

**WARNINGs**

- Avoid extended exposure to light, organic solvents, ionizing radiation, and RF fields.
- Intended for one-time use. Sterile if package is unopened or undamaged.
- Consult the balloon compliance chart packaged with the device before inflating the balloon. Use the guide pressure as a starting point and increase or decrease it based on the clinical condition of the patient.

**CONTRAINDICATIONS**

- The Advocate PTA catheter is intended for balloon dilation of the vascular lesion with a guidewire or for the expansion or delivery of stents only.
- Avoid percutaneous transmural coronary angioplasty (PTCA) and stenting procedures.
- It is not recommended for pressure measurement or as a pressure transducer.
- The Advocate PTA catheter is not recommended for pressure measurement or as a pressure transducer.

**DEVICE DESCRIPTION**

- The Advocate PTA catheter is a compliant, coaxial design catheter with a balloon mounted on a polyethylene manifold connector. The manifold connector consists of a Guidewire lumen, an Introducer Sheath lumen, and an Inflation Port lumen. A marker band is placed at 5.0 cm from the distal end of the catheter. The catheter is compatible with .035 inch (0.89 mm) wire guides.

**USE**

- Under fluoroscopy, advance the balloon to the lesion site. Carefully position the balloon across the lesion using both the inflation and deflation lumen to advance the balloon over the guidewire. Under fluoroscopic guidance, advance the balloon over the guidewire to the lesion site. Then, carefully position the balloon across the lesion using both inflation and deflation lumen to advance the balloon over the guidewire. Use a 20 ml syringe to inflate the balloon to an initial pressure of approximately 60-120 seconds. Allow adequate time for the inflation to occur. If balloon pressure is lost and/or balloon rupture occurs, continued inflation may result in complications.

**INFLATION**

- Calculate the inflation pressure required based on the lesion length and vessel diameter. The catheter is compatible with .035 inch (0.89 mm) wire guides.
- Choose a balloon appropriate to lesion length and vessel diameter.
- Inflate balloon to desired pressure. Adhere to recommended balloon inflation pressures (See Compliance Card).
- Inflation is recommended in agreement with the results of the manometry pressure test. Balloon inflation pressures are presented in Table 1.

**INFLATION PRESSURE**

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**MAXIMUM INFLATION PRESSURE**

- Inflation pressures may require longer deflation times. The larger the syringe size, the longer the deflation time.
- Maximum deflation a 50ml syringe is recommended.

**DEFLEATION**

- Maximum deflation a 50ml syringe is recommended.
- If balloon pressure is lost and/or balloon rupture occurs, continued inflation may result in complications.
- Balloons with large diameters and/or longer lengths may require longer deflation times.

**AFTER USE**

- After use, eliminate the product according to safety measures. Before removing the catheter from the introducer sheath, it is recommended to grasp the catheter firmly using a gently twisting motion. This may be accomplished by firmly grasping the catheter around the catheter shaft as constriction may occur affecting the catheter in normal saline for approximately 30-60 seconds, followed by the use of the gauze.

**REUSE / RESTERILIZATION**

- Catheters are coated with a hydrophilic coating. Prior to use, carefully inspect the package and the catheter to ensure that the coating is intact. The coating is not recommended for pressure measurement or as a pressure transducer.
- The catheter is not recommended for pressure measurement or as a pressure transducer.

**GENERAL CONSIDERATIONS**

- The Advocate PTA catheter is a compliant, coaxial design catheter with a balloon mounted on a polyethylene manifold connector. The manifold connector consists of a Guidewire lumen, an Introducer Sheath lumen, and an Inflation Port lumen. A marker band is placed at 5.0 cm from the distal end of the catheter. The catheter is compatible with .035 inch (0.89 mm) wire guides.
- It is not recommended for pressure measurement or as a pressure transducer.

**RATED BURST PRESSURE**

- Rated Burst Pressure is based on the results of in-vitro testing. The results of the manometry pressure test are presented in Table 1.

**REFERENCES**

- The Advocate PTA catheter is a compliant, coaxial design catheter with a balloon mounted on a polyethylene manifold connector. The manifold connector consists of a Guidewire lumen, an Introducer Sheath lumen, and an Inflation Port lumen. A marker band is placed at 5.0 cm from the distal end of the catheter. The catheter is compatible with .035 inch (0.89 mm) wire guides.
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**ADDITIONAL CONSIDERATIONS**

- The Advocate PTA catheter is a compliant, coaxial design catheter with a balloon mounted on a polyethylene manifold connector. The manifold connector consists of a Guidewire lumen, an Introducer Sheath lumen, and an Inflation Port lumen. A marker band is placed at 5.0 cm from the distal end of the catheter. The catheter is compatible with .035 inch (0.89 mm) wire guides. The manometry pressure test results are presented in Table 1.