Advocate™

PTA Catheter

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. FAILURE TO OBSERVE ALL WARNINGS AND PRE-CAUTIONS MAY RESULT IN COMPLICATIONS.

The balloon compliance table is available on the product hoop label. Balloon compliance is measured at 37°C (in vitro compliance). Information regarding compatibility with accessories is available on the product label. The Balloon Nominal Pressure (NP) and Rated Burst Pressure (RBP) are indicated on the label affixed to the inner package and on the packaging box. Do not exceed the RBP recommendation.

DEVICE DESCRIPTION

The Advocate Percutaneous Transluminal Angioplasty (PTA) Catheter Family are a non-reusable over the wire (OTW), semi-compliant, coaxial design catheter with a balloon mounted on its distal tip. The distal portion of the catheter has a hydrophilic coating.

The OTW coaxial shaft design has a balloon at the distal tip the catheter. The manifold connector consists of a Guidewire lumen, allowing the catheter to track over a guidewire, and an Inflation Port, used to inflate and deflate the balloon. The radiopaque markers are positioned on the shaft within the balloon to enable the visualisation of the catheter/balloon under fluoroscopy. The catheter is compatible with .035 inch (0.89 mm) wire guides.

The Advocate PTA Catheter Family includes multiple balloon sizes. Inscribed on the guidewire hub of the manifold are the nominal balloon diameter (mm) and the balloon length (mm). Consult the balloon compliance chart packaged with the device for the diameters of the balloons at given pressures. Pressures in excess of Rated Burst Pressure may cause the balloon to burst.

HOW SUPPLIED

Supplied sterilised by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light, organic solvents, ionizing radiation or ultraviolet light. Upon removal from package, inspect the product to ensure no damage has occurred. Non-pyrogenic.

INDICATIONS

The Advocate PTA catheter is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal, and renal arteries.

CONTRAINDICATIONS

The Advocate PTA Catheter is contraindicated for use in coronary arteries or the neurovascular, or when unable to cross the target lesion with a guidewire or for the expansion or delivery of stents

WARNINGS

- This device is supplied STERILE and is intended for single patient use. Reuse, reprocessing or resterilisation may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilisation may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- This device should only be used by physicians who are experienced and knowledgeable of the clinical and technical aspects of percutaneous transluminal angioplasty.
- To reduce the potential for vessel damage, the inflation diameter of the balloon should approximate the diameter of the vessel lumen at the intended inflation site.
- CAUTION: Do not exceed the Rated Burst Pressure (RBP). A pressure gauge is recommended to monitor pressure. Pressure in excess of the Rated Burst Pressure can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath.
- Never use air or any gaseous medium to inflate the balloon.
- When the catheter is exposed to the vascular system, it should be manipulated under high-quality fluoroscopic observation.
- Do not manipulate the balloon in an inflated state.
- Use the catheter prior to the expiration date specified on the package.
- The catheter is not recommended for pressure measurement or fluid injection.

PRECAUTIONS FOR USE

- To avoid kinking, advance the catheter slowly, in small increments until the proximal end of the guidewire emerges from the catheter.
- Dilation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- The device should be used with caution for procedures involving calcified lesions due to the abrasive nature of these lesions.
- Care should be taken not to over tighten haemostatic valve around the catheter shaft as constriction may occur affecting inflation/deflation of the balloon.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to device or lumen. Carefully withdraw the catheter.
- If resistance is felt upon removal, then the balloon, guidewire and the introducer sheath should be removed together as a unit, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and introducer sheath as a unit and withdrawing both together, using a gently twisting motion combined with traction.
- Before removing the catheter from the introducer sheath it is very important that the balloon is completely deflated.
- After use, eliminate the product according to safety requirements related to products contaminated by blood.

