INSTRUCTIONS FOR USE

Drug Eluting Balloon

Description:
The distal segment of the catheter incorporates a dual-lumen design, with one lumen intended for balloon inflation and deflation and the second lumen accommodating a 0.014 in (0.36 mm) guidewire to facilitate advancement of the catheter to and across the stenotic lesion. The proximal segment of the catheter consists of a single-lumen stainless steel hypo tube and is provided with a single female luer connector for attachment to a compatible inflation/deflation device. The balloon is equipped with two radiopaque marker bands to aid fluoroscopic visualization and accurate positioning within the target lesion, and additional reference markers are located on the proximal portion of the catheter shaft cm to indicate the exit of the distal catheter tip from the guide catheter. The balloon surface is coated with the active pharmaceutical ingredient Paclitaxel, incorporated into a drug-coating matrix on the balloon exterior, which enables localized drug transfer to the vessel wall upon balloon inflation when the coated surface comes into direct contact with the vascular tissue. The total amount of Paclitaxel delivered is dependent on the balloon diameter and length, with the coated portion of the balloon containing a nominal Paclitaxel surface density of 3 µg/mm².

Available	BALLOON LENGTH (MM)						
Balloon Diameter (mm)	10	15	20	25	30	35	40
1.50	✓	✓	✓	✓	✓	✓	✓
2.00	✓	✓	✓	✓	✓	✓	✓
2.25	✓	✓	✓	✓	✓	✓	✓
2.50	✓	✓	✓	✓	✓	✓	✓
2.75	✓	✓	✓	✓	✓	✓	✓
3.00	✓	✓	✓	✓	✓	✓	✓
3.50	✓	✓	✓	✓	✓	✓	✓
4.00	✓	✓	✓	✓	✓	✓	✓

Intended Purpose / Intended Use:
The Drug Eluting Balloon PTCA dilatation catheter is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial reperfusion in patients during a percutaneous coronary interventional (PCI) performed in a blood vessel.

Indications:
• Indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, including in-stent restenosis (ISR), for the purpose of improving myocardial reperfusion in de novo lesions and small vessels (SVD).
• Pre- and post-balloon dilatation during coronary stent procedures.

Contra-Indications:
The use of the balloon dilatation catheter is contraindicated for:
• Intolerance or allergy to Paclitaxel
• Unprotected left main coronary artery
• Coronary artery spasm in the absence of a significant stenosis
• Patients that are (potentially) pregnant

Patient Target Groups
The DEB PTCA Dilatation catheter is intended to be used in patients suffering from stenotic lesions in the coronary vascular system who require a PCI.

Intended User(s):
The target users are medical professionals (e.g. Interventional Cardiologists, cardiovascular technicians) who perform and assist in catheterization procedures in a clinical laboratory setting, during percutaneous intervention (e.g. PTCA, coronary stent placement).
Use of the product is restricted to healthcare professionals in an interventional suite with angiography equipment, with personnel with relevant and adequate training and who are familiar with the possible/conceivable complications.

Clinical Benefits:
Intended to provide effective balloon dilatation of the target lesion with simultaneous localized delivery of an antiproliferative drug to the vessel wall.
• May support inhibition of neointimal hyperplasia following percutaneous transluminal angioplasty.
• Designed to deliver the therapeutic agent without leaving a permanent implant in the vessel.
• Intended to preserve the native vessel anatomy and physiological vessel motion.
• May reduce the need for additional metallic stent implantation in suitable lesions.
• Intended to support vessel patency following the angioplasty procedure.
• Provides a treatment option for lesions where avoiding permanent implants may be clinically desirable.

