Shockwave Medical, Inc. Peripheral Lithoplasty® System

Instructions for Use (IFU)
For use with the Shockwave Medical, Inc. Lithoplasty Generator REF M732LG825D1 delivered after April 25, 2017

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Shockwave Medical, Inc. Peripheral Lithoplasty® System (Lithoplasty System)
Shockwave Medical, Inc. Peripheral Lithoplasty® Balloon Dilatation Catheter (Lithoplasty Catheter)

- For use exclusively with the Shockwave Medical, Inc. Lithoplasty Generator REF M732LG825D1 (Lithoplasty Generator)
- For use exclusively with the Shockwave Medical, Inc. Connector Cable REF M732LCC825D1 (Connector Cable)

Indication for Use

The Shockwave Medical Lithoplasty 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 or cerebral vasculature.

Contents

- Lithoplasty Catheter:
  - The following balloon diameters are available: 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm and 7.0mm
  - Folded balloon diameters are: 0.064" max. for 3.5 to 6.0mm and 0.072" max. for 6.5 and 7.0mm
  - 60mm balloon length
  - 110cm catheter working length
  - 3.5 – 6.0mm balloon is 6 Fr. introducer sheath compatible; 6.5 - 7.0mm balloon is 7 Fr. introducer sheath compatible.
  - 0.014" (0.36mm) guidewire compatible (OTW - 300cm wire)

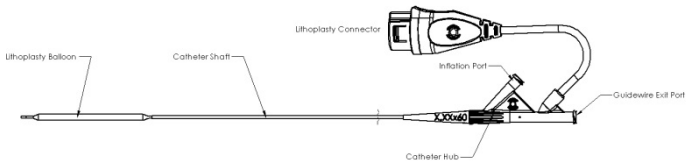
How Supplied

The Lithoplasty Catheter is supplied sterile via e-beam sterilization. The Lithoplasty 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 Lithoplasty 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 Lithoplasty Catheter is a proprietary balloon catheter system designed to deliver a lithotripsy device 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 pulsatile mechanical energy within the target treatment site, disrupting calcium within the lesion and allowing subsequent dilation of a peripheral artery stenosis using low balloon pressure. The Lithoplasty Catheter combines an angioplasty catheter design with integrated lithotripsy emitters to enable the localized delivery of pulsatile mechanical energy. The system consists of the Lithoplasty Catheter, a Connector Cable and a Generator. The Lithoplasty Catheter is available in eight (8) sizes: 3.5 x 60mm, 4.0 x 60mm, 4.5 x 60mm, 5.0 x 60mm, 5.5 x60mm, 6.0 x 60mm, 6.5 x 60mm, and 7.0 x 60mm. The Lithoplasty Catheter is compatible with a 6 or 7Fr sheath and has a working length of 110cm. Refer to Figure 1 below for Lithoplasty Catheter components.

Figure 1: Lithoplasty Catheter



The 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 110cm 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 pulsatile mechanical energy. The balloon is located near the distal tip of the catheter. 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 Connector Cable.

Required Devices for the Lithoplasty Procedure

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

Devices Required But Not Supplied By Shockwave Medical, Inc.

- 6F or 7F introducer sheath
- 0.014" (0.36mm) Guide Wire (300cm Length)
- 5"x96" minimum Sterile Sleeve

Balloon Compliance Chart

Pressure	3.5 x 60mm	4.0 x 60mm	4.5 x 60mm	5.0 x 60mm
ATM - kPa	Ø (mm)*	Ø (mm)*	Ø (mm)*	Ø (mm)*
4 - 405	3.55	3.94	4.49	4.92
5 - 507	3.58	3.97	4.53	4.95
6 - 608	3.61	4.01	4.57	4.98
7 - 709	3.65	4.06	4.63	5.03
8 - 811	3.68	4.09	4.67	5.07
9 - 912	3.72	4.14	4.72	5.10
10 - 1013	3.75	4.19	4.77	5.16

Pressure	5.5 x 60mm	6.0 x 60mm	6.5 x 60mm	7.0 x 60mm
ATM - kPa	Ø (mm)*	Ø (mm)*	Ø (mm)*	Ø (mm)*
4 - 405	5.39	5.92	6.39	6.77
5 - 507	5.43	5.96	6.45	6.85
6 - 608	5.48	6.02	6.59	6.91
7 - 709	5.55	6.09	6.65	6.98
8 - 811	5.61	6.15	6.72	7.05
9 - 912	5.66	6.24	6.80	7.12
10 - 1013	5.74	6.34	6.92	7.22

Note: 4 ATM is lithotripsy treatment balloon pressure, 6 ATM is nominal balloon pressure and post- treatment angioplasty pressure and 10 ATM is RBP (Rated Burst Pressure) of the balloon.

