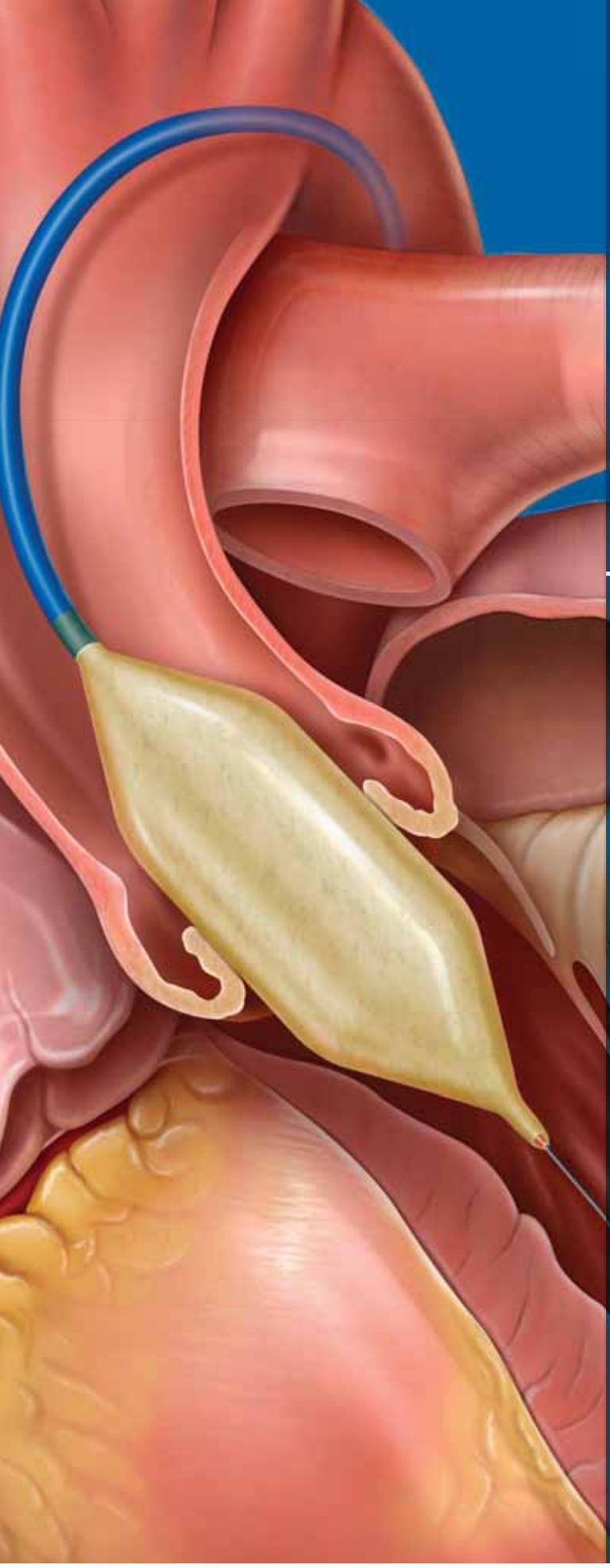

Dilate Aortic Valves with **Precision and Speed**

TRUE® DILATATION

Balloon Valvuloplasty Catheter

BD

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Truly **Precise**

The TRUE® DILATATION Balloon Valvuloplasty Catheter is true to size, exhibiting less than 1.0% stretch between 1 ATM and RBP.[1]

[1] Bench data on file. Results may not necessarily be indicative of clinical performance. Different tests may yield different results. Percentage stretch calculated using 22 mm balloons.

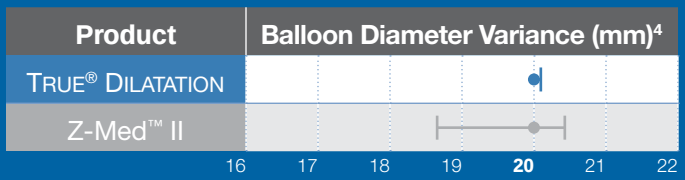
Truly **Fast Inflation & Deflation**

Designed to minimize rapid pacing times, the TRUE® DILATATION Balloon Valvuloplasty Catheter inflates and deflates in 5.6 seconds.[2]

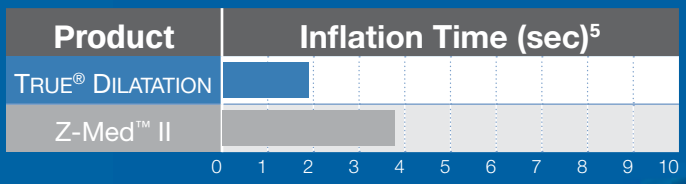
[2] N=10. Bench data on file. Results may not necessarily be indicative of clinical performance. Different tests may yield different results. Data for 22 mm balloon.

