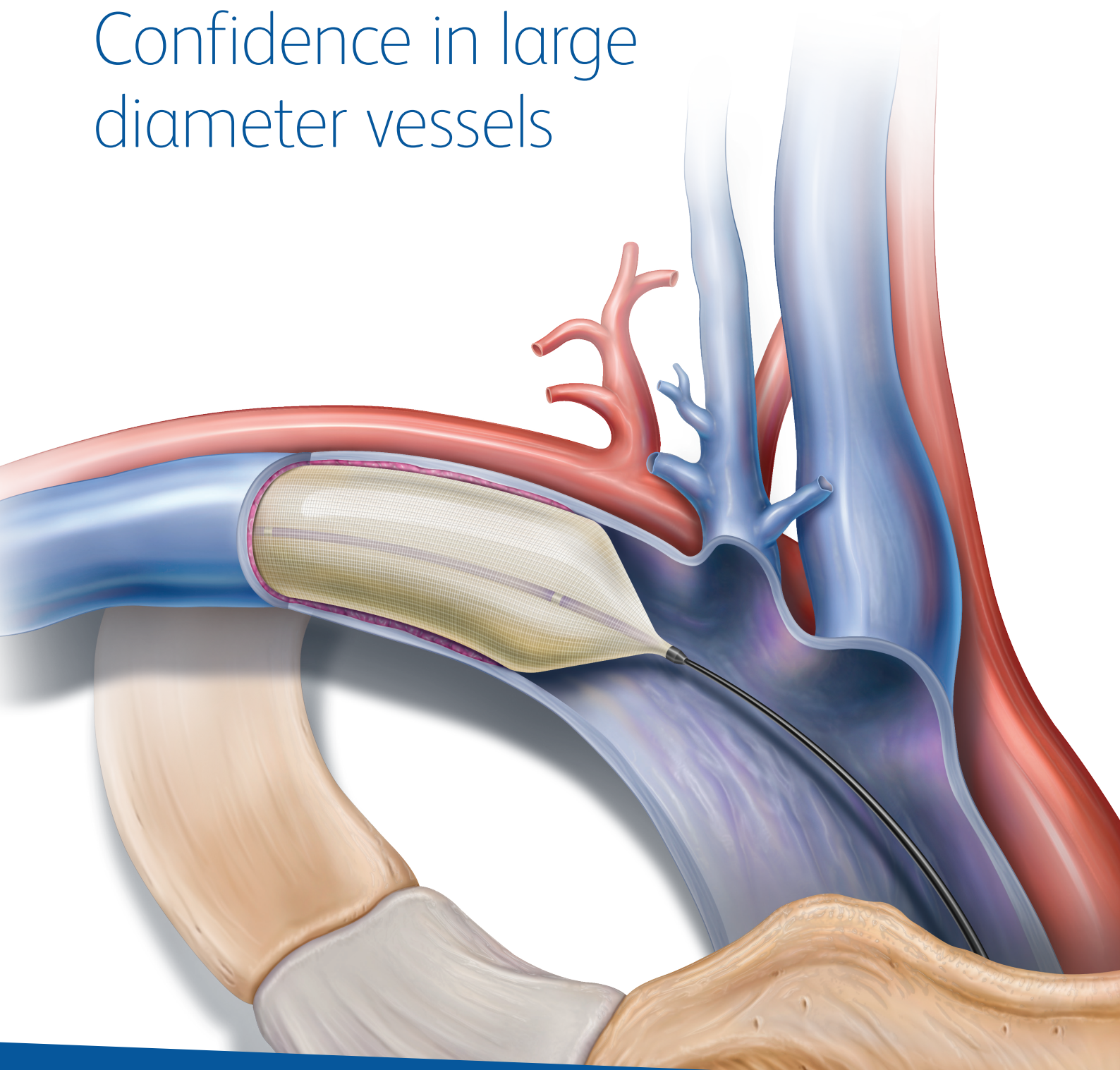


Atlas™ Gold

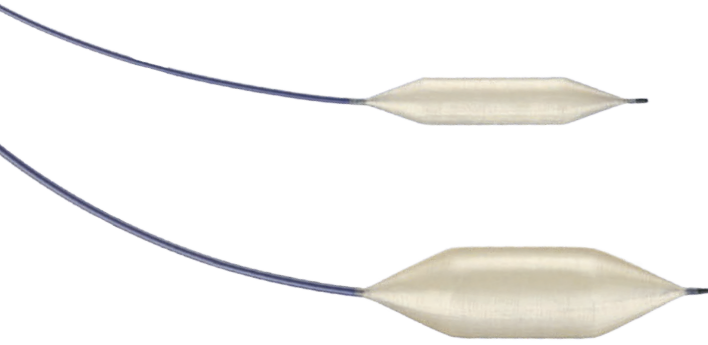
PTA Dilatation Catheter

Confidence in large
diameter vessels

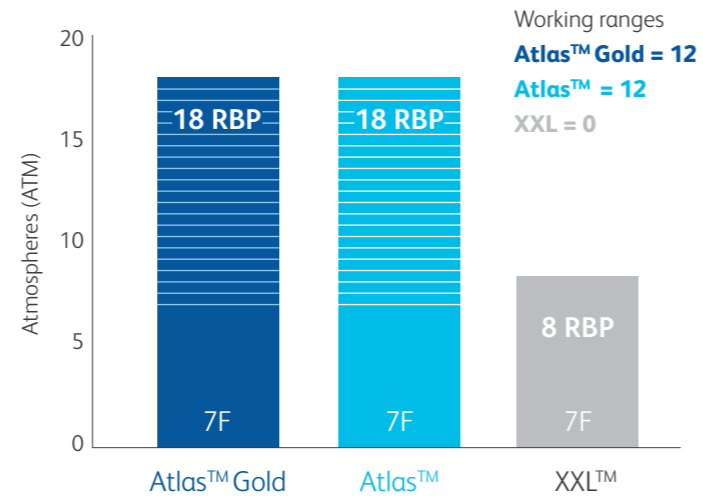


Confidence in dilating resistant lesions

- Delivers maximum force to areas of most resistance (up to 18 ATM)
- Most non-compliant large diameter balloon on the market
- Largest working range available offering lesion specific pressures



Highest rated burst pressure and largest working range

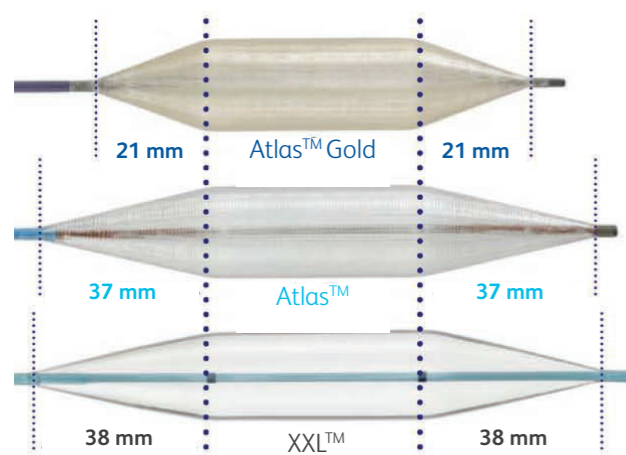


Information taken from product labeling. 14 mm x 4 cm balloons.

Engineered to dilate lesions in curved vessels

