INSTRUCTION FOR USE CENTRAL VENOUS CATHETER

VENEX PULSE IVL SYSTEM

Intravascular Lithotripsy Catheter

Device Description

The VENEX PULSE intravascular Lithotripsy Catheter is a proprietary lithotripsy device delivered through the coronary arterial system of the heart to the site of an otherwise difficult to treat calcified stenosis, including calcified stenoses that are anticipated to exhibit resistance to full balloon dilatation or subsequent uniform coronary stent expansion. The IVL Catheter contains integrated lithotripsy emitters for the localized delivery of acoustic pressure pulse therapy. The lithotripsy technology generates acoustic pressure pulses within the target treatment site, disrupting calcium within the lesion allowing subsequent dilatation of a coronary artery stenosis using low balloon pressure. The system consists of the IVL Catheter, IVL Connector Cable and IVL Generator. The Venex Pulse IVLCatheter is available in four (4) sizes: 2.50x12 mm, 3.00x12 mm, 3.50x12 mm, and 4.00x12 mm. The Excedo IVF is compatible with a 6F guiding catheter and extensions, has a working length of 138 cm, and shaft depth markers at the proximal end. The catheter is coated with hydrophilic coating to 22.75 cm from the distal tip to reduce friction during device delivery. Refer to Figure 1 below for the Venex Pulse IVLCatheter components.

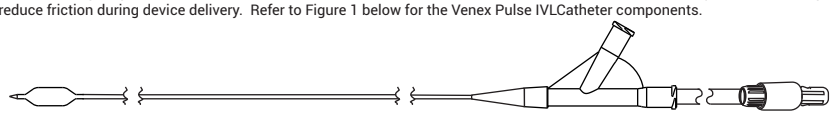

Figure 1: Venex Pulse IVLCatheter

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" (0.36 mm) guidewire to facilitate advancement of the catheter to and through the target stenosis. The system is designed as "Rapid Exchange" (Rx), so a length (190 cm – 300 cm) guidewire is indicated. The emitters are positioned along the length of the balloon working length for delivery of lithotripsy therapy. The balloon is located near the distal tip of the catheter. Two radiopaque marker bands within the balloon denote the working 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 two ports: one for inflation/deflation of the balloon and one for the connection to the IVL Connector Cable.

Intended use of Device:

The Venex Pulse IVL catheter System is intended for use as an Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting. This system is designed to facilitate the treatment of calcified stenosis that are resistant to full balloon dilation or uniform coronary stent expansion.

Indications for Use

The Venex Pulse IVL catheter system with generator is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting This system are designed to facilitate the treatment of calcified stenosis that are resistant to full balloon dilation or uniform coronary stent expansion.

Contraindications for Use

The Venex Pulse IVLCatheter System is contraindicated for the following:
1. This device is not intended for stent delivery.
2. This device is not intended for use in carotid or cerebrovascular arteries.

Warnings

1. Physicians must read and understand these instructions prior to use the device. Failure to abide by the warnings in this labeling might result in damage to the device hydrophilic coating.
2. Do not use a device past the expiration date on the label. Use of expired products may result in patient injury.
3. Use the IVL Generator in accordance with recommended settings as stated in the IVL Generator Operator's Manual. DO NOT deviate from recommended settings as this may cause patient injury.
4. IVL Connector Cable is non-sterile and must be enclosed in a sterile sleeve prior to and during use.
5. Inspect all product components and packaging prior to use. Do not use the device if the device or the packaging has been damaged or if sterility has been compromised. Damaged products could result in patient injury.
6. Do not use the device if the balloon protective sheath cannot be removed easily prior to use. If excessive force is used, the catheter could be damaged. Damaged products could result in patient injury.
7. Ensure that the IVL Catheter is used with a 0.014" (0.36 mm) guidewire and is inserted through a 6F guiding catheter at least 0.068" (1.72 mm) ID. Failure to do so could result in inadequate device performance or patient injury
8. If an inability to inflate or maintain balloon pressure occurs, remove the catheter and use a new device.
9. Do not use excessive force or torque on the catheter as this could result in damage to the device components and result in patient injury.
10. The risk of dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available.
11. Balloon loss of pressure was observed in 6.3% of patients in the clinical trial that were treated with the currently marketed product and was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure.
12. Treat patients per standard medication or interventional procedures in the event of complications associated with the procedure or device.
13. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy. In the CAD III study, there were no serious adverse events associated with IVL-induced capture including arrhythmia.