Lithoplasty System Sequence Chart

The following Lithoplasty System pulsing sequence must be followed during treatment. Do not utilize a pulsing sequence other than those outlined in the Lithoplasty System Sequence Chart below. Insertion of any size catheter will automatically program the Generator with the following treatment sequence:

Treatment Frequency	1 Pulse per Second
Maximum Number of Continuous Pulses (1 cycle)	30 Pulses
Minimum Pause Time	10 Seconds
Maximum Total Pulses Per Catheter	180 (6 Cycles)

In the event the user attempts to deliver more than the maximum number of continuous pulses allowed, the 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 Generator Operator's Manual.

The catheter will deliver a maximum of 180 pulses or 6 cycles noted above. If further therapy is needed, discard this catheter and obtain a new one. For more information, refer to the Generator Operator's Manual.

Contraindications for Use

The Lithoplasty 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 connector cable into the 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 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 Lithoplasty System Sequence Chart.
8. This device should only be used by physicians who are familiar with interventional vascular procedures.
9. Physicians must be trained 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 Generator and its accessories refer to the Generator 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 pulsatile mechanical energy, 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 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)
- Device malfunction or failure
- Excess heat at target site due to malfunction of Generator

Summary of Clinical Studies

To evaluate the safety and performance of the Lithoplasty System, Shockwave Medical, Inc. conducted a two-phased, non-randomized, multi-center study for the treatment of peripheral stenotic lesions (PAD I and PAD II, combined referred to as the DISRUPT PAD Program). Patients with peripheral arterial disease of Rutherford Category 2, 3, and 4 who were candidates for percutaneous therapy and met the study criteria were enrolled and treated. Thirty-four (34) investigators participated at seven (7) sites in Austria, New Zealand, and Germany. A total of 95 subjects were enrolled. This clinical study summary presents outcomes from all 95 subjects at 30 days and at 6 months.

A total of 95 subjects were enrolled in the study. Baseline characteristics were consistent with a complex, calcified patient population. Calcium burden was significant with severe calcification involving both sides of the arterial wall observed by the Core Lab in 54.7% of the subjects, and an average length of calcium of 93.4 mm. Ninety-four (94) of the 95 subjects received treatment with the Lithoplasty System. The procedures were completed with a low use of adjunctive therapies including pre and post-dilatation balloons and embolic protection filters, along with a low use of stents in this difficult to treat population.

The study met its primary safety endpoint. The lower bound of the 95% confidence interval for freedom from Major Adverse Events (MAE) at 30 days of 97.0% was above the performance goal of 91.3%. The freedom from MAE at 30 days was 100%.

The study also met its primary effectiveness endpoint. The lower bound of the 95% confidence interval for procedural success of 97.0% was above the performance goal of 89.3%. Procedural success was defined as <50% with or without adjunctive therapy was 100%.

The secondary safety endpoint, freedom from MAE at 6 months, continued to be favorable as shown in the table below. Freedom from MAE at 6 months was 96.8%. There were no cardiovascular deaths, target limb major amputations, perforations, symptomatic thrombus or distal embolization events.

Freedom from Major Adverse Events at 6 Months

	N=95	
	30 days n=94[1]	6 months n=93[2]
Major adverse events (MAE)	0 (0.0%)	3 (3.2%)
Death (cardiovascular)	0 (0.0%)	0 (0.0%)
TLR	0 (0.0%)	3 (3.2%)
Unplanned target limb amputation (above the ankle)	0 (0.0%)	0 (0.0%)
Freedom from Major adverse events (MAE)	94 (100%)	90 (96.8%)
Exact Binomial one-sided lower 95% CI[1]	97%	92%
Death (cardiovascular)	94 (100%)	93 (100%)
TLR	94 (100%)	90 (96.8%)
Unplanned target limb amputation (above the ankle)	94 (100%)	93 (100%)

[1]One subject withdrew consent and was not available for analysis
[2] Two subjects withdrew consent and were not available for analysis

Secondary effectiveness endpoints were also favorable. Procedural success defined as <50% without adjunctive therapy was achieved in 91.6% of subjects. In addition, procedural success defined as ≤30% with or without adjunctive therapy was achieved in 89.5%.

