INSTRUCTIONS FOR USE

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PTCA Balloon Dilatation Catheter

DESCRIPTION:
The Rapid Exchange Balloon Dilatation Catheter is a Percutaneous Transluminal Coronary Angioplasty (PTCA) Rapid Exchange system. The distal section of this catheter consists of a balloon and dual lumen shafts (co-axial). The outer lumen is used for inflation and deflation of the balloon with contrast medium diluted with saline solution. The inner lumen (the guidewire lumen; from the distal tip to the guidewire port) is for inserting a compatible guidewire to facilitate advancing the catheter through the stenotic lesion or stent to be dilated. The proximal section is a single lumen shaft with a single luer port hub for connecting an inflation/deflation device. Inside the balloon, two radiopaque markers which indicate the working length of the balloon, are placed to guide the physician for positioning the balloon properly in the targeted lesion under fluoroscopy. POLYMED PTCA Balloon Dilatation Catheter is available in various balloon sizes by its diameter and length at recommended inflation pressures (Nominal pressure). Upon inflation, the balloon diameter varies according to the inflating pressure. The balloon compliance chart for PTCA Balloon Dilatation Catheter is provided at the end of this Instructions for Use. In the sterilization package, the device is equipped with protective materials: a balloon protective tube and a stylet, which are to be removed before use. The catheter's distal tip is tapered to facilitate advancing into the stenotic lesion or stent. The catheter's outer surface is partially coated with hydrophilic polymer to generate lubricity when wet.

INTENDED PURPOSE:
PTCA Balloon Dilatation Catheter intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.

INDICATIONS:
PTCA Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion in the coronary artery or bypass graft stenosis for the purpose of myocardial perfusion. This product is also indicated for the post-delivery expansion of balloon expandable stents.
INTENDED USER:
Qualified healthcare professionals (Cardiologists, Surgeon, or doctors who specialize in the heart, especially for coronary artery angioplasty).

PATIENT TARGET POPULATION:
Patients suffering with hemodynamically significant coronary artery or require bypass graft stenosis.

CONTRAINDICATIONS:
The use of the PTCA Balloon Dilatation Catheter is contraindicated in the following patient type:
Patients with an unprotected left main coronary artery.
Patients with coronary artery spasm in the absence of a significant stenosis

LIMITATION OF DEVICE:
Use of PTCA Balloon Dilatation Catheter limited to PTCA procedure only.

USE ENVIRONMENT: Hospital/Cath. Laboratory

INFORMATION ON MEDICAL DEVICE INTENDED TO BE USED WITH OTHER DEVICES:
PTCA Balloon Dilatation Catheter designed to be used with:
Guidewire
Pressure device
Extension line
Flushing Cannula
Re-Collapse Device
Re-use Clip
Guiding catheter
Y- connector, Guidewire,
Torque device,

EXPECTED CLINICAL BENEFITS:
The clinical benefits derived from PTCA Balloon Dilatation Catheter are achieved indirectly. The device itself helps in the balloon dilatation of the stenotic portion in the coronary artery or bypass graft stenosis for the purpose of myocardial perfusion.

RISKS ASSOCIATED WITH RE-USE:
Cross contamination/infection, device will not function as per intended use.

STORAGE AND HANDLING CONDITION: Store in between 15°C to 25 °C and protect from excessive heat, direct sunlight, and moisture.

Reporting of Incident to Manufacturer & Regulatory Authority: For providing feedback on this product write to customercare@polymedicure.com

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WARNINGS
- For single patients, single procedure use only.
- Do not resterilize
- Do not use the catheter if its package has been opened or damaged.
- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum as this can potentially result in damage to the vessel wall. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure indicated on the package label for each balloon. The rated burst pressure is based on the results of in vitro testing. Use of a pressure monitoring device is recommended to prevent over pressurization.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium. To prevent the possibility of an air embolus, never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use By" date (Expiration Date) specified on the package.

PRECAUTIONS
The compatablity of the device has not been evaluated for the delivery of materials (e.g alcohol or nitroglycerine, stem cells etc.) through the guidewire lumen other than those required for normal use.
- If the device is kinked, it should not be used.
- The catheter system should be used only by physicians trained in the performance of percutaneous translumninal coronary angioplasty.
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the procedure for which it is to be used.
- Appropriate anticoagulation, antiplatelet and vasodilator therapy should be administered to the patient.
- When using two guidewires, care should be taken when introducing, torquing, and removing one or both guidewires to avoid entanglement. It is recommended that one guidewire be completely withdrawn from the patient before removing any additional equipment.
- Care should be taken not to apply excessive force during preparation or use, as this may damage the device.