Warnings:
For single patients, single procedure uses only. Do NOT resterilize and/or reuse as this can potentially result in compromised device performance and increased risk of inappropriate reserialization and cross contamination.
• To reduce the potential vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
• Drug eluting PTCA dilatation catheter in patients who are acceptable candidates for coronary artery bypass graft surgery requires careful consideration. This includes possible hemodynamic support during PTCA as treatment of this patient population carries special risk.
• When the balloon dilatation catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic guidance. 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.
• Balloon Pressure: do not exceed the rated burst pressure (RBP) indicated on the packaging. The rated burst pressure (RBP) is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure (RBP).
• Use of a pressure-monitoring device is recommended to prevent over pressurization.
• Drug eluting PTCA Dilatation Catheter should only be performed at hospitals where emergency coronary bypass surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
• Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
• Use the catheter prior to "Use Before" ("expiry") date specified on the package.
• Do not use it if packaging is damaged or unintentionally opened prior to use.
• Treatment of vessels with moderate or heavy lesion calcification is associated with decreased success rates up to 60-85% and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment and associated complications (<1%).
• Paclitaxel is in potential a genotoxic (in particular lactogenic) agent based upon its pharmacodynamic mechanism of action, which is interference with the microtubule disassembly. The relevance of this specific mechanism of genotoxicity for human carcino genity risk is currently not known.
• Breastfeeding should be withheld for at least 6 days after treatment.
• An incorrectly prepared balloon catheter may prolong the deflation time.
• Loss of vacuum or a continuous stream of air entering the syringe upon aspiration indicates the presence of a leak in the system (inspect the system for integrity).
• Do not torque the balloon catheter shaft.
• An incorrectly prepared balloon catheter may prolong the deflation time.
• Loss of vacuum or a continuous stream of air entering the syringe upon aspiration indicates the presence of a leak in the system (inspect the system for integrity).
• Do not torque the balloon catheter shaft.

Interactions with other drugs:
The total load of Paclitaxel is only a fraction of less than 0.03% of the volume generally applied in chemotherapies. The risk of interactions with other active agents is therefore high improbable. Nonetheless caution should be exercised when concurrently administering known CYP3A4 and/or CYP2C8 substrates (like cyclosporine, lovastatin, midazolam, ondansetron, terfenadine) or drugs with high PPB (like sulfonureas, coumarin type anti-coagulants, digitoxin, salicylic acid, sulfonamides) the specific instructions for use for these active agents should be consulted in addition.

Precautions
• Prior to angioplasty procedure, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it will be used.
• Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the catheter.
• Direct touching of the balloon, wiping of balloon surface or contact with organic solvents, e.g. alcohol, should be strictly avoided, since this can cause delamination of the balloon coating.
• During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

Potential complications and adverse effects
The following complications, among others, can occur by performing of a Percutaneous Transluminal Coronary Angioplasty
• Death • Acute myocardial infarction • Total occlusion of the coronary artery or bypass graft.
• Coronary vessel dissection, perforation, rupture or injury.
• Restenosis of the dilated vessel • Haemorrhage or haematoma.
• Unstable angina • Arrhythmias, including ventricular fibrillation
• Drug reactions, allergic reaction to contrast medium
• Hypo/hypertension • Infection • Coronary artery spasm • Arteriovenous fistula • Embolism

Pharmaceutical information on included drug
Minor traces of Paclitaxel in the blood plasma appear less relevant than for a systemic treatment. However, side effects cannot be completely ruled out
• Abnormal liver enzyme values
• Allergic or immunological reaction to the drug or similar agents
• Alopecia • Anaemia • Disorders of the heart conduction system

- Gastro-intestinal tract impairment
- Hematological dyscrasia (incl. leukotopenia, neutropenia, thrombocytopenia)
- Histological changes in the vascular wall, incl. inflammation, cell damage or necrosis
- Myalgia / arthralgia • Peripheral neuropathy • Pseudomembranous colitis

Prior to use inspection

Prior to use the balloon dilatation catheter in PTCA, all equipment to be used for the procedure, including the dilatation catheter should be carefully examined for defects. Examine the dilatation catheter for bends, kinks or other damage. Do not use any defective equipment. Prepare equipment to be used following manufacturer's instruction or standard procedure.

