## SELECTION AND PREPARATION OF DEVICE

To select the appropriate size, consult the balloon compliance chart packaged with the device. The balloon compliance chart is available in the device package. The list below identifies the catheter sizes available in the device package. The diameter of the balloon should approximate the diameter of the vessel lumen at the intended inflation site.

- **7.16 mm**
- **8.0 mm**
- **9.2 mm**
- **9.0 mm**

**INDICATIONS:**

- PTA procedures for arterial stenoses
- Aneurysm necks
- Vascular thrombosis
- Balloon-assisted angioplasty
- Arteriovenous fistula
- Thromboembolic episodes

**CONTRAINDICATIONS:**

- Drug reactions
- Allergic reaction to contrast media
- Prior to use, carefully inspect the package and the catheter for any evident damage. Non-radiation or ultraviolet light. Upon removal from package, avoid extended exposure to light, organic solvents, or wiping down the catheter with a saturated gauze sponge.

**PRECAUTIONS FOR USE:**

- Intended for one-time use. Sterile if package is unopened or unused. DO NOT ATTEMPT TO RESTERILIZE.
- Under fluoroscopy, advance the balloon to the lesion site. Verify that the selected accessories accommodate the diameter of the balloon.
- The balloon rupture and potential inability to withdraw the device may result in complications.

**POTENTIAL ADVERSE EVENTS:**

- The balloon rupture may result in patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one person to another. Any such occurrence shall be reported to ArraVasc immediately.
- If resistance is encountered at any time during the insertion or inflation process, do not continue; remove the catheter.
- If resistance is encountered during balloon withdrawal, do not continue; remove the catheter.
- The device supplied STERILE and is intended for single use. DO NOT ATTEMPT TO RESTERILIZE.

**GUIDEWIRE LUMEN Labeled Using Heparinized Saline:**

Flush the Guidewire lumen labeled using heparinized saline to allow the catheter to track over a guidewire, and an Inflation Port lumen prior to inflation. This step is required to verify no damage occurred during shipment.

**BALLOON INTRODUCTION AND INFLATION:**

Under fluoroscopy, advance the balloon to the lesion site. Verify that the selected accessories accommodate the diameter of the balloon. The balloon rupture may result in patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one person to another. Any such occurrence shall be reported to ArraVasc immediately.

**BALLOON DEFLATION AND WITHDRAWAL:**

- The rated burst pressure is the pressure at which 99.9% of balloons can survive with 95% confidence. This information is provided for the diameters of the balloons at given pressures. Pressures in atm/kPa are obtained with an average bursting rate of 10%, using criteria described in the standard for the burst testing of medical gas and vacuum terminal fittings in ISO 6247:2005. The Rated Burst Pressure table is available on the product label. The Balloon Compliance Card is available on the product label.

**CAUTION:** Do not wipe down the catheter surface with dry gauze or wiping down the catheter with a saturated gauze sponge.

**FLUSH THE GUIDEWIRE LUMEN LABELED USING HEPARINIZED SALINE:**

Flushing the guidewire lumen labeled using heparinized saline is required to allow the catheter to track over a guidewire, and an Inflation Port lumen prior to inflation.

**DISPOSAL:**

After use, dispose of the device according to applicable national, state, and local requirements related to products contaminated by blood.

**NOTICE:**

The Rated Burst Pressure is based on the results of in-vitro testing.