VIDA™

PTV Dilatation Catheter

Training Manual

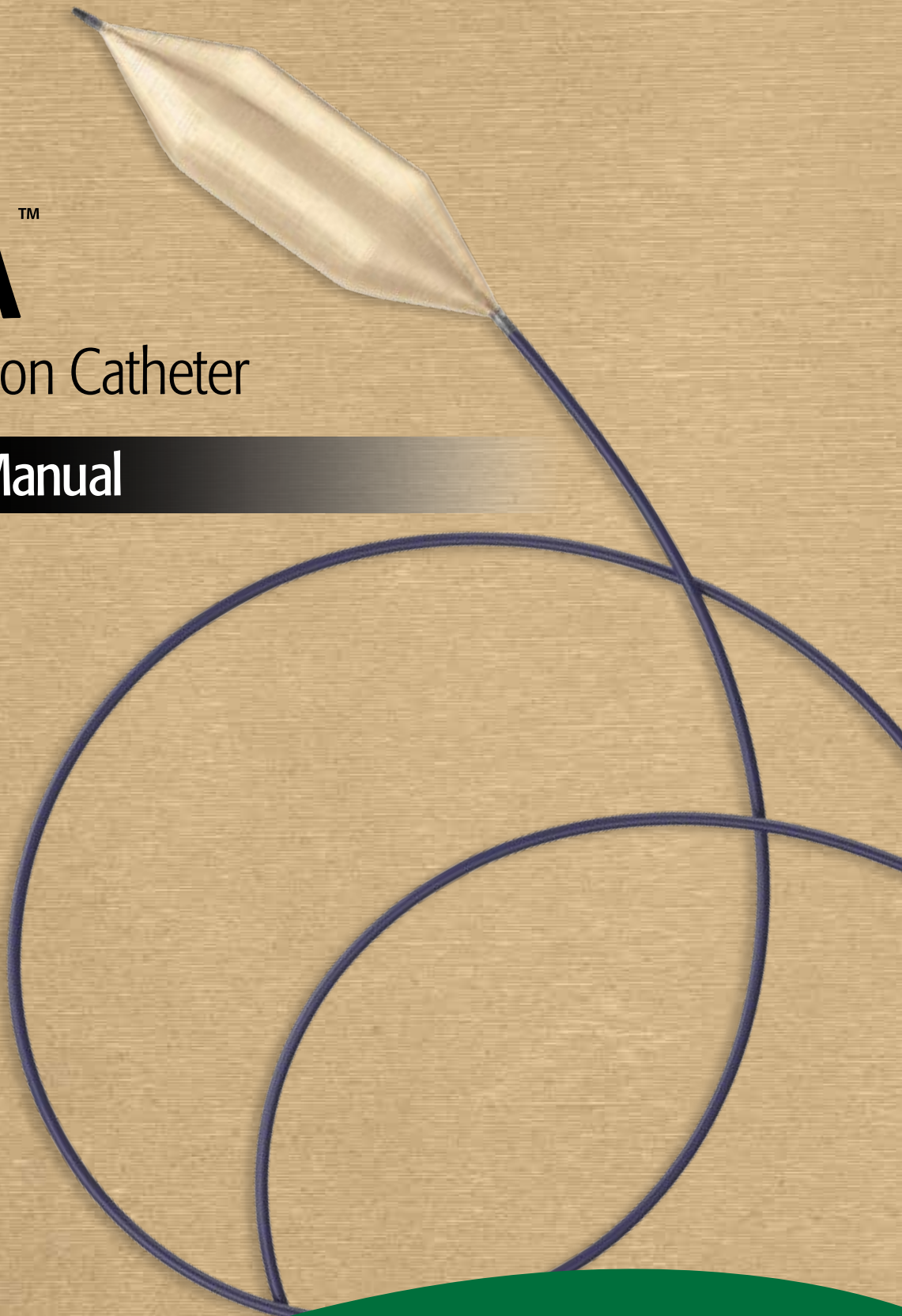

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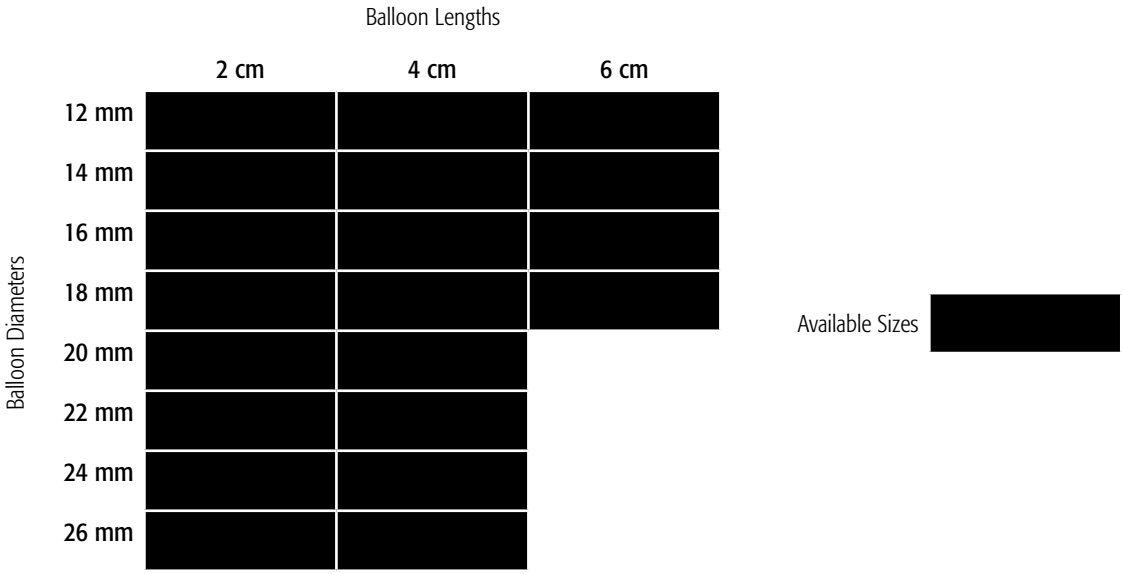
Table of Contents

