INSTRUCTIONS FOR USE

3V PAULO

[Rapid Exchange Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter]

STERILE. Sterilized with ethylene oxide gas. Non pyrogenic. For one procedure only. Do not re-sterilize. Do not use opened or damaged packages. Destroy product after use. Store in a dry place 20°C to 40°C, keep away from light. Refer to accompanying Instructions for Use.

1. Description

The 3V PAULO Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter is a double lumen catheter with a balloon located near the distal tip. The distal shaft comprises two lumens, one is used for inflation of the balloon and the other permits the use of a guidewire (0.014"max.) to enable advancement of the catheter to and through the stenosis to be dilated.
A tip with a progressive flexibility has been placed at the distal part for a traumatic stenosis crossing. The balloon has two radio-opaque markers, proximal and distal, to aid the balloon positioning under fluoroscopy. The balloon material provides an expandable segment of known diameter at specific pressure. The distal part of the 3V PAULO benefits of a hydrophilic coating to facilitate access to the lesion site. The proximal shaft is made of a stainless steel hypotube. A clip is provided to facilitate the handling of the catheter; a needle is also included to flush it. Proximal visual markers located approximately 90 cm and 100 cm from the distal tip aid catheter positioning without fluoroscopy assistance.

2. Indications

The 3V PAULO PTCA Catheter is intended for use in the treatment of patients with clinical symptoms of myocardial ischemia related to the pathological condition of one or more coronary arteries. The 3V PAULO PTCA catheter is therefore indicated to dilate the diseased segment(s) in a coronary artery or a coronary bypass, to improve myocardial perfusion. The patients should fulfill one or more of the following criteria;

1. Patients must be judged to be acceptable candidates for coronary bypass surgery.
2. Patients with single vessel atherosclerotic lesion(s), non-calcified, subtotal and accessible to dilatation with guidewire and catheter.
3. Certain multi-vessel diseased patients may also be candidates for this procedure.
4. Certain patients, who have undergone previous coronary bypass surgery with recurrence of symptoms and progression of the disease in the coronary artery, or stenosis and closure of the grafts, may also be candidates.

3. Contra-indications

- Severe stenosis of the unprotected left main coronary artery.
- Patients who are judged not to be candidates for coronary artery bypass surgery.
- Patients with totally obstructed coronary arteries.
- Diffuse, multiple and calcified lesions.
- Arterial spasm.
- Possible or confirmed presence of thrombus inside the target vessel lumen.
- Patients presenting cardiogenic shock antecedent.

4. Warning

- The 3V PAULO PTCA catheter is designed and intended for single use. Check that the sterile pouch is not damaged before use. Do not re-sterilize or re-use, destroy product after use. Re-use & re-sterilization may compromise the device performance
- Use the product before the expiry date clearly shown on the packaging.
- PTCA procedures should only be performed in hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of potentially injurious or life threatening complications.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during the procedure, as treatment of this patient population carries special risk.
- When the PTCA balloon catheter is exposed to the vasculature, it should be manipulated while under high-quality fluoroscopic observation.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Use only diluted contrast medium to inflate the balloon. Do not use air or any gaseous medium.
- Do not attempt to inflate the balloon before it is correctly positioned on the level of the lesion to treat.
- To reduce the potential for damage in coronary vessels and to avoid any balloon rupture, the balloon inflation pressure should not exceed the rated burst pressure (RBP) (cf. compliance chart).
- Inflation of the balloon should be monitored by a manometer system.
- Do not attempt to reposition a fully or partially inflated balloon; it may result in severe vessel damage.
- Do not use, or try to straighten a bent or kinked catheter: not following these instructions could result in the shaft rupture. In case of defective product, use another catheter.
- The 3V PAULO PTCA catheter must be used in patients who have been exclusively appropriately prepared with an anti-coagulant or antiplatelet therapy.

5. Precautions for use

- These devices should be used only by physicians trained in PTCA and stent implantations. It is recommended to the physician to consult current peer- reviewed publications on the interventional cardiology techniques.
- Ensure that the medical team is trained on the products and their reference system to avoid any error in choosing equipment.
- Inspect the balloon prior to use for any kinks, curves or potential catheter damage, which could alter the catheters performances (see procedure for preparing the 3V PAULO as specified below).

