SHOCKWAVE JAVELIN PERIPHERAL

Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave Javelin Peripheral Intravascular Lithotripsy (IVL) Catheter

Instructions for Use (IFU)

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

℞ **Only**

Indication for Use
The Shockwave Medical IVL System with the Javelin Peripheral IVL Catheter is intended for lithotripsy-enabled modification and crossing of calcified lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries, prior to final treatment.
Not for use in the coronary, carotid, cerebral or pulmonary vasculature.

Contents: Shockwave Javelin Peripheral IVL Catheter

- The following configurations are available:
  - Javelin FLX with 25 cm flexible distal section
- Crossing profile ≤ 1.5 mm
- 150 cm catheter working length
- 5 Fr introducer sheath compatible
- 0.014" (0.36 mm) guidewire compatible (OTW – 300 cm wire)
- 5"x96" (13x244 cm) Sterile Cable Sleeve

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 Shockwave Javelin Peripheral 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. Intravascular Lithotripsy (IVL) is an interventional procedure that utilizes a fluid-filled catheter connected to a power source that generates acoustic shock waves; the shock waves modify calcified plaque in peripheral arteries. Energizing the intravascular lithotripsy device will generate acoustic pressure pulses within the target treatment site, disrupting calcium within the lesion and allowing subsequent dilatation of a peripheral artery stenosis. The Javelin Peripheral IVL Catheter comprises a forward-shifted lithotripsy emitter for the localized delivery of acoustic pressure. The system consists of the IVL Catheter, an IVL Connector Cable and an IVL Generator. The Javelin Peripheral IVL Catheter has a 25 cm distal segment for flexibility. The IVL Catheter is compatible with a 5 Fr sheath and has a working length of 150 cm. Refer to Figure 1 for IVL Catheter components.

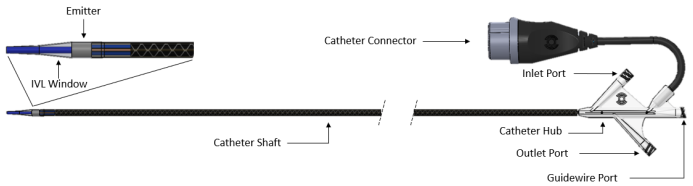

Figure 1: Shockwave Javelin Peripheral IVL Catheter

The Shockwave Javelin Peripheral IVL Catheter shaft contains a lumen to pressurize to treatment pressure, a lumen to flush the catheter, a guidewire lumen, and a lithotripsy emitter. The lumen is used to pressurize and flush the catheter with sterile saline. The guidewire lumen enables the use of a 0.014" (0.36 mm) guidewire to facilitate advancement of the catheter to and through the target stenosis. The system is designed as 'Over-the-wire' (OTW) with 150 cm shaft working length. The emitter is located at the distal end of the catheter for delivery of acoustic pressure pulses. The IVL Catheter has a 50 cm hydrophilic coating on the distal end designed to increase lubricity during advancement of the catheter to the treatment site. The emitter is radiopaque to facilitate catheter visibility under fluoroscopy and it is surrounded by an IVL Window that allows for the transmission of acoustic pressure pulses. The proximal hub has four ports: one to pressurize the system (Inlet Port), one to flush the system (Outlet Port), one for guidewire lumen (Guidewire Port), 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 Fr introducer sheath
- 0.014" (0.36 mm) guidewire (300 cm length)
- Indeflator
- Sterile Saline
- Syringe
- Stopcock

Shockwave Javelin Peripheral IVL Catheter Sequence Chart
The following pulsing sequence must be followed during treatment. Do not utilize a pulsing sequence other than those outlined in the IVL System Sequence Chart below.

Treatment Frequency	1 Pulse per Second
Maximum Number of Continuous Pulses (1 cycle)	10 Pulses
Minimum Pause Time	10 Seconds
Maximum Total Pulses Per Catheter	120 Pulses (12 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 120 pulses or 12 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 120 pulses in the same treatment segment.
Note: 4 atm is IVL window treatment pressure and

6 atm is catheter de-pressurization (flushing) pressure.
Caution: Do not exceed 6 atm of pressure when flushing the catheter.