ADVERSE EVENTS
Possible adverse effects include, but are not limited to the following:
- Acute myocardial infarction
- Total occlusion of the coronary artery or bypass graft
- Restenosis of the dilated vessel
- Hemorrhage or hematoma
- Arrhythmias, including ventricular fibrillation.
- Drug reactions, allergic reaction to contrast medium.
- Hypo/hypertension
- Death
- Infection
- Coronary artery spasm
- Coronary vessel dissection, perforation, rupture, or injury
- Arteriovenous fistula
- Embolism
- Unstable angina

DIRECTION FOR USE
These directions are general guidelines intended for use by qualified healthcare professionals. Any instructions, indications and contraindications given are not exhaustive and it is the clinician's responsibility to ensure safe, correct use of this product considering medical conditions of the patient

1) PREPARATION
a. Select an appropriate balloon catheter for the target vessel.
b. Remove the device from the sterile packaging.

NOTE: This device allows the guidewire lumen to be flushed in two formats:
1) With device contained within its hoop (Ref. In-Hoop Flushing section).
2) With device removed from its hoop.
b.1 Remove the balloon protector (III) from around the balloon. Removing the balloon protector will also remove the balloon stylette.

NOTE: Do not discard the balloon stylette until the end of the angioplasty procedure as it may be required for balloon refolding.
b.2 Fill a 20cc syringe with 20cc of a saline solution.
b.3 Remove the flushing cannula (V) from the accessiories pouch (III) and, without removing the cover, attach directly to the syringe.
b.4 Remove the cover of the flushing cannula holder leaving the flushing cannula attached to the syringe.
b.5 Insert the flushing cannula into the guidewire entry port (exchange joint).
b.6 Depress the syringe to flush the guidewire lumen until fluid emerges from the tip (distal end of the balloon catheter).
b.7 Remove the flushing cannula from the guidewire entry port (exchange joint).

NOTE: Do not discard the flushing cannula until the end of the angioplasty procedure as additional flushing may be required.

2) BALLOON PURGING
Purge air from the catheter using a 20cc syringe filled with 2 to 3cc of the inflation medium with the balloon catheter pointing downward. Attach an inflation device to the balloon inflation port. Ensure that a meniscus of contrast medium is evident in both the catheter luer connector and the inflation device. Apply negative pressure with the inflation device. A flow of bubbles will move the balloon catheter into the inflation device. Balloon purging is complete when the flow of bubbles stops. Do not attempt Pre-inflation technique to purge the balloon lumen.

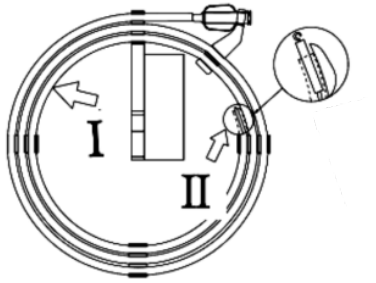
3) INSERTION TECHNIQUE
a. Place the guidewire catheter, with a hemostasis valve attached, in the orifice of the target coronary artery.
b. Advance a guidewire through the guiding catheter to reach and cross the target lesion. Advance the distal tip of the balloon catheter over the proximal end of the guidewire. Ensure that the guidewire exits the balloon catheter through the guidewire exit port(exchange joint).
c. The hemostasis valve should be gradually tightened to control back flow. Excessive valve tightening may affect balloon inflation/deflation time as well as movement of the guidewire.
d. Track the balloon catheter over the wire to cross the lesion using the radiopaque marker (s) to relocate the balloon across the lesion.

4) BALLOON INFLATION
a. Inflate the balloon to dilate the lesion using standard PTCA techniques.
b. After each subsequent inflation, the distal blood flow should be assessed.
c. If a significant stenosis persists, successive inflations may be required to resolve the stenosis. Do not exceed the rated burst pressure (see labeling).
d. Confirm the results with fluoroscopy.

5) REMOVING THE CATHETER
a. Apply negative pressure to the inflation device and confirm that the balloon is fully deflated.
b. Withdraw the balloon catheter into the guiding catheter while preserving guidewire postion and adjusting the hemostasis valve appropraitely. Remove the ballloon catheter from the system.
c. After the deflated balloon catheter is withdrawn, it should be wiped clean with gauze soaked with sterile normal saline.
d. Inspect the balloon catheter integrity.
e. If reinserting the same balloon catheter, flush the guidewire lumen by using the flushing cannula to flush saline through the guidewire entry port (exchange joint) until fluid emerges from the tip (distal end of the balloon catheter). Prior to reinsertion, the balloon catheter should be wiped clean with gauze soaked with sterile normal saline. The balloon may be refolded using the Re-collapse Device as described in the Re-Collapse Device Instruction for use.

NOTE: Do not discard the balloon stylette until the end of the angioplasty procedure as it may be required for balloon refolding.

IN-HOOP FLUSHING:
The in-hoop flushing cannula (V) enables the guidewire lumen to be flushed without removing the catheter from its packaging hoop



INSTRUCTION FOR USE:
1. With the balloon catheter contained within its hoop (I).
2. Remove the balloon protector (III) from around the balloon. Removing the balloon protector will also remove the balloon stylette.