Preparation of the Dilatation catheter

Complete the following steps to prepare the catheter:
- Remove dilatation catheter from the package.
- Remove catheter from hoop.
- Remove protective sheath with the stylet from balloon catheter. Prepare an inflation device with the recommended contrast medium according to manufacturer's instruction. To evacuate air from the balloon segment, the following procedures should be followed.
- Fill a 10cc syringe with approximately 2cc 50/50-mixture contrast/saline.
- Connect the 10cc syringe to the balloon dilatation catheter, hold the nozzle downwards and pull the plunger to create negative pressure (hold this for at least 15 seconds).
- Slowly release plunger to neutral (with nozzle of syringe pointed downwards), allowing contrast to fill the shaft of the balloon dilatation catheter.
- Disconnect syringe from balloon dilatation catheter and remove air out of syringe.
- Repeat the above points until no more bubbles appear in the syringe.
- Disconnect syringe from the balloon catheter and connect the inflation device, with a fluid-fluid connection, to the balloon catheter.
- Pull the plunger of the inflation device to create negative pressure

Insertion technique
- First advance the guiding catheter and connect to Y-connector (minimal 0.056" / 1.42 mm ID) and cross the stenosis with a 0.014"/ 0.36 mm (or smaller) guide wire according to the manufacturer's instructions.
- Wipe the extending guide wire with a sponge or gauze to remove residuals of blood or contrast.
- Load the guide wire into the distal tip of the balloon dilatation catheter guide wire lumen and ensure that the guide wire exits at the transition point 25 cm proximal of the distal tip.
- Advance the balloon dilatation catheter over the guide wire until it approaches the Y-connector.
- Loosen the valve of the Y-connector and insert the balloon dilatation catheter for minimal 30 cm while maintaining the guide wire position.
- Close the Y-connector to create a seal around the balloon dilatation catheter but ensure that movement is not restricted.
- Advance the balloon to the stenosis under fluoroscopy.
- Inflate the balloon while monitoring the inflation pressure, the balloon position, the ECG, blood pressure and other vital conditions of the patient.
- After dilatation of the stenosis deflates the balloon, check deflation under f luoroscopy.
- Pull the balloon dilatation catheter back, into guiding catheter, while maintaining the guide wire position.
- Perform a control angiography.
- Continue the procedure according to the accepted PTCA protocol.

Catheter exchange procedure:
- Loosen the hemostatic valve.
- Hold the guide wire and hemostatic valve in one hand, while holding the balloon shaft in the other hand. Maintain guide wire position in the coronary artery by holding the wire stationary and pull the balloon dilatation catheter out of the guiding catheter while monitoring wire position under fluoroscopy.
- Withdraw the deflated balloon dilatation catheter until the transition point in the guide wire lumen is reached. Carefully pull the flexible, distal portion of the balloon catheter out of the haemostatic valve while maintaining the guide wire position across the lesion.
- Prepare the next balloon catheter to be used, as previously described
- Backload the new balloon catheter onto the guide wire as previously described and continue the procedure accordingly.

DISCLAIMER OF WARRANTY:

NOTE: Although the catheter, thereafter referred to as "product", has been manufactured under carefully controlled conditions, polymed and its affiliates has no control over conditions under which this product is used. Polymed and its affiliates, therefore, disclaims all warranties, both expressed and implied, with respect to the product, including, but not limited to, any implied warranty of merchant/ability or fitness for a particular purpose. Polymed and its affiliates shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind polymed and it's affiliated to any representation or warranty with respect to the product.

REFERENCES:

The physician should consult recent literature on current medical practice on balloon dilatation, such as published by American College of Cardiology/American Heart Association. The exclusion and limitations set out above are not intended to and should not be construed to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court or competent jurisdiction, the validity of the remaining portions of this disclaimer of warranty shall not be affected.

Reg No. under Rule-13(2) of PWM Rules:
BO-04-000-12-AAACP3891P-24

POLY MEDICURE LTD.
Plot No. 33-34, Sector 68, IMT, Faridabad,
Haryana-121004, India,
Web : www.polymedicure.com,
Contact customer care executive: +91-129-4287053,
Email: customercare@polymedicure.com,
Address: Same as above


Cautions


See Instructions for use


Product reference/Art. No.


For single use only


Do not Resterilize


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


Batch Number


Date of Manufacturing


Use by / Expiry date


Sterilised by Ethylene Oxide


Double Sterile Barrier System


Manufactured by


Non Pyrogenic

Storage Condition


Keep Away from Sunlight


Keep Dry


Medical Devices


Unique Device Identifier


Do not use If package (Sterile barrier system) is damaged and check IFU

Rev. 00-25/12