

PTS-X™

SIZING BALLOON CATHETER

Instructions for Use

CAUTION:

Federal (USA) Law restricts this device to sale by or on the order of a physician.



Manufactured for:

B. Braun Interventional Systems Inc.

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Manufacturer:

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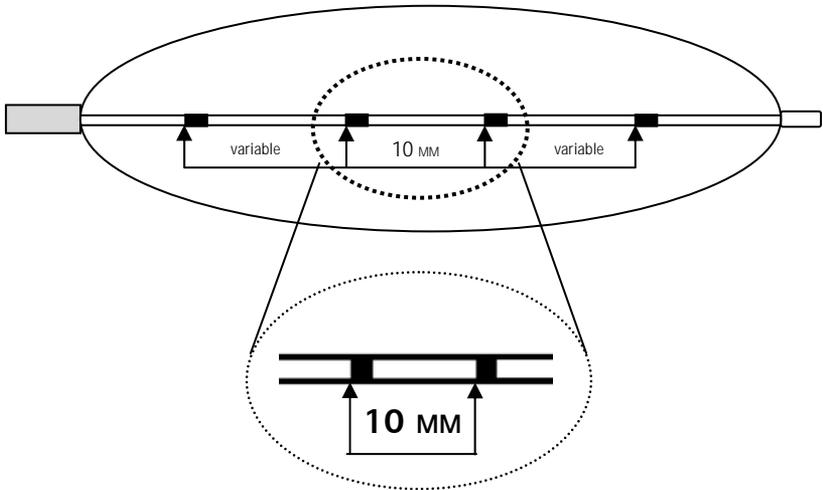


INDICATIONS:

Recommended for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.

DESCRIPTION:

The PTS-X Sizing Balloon Catheter is a coaxial design catheter with a balloon mounted on its distal tip. The lumen labeled with the balloon size is for balloon inflation while the through lumen allows the catheter to track over a guidewire. This lumen has two radiopaque platinum marker bands under the balloon shoulders and there are two additional radiopaque platinum marker bands spaced at 10 mm (as measured from leading edge to leading edge). These bands are located at the balloon center and are used as a distance reference (the 1cm balloon lengths have only two radiopaque marker bands under the balloon shoulders). Each balloon inflates to the stated diameter and length at a specific pressure. The balloon size is $\pm 10\%$ at the Rated Burst Pressure (RBP). The RBP is different for each size. Check the package label for the RBP. It is important that the balloon not be inflated beyond RBP.



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.

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.
- Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.
- Do not advance the guidewire, balloon dilatation 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.
- Do not remove the guidewire from the catheter at any time during the procedure.
- 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.

PRECAUTIONS:

- One should always select a PTS-X diameter larger than the unstretched defect diameter, i.e., TEE ASD size 12mm - select 20 or 25 mm PTS-X.
- Caution should be used when inflating the balloon, over inflation can cause trauma and overstretching of the septum.
- Sizing 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 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 catheter from 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:

- Potential complications related to the introduction of the catheter into the body include, but are not limited to, the following: infection, air embolism, and hematoma formation.
- 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.
- Complications associated with sizing include, but are not limited to : clot formation and embolism, nerve damage, vascular perforation requiring surgical repair, damage to the vascular intima, cerebral accident, cardiac arrhythmias, myocardial infarction, or death.

NOTE: There have been infrequent reports of larger diameter balloons bursting circumferentially, possibly due to a combination of 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: Tegtmeier, Charles J., M.D. & Bezirdijan Diran R., M.D. "Removing the Stuck, Ruptured Angioplasty Balloon Catheter." Radiology, Volume 139, 231-232, April 1981.

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. Perform sizing using either a 1:3 or a 1:4 solution of saline and contrast medium, respectively.
4. Attach an inflation device with pressure gauge half filled with the contrast solution to the balloon port of the catheter.
5. Purge the catheter through lumen thoroughly, observing for leaks.
6. To check inflation/deflation times, use a stopwatch. Repeat the procedure several times to verify the inflation / deflation time.
7. Point the inflation device with pressure gauge nozzle downward and aspirate until all air is removed from the balloon, and bubbles no longer appear in the contrast solution.
8. Turn the stopcock off to maintain the vacuum in the balloon.
9. Remove guidewire.

INSERTION: VASCULAR

1. Enter the vessel percutaneously using the standard Seldinger technique over a 0.035"superstiff wire positioned in the left upper pulmonary vein or left atrial appendage.
2. Position the balloon across the defect and slowly inflate with diluted contrast. Both the Transesophageal echocardiogram (TEE) and fluoroscopy monitor the inflation.
3. When the defect is completely occluded there will be no color flow shunt by TEE and a waist appears in the balloon.
4. The balloon waist size is measured by TEE or cineangiogram. This size corresponds to the stretched size of the defect.

DEFLATION AND WITHDRAWAL

1. Deflate the balloon by drawing a vacuum with an inflation device with pressure gauge. Note: The greater the vacuum applied and held during withdrawal, the lower the deflated balloon profile.
2. Gently withdraw the catheter. As the balloon exits the vessel, use a smooth, gentle, steady motion. If resistance is felt upon removal, then 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.
3. Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.

WARNING:

These 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 or cessation of 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.

WARRANTY AND LIMITATIONS:

Catheters and accessories are sold in an 'as is' condition. The entire risk as to the quality and performance of the catheter is with the buyer. B. Braun Interventional Systems Inc. disclaims all warranties, expressed or implied, with respect to catheters and accessories, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. B. Braun Interventional Systems Inc. shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any catheter or accessory or caused by any defect, failure, or malfunction of any catheter or accessory, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind B. Braun Interventional Systems Inc. to any representation or warranty with respect to catheters and accessories.

REFERENCES:

Zhu W, Cao QL, Rhodes J, Hijazi ZM. Measurement of atrial septal defect size: a comparative study between three-dimensional transesophageal echocardiography and the standard balloon sizing methods. *Pediatric Cardiology* 2000 Sep-Oct;21(5):465-9.

Acar P, Saliba Z, Bonhoeffer P, Aggoun Y, Bonnet D, Sidi D, Kachaner J. Influence of atrial septal defect anatomy in patient selection and assessment of closure with the Cardioseal device: a three-dimensional transesophageal echocardiographic reconstruction. *Eur. Heart Journal* 2000 Apr;21(7):573-81.

GU X, Han YM, Berry J, Urness M, Amplatz K. A new technique for sizing of atrial septal defects. *Catheter Cardiovascular Intervention* 1999 Jan;46(1):51-7.

PTS-X™ Balloon Sizing Chart

Applied Press.	10.0 (mm)	12.0 (mm)	15.0 (mm)	20.0 (mm)	25.0 (mm)	30.0 (mm)	35.0 (mm)	40.0 (mm)
0.5 ATM	8.35	9.77	12.57	-	-	-	31.74	38.72
1.0 ATM	9.16	10.57	13.59	19.87	24.81	30.12	34.28	
1.5 ATM	9.67	11.43	14.82	20.86	26.56			
2.0 ATM	10.08	12.03	15.52					
2.5 ATM	10.37							

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.



Do not reuse



Batch code



Keep dry



Not made with DEHP



Model number



Keep away from sunlight



Non-pyrogenic

Store at room temperature



Sterilized using ethylene oxide



Use by



Catalog number



Do not resterilize



Consult instructions for use

Rx only



Not made with natural rubber latex



Do not use if package is damaged



Manufacturer