Insertion: Vascular (continued)

If necessary the catheter can be repositioned in the left atrium and the process can be repeated. The number of repeated septostomies performed during one catheterization is determined by the clinical state of the patient and the estimation of effective palliation.

6. Gently withdraw the catheter. As the balloon exits the vessel, use a smooth, gentle, steady motion. If resistance is felt upon removal, the balloon, guidewire, 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.

7. Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.

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**Warning**

B. Braun Interventional Systems Inc. Atrioseptostomy 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.

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**References**


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**RESULTANT INJECTED BALLOON VOLUME**

<table>
<thead>
<tr>
<th>Volume</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 cc</td>
<td>7.95 mm ± 0.5 mm</td>
</tr>
<tr>
<td>0.8 cc</td>
<td>8.00 mm ± 0.5 mm</td>
</tr>
<tr>
<td>1.0 cc</td>
<td>8.65 mm ± 0.5 mm</td>
</tr>
<tr>
<td>1.5 cc</td>
<td>9.35 mm ± 0.5 mm</td>
</tr>
</tbody>
</table>

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**RESULTANT INJECTED BALLOON VOLUME**

<table>
<thead>
<tr>
<th>Volume</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.7 cc</td>
<td>7.95 mm ± 0.5 mm</td>
</tr>
<tr>
<td>0.8 cc</td>
<td>8.00 mm ± 0.5 mm</td>
</tr>
<tr>
<td>0.9 cc</td>
<td>8.65 mm ± 0.5 mm</td>
</tr>
<tr>
<td>1.0 cc</td>
<td>9.35 mm ± 0.5 mm</td>
</tr>
</tbody>
</table>

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**B. Braun Interventional Systems Inc.**

824 Twelfth Avenue
Bethlehem, PA 18018
www.bisusa.org

Made in the U.S.A.
Instructions For Use

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.

INDICATIONS:
Recommended for balloon atrioseptostomy, an accepted technique in most pediatric cardiology centers for the palliation of several congenital cardiac defects. Ballon atrioseptostomy is performed in conjunction with diagnostic cardiac catheterization and has been carried out after the diagnosis of several congenital cardiac defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.

The 611200 - 9.5 mm is primarily for infants less than 2 kg.

Catheter Description
The B. Braun Interventional Systems Inc. Atrioseptostomy Catheter is a balloon catheter designed for the neonate with congenital heart disease requiring septostomy. It is a dual lumen catheter, 50 cm in length. The 611200 atrioseptostomy catheter has a 9.5 mm ± 0.5 mm non-compliant balloon, at 1.0 cc volume, on the distal end. The 611100 atrioseptostomy catheter has a 13.5 mm ± 0.5 mm non-compliant balloon, at 2.0 cc volume on the distal end.

The 9.5 mm catheter also features an end hole that will accommodate a 0.014” guidewire, 13.5 mm catheter also features an end hole that will accommodate a 0.018” to 0.021” guidewire. The inflated geometry of the balloon is a sphere. There is an imaging band under the balloon for balloon positioning in the left atrium. The catheter tip is angled at 35° to facilitate passage through the interarterial opening in the left atrium. To inflate the balloon of the 9.5 mm catheter to its maximum diameter, 1.0 cc of diluted contrast media is pushed into the balloon extension after purging. To inflate the balloon of the 13.5 mm catheter to its maximum diameter, 2.0 cc of diluted contrast media is pushed into the balloon extension after purging. Catheters are supplied with a one-way stopcock for balloon sealing.

How Supplied
Supplied sterilized by ethylene oxide gas. Sterile and non-pyrogenic if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

Warning
- **CAUTION:** Do not exceed the rated volume of 1.0 cc for the 9.5 mm catheter. Over inflation may cause balloon rupture.
- **CAUTION:** Do not exceed the rated volume of 2.0 cc for the 13.5 mm catheter. Over inflation may cause balloon rupture.
- Do not exceed the rated volume of 2.0 cc for the 13.5 mm catheter. Over inflation may cause balloon rupture.
- Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.
- Use only a 3.0 cc inflation device with pressure gauge for inflation.
- Use a 3.0 cc inflation device with pressure gauge for deflation. (For faster deflation, up to a 10.0 cc inflation device with pressure gauge may be used).
- Do not exceed an injection pressure of 300 psi for the 9.5 mm catheter.
- Do not exceed an injection pressure of 600 psi for the 13.5 mm catheter.
- Do not advance the guidewire, septostomy catheter, or any other component if resistance is met, without first determining the cause and taking remedial action.
- This catheter is not recommended for pressure measurement or fluid injection.
- This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross-contamination.
- The use of excessive force to pull the balloon across the atrial septum must be avoided.

Precautions
- B. Braun Interventional Systems Inc. recommends the 9.5 mm catheter be used with a 5F introducer to ensure admittance.
- B. Braun Interventional Systems Inc. recommends the 13.5 mm catheter be used with a 6F introducer to ensure admittance.
- Balloon atrioseptostomy should not be performed for infants older than six weeks. These infants will have thick atrial septums. Reference AHA/ACC guidelines.
- Dilatation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- Guidewires are delicate instruments. Care should be exercised while handling to help prevent the possibility of breakage.
- Careful attention must be paid to the maintenance of tight catheter connections and by aspiration before proceeding to avoid air introduction into the system.
- Under no circumstances should any 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 the 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 sheath as a unit and withdrawing both 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 on its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forceful wiping of the catheter.

Potential Complications include, but are not limited to:
- Infection
- Inflammation
- Thromboembolic Events
- Air embolism
- Potential balloon separation with subsequent need of snare
- Vascular perforation requiring surgical repair
- Rhythm and conduction disturbances
- Perforation of the left atrial appendage
- Damage to the vascular intima
- Bleeding
- Hematoma Formation
- Conduction system injury
- Death

Inspection and Preparation
1. Insert guidewire through the distal tip until guidewire exceeds proximal port.

Instructions For Use (continued on next page)