6. Instructions for use

To verify the integrity, it is necessary during preliminary inflations tests to make sure that all the air is eliminated and that there is no leakage through any of the different connections (see procedure for preparing the 3V PAULO specified below).

A. Choice of the 3V PAULO PTCA Catheter

- The balloon diameter, when the balloon has been inflated to its nominal pressure should not be larger than the artery proximal and distal to the stenosis.

B. 3V PAULO Preparation

- Prepare the inflation device according to the manufacturer's instructions.
- Fill a 10 or 20 cc syringe with sterile saline solution.
- Attach the needle supplied with the 3V PAULO to the syringe and insert it into the distal tip of the 3V PAULO catheter.
- Then flush the guidewire lumen by gently applying pressure to the syringe.

- Prepare a diluted solution of contrast medium and sterile saline solution, in accordance with the contrast medium manufacturer's instructions.
- Fill a 10 or 20cc luer lock syringe with 1 to 3cc of the diluted contrast medium.
- Connect a stopcock to the hub of the 3V PAULO PTCA catheter.
- Connect the syringe to the stopcock.
- Position the syringe vertically with the plunger pointing upwards.
- Apply strong suction with the syringe to evacuate all air from the balloon.
- Maintain the suction for 15 to 20 seconds and make sure that no more bubbles are seen passing through the diluted contrast medium.
- Release the plunger carefully and, if necessary, repeat the procedure, in case of residual bubbles.
- Maintain the vacuum in the 3V PAULO PTCA catheter and close the stopcock
- Connect the inflation system, avoiding any bubble presence. Open the stopcock and inflate the balloon to its nominal pressure (see compliance table).
- Verify the integrity of the system.
- In case of defects, do not use the catheter.
- After inflation, apply negative pressure and close the stopcock.

C. 3V PAULO Coating

- The coaxial distal portion of the 3V PAULO is covered with a hydrophilic coating.
- Immerse the distal part of the catheter in a sterile saline solution before use.
- Do no reinsert in dispenser.

D. 3V PAULO Manipulation

- Attach the «Y» connector to the guiding catheter, which has been previously placed in the vasculature. The choice of the guidewire and the «Y» connector remains the responsibility of the physician within a compatibility limit of 0.014'' maximum for the guidewire.
- Insert the guidewire (0.014" max.) into the guiding catheter (5F, 0.058'' Internal Diameter minimum, except for 3V PAULO PTCA catheter 4.5 and 5.0 compatible with 6F, 0.070") and advance it through to the tip.
- To avoid any movement of the guidewire, tighten the knob of the «Y» connector so that it closes firmly around the guidewire.
- Back-load the guidewire into the distal tip of the 3V PAULO ensuring that it exits through the notch located approximately 25 cm proximal to the dilatation catheter tip.
- Open the valve and advance the 3V PAULO to the distal end of the guiding catheter.
- Two markers located on the proximal part of the shaft may be used to estimate when the 3V PAULO has reached the distal end of the guiding catheter (depending on whether the approach is brachial or femoral).
- The radio-opaque markers aid the positioning of the balloon in the stenosis.
- Continue the procedure according to accepted coronary angioplasty technique.

CAUTION: Always advance the 3V PAULO fully deflated and always on the guidewire.

NOTES

- It is recommended that the guidewire and/or the balloon catheter remain across the lesion until the procedure is complete.
- Contrast media have different viscosities and may affect the inflation/deflation time.

7. Catheter Exchange Procedure

- Loosen the «Y» connector.
- Hold the guidewire and the «Y» connector in one hand, while grasping the 3V PAULO balloon shaft in the other hand.
- Maintain the guidewire's position in the coronary artery by holding the wire stationary and begin pulling the 3V PAULO dilatation catheter out of the guiding catheter. Note: During this exchange, monitoring of the guidewire may be done under fluoroscopy.
- Pull the 3V PAULO catheter until the opening in the guidewire is reached, then proceed the same way as with an over the wire system.
- Prepare the next balloon catheter to be used as previously described.
- Back-load the new balloon onto the guidewire.
- Open the «Y» connector and advance the balloon catheter while holding the guidewire and maintaining its position in the coronary artery.
- Be careful not to twist, or rotate the 3V PAULO balloon catheter around the guidewire.