Contraindications for Use
The IVL System is contraindicated for the following:

1. Unable to pass 0.014" (0.36 mm) guidewire across the treatment site.
2. This device is not intended for treatment of in-stent restenosis.
3. This device is not intended for use in coronary, carotid, cerebrovascular or pulmonary 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. IVL window pressure should not exceed the recommended working IVL treatment pressure of 4 atm.
5. IVL window flushing should not exceed the recommended flushing pressure of 6 atm.
6. 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. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
13. 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 sterile saline to pressurize the IVL window of the catheter. Do not use contrast.
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. Ensure a guidewire is placed in procedure sequence, when delivering IVL and advancing the catheter to prevent damage to distal end of the catheter during use.
7. If an inability to pressurize or maintain pressure occurs, remove the catheter and use a new device.
8. Care must be taken to avoid applying acoustic pressure pulses (i.e. press the therapy button of patient cable) while the IVL Window is not filled with sterile saline. It may damage the IVL Window.
9. If the catheter does not deliver lithotripsy acoustic pressure pulses, remove and replace it with another catheter.
10. When using IVL in the vicinity of temporary or permanent implantable devices, observe for any potential interaction with the IVL acoustic pressure pulses.
11. 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 intravascular procedures 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 guidewire 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) or coating
- Device malfunction or failure

Clinical Study Summary (Pooled US & New Zealand/Australia)
The prospective, multi-center, single arm FORWARD PAD IDE study (FORWARD) & the New Zealand/Australia Mini-S Feasibility Study (Feasibility Study) were conducted to evaluate the safety and effectiveness of the Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave Javelin Peripheral IVL Catheter for the treatment of heavily, calcified, stenotic peripheral arteries. Patients with moderately to severely calcified peripheral artery disease (PAD), Rutherford Category (RC) of 2, 3, 4, or 5 of the target limb, a target lesion located in a native, *de novo* superficial femoral, popliteal or infrapopliteal artery that met all additional study criteria were enrolled and treated. A total of 90 pooled subjects were enrolled at 19 clinical sites: 15 sites located in the United States, and 4 sites in Australia & New Zealand. Subjects have completed 30 day follow-up.

The primary safety endpoint for the FORWARD and Feasibility studies was major adverse events (MAEs) at 30 days post-index procedure, defined as a composite of: Cardiovascular death; Clinically-driven target lesion revascularization (CD-TLR); and unplanned target limb major amputation (above the ankle). All MAEs were adjudicated by an independent Clinical Events Committee (CEC). The primary safety endpoint performance goal (PG) for 30-Day MAE rate was 11.2%. The primary effectiveness endpoint for the FORWARD PAD study was Technical Success, defined as final residual stenosis ≤50% without flow-limiting dissection (≥ Grade D) of the target lesion by angiographic core lab. The primary effectiveness PG for the Javelin program was 85.0% for Technical Success.

Baseline characteristics were consistent with those presenting with PAD including those with moderate to severely calcified PAD. A total of

103 target lesions had angiographic images available for analysis by the core lab and were treated in 90 enrolled subjects. Target lesion(s) included those in a native, de novo superficial femoral, popliteal or infrapopliteal artery with RC 2-5. The majority of subjects had a baseline target limb(s) categorized as RC 3 (Severe Claudication) 43.3% (39/90), followed by RC 5 (Ischemic ulceration not exceeding ulcer of the digits of the foot) 41.1% (37/90). Pre-procedure lesion characteristics, as determined by the Core Lab, presented a mean reference vessel diameter (RVD) of 4.2 mm (1.1, 7.4), mean lumen diameter (MLD) of 0.7 mm (0.0, 2.4) with a corresponding mean percentage diameter stenosis of 82.9% (49.9, 100), a mean average lesion length of 76.9 mm, and a mean calcium length of 127.5 mm, with severe calcification present in 82.5% (85/103), and 24.8% (25/101) of lesions were eccentric. 42.7% (44/103) of lesions were located below the knee (BTK). 53.3% (48/90) of subjects presented with chronic limb-threatening ischemia (CLTI) and 38.0% (38/100) with Chronic Total Occlusion (CTO) lesions. Detailed Pre-Procedure Angiographic Characteristics assessment by Core Laboratory are provided in **Table 1**.