POTENTIAL ADVERSE EVENTS

The following complications may result from a balloon dilatation procedure, but may not be limited to:

- Air Embolism
- Aneurysm
- Arrhythmias
- Arteriovenous fistula
- Death
- Drug reactions, allergic reaction to contrast media
- Endocarditis
- Haematoma or Haemorrhage
- Hypotension
- Pyrogenic reaction
- Sepsis/infection
- Systemic Embolization
- Thromboembolic episodes
- Vascular thrombosis
- Vessel dissection, perforation, rupture or injury

SELECTION AND PREPARATION OF DEVICE

- Choose a balloon appropriate to lesion length and vessel diameter.
- Verify that the selected accessories accommodate the balloon catheter as labelled.
- Prior to use, carefully inspect the package and the catheter to verify no damage occurred during shipment.
- Remove the protective balloon sheath from balloon, and shipping mandrel from the device.
- Prepare balloon lumen with standard contrast-saline mixture as follows:
  - Prepare a mixture of contrast medium and normal saline as per standard procedure (1:1)
  - Attach a stopcock and a 20ml or larger syringe half filled with the contrast solution to the Inflation Port.
  - Point the syringe nozzle downward and aspirate until all air is removed from the balloon.
  - Turn the stopcock off and maintain the vacuum in the balloon.
- The Advocate Percutaneous Transluminal Angioplasty (PTA) Catheters are coated with a hydrophilic coating. Prior to inserting the catheter, activate the coating by immersing the catheter in normal saline for approximately 30-60 seconds, or wiping down the catheter with a saturated gauze sponge. CAUTION: Do no wipe down the catheter surface with dry gauze.

LOCATION INTRODUCTION AND INFLATION

- The Advocate PTA Catheter is designed to be introduced percutaneously using the Seldinger technique.
- Flush the Guidewire lumen labelled using heparinised saline solution.
- Apply negative pressure to Inflation Port lumen prior to introduction. Advance the balloon dilation catheter counter-clockwise over a pre-positioned 0.035 inch (0.89 mm) guidewire.
- Under fluoroscopy, advance the balloon to the lesion site. Carefully position the balloon across the lesion using both the distal and proximal radiopaque balloon markers.
- Inflate balloon to desired pressure. Adhere to recommended balloon inflation pressures (See Compliance Card).
- If difficulty is experienced during balloon inflation, do not continue; remove the catheter. Repeat inflation of the balloon (maximum 10 times), until desired result is achieved.
- If balloon pressure is lost and/or balloon rupture occurs, deflate balloon and remove balloon and introducer sheath as a unit.

BALLOON DEFLATION AND WITHDRAWAL

- Completely deflate the balloon using an inflation device or syringe. Apply negative pressure to the balloon for approximately 60-120 seconds. Allow adequate time for the balloon to deflate.
  NOTE: Balloons with large diameters and/or longer lengths may require longer deflation times. The larger the syringe diameter, the greater the suction that is applied. For Maximum deflation a 50ml syringe is recommended. Deflate the balloon by pulling vacuum on the inflation syringe or inflation device.
- Maintain vacuum on the balloon and withdraw the catheter. As the balloon is withdrawn from the vessel, use a smooth, gentle, steady, clockwise motion. If resistance is felt upon removal then the balloon and the sheath should be removed together as a unit under fluoroscopic guidance, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

AraVasc has exercised reasonable care in the manufacture of this device. AraVasc excludes all warranties, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device as well as factors relating to the patient, the diagnosis, treatment, surgical procedures, and other matters beyond AraVasc control directly affect this device and the results obtained from its use. AraVasc shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this device. AraVasc neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

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Pressure (atm / kPa)	3.0mm	4.0mm	5.0mm	6.0mm	7.0mm
8 / 811 *	3.00	4.00	5.00	6.00	7.00
10 / 1013	3.05	4.06	5.08	6.11	7.14
12 / 1216	3.09	4.12	5.16	6.23	**7.29**
14 / 1419	3.14	4.18	5.25	**6.36**	
16 / 1621	**3.19**	**4.25**	**5.34**		

Pressure (atm / kPa)	8.0mm	9.0mm	10.0mm	12.0mm
8 / 811 *	8.00	9.00	10.00	12.00
10 / 1013	8.17	9.18	10.20	12.36
12 / 1216	**8.35**	**9.38**	**10.46**	
14 / 1419				
16 / 1621				

* Nominal Pressure

Rated Burst Pressure - Rated Burst Pressure is based on the results of in-vitro testing. The Rated Burst Pressure is the pressure at which 99.9% of balloons can survive with 95% confidence.

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