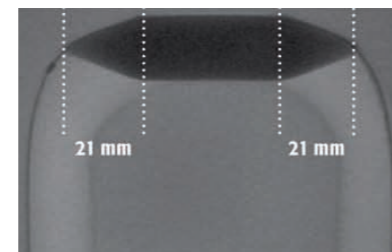
- Shorter shoulders
- Designed to minimise vessel straightening
- Allows for better fit

Shorter shoulders

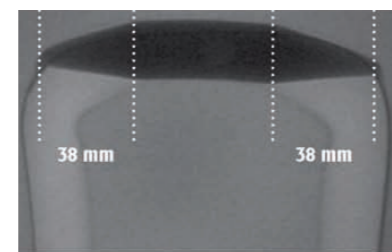


18 mm x 4 cm balloons*

Designed to minimise vessel straightening for better fit in curved vessels



Atlas™ Gold



XXL™

18 mm x 4 cm balloons*

Atlas™ Gold PTA Dilatation Catheter indicated for post-dilatation of stents and stent grafts in peripheral vasculature*

*Data on file. Bench testing using same test methods and sample sizes, n = 10. Bench data may not be representative of chemical outcomes.

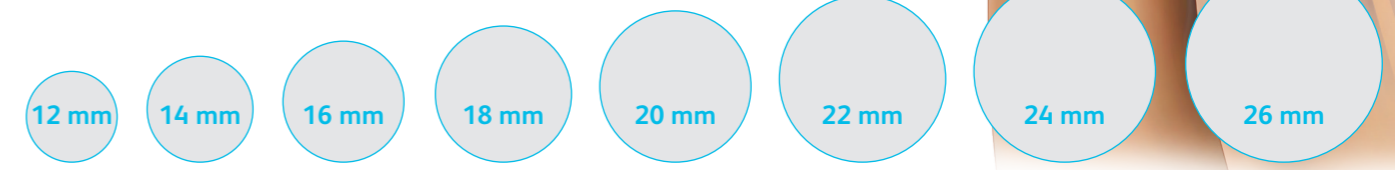
Protects with ultra non-compliant technology

