

TURQUOISE™ PTCA BALLOON DILATATION CATHETER

HYDROPHILIC COATED PTCA BALLOON DILATATION CATHETER

DEFINITION

ALVIMEDICA TURQUOISE™ PTCA Balloon Dilatation Catheter has been designed to dilate stenotic atherosclerotic lesions in coronary arteries or in bypass grafts. The dilating part of the catheter is the balloon near the distal tip. The catheter is hydrophilic coated excluding the effective length of the balloon and 45 cm of proximal shaft. There are radiopaque marker bands on both the proximal and distal shoulders of the balloon, while there is only one radiopaque marker in the middle section of the balloon for single marker ones. There is a separate lumen on the catheter shaft to be used as guidewire lumen starting at approximately 27 cm from the distal tip. The proximal tip of the catheter is used as the balloon inflating port. The balloon is inflated by injecting a contrast material from this tip. The balloon material is capable of reaching a certain size at a certain pressure.

INDICATIONS

TURQUOISE™ PTCA Balloon Dilatation Catheter is used to dilate the stenosis in the coronary artery or in bypass graft in order to increase myocardial perfusion.

- Patients should be eligible for coronary bypass surgery.
- It is indicated in patients with single-artery non-calcific atherosclerotic lesions that can be dilated by means of a PTCA catheter.
- This operation can also be indicated in certain patients who have multi-artery disease, and in patients who underwent aorta-coronary bypass surgery but still have,
 - recurrent symptoms,
 - progressive coronary artery disease,
 - stenosis or obstruction in bypass grafts.

CONTRAINDICATIONS

It is contraindicated in patients;

- who are not eligible for coronary bypass surgery,
- who have completely obstructed coronary arteries,
- who have diffuse lesions,
- who have severe stenosis of left main coronary artery.

WARNINGS / PRECAUTIONS

- TURQUOISE™ PTCA Balloon Dilatation Catheter has been designed for single-use and re-use is not recommended. Do not re-sterilize it.
- Keep the catheter in a cool, dry and dark place.
- Do not use the catheter after the expiry date printed on the package.
- Use diluted contrast material only.
- Do not use air or any other gas to inflate the balloon.
- Check the package for any damage.
- Do not exceed the rated burst pressure mentioned in Instructions for Use while inflating the balloon.
- It is recommended to use an inflating device with a built-in manometer.
- The diameter of inflated balloon should not exceed at the points just proximal and distal

to the stenosis.

- TURQUOISE™ PTCA Balloon Dilatation Catheter should only be used by experienced physicians who have been trained on PTCA operations.
- Give appropriate anticoagulation and vasodilatation therapy prior to catheterization.
- The PTCA operation should only be performed at centers capable of doing emergency coronary bypass surgery in case of severe complications.
- Do not tighten the hemostatic adapter in the Y-connector; otherwise it can compress the shaft thus impeding inflation and deflation of the balloon.
- All the operations after the catheter is introduced into the body should be performed under quality fluoroscopy. Never pull or push the catheter unless the balloon is completely deflated under vacuum. If you experience any resistance, just stop and try to identify the cause and advance the balloon catheter with short distance to prevent the occurrence of the kink on the proximal shaft. If you fail to identify, remove the system as whole.
- Do not use contrast materials Ethiodol and Lipiodol.
- Do not expose the insertion system to organic solvents (i.e. alcohol, etc.).

ADVERSE EFFECTS / COMPLICATIONS

- Dissection of coronary artery
- Tearing or perforation of, or damage to, coronary artery
- Complete obstruction of coronary artery or bypass graft
- Thrombosis of coronary artery
- Unstable angina
- Acute myocardial infarction
- Restenosis of dilated artery
- Spasm of coronary artery
- Arrhythmias, including ventricular fibrillation
- Hemorrhage and hematoma
- Drug reactions, allergic reaction to contrast material
- Hypertension - hypotension
- Infection
- Arteriovenous fistula
- Embolism
- Death
- Urgent coronary artery bypass graft surgery
- Dissection
- Perforation
- Ventricular fibrillation
- Renal failure
- Spasm
- Vascular thrombosis

PRE USE TESTING OF DILATATION CATHETER

To ensure the sterility of the catheter, it is crucial to check the package for any damage. It is also important to check if the catheter is the right type for the operation planned. To check the integrity of the catheter, inflate the balloon and after completely discharging the air, check if there is any leakage from the connections.

