Peripheral Intravascular Lithotripsy (IVL) Catheter
Instructions for Use (IFU)

For use with the Shockwave Medical, Inc. IVL Generator and Connector Cable

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Indication for Use

The Shockwave™ Medical Peripheral Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary, carotid or cerebral vasculature.

Contents: **Shockwave™ E8 Peripheral IVL Catheter**

- The following balloon diameters are available: 2.5mm, 3.0mm, 3.5mm, 4.0mm, 5.0mm, 6.0mm, 7.0mm, 8.0mm
- Folded balloon diameters are: 0.054" max for 2.5mm and 3.0mm, 0.056" max for 3.5mm and 4.0mm, 0.068" max for the 5.0mm and 6.0mm, and 0.075" max for the 7.0mm and 8.0mm.
- 80mm balloon length
- 150cm catheter working length
- 2.5 – 4.0mm balloon is 5 F introducer sheath compatible; 5.0 – 6.0mm balloon is 6 F introducer sheath compatible; 7.0 – 8.0mm balloon is 7 F* introducer sheath compatible
    - For reinsertion use one (1) sheath size larger than the labeled sheath compatibility after initial use (i.e., following IVL Catheter removal: 6 F introducer sheath to be used with 2.5-4.0mm balloon; 7 F introducer sheath to be used with 5.0-6.0mm balloon; 8 F introducer sheath to be used with 7.0-8.0mm balloon).
- 0.014" (0.36mm) guidewire compatible (OTW - 300cm wire)
- 5"x96" Cable Sleeve

*6F compatible with .087" sheaths only.

How Supplied

The IVL Catheter is supplied sterile via E-beam sterilization. The IVL Catheter is intended for single use only and is not intended for reuse or re-sterilization. Carefully inspect all packaging for damage or defects prior to use. Do not use the device if any sign of damage or breach of the sterile barrier is observed as this could lead to malfunction of the device and/or injury to the patient. Store the IVL Catheter in a cool, dark, dry place. Storage of the device in extreme conditions may affect device performance and lead to patient injury.

Device Description

The IVL Catheter is a proprietary lithotripsy device delivered through the peripheral arterial system of the lower extremities to the site of an otherwise difficult to treat calcified stenosis. Energizing the lithotripsy device will generate ultrasonic acoustic pressure waves within the target treatment site, disrupting calcium within the lesion and allowing subsequent dilation of a peripheral artery stenosis using low balloon pressure. The IVL Catheter comprises an array of integrated lithotripsy emitters for the localized delivery of ultrasonic acoustic pressure waves and an integrated balloon. The system consists of an IVL Catheter, an IVL Connector Cable and an IVL Generator. The IVL Catheter is available in eight (8) sizes: 2.5 x 80mm, 3.0 x 80mm, 3.5 x 80mm, 4.0 x 80mm, 5.0 x 80mm, 6.0 x 80mm, 7.0 x 80mm, and 8.0 x 80mm. The E8 Peripheral IVL Catheter sizes 2.5x80mm to 6.0x80mm are compatible with a 5-6 F sheath. The E8 Peripheral IVL Catheter sizes 7.0x80mm and 8.0x80mm are compatible with a 7 F sheath. Refer to Figure 1 below for IVL Catheter components.

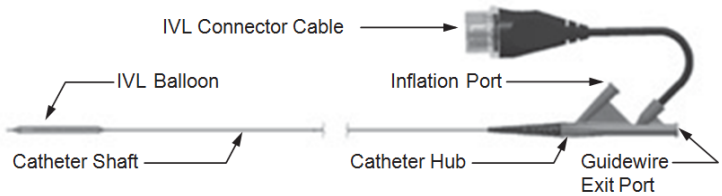

Figure 1: Shockwave E8 Peripheral IVL Catheter

The Shockwave E^8 Peripheral IVL Catheter shaft contains an inflation lumen, a guidewire lumen, and the lithotripsy emitters. The inflation lumen is used for inflation and deflation of the balloon with 50/50 saline/contrast medium. The guidewire lumen enables the use of a 0.014" guidewire to facilitate advancement of the catheter to and through the target stenosis. The system is designed as 'Over-the-wire' (OTW) with 150cm shaft working length, so an exchange length (300cm) guidewire is indicated. The emitters are positioned along the length of the balloon working length for delivery of ultrasonic acoustic pressure waves. The balloon is located near the distal tip of the catheter and contains a hydrophilic coating designed to increase lubricity during advancement of the catheter to the treatment site. Two radiopaque marker bands within the balloon denote the length of the balloon to aid in positioning of the balloon during treatment. The balloon is designed to provide an expandable segment of known length and diameter at a specific pressure. The proximal hub has three ports: one for inflation/deflation of the balloon, one for guidewire lumen, and one for connection to the IVL Connector Cable.

