ATLAS®

PTA Dilatation Catheter

Confidence in Large Diameter Vessels

BARD | PERIPHERAL VASCULAR

confidence

IN LARGE DIAMETER VESSELS

The combination of the most non-compliant balloon available with the largest working range available offers lesion specific pressures with confidence.[1]

- **Delivers Maximum Forces to Areas of Most Resistance**

protects

WITH ULTRA NON-COMPLIANT TECHNOLOGY

- **Virtually No Balloon Growth**
- **Predictable Balloon Diameters**
- **Reduces Risk of Overdilatation**

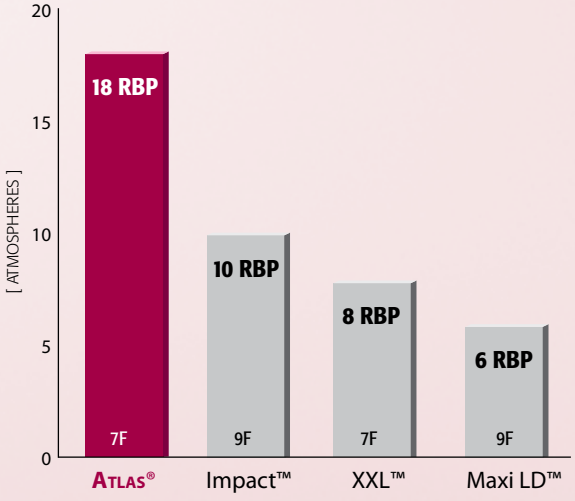
ATLAS®
PTA Dilatation Catheter

delivers

HIGH OR LOW PRESSURE ANGIOPLASTY

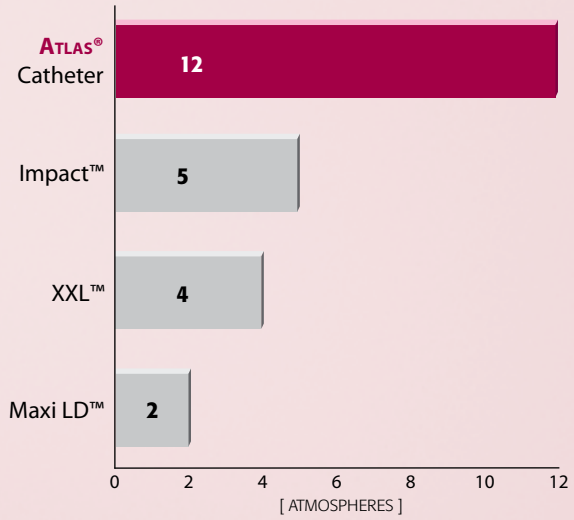
- **Largest Working Range Enables Lesion Specific Treatment**

HIGHEST RATED BURST PRESSURE*



The ATLAS® PTA Dilatation Catheter has rated burst pressures of up to 18 atmospheres, by far the highest rated burst pressures of any large diameter balloon.