Appendix

Introduction

The VIDA™ PTV Dilatation Catheter is our first pulmonary valvuloplasty balloon. Balloon sizes range from 12 mm to 26 mm in diameter and 2 cm to 6 cm mounted on a shaft that is 100 cm long.

Available Balloon Sizes - 100 cm Shaft Length



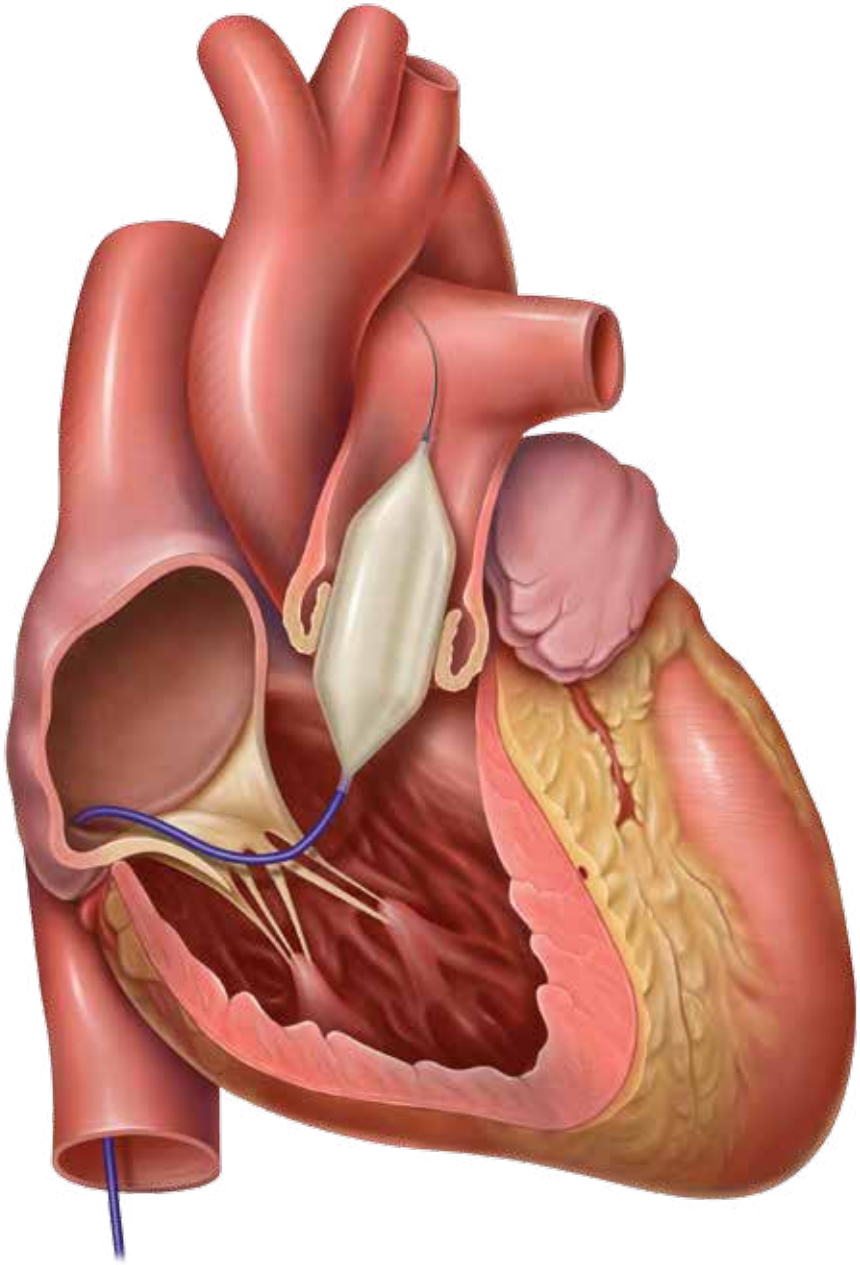
Product Description

The VIDA™ PTV Dilatation Catheter is a large diameter balloon catheter consisting of a fiber based balloon designed for use in pulmonary valvuloplasty procedures.

Indications

The VIDA™ PTV Dilatation Catheter is recommended for Percutaneous Transluminal Valvuloplasty of the pulmonary valve in the following:

- A patient with isolated pulmonary valve stenosis.
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.



Value Proposition

Clinical Value Proposition

1. Precise and accurate balloon sizing designed to limit damage to healthy tissue.
2. Reduce the potential complications associated with a large sheath size.

Economic Value Proposition

1. Adequately dilate calcified valves, limiting costs from complications due to a balloon rupture in the valve.
2. Eliminate the need for a second pull balloon.

