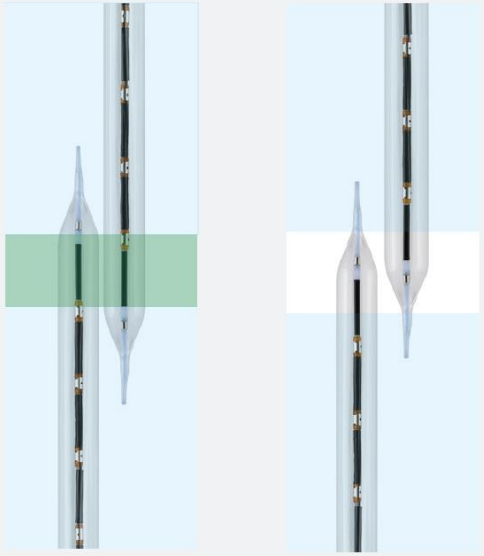
Wall apposition facilitates efficient energy transfer. Optimized balloon sizing leads to improved patency

Energy transfer is not improved by over-inflation.
Only deliver energy at 4atm.

Overlap Segments 1cm

to Avoid Therapeutic Miss

Full Therapeutic Coverage **Therapeutic Miss**



The sonic pressure waves create a spherical field effect that drops as the longitudinal distance from the emitters increases

Purge Air

to Facilitate Effective Energy Delivery

1. Purge balloon 2-3 times with a 10 or 20mL syringe prior to use
2. Deflate balloon between each cycle

Sonic pressure waves produce air within the catheter and deflating the balloon will clear out the bubbles (air/water vapor bubbles act as a barrier to sonic energy deliver)

[1]Refer to the Generator Manual for full details and Warnings and Precautions.
[2]Refer to the Catheter IFU for full details and Warnings and Precautions.

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Catheter and System Errors

	What it means	Recommended Actions
ERROR 80 Catheter beginning of life unsuccessful	The generator was unable to mark the catheter for beginning of life. ***Possible causes are:*** • Loose connection between the generator and catheter. • Defective Connector cable • Defective Catheter	1. Turn the generator power OFF • Disconnect catheter and connector cable • Ensure that the sterile sleeve is not interfering with the connection 2. Reconnect and ensure that both connections are secure 3. Turn the generator power ON 4. If error condition persists, purge and re-prep balloon 5. If error condition persists, replace the catheter 6. If error condition persists, replace the connector cable **NOTE:** *The same catheter will not work with a replacement generator*
ERROR 81 Catheter identification unsuccessful	Generator was unable to identify the catheter type. ***Possible causes are:*** • Loose connection between the generator and catheter. • Defective Connector cable • Defective Catheter	
ERROR 88 Pulse delivery timeout	The generator was unable to measure pulse energy delivery to the catheter within allowed time limit. ***Possible causes are:*** • Gas bubbles in the balloon • Loose connection between the generator and catheter. • Defective Connector cable • Defective Catheter	
ERROR 90 AND 93 Internal Generator Error	The generator has detected an error. ***Possible causes are***: • Voltage out of range	1. Recommended actions 1-3 above 2. If the error condition persists, contact Shockwave Medical representative or Customer Service

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Generator Self-Test

What is the IVL Generator Self-Test?

- The generator automatically performs a series of self-tests every time it is powered on.
- Additionally, the self-test performs a high-voltage check to ensure that the generator output is within the expected range
- You may choose to run a self-test at any time if the generator seems to be behaving unexpectedly.
- There is no specific recommendation as to when to perform the self-test

SELF TEST	• Plug the charger into the generator and an AC outlet • Ensure that the battery symbol indicates charging (lightning bolt) • Turn the generator power ON • Once the generator finishes the power on sequence, press and hold the THERAPY button until the THERAPY button lights green • The self-test will complete in approximately 20 seconds
OUTPUT	• PASS is indicated by four audible beeps and GREEN POWER button • FAIL is indicated by three audible beeps and RED POWER button

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Generator Examples

Normal Power On

Normal Ready/Standby

Normal Ready

Catheter Error

System Error

Passed Self Test

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