NOTE: Do not discard the balloon stylette until the end of the angioplasty procedure as it may be required for balloon refolding.
3. Fill a 20cc syringe with 20cc of a saline solution.
4. Remove the flushing cannula from the accessories pouch (III) and, without removing the

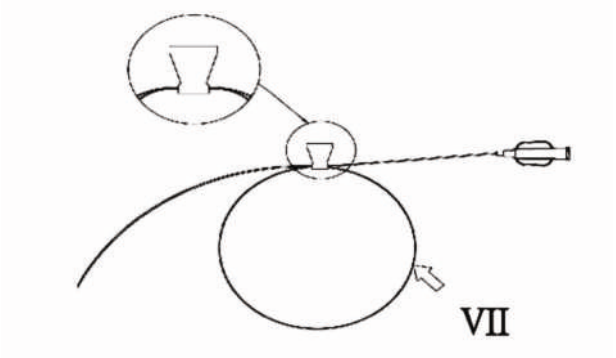
cover, attach directly to the syringe.
5. Remove the cover of the flushing cannula holder leaving the flushing cannula attached to the syringe.
6. Insert the flushing cannula into the tip (distal end of the balloon catheter).
7. Depress the syringe to flush the guidewire lumen, until fluid emerges from the guidewire entry port (exchange joint). Droplets will be visible in the hoop.
8. Remove the flushing cannula from the distal tip of the balloon.

RE-COLLAPSE DEVICE:
This Re-Collapse Device (VI) is an accessory component that allows the balloon to be re-folded if required.

Instruction for use:
1) Deflate the balloon by applying negative pressure to the inflation device and maintain under vacuum.
2) Visually inspect the balloon to confirm that it is fully deflated.
3) Remove the Re-Collapse Device from the accessories pouch (III).
4) Ensure the balloon protector is not on the balloon stylette and load the non-flared end of the Re-Collapse Device onto the straight end of the stylette.
5) Carefully load the stylette back through the diatal tip of the catheter and past the proximal end of the balloon.
6) While holding the catheter just proximal to the balloon, push the re-fold device over the balloon in a gentle twisting motion until the entire balloon is covered.
7) Gently remove the Re-Collapse Device and stylette.
8) Inspect the balloon for any potential damage. Discard the balloon catheter if there is any visible damage present on the balloon.

Re-use Clip:
The Re-use Clip (IV) from the accessiores component for use with Polymed Rapid Exchange balloon catheters. The device allows the catheter to be fastened in a coiled configuration for ease of handling during use.

Instruction for use:
1. Remove the Re-use Clip from the accessiores pouch (III).
2. Form the catheter into a single or double loop when required.
3. Press down the wings of the Re-use Clip to open the clipping section for retention of the hypotube (VII).
4. Release the wings of the Re-use Clip with the hypotube inside the clipping section to secure the catheter in a coiled configuration.



DISCLAIMER OF WARRANTY:

NOTE: Although the catheter, thereafter refered 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 its 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.

Table 1: Semi-compliant PTCA Balloon Dilatation Catheter

Inflation pressure		Balloon diameter											
kPa	(atm)	1.25 mm	1.50 mm	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm
405	4	1.18	1.42	1.91	2.18	2.41	2.66	2.91	3.15	3.42	3.63	3.88
507	5	1.20	1.46	1.95	2.22	2.45	2.71	2.96	3.21	3.46	3.68	3.94
608	6	1.23	1.51	1.99	2.26	2.49	2.77	3.02	3.26	3.53	3.73	4.02
709	7	1.25	1.55	2.03	2.3	2.53	2.81	3.07	3.31	3.58	3.78	4.07
811	8	1.26	1.59	2.07	2.34	2.57	2.85	3.12	3.37	3.63	3.82	4.12
912	9	1.28	1.63	2.11	2.38	2.61	2.89	3.17	3.41	3.68	3.87	4.18
1013	10	1.30	1.67	2.15	2.41	2.66	2.93	3.21	3.46	3.72	3.91	4.24
1115	11	1.32	1.71	2.19	2.45	2.70	2.97	3.26	3.51	3.77	3.96	4.30
1216	12	1.34	1.75	2.23	2.49	2.75	3.01	3.31	3.56	3.81	4.01	4.35
1317	13	1.36	1.79	2.27	2.53	2.79	3.05	3.36	3.60	3.86	4.06	4.41
1419	14	1.38	1.83	2.31	2.57	2.83	3.08	3.41	3.64	3.91	4.12	4.46
1520	15	1.40	1.88	2.35	2.61	2.88	3.13	3.45	3.69	3.95	4.17	4.51
1621	16	1.42	1.92	2.39	2.66	2.92	3.17	3.50	3.74	3.99	4.22	4.56
1723	17	1.45	1.96	2.43	2.70	2.96	3.21	3.54	3.78	4.04	4.26	4.61


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


Single sterile barrier system with protective packaging inside


Manufactured by


Non Pyrogenic

Storage Condition


Keep Away from Sunlight


Keep Dry

Medical Device

Do not Exceed Rated Burst Pressure


Balloon Outer Diameter


Balloon Length


Maximum Guidewire Diameter

POLYMED

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

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