- Virtually no balloon growth
- Predictable balloon diameters
- Reduces risk of over-dilatation

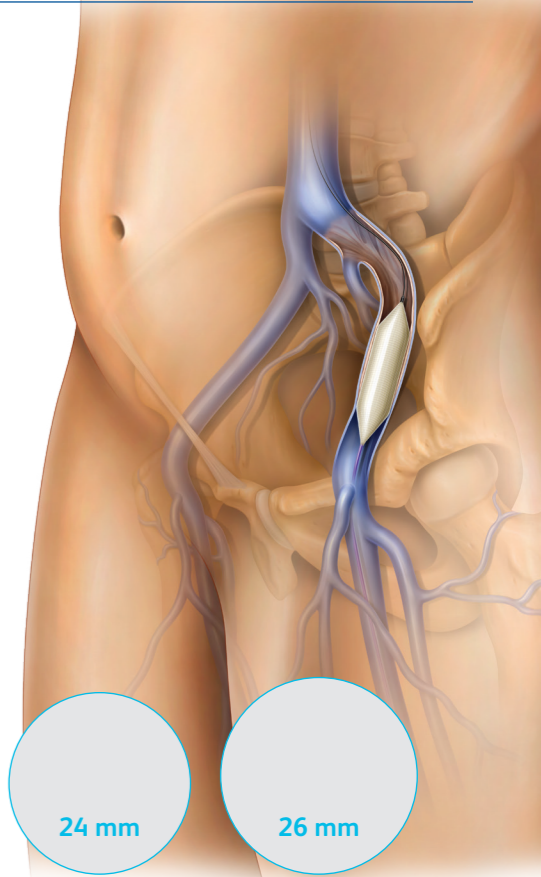
120 cm shaft lengths
Packaged in compact 'Pizza boxes'

Broad range of diameters

All sizes available in 120 cm shaft lengths

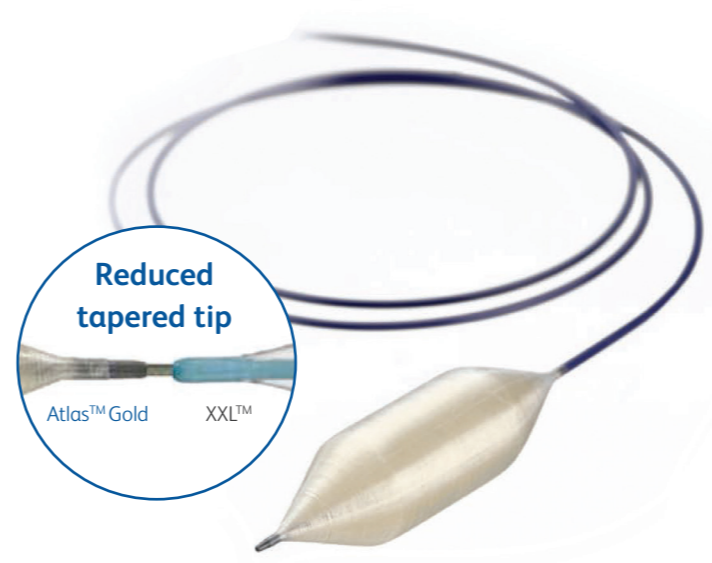


Actual diameter sizes



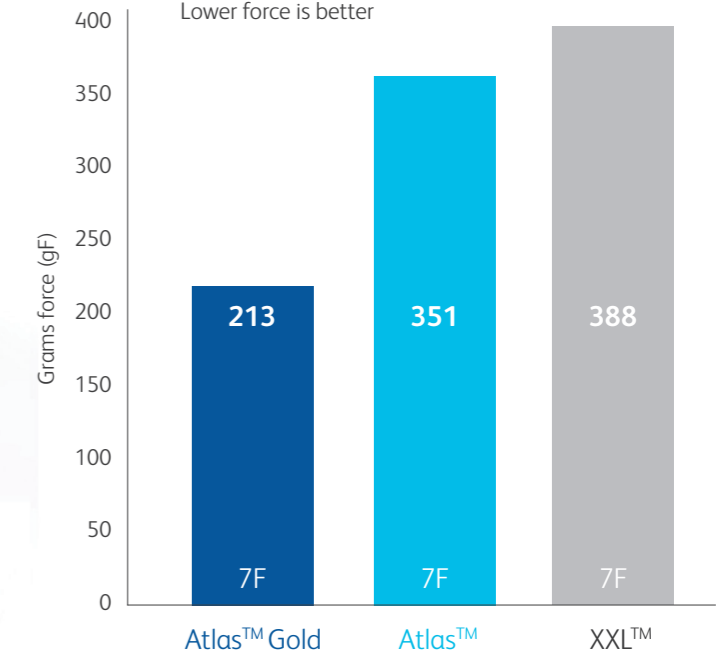
Enhanced trackability

- Reduced tapered tip designed to optimise performance
- Balloon design improved for better trackability
- Requires up to 45% less force to track



Trackability

Lower force is better



The trackability test measures the peak force necessary to track a catheter through a tortuous anatomical model.

