### Z-MED X™

#### PTV Balloon Sizing Chart

<table>
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<tr>
<th>Applied Pressure</th>
<th>8.0 mm</th>
<th>9.0 mm</th>
<th>10.0 mm</th>
<th>12.0 mm</th>
<th>14.0 mm</th>
<th>15.0 mm</th>
<th>16.0 mm</th>
<th>18.0 mm</th>
<th>20.0 mm</th>
<th>22.0 mm</th>
<th>25.0 mm</th>
<th>28.0 mm</th>
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<tbody>
<tr>
<td>1.5 ATM</td>
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<td>9.54</td>
<td>11.65</td>
<td>13.66</td>
<td>14.84</td>
<td>15.64</td>
<td>17.44</td>
<td>19.89</td>
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<td>11.93</td>
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<td>18.58</td>
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<td>9.0 ATM</td>
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</table>

**FOR ALL B. BRAUN INTERVENTIONAL SYSTEMS INC. CATHETERS, AN INFLATION DEVICE WITH PRESSURE GAUGE SHOULD BE USED.**

The figures in bold print represent Balloon diameter at Rated Burst Pressure.

The balloon size is ± 10 % at the Rated Burst Pressure.

### REFERENCES:


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**Warning:**

B. Braun Interventional Systems Inc. Catheters are placed in the extremely hostile environment of the human body. Catheters may fail to function for a variety of causes including, but not limited to, medical complications or failure of catheters by breakage. In addition, despite the exercise of all due care in design, component selection, manufacture and testing prior to sale, catheters may be easily damaged before, during or after insertion by improper handling or other intervening acts. Consequently, no representation or warranty is made that failure of cessation or function of catheters will not occur or that the body will not react adversely to the placement of catheters or that medical complications will not follow the use of catheters.

B. Braun Interventional Systems Inc. cannot warrant or guarantee B. Braun Interventional Systems Inc. accessories because the structure of the accessories may be damaged by improper handling before or during use. Therefore, no representations or warranties are made concerning them.

Z-MED X is a trademark of NuMED Inc.
Instructions For Use

Contents of unopened, undamaged package are:
STERILE • NONPYROGENIC
Sterile in unopened and undamaged package if the word “gas-chex” on the sterility indicator strip has changed from red to green.
Non-sterile if the package has been opened or damaged or the word “gas-chex” on the sterility indicator strip is not green.
Disposable – This device is intended for one use only.
Do not reuse or resterilize. Sterilized with Ethylene Oxide.

Indications:
Recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.
• A patient with isolated pulmonary stenosis.
• A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

Description:
The B. Braun Interventional Systems Inc. PTV Catheter is a non-reusable, co-axial, designed catheter with a balloon mounted on its distal tip. The lumen labeled with the balloon size is utilized for balloon inflation while the through lumen allows the catheter to track over a guidewire. A radiopaque band(s) defines the center (or shoulders, if two) of the dilatation balloon.

Contraindications:
Other than the standard risks associated with the insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient’s medical condition could effect successful use of this catheter.
• Patients with mild valvular stenosis.
• A patient with valvular stenosis with major congenital heart defects that require open heart surgery.

Warnings:
• CAUTION: Do not exceed the RBP. An inflation device with pressure gauge is recommended to monitor pressure. Pressure in excess of the RBP can cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath.
• Catheter balloon inflation diameter must be carefully considered in selecting a particular size for any patient. The inflated balloon diameter should not be significantly greater than the valvular diameter. The choice of the balloon size to be used for valve stenosis has been established by the Valvuloplasty and Angioplasty of Congenital Anomalies Registry. (VACA) to be approximately 1.2 to 1.4 times the valve annulus. It is important to perform an angiogram prior to valvuloplasty to measure the size of the valve in the lateral projection.
• Balloons ≥ 4 cm in length may impinge upon the tricuspid valve mechanism and may injure it. Balloons longer than 4 cm are not recommended for children < 10 years old.
• Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.
• This catheter is not recommended for pressure measurement or fluid injection.

Directions For Use:
Prior to valvuloplasty, carefully examine all equipment to be used during the procedure, including the catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended. Also, inflate the dilatation catheter to the appropriate RBP and deflate to verify proper function.

1. Remove the balloon protector. Inspect the catheter for damage prior to insertion.
2. Check that all connections are tight. Fill and purge the dilatation balloon. Prime and flush the distal lumen. It is important to perform a careful angiogram prior to valvuloplasty to measure the size of the valve in the lateral projection.
3. Balloons ≥ 4 cm in length may impinge upon the tricuspid valve mechanism and may injure it. Balloons longer than 4 cm are not recommended for children < 10 years old.
4. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.
5. This catheter is not recommended for pressure measurement or fluid injection.

Do not remove the guidewire from the catheter at any time during the procedure.
• This catheter should be used prior to the expiration date noted on the package label.
• Right ventricular outflow tract damage has occurred with balloons larger than 1.5 times the size of the valve annulus.
• The catheter is intended for valvuloplasty applications only, and is not intended for angioplasty.
• The catheter is not intended for redilatation of stents.

Precautions:
• Dilatation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
• Guidewires are delicate instruments. Care should be exercised while handling to prevent the possibility of breakage.
• The sealed catheter container should be inspected prior to opening. If the seal is broken, or the container has been damaged or wet, sterility cannot be assured.
• Careful attention must be paid to the maintenance of tight catheter connections. Aspirate before proceeding to avoid air introduction into the system.
• Under no circumstances should the portion of the catheter system be advanced against resistance. The cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem.
• If resistance is felt upon removal, then the balloon, guidewire and sheath should be removed as a unit, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter, guidewire and sheath as a unit and withdrawing them together, using a gentle twisting motion combined with traction.
• Before removing the catheter from the sheath, it is very important that the balloon is completely deflated.
• Proper functioning of the catheter depends upon its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forcible wiping of the catheter.

Potential Complications/Adverse Effects:
Potential balloon separation following balloon rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces.

NOTE: There have been infrequent reports of larger diameter balloons bursting circumferentially, possibly due to tight focal strictures in large vessels. In any instance of a balloon rupture while in use, it is recommended that a sheath be placed over the ruptured balloon prior to withdrawal through the entry site. This can be accomplished by cutting off the proximal end of the catheter and slipping an appropriately sized sheath over the catheter into the entry site. For specific technique, refer to: Tegtmeyer, Charles J., M.D. & Bezirdjian Diran R., M.D. “Removing the Stuck, Ruptured Angioplasty Balloon Catheter.” Radiology. Volume 139, 231-232, April 1981.

Potential complications and related adverse effects associated with the valvuloplasty catheter use include, but are not limited to:
• Perforation
• Conduction System Injury
• Thromboembolic Events
• Hematoma
• Cardiovascular Injury and Infundibulum
• Arrhythmia Development
• Valvular Tearing or Trauma
• Restenosis Development
• Inflammation
• Infection