Atrioseptostomy Balloon Catheter

- 611200 - 9.5 mm diameter
- 611100 - 13.5 mm diameter

One

**References**


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**Insertion: Vascular (continued)**

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.

**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**


**Contents of unopened, undamaged package are:**

**STERILE • NONPYROGENIC**

**Sterile**

Diameter, 1.0 cc of diluted contrast media is pushed into the balloon for balloon positioning in the left atrium. The catheter tip is angled at a 0.014” guidewire, 13.5 mm catheter also features an end hole that is primarily for infants less than 2 kg.

**Non-sterile**

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 0.9 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 × 0.65 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 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.

**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.
- 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.

**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

**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.
- 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 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 grabbing 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 wipping of the catheter.

**Insertion: Vascular**

1. Prepare a 30% mixture by volume of contrast medium and normal saline.
2. Prepare the subject for the procedure.
3. Catheters may be introduced by percutaneous approach or by transumbilical vein. The 9.5 mm catheter requires a 5F introducer sheath and the 13.5 mm catheter requires a 6F introducer sheath (see Precautions) when utilizing this approach. In case of failure of this access technique, venous cutdown may be used.
4. The placement of the catheter can be accomplished under fluoroscopic guidance or under special conditions using two-dimensional echocardiographic guidance. Once through the sheath, the catheter is passed to the inferior vena cava and into the right atrium. The angled tip facilitates passage across the interarterial opening to the left atrium. In case of difficulty in positioning, a 0.014” guidewire for the 9.5 mm catheter, or a 0.021” guidewire for the 13.5 mm catheter may be used to achieve safe positioning. The guidewire should be pulled back into the catheter shaft or removed completely before proceeding with septostomy.
5. Balloon Septostomy is most safely performed under fluoroscopy or 2-D echo. The balloon must be well-identified in the left atrium. The balloon of the 9.5 mm catheter is inflated with 1.0 cc of fluid, the balloon of the 13.5 mm catheter is inflated with 2.0 cc of fluid and a balloon Lucia (see Precautions). **CAUTION:** Do not exceed the 1.0 cc volume for the 9.5 mm catheter or the 2.0 cc volume for the 13.5 mm catheter. Over-inflation may cause balloon rupture. The balloon is then pulled into the right atrium with fast, snapping motion. This pulling maneuver must be stopped at the inferior vena cava-right atrial junction and the balloon rapidly readvanced into the right atrium (since balloon is non-compliant, it will not conform to the shape of the IVC and vessel tearing is a possibility). Immediately deflate the balloon by applying negative pressure to the inflation device (a 3.0 cc inflation device is recommended unless faster deflation is needed, then up to a 10.0 cc inflation device may be used).

The use of excessive force to pull the balloon across the atrial septum must be avoided. Specifically, the physician should avoid using the entire arm when pulling the balloon across the septum and should instead use only the motion of the wrist. If the balloon does not easily cross the septum using this method, it is recommended that a smaller volume of fluid be used initially. The amount of fluid can then be gradually increased in volume until the desired result is achieved. If the first two steps are not successful, consider static balloon dilation of the atrial septum. 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.

**Inspection and Preparation**

1. Insert guidewire through the distal tip until guidewire exceeds proximal port.
2. Remove balloon protector. Inspect the catheter for damage prior to insertion.

(continued on next page)