TYSHAK®

DILATATION 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.
824 Twelfth Avenue
Bethlehem, PA 18018

Customer Service:
TEL: (877) 836-2228
FAX: (610) 849-1334

Technical Support:
TEL: (800) 443-8362
Made in the U.S.A.

Manufacturer:
NuMED, Inc.
2880 Main Street
Hopkinton, NY 12965

INSTRUCTIONS FOR USE (PTV)

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 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. A radiopaque band[s] defines the center [or shoulders, if two] of the dilatation balloon. Each balloon inflates to the stated diameter and length at a specific pressure. The balloon size is ±10% at the Rated Burst Pressure (RBP). The RBP is different for each size. Please check the package label for the RBP. It is important that the balloon not be inflated beyond the 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.

CONTRAINDICATIONS:

Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient's medical condition could affect successful use of this catheter.

- Patients with mild valvular stenosis.
- A patient with valvular stenosis with major congenital heart defects that requires 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 valvular diameter. The choice of the balloon size to be used for valve stenosis has been established by the VACA Registry 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 $\geq$ 4cm in length may impinge upon the tricuspid valve mechanism and may injure it. Balloons longer than 4cm are not recommended for children $\leq$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.
- 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.
- The catheter should be used prior to the 'Use Before' date noted on the package label.
- Right ventricular outflow tract damage has occurred with balloons larger than 1.5 times the size of valve annulus.
- **THE CATHETER IS NOT INTENDED FOR USE WITH 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 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.

INSTRUCTIONS FOR USE:

Prior to valvuloplasty, carefully examine all equipment to be used during the procedure, including the catheter, to verify proper function 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 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.
3. Prepare a peripheral vein site for catheter insertion. The femoral vein is a recommended site for insertion.
4. Under fluoroscopic guidance advance the guidewire to the desired position. Pass the catheter over the guidewire. An introducer should be utilized to facilitate catheter insertion.
5. Advance the catheter into the heart and through the valve under fluoroscopic guidance. Place the catheter to position the mid-length of the balloon within the valve. A radiopaque band[s] defines the center [or shoulders, if two] of the dilatation balloon.
6. The distal lumen is provided for guidewire tracking. An inflation device with pressure gauge is required to monitor inf
7. lation pressure [refer to package label for RBP].
8. Perform dilatations using either a 50/50 or a 75/25 solution of saline and contrast medium, respectively. Patient monitoring is required during dilatations. Balloon can be either partially or fully inflated to achieve dilatation. DO NOT EXCEED THE RBP.
9. 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. 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.
10. Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.

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 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: Tegtmeyer, Charles J., M.D. & Bezirdijan 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
- Arrhythmia Development
- Valvular Tearing or Trauma
- Restenosis Development
- Inflammation
- Infection

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.

INSTRUCTIONS FOR USE (PTA)

INDICATIONS:

Recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac and renal arteries. This catheter is not indicated for use in the coronary arteries.

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.
- In PTA, the dilated balloon should not markedly exceed the diameter of the artery lying just proximal to the stenosis.
- 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:

- 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 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 PTA 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. For specifics, refer to: Fellows, K. et al.: Acute Complications of Catheter therapy for Congenital Heart Disease, Amer Journ of Cardiol, 60;679(1987).

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: Tegtmeyer, 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 dilatations using either a 50/50 or a 75/25 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 inflation device with pressure gauge nozzle downward, 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 the appropriate guidewire for the size catheter being used.
2. Advance the catheter across the lesion with fluoroscopic guidance using accepted percutaneous transluminal angioplasty technique (see references). In most patients, the balloon should meet with minimal resistance to insertion. Do not advance the catheter unless the guidewire is in place.
3. Referring to the balloon-sizing chart, inflate the balloon with contrast medium until the desired diameter is achieved or the RBP is reached, whichever comes first. DO NOT EXCEED THE RBP.

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.

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.

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Tyshak® Balloon Sizing Chart

Applied Press.	2.0 (mm)	4.0 (mm)	5.0 (mm)	6.0 (mm)	7.0 (mm)	8.0 (mm)	9.0 (mm)	10.0 (mm)	11.0 (mm)	12.0 (mm)	13.0 (mm)
1.0 ATM	1.78	3.79	4.77	5.81	6.78	7.70	8.30	9.56	10.36	11.56	12.26
1.5 ATM											
2.0 ATM	1.82	3.85	4.89	5.95	6.87	7.90	8.56	9.94	10.54	11.88	12.51
3.0 ATM	1.86	3.94	4.98	6.06	7.00	8.06	8.84	10.11	10.72	12.13	13.05
3.5 ATM											
4.0 ATM	1.89	4.00	5.06	6.16	7.08	8.21	9.07	10.26	10.89	12.34	**13.36**
4.5 ATM									**11.08**	**12.44**	
5.0 ATM	1.92	**4.06**	**5.15**	**6.25**	**7.17**	**8.33**	**9.26**	**10.45**			
6.0 ATM	1.96										
7.0 ATM	1.98										
8.0 ATM	2.00										
9.0 ATM	2.01										
10.0 ATM	**2.02**										

Applied Press.	14.0 (mm)	15.0 (mm)	16.0 (mm)	17.0 (mm)	18.0 (mm)	19.0 (mm)	20.0 (mm)	22.0 (mm)	23.0 (mm)	25.0 (mm)
1.0 ATM	13.40	14.24	15.40	16.35	17.73	18.53	19.73	21.64	22.74	24.08
1.5 ATM										**24.77**
2.0 ATM	13.77	14.67	15.91	**16.62**	**18.39**	**19.29**	**20.46**	**22.54**	**24.04**	
3.0 ATM	14.08	15.00	16.54							
3.5 ATM	**14.18**	**15.13**	**16.83**							
4.0 ATM										
4.5 ATM										
5.0 ATM										
6.0 ATM										
7.0 ATM										
8.0 ATM										
9.0 ATM										
10.0 ATM										

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.

TYSHAK®

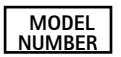
DILATATION CATHETER

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

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