BAV At Your Patient’s Pace
With the First Flow-Through Valvuloplasty Catheter
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.

- The TRUE® FLOW Valvuloplasty Perfusion Catheter is engineered to be true to size, exhibiting less than 1% stretch between nominal and rated burst pressure (RBP)\(^1\)
- The TRUE® FLOW Valvuloplasty Perfusion Catheter is designed to provide low hemodynamic resistance on the balloon while inflated
- BD’s proprietary fiber-based shell is designed to be rupture resistant

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\(^1\) Based on simulated bench testing for 20 mm TRUE® FLOW balloon, N = 30. May not be indicative of actual clinical performance. Data on file at Bard Peripheral Vascular. Different tests may yield different results.
Clinical Performance

In the TRUE-FLOW study\(^2\), 91.3% of patients underwent successful BAV without rapid pacing.*

TRUE-FLOW Study

<table>
<thead>
<tr>
<th>Design</th>
<th>Single center, prospective trial</th>
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</thead>
<tbody>
<tr>
<td>Objective</td>
<td>Assess acute performance and safety of the True(^\circ) Flow Valvuloplasty Perfusion Catheter during dilatation of the aortic valve in preparation for TAVR</td>
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<tr>
<td>As Treated Population</td>
<td>24 patients at risk for pacing related complications</td>
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<tr>
<td>Principal Investigator</td>
<td>Axel Linke, MD</td>
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</tbody>
</table>

**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\(^\circ\) 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\(^\circ\) Flow catheter
- **Safety**
  - No significant change in intraventricular pressures
  - No device related adverse events

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

* 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.

Data on file, Bard Peripheral Vascular, Inc. Tempe, AZ
The TRUE® FLOW Valvuloplasty Perfusion Catheter is indicated for balloon aortic valvuloplasty.

Contraindications
None known

Warnings
1) Do not use in patients with annular dimensions <18mm. 2) Contents supplied STERILE using ethylene oxide (EO). Non-sterile. Do not use if sterile barrier is opened or damaged. Single patient use only. Do not re-use, re-process or re-sterilize. 3) 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. 4) Do not re-sterilize. After re-sterilization, 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 re-sterilization 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. 5) Catheter balloon inflation diameter must be carefully considered in selecting a particular size for the procedure for which it is to be used. Do not use if product damage is evident. 6) The inflated diameter should not be significantly greater than valvular diameter. 7) Do not exceed the RBP recommended for this balloon size. 8) 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. 9) Do not remove guidewire from catheter during procedure. 10) Do not attempt to pass the catheter through a smaller size sheath introducer than indicated on the label. 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. 11) Dilation procedures should be conducted under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is met during the procedure for which it is to be used. Do not use if product damage is evident. 12) 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. 13) 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. 14) 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. 15) Do not remove guidewire from catheter during procedure. 16) Do not attempt to pass the catheter through a smaller size sheath introducer than indicated on the label. 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. 17) Do not attempt to clear catheter lumen by any means other than 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. 18) Do not exceed the RBP recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over-pressureisation, use of a pressure monitoring device is recommended. 19) After use, this product may be a potential hazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state, and federal laws and regulations. 20) 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. 21) 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
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 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 1/3 to 2/3 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) 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. 8) 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. 9) Do not remove guidewire from catheter during procedure. 10) Do not remove guidewire from catheter during procedure. 11) Dilation procedures should be conducted under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is met during the procedure for which it is to be used. Do not use if product damage is evident. 12) 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. 13) 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. 14) 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. 15) Do not remove guidewire from catheter during procedure. 16) Do not attempt to clear catheter lumen by any means other than 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. 17) Do not exceed the RBP recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over-pressureisation, use of a pressure monitoring device is recommended. 18) After use, this product may be a potential hazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state, and federal laws and regulations. 19) 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. 20) 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.

Potential Adverse Reactions
The complications which may result from a percutaneous transluminal valvuloplasty procedure include:
- Additional intervention
- Allergic reaction to drugs or contrast medium
- Asystole or pseudoasystole
- Arrhythmia
- Cardiac arrest
- Coronary system injury
- Death
- Embolization
- Hematoma
- Hemorrhage, including bleeding at the puncture site
- Hypotension/hypertension
- Inflammation
- Occlusion
- Pain or tenderness
- Pneumothorax or hemotorax
- Septic infection
- Shock
- Short term hemodynamic deterioration
- Stroke
- Thrombosis
- Vascular tearing or trauma
- Vessel dissection, perforation, rupture, or spasm
- None known

Contraindications
None known

Indications for Use
Percutaneous transluminal balloon valvuloplasty.

Thrombosis • Valvular tearing or trauma • Vessel dissection, perforation, rupture, or spasm • Sepsis/infection • Shock • Short term hemodynamic deterioration • Stroke • Conduction system injury • Death • Embolization • Hematoma • Hemorrhage, including bleeding at the puncture site • Hypotension/hypertension • Inflammation • Occlusion • Pain or tenderness • Pneumothorax or hemotorax • Septic infection • Shock • Short term hemodynamic deterioration • Stroke • Thrombosis • Vascular tearing or trauma • Vessel dissection, perforation, rupture, or spasm

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

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