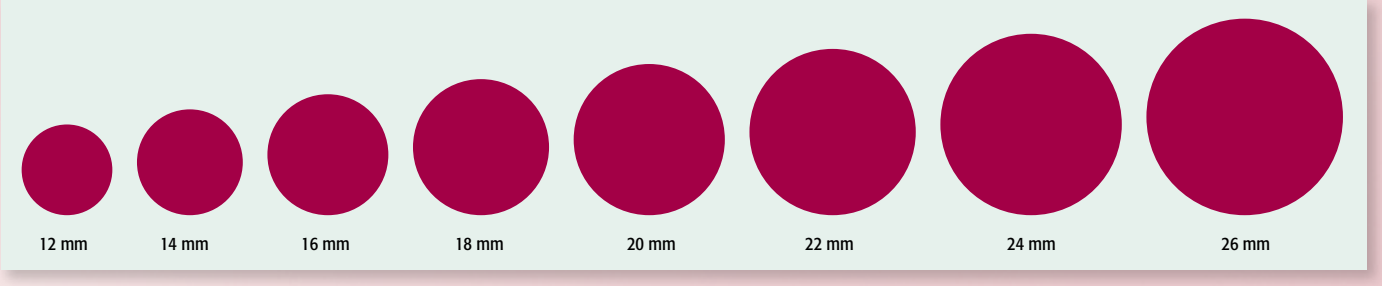
LARGEST WORKING RANGE*



The ATLAS® PTA Dilatation Catheter offers nominal pressures starting at 4 atm's and rated burst pressures of up to 18 atm's, delivering the flexibility of high or low pressure angioplasty.

Rated burst pressures, introducer sheath requirements, and working ranges for 14x4 balloons.
* Information taken directly from each manufacturer's product brochure and IFU.

ATLAS® PTA Dilatation Catheter available in 12-26 mm diameters



Large Diameter PTA Dilatation Catheter

Atlas® PTA Dilatation Catheter Product Offering

Shaft Length		Balloon Size					
75 cm	120 cm	Diameter (mm)	Length (cm)	RBP† (atm)	Working Range (atm)	Nominal Pressure* (atm)	Sheath Size (Fr)
☐ AT75122	☐ AT120122	12	2	18	12	6	7
☐ AT75124	☐ AT120124	12	4	18	12	6	7
☐ AT75126		12	6	18	12	6	7
☐ AT75142	☐ AT120142	14	2	18	12	6	7
☐ AT75144	☐ AT120144	14	4	18	12	6	7
☐ AT75146		14	6	18	12	6	8
☐ AT75162	☐ AT120162	16	2	18	12	6	8
☐ AT75164	☐ AT120164	16	4	18	12	6	8
☐ AT75166		16	6	16	10	6	8
☐ AT75182	☐ AT120182	18	2	16	10	6	8
☐ AT75184	☐ AT120184	18	4	16	10	6	8
☐ AT75186		18	6	16	10	6	9
☐ AT75202	☐ AT120202	20	2	16	10	6	9
☐ AT75204	☐ AT120204	20	4	16	10	6	9
☐ AT75222		22	2	14	10	4	10
☐ AT75224		22	4	14	10	4	10
☐ AT75242		24	2	14	10	4	10
☐ AT75244		24	4	14	10	4	10
☐ AT75262		26	2	12	8	4	12
☐ AT75264		26	4	12	8	4	12
Caliber™ Inflation Device REORDER CODE CL3030							

† RBP (Rated Burst Pressure): the pressure at which Bard has 95% confidence that 99.9% of the balloons will not burst at or below upon single inflation

* Nominal pressure: the pressure at which the balloon reaches its labeled diameter

[1] Most non-compliant and largest working range for Large Diameter PTA balloons

Please contact your local Bard Peripheral Vascular Sales Representative for availability of sizes.

PHYSICIAN'S SIGNATURE

REPRESENTATIVE NAME

CONTACT PHONE NO.

Bard® Atlas® PTA Dialation Catheter

Indications for Use: Atlas® PTA Balloon Dilatation Catheters are recommended for use in Percutaneous Transluminal Angioplasty of the iliac arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

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)** To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length of the vessel just proximal and distal to the stenosis. **5)** 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. **6)** 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. **7)** 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 Atlas catheter shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty. **3)** The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label. **4)** Use the recommended balloon inflation medium. Never use air or other gaseous medium to inflate the balloon. **5)** If resistance is felt during post procedure withdrawal of the catheter, it is recommended to remove the balloon catheter and guidewire/introducer sheath as a single unit. **6)** Do not continue to use the balloon catheter if the shaft has been bent or kinked. **7)** 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.

Potential Adverse Reactions: The complications which may result from a peripheral balloon dilatation 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

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions and instructions for use. Warning: Do not exceed RBP as balloon rupture may occur. To prevent over pressurization, use of a pressure monitoring device is recommended.

S11549 Rev 2

BARD | PERIPHERAL VASCULAR

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