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.

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.

References


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. Balloon 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 ± 0.5mm 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 angled tip facilitates passage across the interarterial opening to the left atrium. In case of difficulty in positioning, a 13.5 mm catheter may be used to achieve safe positioning. The balloon of the 9.5 mm catheter is inflated with 1.0 cc of fluid, while the balloon of the 13.5 mm catheter is inflated with 2.0 cc of fluid.

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 or 2.0 cc for the 13.5 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.

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.

2. Remove balloon protector. Inspect the catheter for damage prior to insertion.
3. Attach a 3.0 cc inflation device with pressure gauge half-filled with normal saline and attach it to the stopcock, already attached to the balloon port.
4. Purge and flush the catheter through lumen thoroughly, observing for leaks.
5. Point inflation device with pressure gauge nozzle downward, aspirate until all air is removed from the balloon, and bubbles no longer appear in the solution.
6. Turn the stopcock off to maintain the vacuum in the balloon.
7. Remove guidewire.

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.

4. The placement of the catheter can be accomplished under fluoroscopic guidance or under special conditions using two-dimensional echocardiographic guidance. Once 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 fluoroscopic guidance 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 the stopcock is closed. 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 with pressure gauge (a 3.0 cc inflation device with pressure gauge is recommended unless faster deflation is needed, then up to a 10.0 cc inflation device with pressure gauge 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.

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