14 mm x 4 cm balloons: Atlas™ GOLD - 80 cm shaft, Atlas™ and XXL™ - 75 cm shaft

Data on file. Bench testing using same test methods and sample sizes, n = 10. Bench data may not be representative of chemical outcomes.

Large diameter ultra non-compliant PTA dilation catheter

Ordering information

Atlas™ Gold

PTA Dilatation Catheter

80 cm shaft length					
Order code	Balloon diameter (mm)	Balloon length (mm)	Nominal pressure* (atm)	Rated burst pressure† (atm)	Sheath size (F)
ATG80122		20	6	18	7
ATG80124	12	40	6	18	7
ATG80126		60	6	18	7
ATG80142		20	6	18	7
ATG80144	14	40	6	18	7
ATG80146		60	6	18	8
ATG80162		20	6	18	8
ATG80164	16	40	6	18	8
ATG80166		60	6	18	8
ATG80182		20	6	16	8
ATG80184	18	40	6	16	8
ATG80186		60	6	16	9
ATG80202		20	6	16	9
ATG80204	20	40	6	16	9
ATG80222		20	4	14	10
ATG80224	22	40	4	14	10
ATG80242		20	4	14	10
ATG80244	24	40	4	14	10
ATG80262		20	4	12	12
ATG80264	26	40	4	12	12

120 cm shaft length					
Order code	Balloon diameter (mm)	Balloon length (mm)	Nominal pressure* (atm)	Rated burst pressure† (atm)	Sheath size (F)
ATG120122		20	6	18	7
ATG120124	12	40	6	18	7
ATG120126		60	6	18	7
ATG120142		20	6	18	7
ATG120144	14	40	6	18	7
ATG120146		60	6	18	8
ATG120162		20	6	18	8
ATG120164	16	40	6	18	8
ATG120166		60	6	18	8
ATG120182		20	6	16	8
ATG120184	18	40	6	16	8
ATG120186		60	6	16	9
ATG120202		20	6	16	9
ATG120204	20	40	6	16	9
ATG120222		20	4	14	10
ATG120224	22	40	4	14	10
ATG120242		20	4	14	10
ATG120244	24	40	4	14	10
ATG120262		20	4	12	12
ATG120264	26	40	4	12	12

0.035" guidewire compatible

Units per case: 1

0.035" guidewire compatible

Units per case: 1

* Nominal pressure: the pressure at which the balloon reaches its labeled diameter. † 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. Please contact your local Bard Peripheral Vascular Sales Representative for availability of sizes.

Bard Atlas™ Gold PTA Dilatation Catheter

Indications for Use: Atlas™ Gold PTA Dilatation Catheter is indicated 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 device is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Contraindications: None known.

Warnings:

- 1) Contents supplied STERILE using ethylene oxide (EO). NonPyrogenic. 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 indeterminate 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 re-sterilize. After re-sterilization, 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 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.
- 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) To reduce the potential for stent or stent graft damage and/or vessel damage from the stent or stent graft, the diameter of the balloon should be no greater than the diameter of the stent or stent graft. Refer to the stent or stent graft IFU for safety information including the WARNINGS, PRECAUTIONS, and potential ADVERSE EFFECTS regarding the use of balloon post-dilatation.
- 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) Atlas™ Gold 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) Do not remove the guidewire in situ to shoot contrast through the wire lumen or perform a wire exchange. If the wire is removed while the balloon catheter is situated in tortuous anatomy, the risk of kinking the catheter is increased.
- 5) Use the recommended balloon inflation medium (a range of 30-50% contrast medium/a range of 50-70% sterile saline solution). It has been shown that a 30/70% contrast/saline ratio has yielded faster balloon inflation/deflation times.
- 6) Never use air or other gaseous medium to inflate the balloon.
- 7) 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.
- 8) 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
- 9) Do not continue to use the balloon catheter if the shaft has been bent or kinked.
- 10) 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.

BD Switzerland Sarl, Terre Bonne Park – A4, Route De Crassier, 17, 1262 Eysins, Vaud. Switzerland.

bd.com



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