Valvuloplasty Balloon Overview

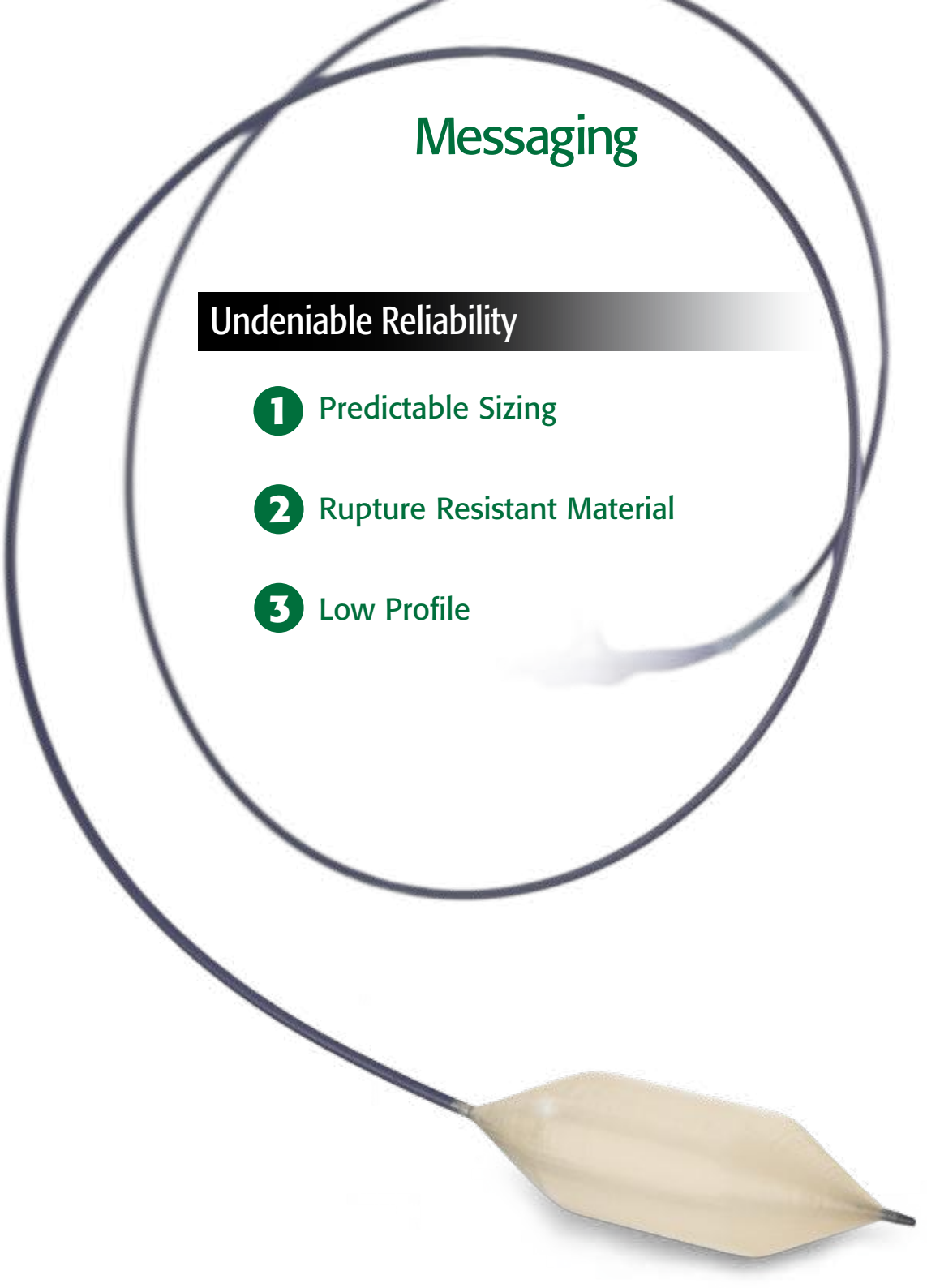
Company	Product	Balloon Diameter (mm)	Balloon Length (cm)	Highest Rated Burst Pressure* (ATM)	Catheter Lengths (cm)	Compliance
Bard	VIDA™	12 - 26	2, 4, 6	**18**	100	Ultra Non-Compliant
B. Braun	Tyshak™	4 - 25	1.5 - 6	**4.5**	70, 85, 100	Non-Compliant
B. Braun	Tyshak™ II	4 - 25	2 - 6	**3.5**	70, 90, 100	Non-Compliant
B. Braun	Nucleus-X™	18 - 30	4 - 6	**4**	110	Non-Compliant
B. Braun	Z-Med™	10 - 25	2 - 4	**7**	100	Non-Compliant
B. Braun	Z-Med™ II	5 - 25	2 - 6	**10**	100	Non-Compliant

*RBP based on diameters ≥12.

