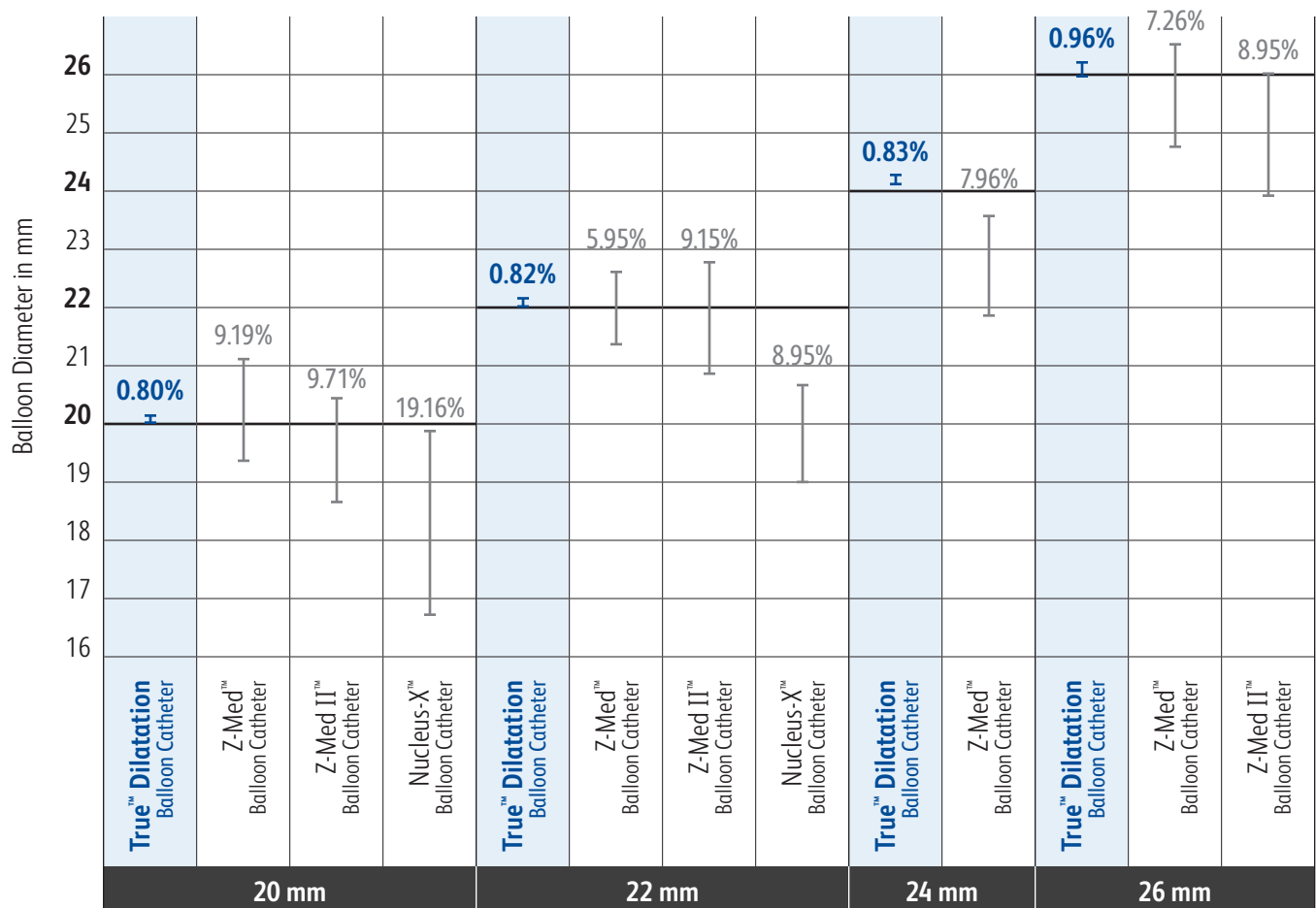


Engineered for Precise Sizing

True™ Dilatation Balloon Valvuloplasty Catheter

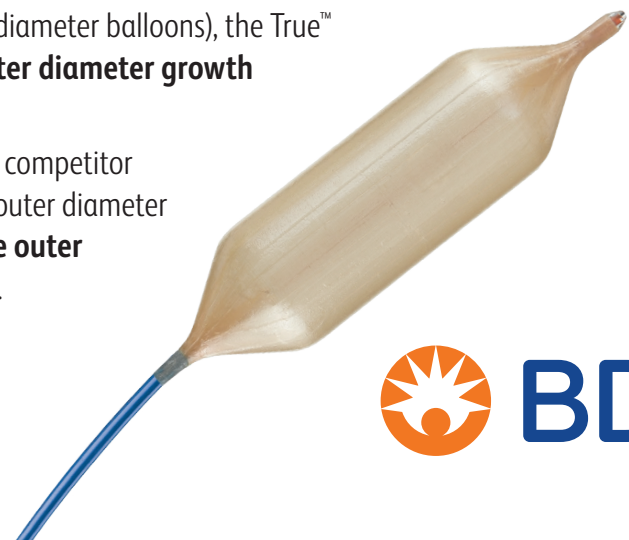
Aortic Valvuloplasty Balloons - Mean Outer Diameter Growth Between 1 atm and Rated Burst Pressure (RBP)



Across a select range of sizes (20, 22, 24, and 26 mm diameter balloons), the True™ Dilatation balloon exhibited an average of **0.85% outer diameter growth** between 1 atm and RBP.¹

Across the same range of sizes, the next best selected competitor (the Z-Med™ Catheter) exhibited an average of 7.59% outer diameter growth between 1 atm and RBP, or **more than 8x the outer diameter growth of the True™ Dilatation Balloon**.

¹ Accuracy measurements based on outer diameter balloon growth between 1 atm and RBP. Balloon outer diameters are measured at center of the balloon. N=10 for each True™ Dilatation Balloon size tested. Bench test data on file. BD, Tempe, AZ. Bench test data may not be representative of actual clinical outcomes. Different test methods may yield different results. Data for competitive balloons obtained from respective manufacturer IFUs.



True™ Dilatation

Balloon Valvuloplasty Catheter

Recommended Guidewire 0.035"						
Diameter (mm)	Length (cm)	Nominal (atm)	RBP (atm)	Sheath Size (F)	Shaft Length (cm)	Order Codes
18	4.5	3	6	11	110	<input type="checkbox"/> 0184511
20	4.5	3	6	11	110	<input type="checkbox"/> 0204511
21	4.5	3	6	12	110	<input type="checkbox"/> 0214512
22	4.5	3	6	12	110	<input type="checkbox"/> 0224512
23	4.5	3	6	12	110	<input type="checkbox"/> 0234512
24	4.5	3	6	12	110	<input type="checkbox"/> 0244512
25	4.5	3	6	13	110	<input type="checkbox"/> 0254513
26	4.5	3	6	13	110	<input type="checkbox"/> 0264513
28	4.5	3	6	14	110	<input type="checkbox"/> 0284514

Indications for Use: The True™ Dilatation Balloon Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Contraindications for Use: The True™ Dilatation Balloon Valvuloplasty Catheter is contraindicated for use in patients with annular dimensions < 18 mm.

Potential Complications: 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: • 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. • 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.

Precautions: • 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 minimal acceptable French size is printed on the package label. Do not attempt to pass the catheter through a smaller size introducer sheath 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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