Table 1. Pre-Procedure Angiographic Characteristics (Core Lab)

Measure	Pooled
Lesion Location (%)	
Common Femoral Artery	1.9 (2/103)
Sup. Femoral Artery	39.8 (41/103)
Deep Femoral / Profunda	0.0 (0/103)
Popliteal Artery (ATK)	15.5 (16/103)
Popliteal Artery (BTK)	8.7 (9/103)
Anterior Tibial Artery	11.7 (12/103)
Tibio-Peroneal Trunk	7.8 (8/103)
Peroneal Artery	5.8 (6/103)
Posterior Tibial Artery	8.7 (9/103)
Calcification by PARC (%)	
None/Mild	4.9 (5/103)
Moderate	12.6 (13/103)
Severe	82.5 (85/103)
Total Length of Ca (mm)	
N	92
Mean ± StdDev	127.5 ± 88.2
Median (Q1, Q3)	112.2 (60.4, 160.9)
Min, Max	11.8, 433.4
Lesion Length (mm)	
N	102
Mean ± StdDev	76.9 ± 59.4
Median (Q1, Q3)	57.3 (32.5, 103.1)
Min, Max	8.9, 335.2
MLD (mm)	
N	100
Mean ± StdDev	0.7 ± 0.7
Median (Q1, Q3)	0.7 (0.0, 1.3)
Min, Max	0.0, 2.4
RVD (mm)	
N	100
Mean ± StdDev	4.2 ± 1.4
Median (Q1, Q3)	4.3 (3.0, 5.3)
Min, Max	1.1, 7.4
Diameter Stenosis (%)	
N	100
Mean ± StdDev	82.9 ± 16.7
Median (Q1, Q3)	83.6 (70.2, 100.0)
Min, Max	49.9, 100.0
Chronic Total Occlusion (%)	38.0 (38/100)

The primary safety performance goal is summarized in **Table 2**. Of 90 subjects, the observed 30-day MAE rate was 1.1% (1/90), with the 95% confidence limit of 6.0%, which was lower than the PG of 11.2%. The 30-Day MAE PG was met.

Table 2. Performance Goal – MAEs at 30 Days

Measure	% (n/N) 95% CI	Hypothesis	P-value	Conclusion
MAEs within 30 days of procedure	1.1% (1/90) 0.0%, 6.0%	H_0: $\pi_s > 11.2\%$ H_A: $\pi_s \leq 11.2\%$	0.0012	Performance Goal Met

The components of the Primary Safety Endpoint are provided in **Table 3** below.

Table 3. Primary Safety Endpoint - Major Adverse Events (MAE) at 30 Days

Measure	Pooled % (n/N) 95% CI
Major Adverse Events (MAE)	1.1% (1/90) 0.0%, 6.0%
Cardiovascular death	1.1% (1/90) 0.0%, 6.0%
Clinically-driven target lesion revascularization (CD-TLR)	0.0% (0/90) 0.0%, 4.0%
Unplanned target limb major amputation (above the ankle)	0.0% (0/90) 0.0%, 4.0%

The primary effectiveness results at the lesion level are summarized in **Table 4**. The observed Final Technical Success rate was 99.0% (97/98), with the corresponding 95% confidence limit of 94.4% which was higher than the PG of 85.0%. Therefore, the primary effectiveness endpoint of Technical Success was met (p<0.0001).

Table 4. Performance Goal – Final Technical Success

Measure	% (n/N) 95% CI	Hypothesis	P-value	Conclusion
Technical Success	99.0% (97/98) 94.4%, 100%	H0: πs ≤ 85.0% HA: πs > 85.0%	< 0.0001	Performance Goal Met

The components of the Primary Effectiveness Endpoint are provided in **Table 5** below.

