

Expand your BAV Options

Introducing the First Flow-Through
Valvuloplasty Catheter

Only balloon valvuloplasty catheter*
designed to provide continuous
cardiac blood flow **independent of
the heart's rhythmic state.**

Designed to provide **low
hemodynamic resistance**
on the balloon while inflated.

Wrapped in a **rupture resistant**
fiber-based shell.

Available in diameters from **18 mm to
26 mm.**

TRUE™ FLOW
Valvuloplasty Perfusion Catheter

*In EU and US markets, as of January 2016.

Technical Specifications

For 18 mm balloon. Additional sizes are available.

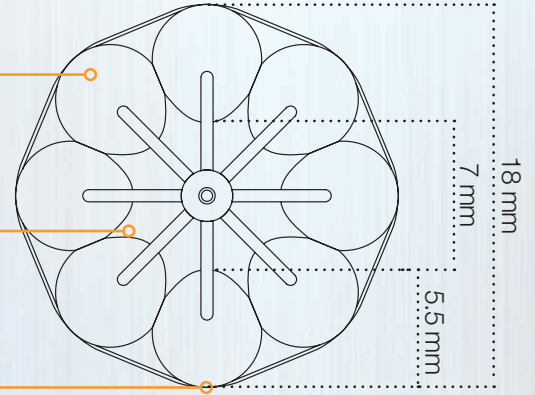
Simulated Hemodynamic Metrics*

| | |
|---------------------------|-----------|
| Cardiac Output | 1.0 L/min |
| Pressure Gradient | 75 mmHg |
| Aortic Regurgitation | 75% |
| Aortic Systolic Pressure | 50.1 mmHg |
| Aortic Diastolic Pressure | 7.7 mmHg |
| Mean Aortic Pressure | 25 mmHg |

Eight individual balloon chambers retain dilation catheter integrity

Open inner lumen is designed to provide continuous cardiac blood flow, independent of the heart's rhythmic state

Proprietary fiber-based shell provides rupture resistance



* Bench testing conducted using a Vivitro Pulse Duplicator System on an 18 mm balloon, HR of 70 bpm, systolic waveform of 35%, CO of 3.5L/min and pressure of 120/80 mmHg. N= 30. Bench data results may not be indicative of actual clinical performance. Different tests may yield different results.

TRUE™ FLOW

Valvuloplasty Perfusion Catheter

Ordering Information

| Diameter (mm) | Length (cm) | Nominal (ATM) | RBP (ATM) | Sheath Size (F) | Shaft Length (cm) | Product Code |
|---------------|-------------|---------------|-----------|-----------------|-------------------|------------------------------------|
| 18 | 3.5 | 3 | 6 | 11 | 110 | <input type="checkbox"/> TF0183511 |
| 20 | 3.5 | 3 | 6 | 11 | 110 | <input type="checkbox"/> TF0203511 |
| 22 | 3.5 | 3 | 6 | 12 | 110 | <input type="checkbox"/> TF0223512 |
| 24 | 3.5 | 3 | 6 | 14 | 110 | <input type="checkbox"/> TF0243514 |
| 26 | 3.5 | 3 | 6 | 16 | 110 | <input type="checkbox"/> TF0263516 |

| |
|-----------------------|
| |
| REPRESENTATIVE'S NAME |
| |
| CONTACT PHONE NO. |
| |
| PHYSICIAN'S SIGNATURE |

True Flow Valvuloplasty Perfusion Catheter

Indications for Use

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-pyrogenic. Do not use if sterile barrier is opened or damaged. Single patient use only. Do not reuse, reprocess 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 indeterminate amount of time. The residue of biological material can promote the contamination of the device with pyrogenic microorganisms which may lead to infectious complications. **4)** Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminate 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. **5)** 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. **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, or cause injury to the patient (such as vessel perforation). **7)** 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. **8)** 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. **9)** 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. **10)** 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

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)** Administer anticoagulant according to hospital protocol. It is recommended to maintain an ACT of ≥200 seconds during use of this device. **4)** 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. **5)** 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. **6)** 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. **7)** 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. **8)** 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. **9)** Do not torque, excessively bend catheter or continue to use if the shaft has

been bent or kinked. **10)** 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. **11)** Do not remove guidewire from catheter during procedure. **12)** Dilation procedures should be conducted under high-quality fluoroscopic guidance. **13)** Careful attention must be paid to the maintenance of tight catheter connections. Aspirate before proceeding to avoid air introduction into the system. **14)** 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.

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Bard Peripheral Vascular, Inc. | 1625 W. 3rd Street | Tempe, AZ 85281 | 1 800 321 4254 | www.bardpx.com

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