Required Devices for the IVL Procedure

The IVL Catheter is to be used exclusively with the IVL Generator and its accessories. Refer to the *Shockwave Medical, Inc. IVL Generator and Connector Cable Operator's Manual* for preparation, operation, warnings and precautions, and maintenance of the IVL Generator and IVL Connector Cable.

Devices Required But Not Supplied By Shockwave Medical, Inc.

- 5-8 F introducer sheath
- 0.014" (0.36mm) Guide Wire (300cm Length)
- Indeflator

Shockwave E^8 Peripheral IVL Catheter Balloon Compliance Chart

Pressure	2.5x80mm	3.0x80mm	3.5x80mm	4.0x80mm	5.0x80mm	6.0x80mm	7.0x80mm	8.0x80mm
ATM - kPa	**Ø (mm)**	**Ø (mm)**	**Ø (mm)**	**Ø (mm)**	**Ø (mm)**	**Ø (mm)**	**Ø (mm)**	**Ø (mm)**
2 - 203	2.43	2.91	3.42	3.87	4.90	5.84	6.81	7.75
3 - 304	2.44	2.93	3.44	3.90	4.93	5.92	6.87	7.84
4 - 405	**2.45**	**2.94**	**3.46**	**3.93**	**4.98**	**6.01**	**6.97**	**7.97**
5 - 507	2.45	2.96	3.49	3.97	5.05	6.11	7.10	8.12
6 - 608	**2.46**	**2.98**	**3.53**	**4.02**	**5.12**	**6.20**	**7.22**	**8.26**

Note: 2 – 4 atm is lithotripsy treatment balloon pressure. 4 atm is nominal balloon pressure and post-treatment pressure. 6 atm is RBP (Rated Burst Pressure) of the balloon.

Shockwave E^8 Peripheral IVL System Sequence Chart

The following Shockwave E^8 Peripheral IVL System pulsing sequence must be followed during treatment. Do not utilize a pulsing sequence other than those outlined in the IVL System Sequence Chart below. Insertion of any size IVL Catheter will automatically program the IVL Generator with the following treatment sequence:

Treatment Frequency	1 Pulse per 0.5 Second
Maximum Number of Continuous Pulses (1 cycle)	40 Pulses
Minimum Pause Time	10 Seconds
Maximum Total Pulses Per Catheter	400 (10 Cycles)

In the event the user attempts to deliver more than the maximum number of continuous pulses allowed, the IVL Generator is designed to stop automatically. To resume pulsing, wait at least the minimum pause time before resuming therapy. The therapy button must be released and pressed again to resume therapy. For more information, refer to the *IVL Generator and Connector Cable Operator's Manual*.

The IVL Catheter will deliver a maximum of 400 pulses or 10 cycles noted above. If this count is reached, the catheter shall not be used any further. If further therapy is needed, discard this catheter and obtain a new one. **Caution: Do not exceed 240 pulses in the same treatment segment.**

Contraindications for Use

The IVL System is contraindicated for the following:

1. Unable to pass 0.014" guidewire across the lesion.
2. This device is not intended for treatment of in-stent restenosis.
3. This device is not intended for use in coronary, carotid, or cerebrovascular arteries.

Warnings

1. This device is intended for single (one) time use only. DO NOT re-sterilize and/or reuse.
2. Do not use a device past the expiration date on the label. Use of expired product may result in patient injury.
3. Always insert the IVL Connector Cable into a sterile sleeve prior to use.