INSTRUCTIONS FOR USE

A. Selection of the right-size

It should be selected that the diameter of the balloon, when inflated at nominal pressure, will not exceed the coronary artery diameter at the points just proximal and distal to the stenosis.

B. Preparation

- Prepare a 1:1 mixture of contrast material and sterile saline solution as the inflation solution.
- Fill a 20 cc syringe with approximately 10 cc of saline solution.
- Put a needle on the syringe and carefully insert the needle through the distal tip of the catheter and rinse the guidewire lumen.
- Attach a stopcock to hub of the TURQUOISE™ PTCA Balloon Dilatation Catheter.
- Attach the syringe to the stopcock and hold the syringe vertically so that its piston is above. Pull the piston and remove all the air in the balloon.
- Apply vacuum with the syringe for 15-20 seconds and make sure that no air bubbles pass through the diluted contrast material.
- Carefully stop vacuuming.
- Repeat the process if necessary.
- Exert a negative pressure and then switch off the stopcock.
- Make sure that no air enters into the system; attach the inflating device to the catheter. Switch on the stopcock and inflate the balloon to nominal pressure and check the integrity of the TURQUOISE™ PTCA Balloon Dilatation Catheter.
- Exert a negative pressure and switch off the stopcock.

C. Insertion

- Attach Y-connector with a hemostatic valve to the guiding catheter already inserted in femoral artery.
- Pass the guidewire (maximum 0.014") through the guiding catheter, advance it and place it as desired.
- Gently tighten the hemostatic valve of the Y-connector onto the guidewire so as to prevent unintended movement of the guidewire.
- Insert the rear tip of the guidewire through the distal tip of the catheter and mount it to the catheter. The rear tip of the guidewire will come out at approximately 27 cm proximal to catheter's distal tip.
- Loosen the hemostatic valve of the Y connector and advance the TURQUOISE™ PTCA Balloon Dilatation Catheter towards the distal part of the guiding catheter. **WARNING:** Always advance the TURQUOISE™ PTCA Balloon Dilatation Catheter when it is deflated and is on the guidewire.
- Do not tighten the hemostatic valve of the Y-connector too much, as this may prevent the passage of the contrast material through the balloon inflation lumen, thus resulting in the prolongation of the deflation/inflation time of the balloon.
- Using the angioplasty techniques known, continue the operation under fluoroscopy. Radiopaque markers can help the balloon to be better positioned in the stenosis.
Note: It is recommended that the guidewire and/or balloon catheter

remain in the lesion until the completion of the dilatation operation. Variations in the viscosity of the contrast material may affect the deflation/inflation time.

D. Removal

- Loosen the hemostatic valve of the Y-connector.
- Hold the hemostatic valve and the guidewire with one hand and the catheter shaft with the other hand.
- While holding the guidewire immobile in order to keep its position in the coronary artery; remove the dilatation catheter out of the guiding catheter.

Note: During removal, check the position of the guidewire by fluoroscopy

- Switch on the hemostatic valve of the Y-connector.
- If necessary, prepare another TURQUOISE™ PTCA Balloon Dilatation Catheter and repeat the dilatation process.

TERMS OF WARRANTY

Alvimedica guarantees that each and every component of this product has been manufactured, packed, tested and sterilized without any defect regarding workmanship or material. Each product has been tested prior to packaging. Alvimedica shall exchange any product with defect(s) from manufacturing or packaging with a new one. Due to biological variations among individuals, no product is 100 % effective in every case. Therefore and since we have no control over the use of the product after sales, the selection of patients and the methods of application; Alvimedica does not guarantee that the outcome will be good enough. Alvimedica is not directly or indirectly responsible. For any injury or damage to or loss of the product resulting from the use of the product, nor is Alvimedica responsible for any injury, damage or loss that may result from re-use or re-sterilization.