Precautions

1. This device should only be used by physicians trained in angiography and intravascular coronary procedures.
2. For preparation, operation, warnings and precautions, and maintenance of the IVL Generator and its accessories, refer to the IVL Generator Operator's Manual.
3. The catheter is intended for single (one) time use only. DO NOT re-sterilize and/or reuse. If a second catheter of the same size is necessary, DO NOT re-use the first catheter. Discard it before preparing the second catheter.
4. Use only an appropriately sized balloon for the vessel to be treated: 1:1 based on balloon compliance chart and reference vessel diameter. The largest diameter balloon should be used if 1:1 size is not available (such as, using a 4.0 mm IVL Catheter in a vessel with a reference diameter of 4.5 mm).
5. Inflate the balloon according to the balloon compliance chart. Balloon pressure should not exceed the rated burst pressure (RBP).
6. Use only the recommended 50/50 contrast/saline medium to inflate the balloon to ensure adequate lithotripsy delivery.
7. If the surface of the IVL Catheter becomes dry, wetting with normal saline will reactivate the hydrophilic coating. Wetting the catheter with solvents other than saline can compromise the coating integrity or performance.
8. Perform all device manipulations under adequate fluoroscopic guidance.
9. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met, determine the cause of the resistance before proceeding.
10. Care must be taken when manipulating, advancing and/or withdrawing the device past sharp objects as it may damage the hydrophilic coating.
11. Do not use or attempt to straighten a catheter if the shaft has become bent or kinked. Instead, prepare a new catheter.
12. During the procedure, appropriate antiplatelet/anticoagulant therapy must be provided to the patient as needed. Antiplatelet/anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.
13. Emitter proximity to balloons may increase the incidence of balloon loss of pressure. Ensure adequate balloon expansion prior to delivering.
14. lithotripsy and consider anatomical restrictions that may place the emitter too close to the balloon material.
15. If the IVL Catheter appears not to deliver lithotripsy therapy, remove and replace it with another catheter.
16. Precautions should be taken when handling the device after exposure to patients, e.g. contact with blood. Used products are considered biohazardous material and should be disposed of properly as per the hospital protocol.
17. Precautions should be taken when treating patients with previous stenting within 5 mm of target lesion.

Adverse Effects

Potential adverse effects are consistent with standard catheter-based cardiac interventions and include, but are not limited to, the following:
Abrupt vessel closure
Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy
Aneurysm
Arrhythmia
Arteriovenous fistula
Bleeding complications
Cardiac tamponade or pericardial effusion
Cardiopulmonary arrest
Cerebrovascular accident (CVA)
Coronary artery/vessel occlusion, perforation, rupture or dissection
Coronary artery spasm • Death
Emboli (air, tissue, thrombus or atherosclerotic emboli)
Emergency or non-emergency coronary artery bypass surgery
Emergency or non-emergency percutaneous coronary intervention
Entry site complications
Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention
Hematoma at the vascular access site(s)
Hemorrhage
Hypertension/ Hypotension
Infection/sepsis/fever
Myocardial Infarction
Myocardial Ischemia or unstable angina
Pain
Peripheral Ischemia
Pseudoaneurysm
Renal failure/insufficiency
Restenosis of the treated coronary artery leading to revascularization
/pulmonary edema
Slow flow, no reflow, or abrupt closure of coronary artery
Stroke
Thrombus
Vessel closure, abrupt
Vessel injury requiring surgical repair
Vessel dissection, perforation, rupture, or spasm

In addition, patients may be exposed to other risks associated with coronary interventional procedures, including risks from conscious sedation and local anesthetic, the radiographic contrast agents used during angiography, the drugs given to manage the subject during the procedure, and the radiation exposure from fluoroscopy.

Risks identified as related to the device and its use:

Allergic/immunologic reaction to the catheter material(s) or coating
Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention
Atrial or ventricular extrasystole
Atrial or ventricular capture

with the predicted rates, including those with a PCI indication of non-ST-elevation MI (NSTE-ACS) and ST-elevation MI (STEMI). As previously noted, patients with these characteristics were excluded from the PAS Cohort.

How Supplied

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

Required Devices for the Coronary IVL Procedure

The IVL Catheter is to be used exclusively with the IVL Generator, IVL Connector Cable and its accessories. The IVL Connector Cable is a remote actuator which connects the IVL Generator to the IVL Catheter and is used to activate the lithotripsy therapy from the IVL Generator. Refer to the IVL Generator and IVL 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 Polymed.

6F guide catheter and extension(s)
0.014" (0.36 mm) Guide Wire (190 cm – 300 cm Length)
5"x96" (13x244 cm) minimum Sterile Sleeve Indeflator

Folded Balloon Diameters:
0.044" max. for 2.5 mm
0.045" max. for 3.0 mm and 3.5 mm
0.047" max. for 4.0 mm

Venex Pulse IVL Catheter Balloon Compliance Chart

Coronary IVL Catheter Balloon Compliance Chart Pressure	2.50x12mm	3.00x12mm	3.50x12mm	4.00x12mm
ATM - kPa	Ø (mm)	Ø (mm)	Ø (mm)	Ø (mm)
4-405	2.36	3.36	3.36	4.36
5-507	2.43	3.43	3.43	4.43
*6-608	2.50	3.50	3.50	4.50
7-709	2.55	3.55	3.55	4.55
8-811	2.60	3.60	3.60	4.60
9-912	2.65	3.65	3.65	4.65
**10-1013	2.70	3.70	3.70	4.70
11-1014	2.75	3.75	3.75	4.75
12-1016	2.80	3.80	3.80	4.80

Note: *Ø (mm) is ± 0.10 mm; 4 atm is IVL treatment balloon pressure
** 6 atm is nominal balloon pressure and post- treatment pressure
*** 10 atm is RBP (Rated Burst Pressure) of the balloon

Venex Pulse IVL catheter System 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. Insertion of any size Venex Pulse IVLcoronary Catheter will automatically program the IVL Generator with the following treatment sequence:

Treatment Frequency	1 Pulse per 1 Second
Maximum Number of Continuous Pulses (1 cycle)	10 Pulses
Minimum Pause Time	10 Seconds
Maximum Total Pulses Per Catheter	Displayed on generator

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 IVL Connector Cable Operator's Manual.