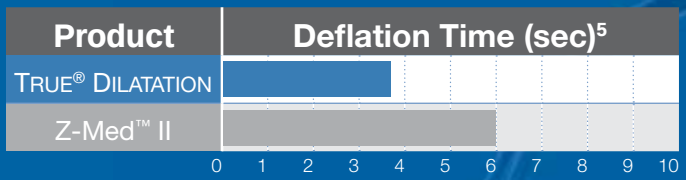
A TRUE **Competitive Advantage**

More **Predictable Sizing** vs. Competition[4]



[4] Data for competitive balloons obtained from manufacturer IFUs. Data for TRUE® based on bench data, on file at Bard Peripheral Vascular, Inc., Tempe, Arizona. Accuracy measurements based on variance in balloon diameter between 1 ATM and RBP for 22 mm balloons.





[5] Compared a TRUE® 20 mm x 4.5 cm balloon to a Z-Med™ II, 20 mm x 4 cm balloon. N=10. Bench data on file. Results may not necessarily be indicative of clinical performance. Different tests may yield different results.

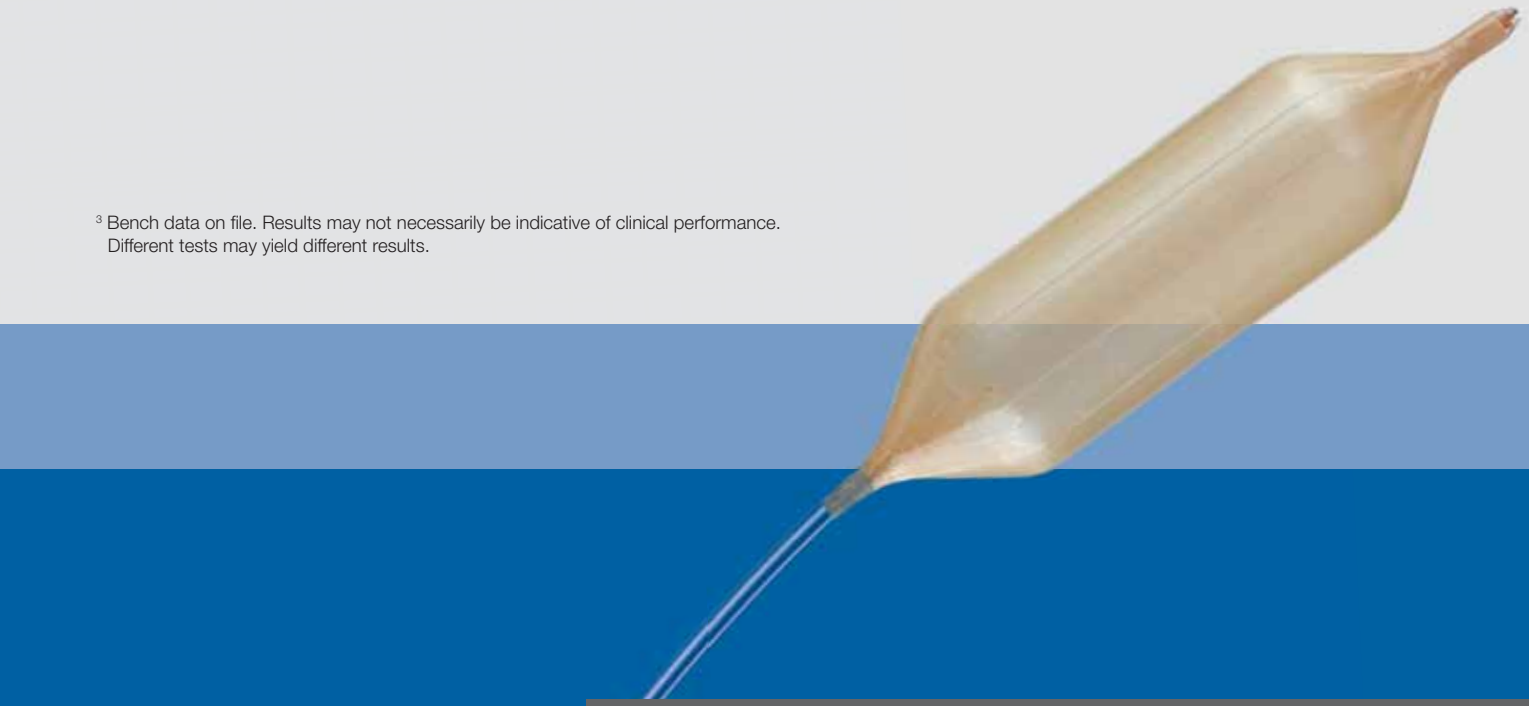
Truly **Rupture Resistant**

The TRUE® DILATATION Balloon Valvuloplasty Catheter is engineered to avoid catastrophic failures and is highly resistant to ruptures, punctures, and tears.[3]

Truly **Tight Re-Wrap**

The TRUE® DILATATION Balloon Valvuloplasty Catheter is engineered to deliver a consistent, tight re-wrap providing a low withdrawal profile after dilatation.