Messaging

Undeniable Reliability

1. Predictable Sizing
2. Rupture Resistant Material
3. Low Profile



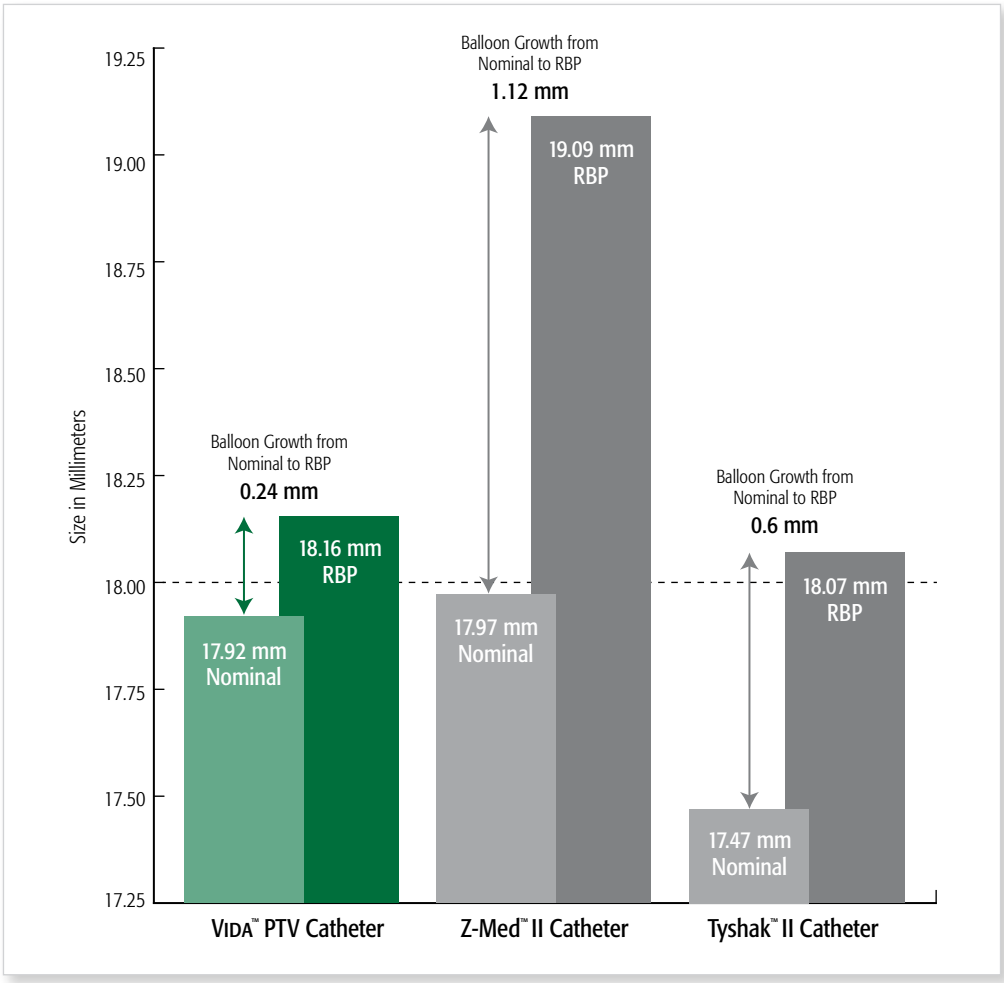
1 Predictable Sizing

Precise sizing is very important in a valvuloplasty procedure as damage to the valve annulus, the ring the leaflets are inside, can be caused by improper sizing. The VIDA™ balloon's ultra non-compliant fiber technology reduces the risk of balloon growth during a procedure.

Company	Product	Labeled Balloon Size (mm)	Actual Size at Nominal (mm)	Actual Size at RBP (mm)
Bard	**VIDA™****	**18**	**17.92**	**18.16**
B. Braun	Z-Med™ II*	18	17.97	19.09
B. Braun	Tyshak™ II*	18	17.47	18.07

*From B. Braun IFU compliance charts.
**Sample size N=30.

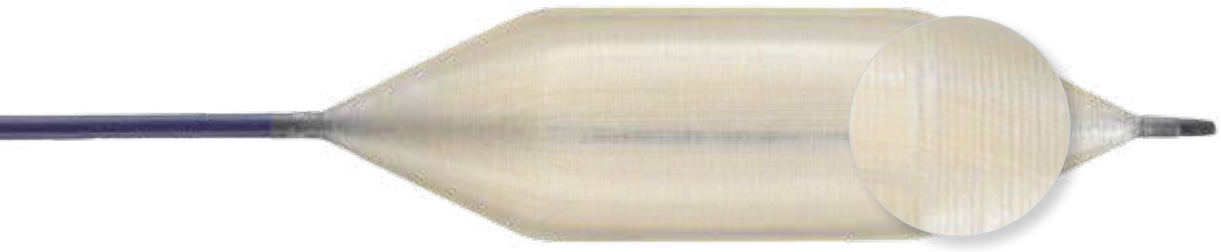
More Predictable Sizing vs. Z-Med™ II and Tyshak™ II



