INSERTION:

1. Direct torque guidewire through the esophageal stricture using fluoroscopic guidance.
2. In most patients, the balloon should meet with minimal resistance to insertion. Do not advance the catheter unless the guidewire is in place.
3. Insert the balloon catheter into the esophagus using short, deliberate, 2-3cm movements over the appropriate guidewire for the size catheter being used (see references).
4. Position the balloon in the appropriate location with the radiopaque marker bands on either side of the stricture.
5. 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.
6. Do not remove the guidewire from the catheter at any time during the procedure.

DEFLATION & 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 over the guidewire. As the balloon exits, use a smooth, gentle, steady motion. If resistance is felt upon removal, then the balloon catheter and guidewire 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 guidewire as a unit and withdrawing them together, using a gentle twisting motion combined with traction.

IMPACT™ Esophageal Balloon Sizing Chart

Applied Press.	16.0 mm	18.0 mm	20.0 mm	22.0 mm	25.0 mm
1.0 ATM	14.73	16.61	18.65	20.88	23.52
2.0 ATM	15.05	17.01	**18.98**	**21.52**	**24.34**
3.0 ATM	15.44	17.49	19.29	22.19	25.21
4.0 ATM	**15.84**	**17.97**	19.93	**22.79**	**25.93**
5.0 ATM	16.24	18.38	**20.46**		
6.0 ATM	16.55	18.73			
7.0 ATM	16.86	**19.09**			
8.0 ATM	**17.17**				

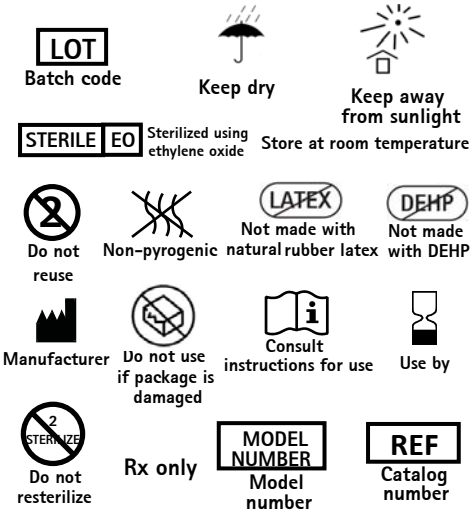
FOR ALL B. BRAUN INTERVENTIONAL SYSTEMS INC. CATHETERS, AN INFLATION DEVICE WITH PRESSURE GAUGE SHOULD BE USED. The highlighted upper figures represent balloon diameter at Nominal Inflation Pressure. The highlighted lower figures represent the balloon diameter at Rated Burst Pressure. The balloon size is ± 10% at the Nominal Inflation Pressure.

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.

REFERENCES:

Athanasoulos, C.A.; PTA: General Principles, Amer Journ of Roent, 135; 893-900, (1980) Gruntzig A.; Kumpe, D.; Technique of PTA with the Gruntzig Balloon Catheter, Amer Journ of Roent132:547-552 (1979) Katzen, B.T.; Chang, J.; PTA with the Gruntzig Balloon Catheter, Radiology, 130:623-626 (1979) Zeitler, E.; Gruntzig, A.; Schoop, W.; (Eds) Percutaneous Vascular Recanalization, Springer-Verlag, Heidelberg/New York (1978) Stanson A.W.; A Perspective of PTA, Cardiovascular Clinics, 12(2):245-259 (1983) Wilson, A.R.; Fuchs, J.C.A.; PTA, Surgical Clinics of North America, 64,1121-1150, (1984) Tegtmeyer, C.J.; Kofler T.J.; Ayers C.A.; Renal Angioplasty: Current Status, AJR 142: 17-21, (1984) Sos, T.A. et. al.; The Current Role of Renal Angioplasty in the Treatment of Renovascular Hypertension, Urology Clinics of North America Vol. 11:3, 503-513, (1984) Fellows, K. et al.: Acute Complications of Catheter Therapy for Congenital Heart Disease, Amer Journ of Cardiol, 60:679 (1987) Rocchini, A.: Balloon Angioplasty for Peripheral Pulmonary Artery Stenosis, in Rao, P.S. (Ed) Transcatheter therapy in Pediatric Cardiology, Wiley-Liss, New York, PP 213-228 (1993)



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.

IMPACT™

BALLOON DILATATION CATHETER

IFU-307B Rev. 00 – 10 November 2015

IMPACT™

BALLOON DILATATION CATHETER

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

IMPACT™ BALLOON 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 Nominal Inflation Pressure. The Rated Burst Pressure (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.

PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY

INDICATIONS:

Percutaneous Transluminal Angioplasty (Cleared for balloon Diameters 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, and 25mm).

Recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac and renal arteries. These catheters are not designed to be used 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.

INSTRUCTIONS FOR USE (PTA)

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

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.

IMPACT™ PTA Balloon Sizing Chart

Applied Pressure	12.0 mm	14.0 mm	16.0 mm	18.0 mm	20.0 mm	22.0 mm	25.0 mm
1.0 ATM	10.80	12.63	14.73	16.61	18.65	20.88	23.52
2.0 ATM	11.01	12.90	15.05	17.01	**18.98**	**21.52**	**24.34**
3.0 ATM	11.25	13.22	15.44	17.49	19.29	22.19	25.21
4.0 ATM	11.54	13.55	**15.84**	**17.97**	19.93	**22.79**	**25.93**
5.0 ATM	11.84	**13.85**	16.24	18.38	**20.46**		
6.0 ATM	**12.06**	14.17	16.55	18.73			
7.0 ATM	12.31	14.40	16.86	**19.09**			
8.0 ATM	12.49	14.63	**17.17**				
9.0 ATM	12.66	14.82					
10.0ATM	**12.83**	**15.06**					

FOR ALL B. BRAUN INTERVENTIONAL SYSTEMS INC. CATHETERS, AN INFLATION DEVICE WITH PRESSURE GAUGE SHOULD BE USED. The highlighted upper figures represent balloon diameter at Nominal Inflation Pressure. The highlighted lower figures represent the balloon diameter at Rated Burst Pressure. The balloon size is ± 10% at Nominal Inflation Pressure.

ESOPHAGEAL BALLOON DILATATION

INDICATIONS:

Esophageal Balloon Dilatation (Cleared for balloon Diameters 16mm, 18mm, 20mm, 22mm, and 25mm). Indicated for use in adult and adolescent patients to dilate esophageal strictures due to: esophageal surgery, primary gastroespoh reflux, radiation therapy.

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 or complications requiring surgical correction.
- 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.
- This catheter is not intended for redilatation of stents.
- Do not remove the guidewire from the catheter at any time during the procedure.
- This device is intended for one-time use only. Do not resterilize or reuse.

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.
- 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 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 and guidewire 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 guidewire as a unit and withdrawing both
- Before removing catheter, 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 esophageal dilatation include, but are not limited to: esophageal perforation, hemorrhage, septicemia/infection, and hematemesis. For specifics, refer to: Kang, S.G. et al.,"Esophageal Rupture During Balloon Dilation of Strictures of Benign or Malignant Causes: Prevalence and Clinical Important," Radiology, Vol. 209, No. 3, (1990), pp 741- 746 and Kim, I.O. et al., "Perforation Complicating Balloon Dilation of Esophageal Strictures in infants and Children," Radiology, Vol.189, No 3, (1993), pp 741-744.

INSTRUCTIONS FOR USE (ESOPHAGEAL)

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.