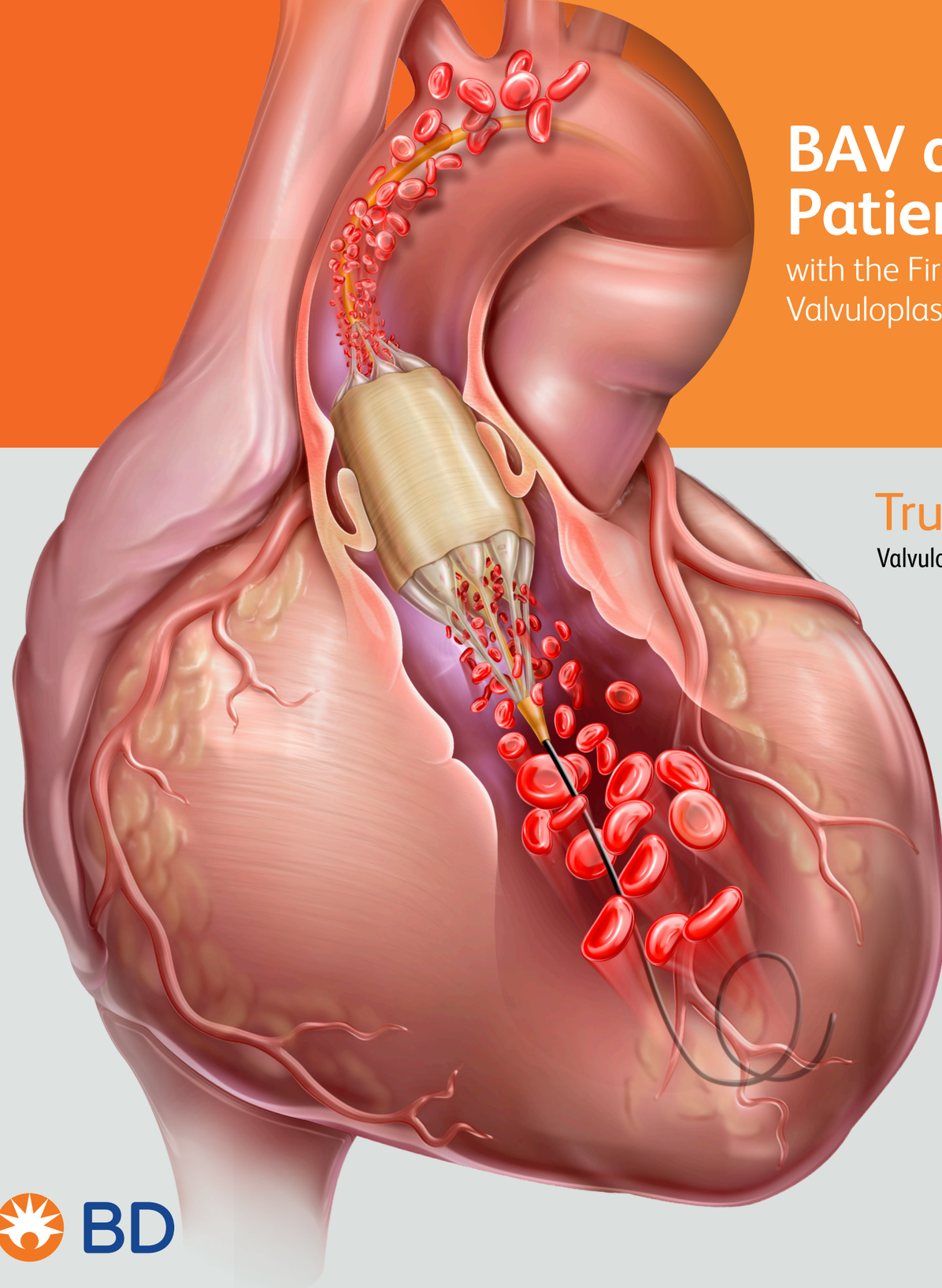
True™ Flow

Valvuloplasty Perfusion Catheter

110 cm Shaft Length

Diameter (mm)	Length (cm)	Nominal (ATM)	RBP (ATM)	Sheath Size (F)	Order Codes
18	3.5	3	6	11	☐ TF0183511
20	3.5	3	6	11	☐ TF0203511
22	3.5	3	6	12	☐ TF0223512
24	3.5	3	6	14	☐ TF0243514
26	3.5	3	6	16	☐ TF0263516