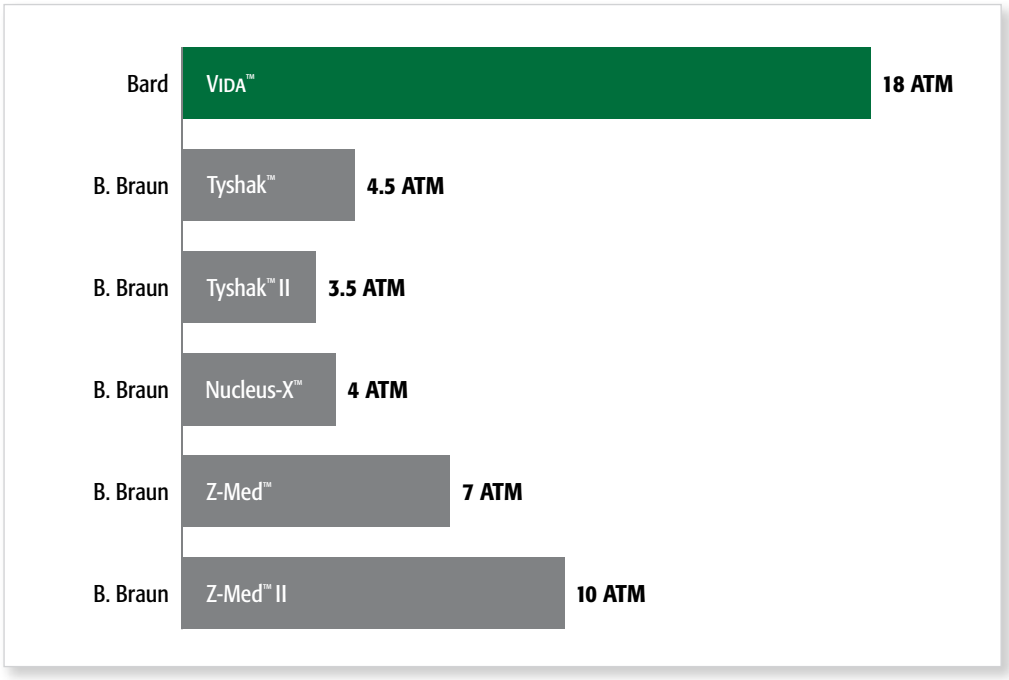
2 Rupture Resistant Material

The VIDA™ PTV Dilatation Catheter balloon is manufactured with fiber-based technology that is strong and puncture resistant. Fiber-based technology is designed to allow for higher rated burst pressures and predictable sizing.

Fiber Based Technology



Valvuloplasty Balloon Rated Burst Pressures*



*RBP based on diameters ≥12.

3 Low Profile

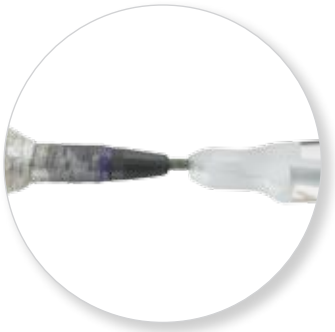
Low profile in a valvuloplasty procedure is mainly the focus in stand-alone procedures where the physician is not putting in a percutaneous valve. The percutaneous valves require large sheaths for implantation of the valve, whereas in stand-alone procedures a small sheath is desired.

Company	Product	Profile* (F)
Bard	**VIDA™**	**9**
B. Braun	Tyshak™	10
B. Braun	Tyshak™ II	8
B. Braun	Nucleus-X™	12
B. Braun	Z-Med™	12
B. Braun	Z-Med™ II	12

*20 mm x 4 cm balloons.

VIDA™ vs. Tyshak™ II

VIDA™ vs. Z-Med™ II



Inflation and Deflation Comparisons

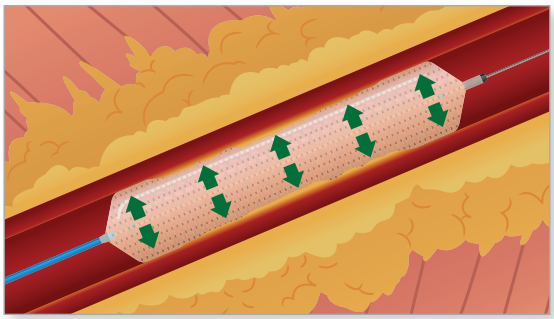
Company	Product	Balloon Size	Inflation* (Average seconds)	Deflation* (Average seconds)
Bard	**VIDA™**	**20 mm x 4 cm**	**6.93**	**5.64**
B. Braun	Tyshak™ II	20 mm x 4 cm	4.83	2.94
B. Braun	Z-Med™ II	20 mm x 4 cm	4.15	2.22

*Based on simulated use testing. Sample size N=5.

Benefits of Ultra Non-Compliance in Valvuloplasty

The two greatest benefits of ultra non-compliant technology for a valvuloplasty procedure are:

1. Predictable sizing of the balloon. Ultra non-compliant balloons have less than 5% growth in the balloon size from nominal pressure to RBP ensuring that the balloon does not "dog bone" and put pressure against structures that do not need dilatation.
2. The balloon material is strong and resistant to damage from calcification commonly seen in aortic valve stenosis.



Ultra non-compliant

Positioning / Targeting

Positioning

The VIDA™ PTV Dilatation Catheter will be positioned as an ultra non-compliant balloon with a low profile, designed to quickly and adequately dilate stenotic/calcified pulmonary valves while minimizing damage due to over dilatation. No competitive balloon will offer an ultra non-compliant valve balloon with the low profiles of the VIDA™ Catheter.

Targeting

Primary Targets

Doctors using B. Braun pulmonary PTV catheters (Specifically Tyshak™ and Tyshak™ II).

Secondary Targets

Large University/Teaching Hospitals doing pulmonary percutaneous valve procedures.