[3] Bench data on file. Results may not necessarily be indicative of clinical performance. Different tests may yield different results.



Fiber Based Technology

TRUE® DILATATION versus Z-Med™ II[6]

Characteristic	TRUE® DILATATION	Z-Med II™
Aortic Valvuloplasty Indication	✔	✔
Precise	✔	
Rupture Resistant	✔	
Fiber Technology	✔	
Fast Inflate/Deflate	✔	

[6] Data for competitive balloons obtained from manufacturer IFUs. Data for TRUE® based on bench data, on file at Bard Peripheral Vascular, Inc., Tempe, AZ. Accuracy measurements based on variance in balloon diameter between 1 ATM and RBP for 22 mm balloons.

INSTRUCTIONS FOR USE

Description: The TRUE® DILATATION Balloon Valvuloplasty Catheter is an over-the-wire co-axial catheter with a balloon fixed at the tip. The catheter is available in110 cm and 55 cm lengths, and has two lumens: one lumen is used to inflate and deflate the balloon and the other permits the use of a guidewire to position the catheter. The balloon inflation luer-lock hub (angled) connects to a syringe inflation device to deliver radiopaque contrast media for inflation. The guidewire luer-lock hub (straight) connects to the guidewire lumen. The balloon is non-compliant and is designed to reach a known diameter and length when inflated within the specified pressure range. Two radiopaque marker bands are provided for fluoroscopic positioning of the device across the aortic valve. These bands are positioned at the proximal and distal balloon shoulders. Balloon catheter dimensions, balloon nominal pressure, maximum inflation pressure, recommended introducer size, and recommended guidewire size are indicated on the package label.

Packaging: Sterile: Sterilized with ethylene oxide gas. Do not use if package is open or damaged.

Storage: Store in a cool, dry place.

This device is available by prescription use only.

Indications for Use: The TRUE® DILATATION Balloon Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Contraindications: The TRUE® DILATATION Balloon Valvuloplasty Catheter is contraindicated for use in patients with annular dimensions < 18 mm.

Potential Complications / Adverse Events: 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, cardiovascular injury, conduction system injury, 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, valvular tearing or trauma, vessel dissection, perforation, rupture, or spasm.

Warnings & Precautions: · 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. · 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 amount of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. · 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. · Catheter balloon inflation diameter must be carefully considered in selecting a particular size for any patient. It is critical to perform a clinical diagnostic determination of valve anatomical dimensions prior to use; imaging modalities such as transthoracic echocardiogram (TTE), computerized tomography (CT), angiography, and/or transesophageal echocardiogram (TEE) should be considered. The inflated balloon diameter should not be significantly greater than valvular diameter. · 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, or cause injury to the patient (such as vessel perforation). · If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter to rupture, resulting in vessel trauma. Remove and replace catheter. · 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. · If using device to support Transcatheter Aortic Valve Implantation (TAVI), consult TAVI system's Instructions for Use for any additional procedural instructions related to selection and use of valvuloplasty balloon. · 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. · The catheter should only be used by physicians trained in the performance of percutaneous transluminal valvuloplasty. · The minimal acceptable 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. · Use the recommended balloon inflation medium of 1/3 to 2/3 contrast to saline ratio. Never use air or other gaseous medium to inflate the balloon. · 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. · 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. · In the very unlikely event of balloon burst or rupture, balloon could be more difficult to remove through the sheath and could require introducer sheath removal. · Do not torque, excessively bend catheter or continue to use if the shaft has been bent or kinked. · Prior to re-insertion through the introducer sheath, the balloon should be wiped clean with gauze and rinsed with sterile normal saline. · Do not remove guidewire from catheter during procedure. · Dilation procedures should be conducted under high-quality fluoroscopic guidance. · Careful attention must be paid to the maintenance of tight catheter connections. Aspirate before proceeding to avoid air introduction into the system. · If inflating balloon in patient to facilitate re-folding, ensure balloon is positioned so that it can be inflated safely.

Please consult package insert for more detailed safety information and instructions for use.

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