Table 5. Primary Effectiveness Endpoint – Final Technical Success

Measure	Pooled % (n/N) 95% CI
Technical Success [1]	99.0% (97/98) 94.4% ,100%
Freedom from Any Serious Flow-Limiting Dissection (D-F)	99.0% (97/98) 94.4% ,100%
Residual Stenosis ≤ 50%	100.0% (98/98) 96.3% ,100%
[1]Technical Success: Final residual stenosis ≤ 50% without flow-limiting dissection (≥ Grade D) of the target lesion by angiographic core laboratory.	

Secondary endpoints

Secondary safety and effectiveness endpoints were favorable. Serious angiographic complications at the final timepoint, defined as flow-limiting dissection (≥ Grade D), perforation, distal embolization, or acute vessel closure as assessed by angiographic core lab, were reported in 1.0% (1/98) of lesions.

IVL Technical Success, defined as post-dilatation residual stenosis ≤50% without flow-limiting dissection (≥ Grade D) of the target lesion by angiographic core lab (measured immediately following mandatory post-dilatation), was achieved in 89.7% (87/97) of lesions.

IVL Device Success, defined as the ability to deliver, advance across the target lesion, pressurize, pulse, flush, and retrieve the Javelin IVL catheter, was achieved with 93.0% (107/115) of catheters.

Technical Success (final), defined as final residual stenosis of ≤30% without flow-limiting dissection (≥ Grade D) of the target lesion by angiographic core lab, was achieved in 78.6% (77/98) of lesions.

Post-Javelin treatment, drug-coated ballons were used in 40.0% (42/105) of lesions and 22.9% (24/105) of the lesions had a stent/Tack implanted. Commercial IVL was used on 25.7% (27/105) of target lesions.

The study collected residual stenosis data post-Javelin, post-dilatation and at the final angiographic time point. Post-Javelin mean residual stenosis was 59.1 ± 18.4% with 36.5% (31/85) of the lesions having a residual stenosis of ≤ 50% and 3.5% (3/85) with a residual stenosis of ≤ 30%. Post-dilatation mean residual stenosis was 31.3 ± 13.7% with 93.8% (91/97) of lesions having residual stenosis of ≤ 50%, and 50.5% (49/97) with a residual stenosis of ≤ 30%. Final mean residual stenosis was 23.0 ± 9.1% with 100% (98/98) of lesions reported with a residual stenosis of ≤ 50%, and with 79.6% (78/98) having a residual stenosis of ≤ 30%.

In conclusion, the Javelin Peripheral IVL Catheter demonstrated a low incidence of MAEs and angiographic complications, consistent with prior peripheral IVL studies. Effectiveness results showed acute luminal gain post-Javelin, and low residual stenosis at the final angiographic timepoints. These results demonstrate the substantial equivalence of the Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave Javelin Peripheral IVL Catheter for the treatment of subjects with moderate to severely calcified lesions in peripheral arteries.

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 preferred vascular access and place an appropriately sized and length introducer sheath.
3. Select appropriate catheter model for target site lesion.
4. Inspect packaging for damage. Open the sterile barrier by peeling away the white flap from the clear pouch.
5. Carefully introduce the catheter aseptically to the sterile field.
6. Remove protective sheath and shipping mandrel from IVL Catheter.
   Caution: Do not use the device if the protective sheath or shipping mandrel are difficult to remove or cannot be removed.
7. Fill indeflator device and syringe with sterile saline only.
   Caution: Use sterile saline only. Do not use saline mixed with contrast. Failure to use saline only can increase the risk of IVL window damage and loss of pressure.
8. Attach a stopcock to the outlet port on the hub and make sure the stopcock is open.
9. Attach indeflator to inlet port on catheter hub.
10. Flush through inlet port until saline comes out of outlet port.
    Caution: IVL window flushing should not exceed the recommended flushing pressure of 6 atm. Higher pressure can increase the risk of IVL window damage and loss of pressure
11. Close the stopcock.
12. Attach syringe to guidewire port.
13. Flush through guidewire port until saline comes out of the distal tip.
14. Remove syringe from guidewire port.
15. Wet the distal end of the catheter with saline (sterile) to activate the hydrophilic coating.
16. Insert the IVL Connector Cable into a sterile sleeve or probe cover.
17. Remove the cap from the proximal end and attach the IVL Catheter's connector (see Fig 1) to the IVL Connector Cable.
18. Attach the non-catheter end of IVL Connector Cable to the IVL Generator.