Pricing

Pricing

VIDA™ PTV Dilatation Catheter		
	12 mm - 16 mm	**18 mm - 26 mm**
List Price	$850	$1200

Product Codes

VIDA™ PTV Dilatation Catheter Product Codes

Diameter (mm)	Length (cm)	Nominal (ATM)	RBP (ATM)	Sheath Size (F)	Shaft Length (cm)	Order Codes
12	2	6	18	7	100	VDA100122
	4	6	18	7	100	VDA100124
	6	6	18	7	100	VDA100126
14	2	6	18	7	100	VDA100142
	4	6	18	7	100	VDA100144
	6	6	18	8	100	VDA100146
16	2	6	18	8	100	VDA100162
	4	6	18	8	100	VDA100164
	6	6	16	8	100	VDA100166
18	2	6	16	8	100	VDA100182
	4	6	16	8	100	VDA100184
	6	6	16	9	100	VDA100186
20	2	6	16	9	100	VDA100202
	4	6	16	9	100	VDA100204
22	2	4	14	10	100	VDA100222
	4	4	14	10	100	VDA100224
24	2	4	14	10	100	VDA100242
	4	4	14	10	100	VDA100244
26	2	4	12	12	100	VDA100262
	4	4	12	12	100	VDA100264

SPIN Examples

Situation Questions

- Do you use pulmonary valvuloplasty both to stabilize patients prior to valve surgery and/or as a stand-alone therapy?
- How many pulmonary percutaneous valves are you doing in your lab?
- Do you pre-dilate and perhaps post-dilate with a balloon catheter?

Problem* Questions

- How often do you experience balloon failure or rupture in the valves?
- What issues do you see with large introducer sheaths?
- Are the valves very calcified?
- How important is sizing of the balloon?

Implication Questions

- What happens when a balloon ruptures in the valve?
- What happens when the balloon is oversized? Or undersized?
- What are the implications of using a large introducer sheath?

Need-Payoff

- Have you heard about our new pulmonary valvuloplasty balloon?
- How would a small profile be of benefit to your cases when treating stand-alone valvuloplasty cases?
  - The VIDA™ PTV Dilatation Catheter is available with balloon diameters up to 26 mm on 12 Fr sheaths; the smallest ultra non-compliant profile large diameter pulmonary valve balloon on the market.
- How important is rupture resistance in a valvuloplasty case?
  - The VIDA™ PTV Dilatation Catheter is made with rupture resistant fibers.
- How important is accurate sizing of the balloon in a valvuloplasty procedure?
  - The VIDA™ PTV Dilatation Catheter is ultra non-compliant, meaning the balloon has very little growth and will not dog-bone.
  - The VIDA™ PTV Dilatation Catheter is also true to its size at both nominal and Rated Burst Pressure.

***If a complaint is made about a Bard product, please follow policy and report it to Field Assurance.**

Common Terminology

Annulus

When defined literally, an “annulus” is no more than a little ring. The annulus described by surgeons is usually the semilunar crown-like structure demarcated by the hinges of the leaflets.

Aortic Valve

The aortic valve lies between the left ventricle and the aorta.

Atrium

The atrium most commonly refers to a chamber in which blood enters the heart, as opposed to the ventricle, where it is pushed out of the organ.

BAV

Balloon Aortic Valvuloplasty.

Leaflets

Flaps that make up the valves of the heart.

Mitral Valve

The mitral valve lies between the left atrium and left ventricle.

Pulmonary Valve

The pulmonary valve lies between the right ventricle and the pulmonary artery.

TAVI

Transcatheter Aortic Valve Implantation.

TAVR

Transcatheter Aortic Valve Replacement.

Tricuspid Valve

The tricuspid valve, which has 3 leaflets, lies between the right atrium and right ventricle.

Valvuloplasty

A balloon valvuloplasty is a minimally invasive procedure, performed in the cardiac catheterization laboratory, to open narrowed or stenosed heart valves including the aortic and pulmonary valve.

Ventricle

The ventricle refers to a chamber in which blood is pushed out of the heart.

Watermelon Seeding or Slippage in Valve

Balloon slipping or sliding out of the valve landing site.

Frequently Asked Questions

What is pulmonary valve stenosis?

Pulmonary valve stenosis is a heart valve disorder in which outflow of blood from the right ventricle of the heart is obstructed at the level of the pulmonic valve. This results in the reduction of flow of blood to the lungs.

What is balloon pulmonic valvuloplasty?

Pulmonic valvuloplasty is the repair of a stenotic pulmonary valve using a balloon catheter inside the valve. The balloon is placed into the pulmonary valve that has become stiff from calcium buildup or congenital defect. The balloon is then inflated in an effort to increase the opening size of the valve and improve blood flow.

What are the symptoms of pulmonary valve stenosis?

Symptoms include jugular vein distension, cyanosis (usually visible in the nailbeds), right ventricular hypertrophy, and general symptoms of lowered oxygenation of the blood. When the stenosis is mild, it can go unnoticed for many years and have no negative symptoms. If stenosis is severe, sudden fainting or dizziness may occur when exercising. An enlarged liver (hepatomegaly) and swelling in the legs (edema) may also be apparent.

What are the advantages of the Melody Valve procedure?

The Melody™ Valve improves the function of the cardiac outflow track that delivers blood to the lungs, thus improving oxygenation and lessening symptoms.

Appendix

Ultra Non-Compliance Review

Non-Compliance Review

Pressure alone does not determine the effectiveness of a balloon in resistant lesions, the degree of compliance should also be considered.

Different angioplasty balloon materials provide differing degrees of compliance, which is typically characterized as the amount of diameter growth in the balloon between nominal and rated burst pressure. Non-compliant balloons inflate to pre-set diameters even at higher pressures while semi-compliant balloons are prone to overstretching in areas of less plaque and do not exert equal forces without balloon distortion.

The VIDA™ PTV Dilatation Catheter balloon is made with a proprietary fiber-based material that provides ultra high pressure strength and ultra non-compliance allowing for the treatment of the most resistant lesions.