Indications for Use: The True™ Flow Valvuloplasty Perfusion Catheter is indicated for balloon aortic valvuloplasty.
Contraindications: None known
Warnings: • Do not use in patients with annular dimensions <18 mm. • 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. • To reduce thrombosis, this device should not be used without appropriate anticoagulation. It is recommended to maintain an ACT of ≥ 200 seconds during use of this device.
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 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. • Do not re-insert the catheter into the body once it has been removed from the sheath, as withdrawing balloon through introducer sheath may damage balloon. • 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.
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 · Cardiovascular injury · Conduction system injury · Death · 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
Please consult package insert for more detailed safety information and instructions for use.



BAV at Your Patient's Pace

with the First Flow-Through Valvuloplasty Catheter

True™ Flow

Valvuloplasty Perfusion Catheter

bd.com BD, Tempe, AZ, USA, 1 800 321 4254

Innovative Design

The True™ Flow Valvuloplasty Perfusion Catheter uses a unique eight chamber inflation design to allow continuous cardiac blood flow through the open central lumen.

IN THE TRUE-FLOW STUDY,[2]

91.3%

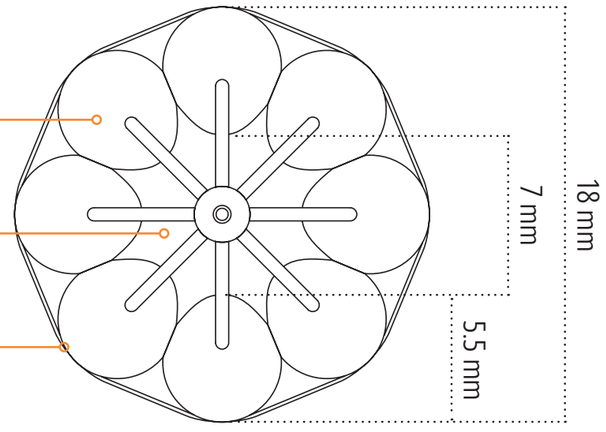
OF PATIENTS UNDERWENT **SUCCESSFUL BAV** WITHOUT RAPID PACING.[3]

- Engineered to be **true to size**, exhibiting less than 1% stretch between nominal and rated burst pressure (RBP)[1]
- Designed to provide **low hemodynamic resistance on the balloon** while inflated
- Designed to be **rupture resistant** with a proprietary fiber-based shell

Eight individual balloon chambers retain dilation catheter integrity

Open inner lumen

Proprietary fiber-based shell



Dimensions of an 18 mm balloon. Different sizes will have different dimensions. More sizes are available.

[1] Based on simulated bench testing for 20 mm True™ Flow balloon, N =30. May not be indicative of actual clinical performance. Data on file, Becton, Dickinson and Company. Different tests may yield different results.

True-Flow Study

Design	Single center, prospective trial
Objective	Assess acute performance and safety of the True™ Flow Valvuloplasty Perfusion Catheter during dilatation of the aortic valve in preparation for TAVI
As Treated Population	24 patients at risk for pacing-related complications
Principal Investigator	Axel Linke, MD
Endpoints	**Performance** · Successful pre-dilatation of a stenotic aortic valve without clinically significant movement of the device while maintaining acceptable intraventricular pressures with or without ventricular pacing **Safety** · Freedom from device or procedure related adverse events defined as death, stroke, annulus rupture, or ventricular perforation from the time of True™ Flow Catheter introduction until TAVI device introduction
Results	**Performance** · 91.3% of patients underwent successful BAV without clinically significant movement as defined by the operator · 91.7% of patients received no ventricular pacing during BAV with a True™ Flow catheter · No significant change in intraventricular pressures **Safety** · No device-related adverse events

Data on file, Becton, Dickinson and Company. Tempe, AZ

[2] Successful BAV defined as complete opening of the device without clinically significant movement while maintaining acceptable intraventricular pressures, as defined by the operator, with or without ventricular pacing. Mean device movement was 2mm and no clinically significant changes in intraventricular pressure were observed. Rapid pacing defined as ≥ 180 BPM. Two patients with preexisting pacemakers paced at an average of 140 BPM.

[3] Any decision regarding the conduct of any specific procedure, including ventricular pacing, must be made by the physician, who should follow appropriate institutional guidelines and consider all circumstances relevant to the clinical situation.