Caution: Care must be taken to avoid applying lithotripsy therapy (i.e. pressing the therapy button of the IVL Connector Cable) while lithotripsy catheter is not pressurized by saline or in the body, as this may damage the IVL window.

Delivering the IVL Catheter to the Treatment Site

1. Advance the 0.014" (0.36mm) guidewire across the treatment site.
2. Load the IVL Catheter over the exchange length (300 cm) 0.014" (0.36 mm) guidewire, into the sheath, and advance catheter to the treatment site.
3. Position the emitter at the treatment site using the radiopaque emitter 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. Pressurize the IVL Catheter to 4.0 atm. Make sure the stopcock is closed.
   NOTE: Lithotripsy should not be delivered if the IVL Catheter is pressurized to >4.0 atm as there is no increase in sonic output, and higher pressure during treatment can increase the risk of IVL window damage and loss of pressure.
4. Deliver IVL treatment (up to 10 pulses per cycle) by pressing the therapy button on the IVL Connector Cable. Advance the IVL catheter from the proximal edge through the target lesion while pulsing.
5. Following IVL treatment, wait for IVL Generator therapy button to return to green (approximately 10 seconds).
   NOTE: The IVL Generator is programmed to force a minimum pause time of 10 seconds following every 10 pulses delivered.
6. Before delivering the next treatment cycle, open the outlet port and pressurize to 6 atm to flush the system. Confirm that saline is coming through the outlet port.
   Caution: IVL window flushing should not exceed the recommended flushing pressure of 6 atm. Higher pressure can increase the risk of IVL window damage and loss of pressure.
7. Close the outlet port and repeat steps 3, 4, 5, and 6 to continue IVL treatment through the distal edge of the target lesion.
   NOTE: IVL treatment may also be delivered while the catheter is retracted through the target lesion.
   Caution: Care must be taken not to exceed 120 pulses in the same treatment segment.
8. Perform a completion arteriogram to assess post-IVL treatment result.
9. Remove the IVL Catheter. If there is difficulty in removing the device through the hemostatic valve due to its lubricity, gently grasp the catheter with sterile gauze.
10. 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 guidewire lumen with sterile saline and clean the outer surface of the catheter with saline, store the catheter in a sealed plastic bag, and contact Shockwave Medical, Inc. at complaints@shockwavemedical.com for further instructions.

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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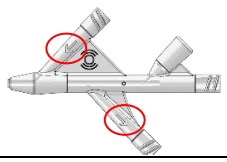
Symbol	Definition
	Do not re-use
	Use by date
STERILE R	Sterilized using irradiation; Single sterile barrier with protective packaging outside
	Caution
	Manufacturer
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from heat
LOT	Batch code
REF	Catalogue number
2 STERILIZE	Do not resterilize
C P	Crossing profile
	Non-pyrogenic
	Consult instructions for use
1	Contains 1 unit (Contents: 1)
GW R	Recommended Guidewire
IS R	Recommended Introducer Sheath
OTW	Over-the-wire
UL	Catheter Working Length (Usable Length, UL)
Rx Only	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.
UDI	Indicates a carrier that contains Unique Device Identifier information.
PAT	Patents. Refer to www.shockwavemedical.com/patents
DISTAL	Flexible Distal Section Length
PAD	Peripheral Arterial Disease
	Inlet port
	Outlet port

Symbol	Definition
Sterile Cable Sleeve Symbols	
QTY	Quantity
STERILE EO	Sterilized using ethylene oxide
LATEX	Does not contain latex
Rx only	For prescription use only

PN 64552 Rev C