When considering competitive threats, it is important to compare RBP and compliance. Competitive RBPs are often found on balloon packaging and compliance is often found on an enclosed compliance card. If one is not available, it can be calculated by using the following formula:

$$C = \frac{d_{RBP} - d_{NP}}{d_{NP}} * 100\%$$

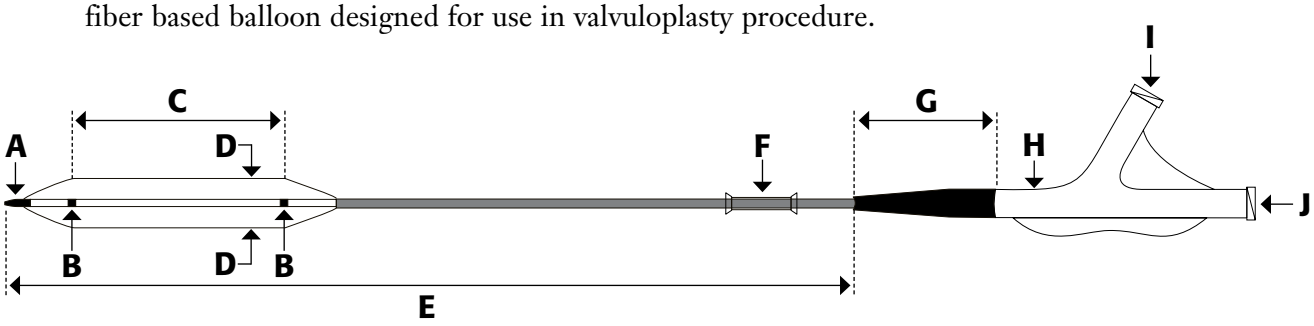
C = compliance % *d_{RBP} = diameter at rated burst pressure* *d_{NP} = diameter at nominal pressure*

The combination of highly non-compliant balloon material and high rated burst pressures will allow the treatment of more lesions.

Appendix

Balloon Schematics

The VIDA™ PTV Dilatation Catheter is a large diameter balloon catheter consisting of a fiber based balloon designed for use in valvuloplasty procedure.



A	Tip of the Balloon Catheter	**F**	Threaded Refold Tool
B	Marker Bands	**G**	Strain Relief
C	Balloon Length	**H**	Hub
D	Balloon Outer Diameter	**I**	Balloon Inflation Port
E	Shaft Length (from the distal end of the strain relief to the distal end of the tip)	**J**	Guidewire Port

NOTE: Drawing is not to scale and represents a general overview of a balloon catheter.

Definitions

Balloon Body Length – Horizontal distance between the shoulders of the balloon.

Balloon Cone Angle – Angle between the balloon body and the portion of the balloon coming off the shaft and the tip (balloon shoulders).

Balloon Cone Length – Horizontal distance from end of balloon body to the shaft and the tip.

Balloon Working Length – Horizontal distance between marker bands.

Deflation Time – Time required to fully deflate the balloon from rated burst pressure.

Inflation Time – Time required to fully inflate the balloon to rated burst pressure.

Nominal Pressure (OP) – The pressure at which the balloon reaches its labeled diameter.

Pushability – Ability to successfully push the balloon catheter to the lesion.

Rated Burst Pressure (RBP) – The pressure at which the manufacturer has 95% confidence that 99.9% of balloons will not burst at or below upon single inflation.

Appendix

Information for Use

VIDA™

PTV Dilatation Catheter

ENGLISH

INSTRUCTIONS FOR USE

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Device Description

The VIDA™ PTV Dilatation Catheter is a high performance balloon catheter consisting of an over-the-wire catheter with a balloon fixed at the distal tip. The proprietary, non-compliant, low profile balloon is designed to provide consistent balloon diameters and lengths even at high pressures. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The coaxial catheter includes an atraumatic tip to facilitate advancement of the catheter to and through the valve. The over-the-wire catheter is compatible with .035" guidewire and is available in 100 cm working length. The proximal portion of the catheter includes a female luer-lock hub connected to the inflation lumen, and a female luer-lock hub connected to the guidewire lumen.

Packaged with every product is a profile reducing sheath that is positioned over the balloon for protection before use. A re-wrapping tool is also provided on the catheter shaft.

This product is not manufactured with any latex.

Indications for Use

The VIDA™ PTV Dilatation Catheter is recommended for Percutaneous Transluminal Valvuloplasty of the pulmonary valve in the following:

- A patient with isolated pulmonary valve stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

Contraindications

None known.

Warnings

1. **Contents supplied STERILE using ethylene oxide (EO). Non-Pyrogenic. Do not use if sterile barrier is opened or damaged. Single patient use only. Do not reuse, reprocess or re-sterilize.**
2. **This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.**
3. **Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.**
4. **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 Valvuloplasty and Angioplasty of Congenital Anomalies Registry (VACA) to be up to 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. Right ventricular outflow tract damage has occurred with balloons larger than 1.5 times the size of valve annulus.
5. **Careful consideration should be given in balloon length selection. Longer length balloons may impinge surrounding structures leading to injury.**
6. **When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Applying excessive force to the catheter can result in tip breakage or balloon separation.**
7. **Do not exceed the RBP recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over-pressurization, use of a pressure monitoring device is recommended.**
8. **After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations.**