4. Use only an appropriately sized balloon for the vessel to be treated.
5. Inflate the balloon according to the balloon compliance chart. Balloon pressure should not exceed the rated burst pressure (RBP).
6. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
7. Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. Do not attempt to override the lifetime pulse limits per device as defined in the IVL System Sequence Chart.
8. This device should only be used by physicians who are familiar with interventional vascular procedures.
9. Physicians must read and understand these instructions prior to use of the device.
10. Do not use excessive force/torque when using this device as this could result in damage to the device components and patient injury.
11. Inspect all product components and packaging prior to use. Do not use the device if it or the packaging has been damaged or if sterility has been compromised. Damaged product could result in patient injury.
12. For preparation, operation, warnings and precautions, and maintenance of the IVL Generator and its accessories refer to the *IVL Generator and Connector Cable Operator's Manual*.

Precautions

1. Perform all device manipulations under adequate fluoroscopic guidance.
2. Use only the recommended balloon inflation medium.
3. Appropriate anticoagulant therapy should be administered by the physician.
4. Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology.
5. Care should be taken not to kink the catheter. If kinking occurs, remove device and prepare a new device.
6. If an inability to inflate or maintain pressure occurs, remove the catheter and use a new device.
7. If the catheter appears not to deliver lithotripsy ultrasonic acoustic pressure waves, remove and replace it with another catheter.
8. Precaution should be taken when handling device after exposure to patient e.g. contact with blood. Used product is considered biohazardous material and should be disposed of properly as per hospital protocol.

Adverse Effects

Possible adverse effects are consistent with standard angioplasty and include:

- Access site pain
- Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy
- Arterial dissection
- Arterial perforation or rupture
- Arterial spasm
- Arteriovenous fistula
- Bleeding complications
- Death
- Emboli (air, tissue, thrombus or atherosclerotic emboli)
- Emergency or non-emergency arterial bypass surgery
- Entry site complications
- Fracture of the guide wire or any component of the device that may or may not lead to device embolism, serious injury or surgical intervention
- Hematoma at the vascular access site(s)
- Hemorrhage
- Hypertension/Hypotension
- Infection/sepsis
- Ischemia
- Placement of a stent
- Pseudoaneurysm
- Renal failure
- Restenosis of the treated segment
- Shock/pulmonary edema
- Total occlusion of the peripheral artery
- Vascular complications which may prolong procedure and/or which may require surgical repair (conversion to open surgery)

Risks identified as unique to the device and its use:

- Allergic/immunologic reaction to the catheter material(s) or coating
- Device malfunction or failure

Procedural Steps

Caution: Refer to the *IVL Generator and Connector Cable Operator's Manual* for preparation, operation, warnings and precautions, and maintenance of the IVL Generator and IVL Connector Cable.

Preparation

1. Prepare the insertion site using standard sterile technique.
2. Achieve vascular access using physician's preferred methodology and location.
3. Place an appropriately sized and length introducer sheath.
    a. For radial access, use preferred sheath of appropriate length to reach target treatment area.
4. Select a balloon catheter size that is 1.1:1 based on balloon compliance chart (above) and reference vessel diameter. The largest balloon diameter should be used if 1.1:1 sizing is not available.
5. Verify the product label matches the catheter selected in the previous step.
6. Inspect the sterile barrier and ensure it is intact.
7. Open the sterile barrier by peeling away the white flap from the clear pouch.
8. Carefully introduce the catheter aseptically to the sterile field.
9. Prepare the balloon using standard technique. Fill a 20cc syringe with 5cc of 50/50 saline/contrast medium. Attach syringe to inflation port on catheter hub. Pull vacuum at least 3 times, releasing vacuum to allow the fluid to replace the air in the catheter.
10. Fill indeflator device with 10cc of 50/50 saline/contrast medium. Disconnect syringe and connect indeflator to inflation port of catheter hub ensuring no air is introduced to the system.
11. Flush the guidewire port with saline.
12. Remove the protection sheath from the catheter.
13. Wet the balloon and distal shaft with sterile saline in order to activate the hydrophilic coating.
14. Insert the IVL Connector Cable into a sterile sleeve or probe cover.
15. Remove the cap from the proximal end and attach the IVL Catheter's connector (see Figure 1) to the IVL Connector Cable.
16. Attach the other side of same IVL Connector Cable to the IVL Generator.

Caution: Do not press the therapy button unless the balloon is filled with 50% saline/ 50% contrast medium because this may damage the balloon.