Target lesion patency assessed by duplex ultrasound at 30 days and 6 months was 100% and 76.7% respectively as shown in the table below. Freedom from target lesion revascularizations (TLR) at 6 months was 96.8% for a true rate of 3.2%.

Patency at 6 Months

	N=95
Patency	
Target lesion patency at 30 days	91/91[1] (100%)
Exact Binomial Two-sided 95% CI[1]	96%, 100%
Target lesion patency at 6 months	69/90[2] (76.7%)
Exact Binomial Two-sided 95% CI[1]	67%, 85%
Freedom from TLR at 6 months	90/93[3] (96.8%)
Exact Binomial Two-sided 95% CI[1]	91%, 99%

[1] Two subjects withdrew consent and data for an additional 2 subjects was not available at 30 days
[2] Two subjects withdrew consent and data for an additional 3 subjects was not available at 6 months
[3] Two subjects withdrew consent and data was not available for analysis

Functional outcomes including change in ankle-brachial index (ABI), Rutherford Category and walking impairment showed a sustained and statistically significant improvement from baseline and data available at 30 days and 6 months.

In conclusion, the DISRUPT PAD program met the study success criteria. The Lithoplasty System demonstrated compelling safety with minimal vessel injury, and minimal use of stenting. Acute effectiveness results showed high procedural success and a large acute gain in vessel diameter post procedure. Patency, TLR and functional outcomes were durable through 6 months in available patients. These results demonstrate the safety and performance of the Lithoplasty System for the treatment of subjects with calcified, stenotic lesions.

Procedural Steps

CAUTION: Refer to the Generator Operator's Manual for preparation, operation, warnings and precautions, and maintenance of the Generator.

Preparation

1. Prepare the insertion site using standard sterile technique.
2. Achieve vascular access and place an introducer sheath.
3. Select a balloon catheter size that is 1.1:1 based on balloon compliance chart (above) and reference vessel diameter.
4. Remove the Lithoplasty Catheter from the package.
5. 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.
6. 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.
7. Flush the guidewire port with saline.
8. Remove the protection sheath from the catheter.
9. Wet the balloon with sterile saline.
10. Insert the Connector Cable into the sterile sleeve or probe cover.
11. Remove the cap from the proximal end and attach the Lithoplasty Catheter's connector (see Fig 1) to the Connector Cable.
12. Attach the other side of same Connector Cable to the Generator.

Caution: Care must be taken to avoid applying pulsatile mechanical energy (i.e. press the therapy button of Connector Cable) while balloon is dry. It may damage the balloon.

Delivering the Lithoplasty Catheter to the Treatment Site

1. Advance the 0.014" guidewire across the treatment site.
2. Load the Lithoplasty 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

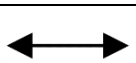
1. Once the Lithoplasty Catheter is in place, record position using fluoroscopy.
2. If position is incorrect, adjust the Lithoplasty Balloon to the correct position.
3. Inflate Lithoplasty Balloon to 4.0 atm.
4. Deliver Lithoplasty System treatment sequence per the Lithoplasty System Sequence Chart.
5. Inflate balloon per balloon compliance chart (above) and record lesion response on fluoroscopy.
6. Following Lithotripsy treatment, deflate balloon and wait 30 seconds to re-establish blood flow.
7. Repeat steps 3, 4, 5, 6 to complete a single treatment with 60 pulses.
8. Additional treatments can be performed if deemed necessary. If multiple inflations are required due to a lesion length greater than the Lithoplasty balloon length, the recommended balloon overlap is at least 1 cm to prevent geographic miss. However care must be taken not to exceed 180 pulses in the same segment.
9. Perform a completion arteriogram to assess post intervention result.
10. Deflate the device and confirm that the balloon is fully deflated prior to removing the Lithoplasty Catheter.
11. Remove the Lithoplasty 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: Lithoplasty Catheter once pulled out of the body should not be reinserted for additional inflation or Lithoplasty treatments. Balloon can be damaged in the process.

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 Lithoplasty 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

Symbol	Definition
	Do not re-use
	Use by date
	Sterilized using irradiation
	Caution
	Manufacturer
	Do not use if package is damaged
	Keep dry
	Authorized Representative in the European Community
	Keep away from heat
	Batch code
	Catalogue number
	Do not resterilize
	Non-pyrogenic
	Consult instructions for use
	Contains 1 unit (Contents: 1)
	Recommended Guidewire
	Recommended Introducer Sheath
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.
CE	Conformité Européene
PAT	Patents. Refer to www.shockwavemedical.com/patents

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SHOCKWAVE

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