Precautions

1. Carefully inspect the catheter prior to use to verify that catheter has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident.
2. The catheter should only be used by physicians trained in the performance of percutaneous transluminal valvuloplasty.
3. The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the catheter through a smaller size sheath introducer than indicated on the label.
4. Use the recommended balloon inflation medium of approximately 25 to 75 contrast to saline ratio. Never use air or other gaseous medium to inflate the balloon.
5. If resistance is felt during post procedure withdrawal of the catheter through the introducer sheath, determine if contrast is trapped in the balloon with fluoroscopy. If contrast is present, push the balloon out of the sheath and then completely evacuate the contrast before proceeding to withdraw the balloon.
6. If resistance is still felt during post procedure withdrawal of the catheter, it is recommended to remove the balloon catheter and guidewire/introducer sheath as a single unit.
7. Do not continue to use the balloon catheter if the shaft has been bent or kinked.
8. Prior to re-insertion through the introducer sheath, the balloon should be wiped clean with gauze, rinsed with sterile normal saline, and refolded with the balloon re-wrap tool. Balloon re-wrapping should only occur while the balloon catheter is supported with a guidewire.
9. Dilatation procedures should be conducted under high-quality fluoroscopic guidance.
10. Careful attention must be paid to the maintenance of tight catheter connections. Aspirate before proceeding to avoid air introduction into the system.

Potential Adverse Reactions

The complications which may result from a percutaneous transluminal valvuloplasty procedure include:

- Additional intervention
- Allergic reaction to drugs or contrast medium
- Aneurysm or pseudoaneurysm
- Arrhythmias
- Embolization
- Hematoma
- Hemorrhage, including bleeding at the puncture site
- Hypotension/hypertension
- Inflammation
- Occlusion
- Pain or tenderness
- Pneumothorax or hemothorax
- Sepsis/infection
- Shock
- Short term hemodynamic deterioration
- Stroke
- Thrombosis
- Vessel dissection, perforation, rupture, or spasm
- Conduction System Injury
- Valvular Tearing or Trauma
- Cardiovascular Injury

Directions for Use

Handling & Storage

Store in a cool, dry, dark place. Do not store near radiation or ultra-violet light sources.

Rotate inventory so that the catheters and other dated products are used prior to the “Use By” date.

Do not use if packaging is damaged or opened.

Equipment for Use

- Contrast medium
- Sterile saline solution
- Luer lock syringe/inflation device with manometer (10 ml or larger)
- Appropriate introducer sheath and dilator set
- .035" guidewire

Dilatation Catheter Preparation

1. Remove Catheter from package. Verify the balloon size is suitable for the procedure and the selected accessories accommodate the catheter as labeled.
2. Remove the balloon guard by grasping the balloon catheter just proximal to the balloon and with the other hand, gently grasp the balloon protector and slide distally off of the balloon catheter.

Appendix

Information for Use

3. Prior to use, the air in the balloon catheter should be removed. To facilitate purging, select a syringe or inflation device with a 10 ml or larger capacity and fill approximately half of it with the appropriate balloon inflation medium. Do not use air or any gaseous medium to inflate the balloon.
4. Connect a stopcock to the balloon inflation female luer hub on the dilatation catheter.
5. Connect the syringe to the stopcock.
6. Hold the syringe with the nozzle pointing downward, open the stopcock and aspirate for approximately 15 seconds. Release the plunger.
7. Repeat step #6 two more times or until bubbles no longer appear during aspiration (negative pressure). Once completed, evacuate all air from the barrel of the syringe/inflation device.
8. Prepare the wire lumen of the catheter by attaching a syringe to the wire lumen hub and flushing with sterile saline solution.

Use of the VIDA™ PTV Dilatation Catheter

1. Backload the distal tip of the VIDA™ PTV Dilatation Catheter over the pre-positioned guidewire and advance the tip to the introduction site.
2. Advance the catheter through the introducer sheath and over the wire to the site of inflation.
3. Position the balloon relative to the valve to be dilated, ensure the guidewire is in place and, while ensuring the balloon is held in a static position, inflate the balloon to the appropriate pressure.
4. Apply negative pressure to fully evacuate fluid from the balloon. Confirm that the balloon is fully deflated under fluoroscopy.
5. While maintaining negative pressure and the position of the guidewire, withdraw the deflated catheter over the wire through the introducer sheath. Use of a gentle counter clockwise motion may be used to help facilitate catheter removal through the introducer sheath.

Balloon Reinsertion

Precaution: Do not continue to use the catheter if the shaft has been bent or kinked.

Precaution: Prior to re-insertion through the introducer sheath, the balloon should be wiped clean with gauze, rinsed with sterile normal saline, and refolded with the balloon re-wrap tool. Balloon re-wrapping should only occur while the catheter is supported with a guidewire.

1. Load the catheter onto a guidewire.
2. Advance the balloon re-wrap tool over the catheter to the proximal end of the balloon.
3. Grasp the catheter shaft just proximal to the balloon with one hand, and with the other hand gently slide the re-wrap tool over the balloon to the catheter tip and then back over the balloon to the catheter.
4. Slide the re-wrap tool to the proximal end of the catheter shaft.
5. Advance the catheter over the pre-positioned guidewire to the introduction site and through the introducer sheath. If resistance is encountered, replace the previously used balloon catheter with a new balloon.
6. Continue the procedure according to the "Use of the VIDA™ PTV Dilatation Catheter" section herein.

Warning: After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations.

Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase, and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion, or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your country.

An issue or revision date and revision number for these instructions are included for the user's information on the last page of this booklet.

In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use.

S120372 Rev 0

BARD | PERIPHERAL VASCULAR

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