8. Complications

Possible complications linked to the use of the balloon catheter during the procedure;

- Dissection or perfusion of the coronary artery
- Injury or rupture of the coronary artery
- Total occlusion
- Thrombosis
- Arterial Spasm
- Ventricular fibrillation
- Disturbance of cardiac conductibility
- Embolism

These complications can directly result in the patient's death.

Possible complications that could occur following an angioplasty procedure with balloon, on short and medium term:

- Restenosis of the dilated artery
- Unstable angina
- Acute myocardial infarction
- Disturbance of cardiac conductibility
- Bleeding complications or hematoma
- These complications can directly result in the patient's death.

9. Storage Requirements

- Use before the expiry date clearly indicated on the label.
- Store at room temperature below 40°C, in a dry place, protected from light.

10. Warranty

S3V Vascular Technologies Pvt. Ltd. warrants that reasonable care has been used in the design and manufacture of this Device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this Device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond S3V Vascular Technologies control directly affect the Device and the results obtained from its use. S3V Vascular

Technologies obligation under this warranty is limited to the replacement of this Device and S3V Vascular Technologies shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this Device. S3V Vascular Technologies neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this Device. S3V Vascular Technologies assumes no liability with respect to Devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such Device.

11. Available Sizes

Length mm	Diameter in mm											
8	**1.5**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.25**	**3.50**	**3.75**	**4.00**	**4.50**	**5.00**
10	○	○	○	○	○	○	○	○	○	○	○	○
12	○	○	○	○	○	○	○	○	○	○	○	○
15	○	○	○	○	○	○	○	○	○	○	○	○
20	○	○	○	○	○	○	○	○	○	○	○	○
25	○	○	○	○	○	○	○	○	○	○	○	○
30	○	○	○	○	○	○	○	○	○	○	○	○

12. Balloon Compliance Chart

Pressure (Bar)	Balloon Diameter (mm)											
	1.50	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.25**	**3.50**	**3.75**	**4.00**	**4.50**	**5.00**
2	1.39	1.85	2.09	2.32	2.55	2.78	3.01	3.24	3.48	3.71	4.17	4.63
4	1.44	1.92	2.16	2.40	2.64	2.88	3.12	3.36	3.60	3.84	4.32	4.80
6*	**1.50**	**2.00**	**2.25**	**2.50**	**2.75**	**3.00**	**3.25**	**3.50**	**3.75**	**4.00**	**4.50**	**5.00**
8	1.54	2.05	2.31	2.56	2.82	3.07	3.33	3.58	3.84	4.09	4.60	5.12
10	1.57	2.09	2.35	2.61	2.87	3.13	3.39	3.65	3.91	4.17	4.69	5.22
12	1.59	2.12	2.39	2.65	2.92	3.18	3.45	3.71	3.98	4.24	4.77	5.30
14	1.62	2.16	2.43	2.70	2.97	3.24	3.51	3.78	**4.05**	**4.32**	**4.86**	**5.40**
16**	**1.65**	**2.20**	**2.48**	**2.75**	**3.03**	**3.30**	**3.58**	**3.85**	**4.13**	**4.40**	4.95	5.50
18	1.68	2.24	2.52	2.80	3.08	3.36	3.64	3.92	4.20	4.48	5.04	5.60

Nominal Pressure

****Rated burst pressure recommendation (RBP)***

From 4.00 - 20mm its 14 bar

13. Packaging

- Delivered in a peelable pouch and cardboard box. One unit per box.
- Sterilized with Ethylene Oxide.
- Non Pyrogenic

14. Conversion Chart

1 cc	1 mL		
1 French	0.0131”	0.33 mm	
1 bar	1.02 atm	14.5 PSI	10^8Pa

15. Symbols Meaning

Qty	Quantity per box
Ø	Diameter
↤↦	Length
	Single use
	Store protected from sun
	Store in a dry place
Ø	Min. guiding catheter internal diameter
Ø	Maximum guide wire diameter
	Temperature limitation
	Manufacturer
	Manufacturing Date
LOT	Lot Number
	Expiry Date

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