If the maximum pulse count is reached as displayed on the generator, 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 80 pulses in the same treatment segment.

Procedural Steps :
Caution: Refer to the IVL Generator and IVL 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 a guidewire and guide catheter.
3. Select a lithotripsy balloon catheter size that is 1:1 based on balloon compliance chart (above) and reference vessel diameter. The largest diameter balloon should be used if 1:1 sizing is not available (such as using a 4.0 mm IVL Catheter in a vessel with a reference diameter of 4.5 mm).
4. Remove the IVL Catheter from the package.
5. Prepare the lithotripsy balloon using standard technique. Fill a 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. Remove the protective sheath and shipping mandrel from the IVL Catheter. Warning: Do not use the device if the protective sheath or shipping mandrel are difficult to remove or cannot be removed.
8. Flush the guidewire port with saline.
9. Wet the lithotripsy balloon and distal shaft with sterile saline in order to activate the hydrophilic coating. Do not wet the balloon with Isopropyl alcohol (IPA) as this can damage the hydrophilic coating integrity.
10. Insert the IVL Connector Cable into the sterile sleeve or probe cover.
11. Remove the cap from the proximal end and attach the IVL Catheter Connector (see Fig 1) to the IVL Connector Cable.
12. Attach the other end of the same 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 balloon is dry and/or uninflated, as this may damage the balloon.

Delivering the Venex Pulse IVL Catheter to the Treatment Site
1. Position guiding catheter proximal to the treatment site.
2. If it is anticipated that the IVL Catheter may not cross the lesion, pre-dilatation or other vessel preparation may be performed using standard technique based on physician discretion.
3. Load the IVL Catheter over the exchange length (190 – 300 cm) 0.014" guidewire and through a guiding catheter and advance IVL Catheter to the treatment site.
4. Position the IVL balloon at the treatment site using the marker bands to aid in positioning.

Treating the Site with Intravascular Lithotripsy
1. Once the IVL Catheter is in place, record position using fluoroscopy.
2. If position is incorrect, adjust the lithotripsy balloon to the correct position.
3. Inflate lithotripsy balloon, not exceeding 4.0 atm to ensure the balloon is inflated and 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 treatment sequence for the pre-programed time of 10 seconds to deliver 10 pulses by pressing the therapy button on the IVL Connector Cable. NOTE: The IVL Generator is programmed to force a minimum pause time of 10 seconds following every 10 pulses delivered.
5. Inflate lithotripsy balloon to reference size per balloon compliance chart and record lesion response on fluoroscopy.
6. Deflate lithotripsy balloon and wait at least 10 seconds to re-establish blood flow. The balloon deflation time is up to 15 seconds, depending upon balloon volume.
7. Repeat steps 3, 4, 5, and 6 for additional treatment cycles until the lesion 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 lithotripsy balloon length, the recommended balloon overlap is at least 2 mm to prevent geographic miss. However, care must be taken not to exceed 80 pulses maximum in the same treatment segment and therefore 160 pulses in an overlap segment.
9. Perform a completion arteriogram to assess post intervention results.
10. Deflate the device and 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 IVL Catheter with sterile gauze.
12. Inspect all components to ensure that the IVL Catheter is intact. If a device malfunction occurs or any defects are noted on the inspection, flush the guidewire lumen and clean the outer surface of the catheter with saline, store the IVL Catheter in a sealed plastic bag, and contact Polymed . at customercare@polymedicure.com for further instructions.

Caution: IVL Catheter once pulled out of the body should not be reinserted for additional inflation or lithotripsy treatments. Balloons can be damaged in the process.

Patient Information :
Physicians should instruct patients to seek medical attention immediately for signs and symptoms of recurrent ischemic heart disease. There are no known limitations to normal daily activities. Patients should be instructed to comply with the medication regimen as prescribed by their physician.

Return of Devices :
If any portion of the IVL System fails prior to or during a procedure, discontinue use and contact with customer care Executive of the Polymed on customercare@polymedicure.com /Customer Care No : +91-129-4287053.

Cautions

See Instructions for use

REF — Product reference/Art. No.

For single use only

Do not Resterilize

Do not use if packaging or product has been damaged or contaminated

LOT — Batch Number

Date of Manufacturing

Use by / Expiry date

STERILE EO — Sterilised by Ethylene Oxide

Single sterile barrier system with protective packaging inside

Manufactured by

Non Pyrogenic

15°C – 25°C — Storage Condition

Keep Away from Sunlight

Keep Dry

MD — Medical Device

RBP — Do not Exceed Rated Burst Pressure

Balloon Outer Diameter

Balloon Length

Maximum Guidewire Diameter

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