VIDA™

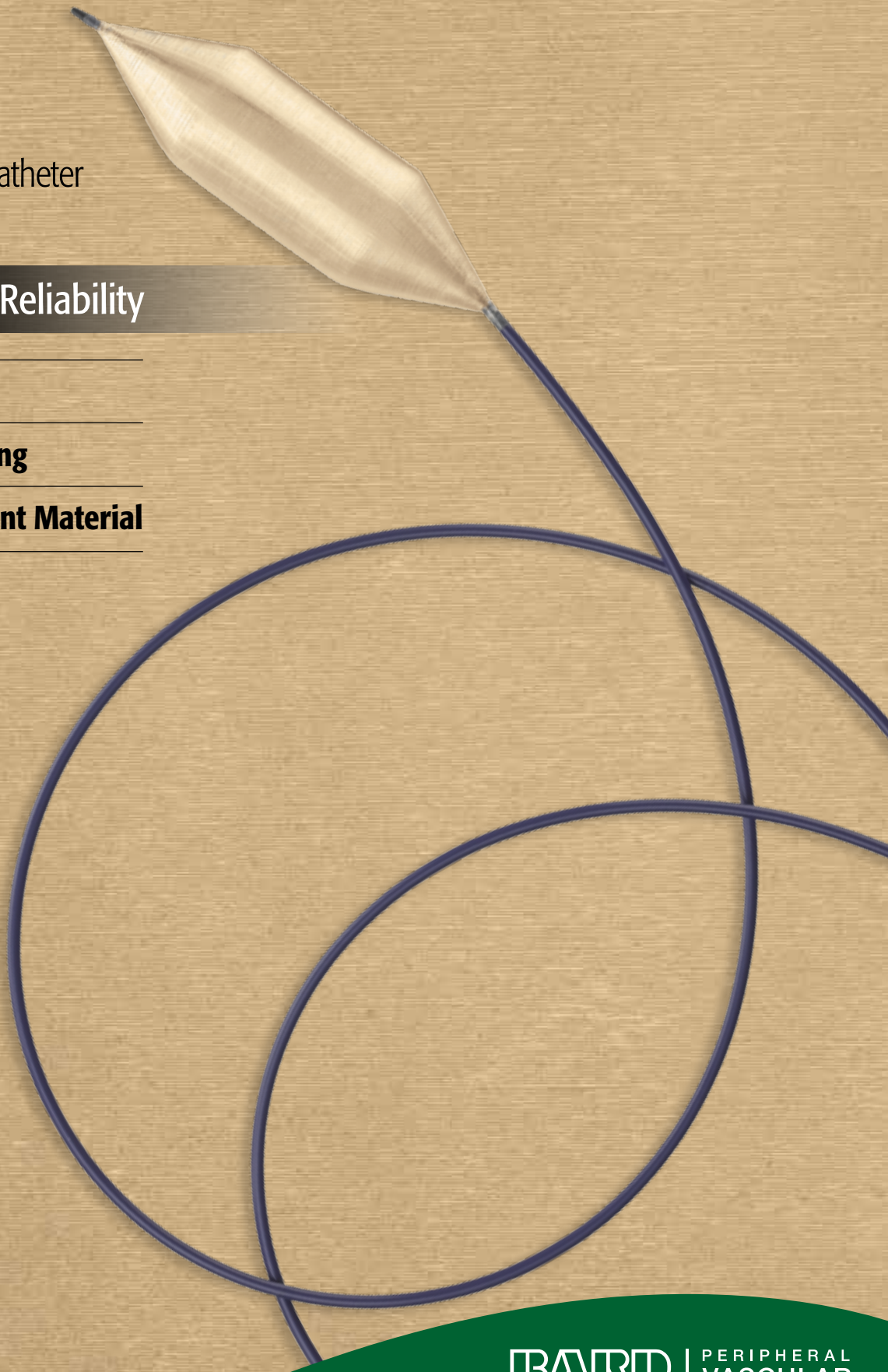
PTV Dilatation Catheter

Undeniable Reliability

Low Profile

Predictable Sizing

Rupture Resistant Material



BARD | PERIPHERAL VASCULAR

VIDA™ PTV Dilatation Catheter **Ordering Information**

Diameter (mm)	Length (cm)	Nominal (ATM)	RBP (ATM)	Sheath Size (F)	Shaft Length	Order Codes
12	2	6	18	7	100	VDA100122
	4	6	18	7	100	VDA100124
	6	6	18	7	100	VDA100126
14	2	6	18	7	100	VDA100142
	4	6	18	7	100	VDA100144
	6	6	18	8	100	VDA100146
16	2	6	18	8	100	VDA100162
	4	6	18	8	100	VDA100164
	6	6	16	8	100	VDA100166
18	2	6	16	8	100	VDA100182
	4	6	16	8	100	VDA100184
	6	6	16	9	100	VDA100186
20	2	6	16	9	100	VDA100202
	4	6	16	9	100	VDA100204
22	2	4	14	10	100	VDA100222
	4	4	14	10	100	VDA100224
24	2	4	14	10	100	VDA100242
	4	4	14	10	100	VDA100244
26	2	4	12	12	100	VDA100262
	4	4	12	12	100	VDA100264

PHYSICIAN'S SIGNATURE

REPRESENTATIVE NAME

CONTACT PHONE NO.

VIDA™ PTV Dilatation Catheter

This product is not manufactured with any latex.

Indications for Use

The VIDA™ PTV Dilatation Catheter is recommended for Percutaneous Transluminal Valvuloplasty of the pulmonary valve in the following:

- A patient with isolated pulmonary valve stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

Contraindications

None known.

Warnings

1.) 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. **2.)** 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 period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. **3.)** 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. **4.)** Catheter balloon inflation diameter must be carefully considered in selecting a particular size for any patient. The inflated balloon diameter should not be significantly greater than valvular diameter. The choice of the balloon size to be used for valve stenosis has been established by the Valvuloplasty and Angioplasty of Congenital Anomalies Registry (VACA) to be up to 1.2 to 1.4 times the valve annulus. It is important to perform an angiogram prior to valvuloplasty to measure the size of the valve in the lateral projection. Right ventricular outflow tract damage has occurred with balloons larger than 1.5 times the size of valve annulus. **5.)** Careful consideration should be given in balloon length selection. Longer length balloons may impinge surrounding structures leading to injury. **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. **7.)** 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.

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 sheath 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 approximately 25 to 75 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.)** Do not continue to use the balloon catheter if the shaft has been bent or kinked. **8.)** Prior to re-insertion through the introducer sheath, the balloon should be wiped clean with gauze, rinsed with sterile normal saline, and refolded with the balloon re-wrap tool. Balloon re-wrapping should only occur while the balloon catheter is supported with a guidewire. **9.)** Dilatation procedures should be conducted under high-quality fluoroscopic guidance. **10.)** Careful attention must be paid to the maintenance of tight catheter connections. Aspirate before proceeding to avoid air introduction into the system.

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 • 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 • Vessel dissection, perforation, rupture, or spasm • Conduction System Injury • Valvular Tearing or Trauma • Cardiovascular Injury

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

S120359 Rev. 0

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