Delivering the IVL Catheter to the Treatment Site

1. Advance the 0.014" guidewire across the treatment site.
2. Load the IVL Catheter over the exchange length (300cm) 0.014" guidewire and through the sheath and advance balloon to the treatment site.
3. Position the balloon at the treatment site using the marker bands to aid in positioning.

Treating the Site with Lithotripsy

1. Once the IVL Catheter is in place, record position using fluoroscopy.
2. If position is incorrect, adjust the IVL Catheter to the correct position.
3. Inflate IVL balloon to 2.0 atm - 4.0 atm to ensure there is full apposition to the vessel wall.
   NOTE: Lithotripsy should not be delivered if the balloon is inflated to >4 atm as there is no increase in sonic output, and higher pressure during treatment can increase the risk that the balloon loses pressure.
4. Deliver IVL System treatment (up to 40 pulses) per the IVL System Sequence Chart by pressing the therapy button on the IVL Connector Cable.
5. Inflate balloon to nominal pressure per Balloon Compliance Chart (above) and record lesion response on fluoroscopy.
6. Deflate balloon and wait at least 10 seconds to re-establish blood flow.
   NOTE: The IVL Generator is programmed to force a minimum pause time of 10 seconds following every 40 pulses delivered.
7. Repeat steps 3, 4, 5, and 6 for additional treatment cycles until the lesions has been sufficiently dilated or if the catheter is re-positioned.
8. Additional treatments can be performed if deemed necessary. If multiple inflations are required due to a lesion length greater than the IVL balloon length, the recommended balloon overlap is at least 1cm to prevent geographic miss. However, care must be taken not to exceed 240 pulses in the same segment.
9. Perform a completion arteriogram to assess post-IVL treatment result.
10. Confirm that the balloon is fully deflated prior to removing the IVL Catheter.
11. Remove the IVL Catheter. If there is difficulty in removing the device through the hemostatic valve due to the lubricity, gently grasp the catheter with sterile gauze.
12. Inspect all components to ensure that the catheter is intact. If a device malfunction occurs or any defects are noted on the inspection, flush the guide wire lumen and clean the outer surface of the catheter with saline, store the catheter in a sealed plastic bag, and contact Shockwave Medical, Inc. for further instructions.

Caution: IVL Catheter once pulled out of the body should be reinserted into one (1) sheath size larger than the labeled sheath compatibility after initial use (i.e., following IVL Catheter removal: 6 F introducer sheath to be used with 2.5-4.0mm balloon; 7 F introducer sheath to be used with 5.0-6.0mm balloon, 8 F introducer sheath to be used with 7.0-8.0mm balloon).

Patient Information

Physicians should instruct patients to seek medical attention immediately for signs and symptoms of decreased peripheral blood flow. There are no known limitations to normal daily activities. Patients should be instructed to comply with the medical regimen as prescribed by their physician.

Return of Devices

If any portion of the Shockwave Medical IVL System fails prior to or during a procedure, discontinue use and contact local representative and/or email complaints@shockwavemedical.com.

Patents: www.shockwavemedical.com/patents

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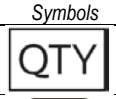
Symbol	Definition
	Do not re-use
	Use by date
	Sterilized using irradiation; Single sterile barrier with protective packaging outside
	Caution
	Manufacturer
	Do not use if package is damaged; If sterile barrier is damaged, consult instructions for use
	Keep dry
	Keep away from heat
LOT	Batch code
REF	Catalogue number
	Do not resterilize
	Crossing profile
	Non-pyrogenic
	Consult instructions for use
	Contains 1 unit (Contents: 1)
	Recommended Guidewire
	Recommended Introducer Sheath
OTW	Over-the-wire
Ø	Balloon Diameter
	Balloon Working Length
UL	Catheter Working Length (Usable Length, UL)

	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.
PAT	Patents. Refer to www.shockwavemedical.com/patents
PAD	Peripheral Arterial Disease
IVL	Intravascular Lithotripsy
	Indicates a carrier that contains Unique Device Identifier information.

Sterile Cable Sleeve Symbols	
	Quantity
	Does not contain latex
	Sterilized using ethylene oxide
	For prescription use only

PN 81501-B