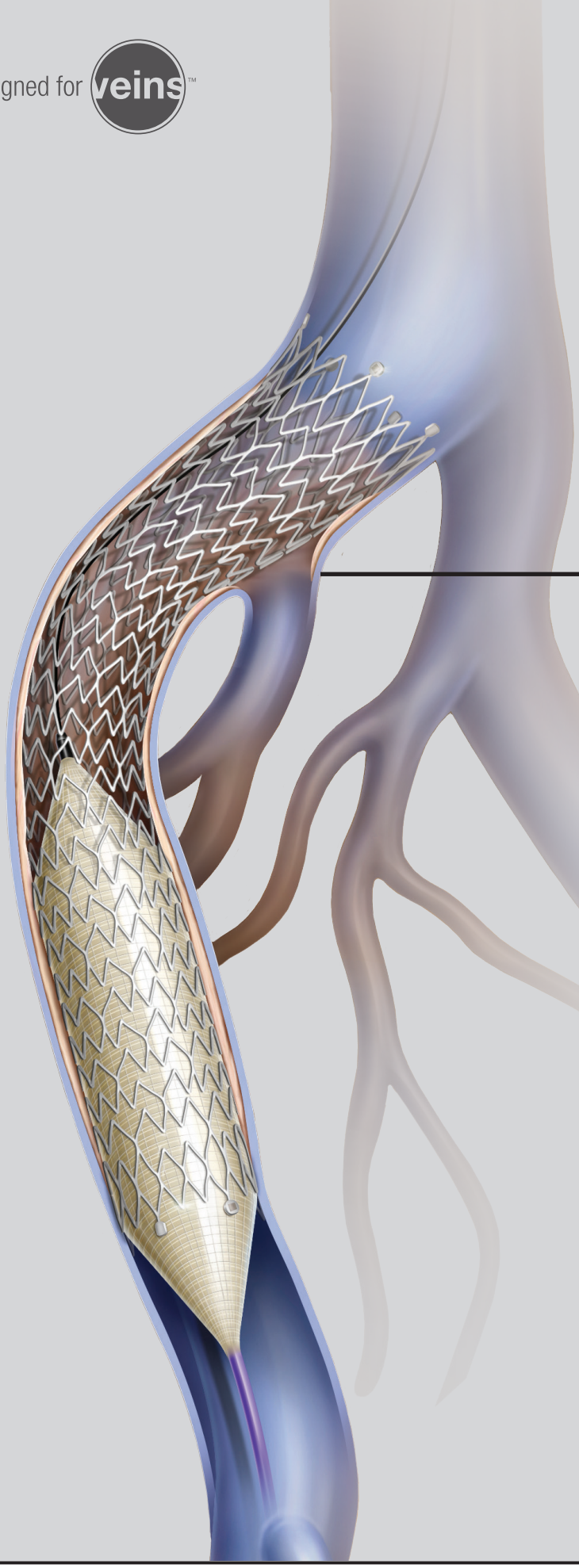
Designed for veins™



The Right Tools for Treating Iliofemoral Venous Lesions

VENOVO®
Venous Stent System

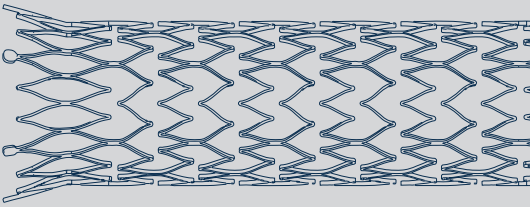
ATLAS® GOLD
PTA Dilatation Catheter

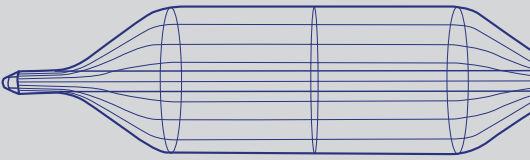
PRESTO®
Inflation Device

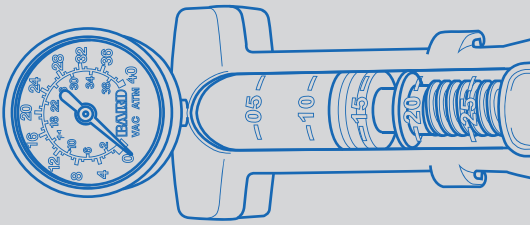
BD

BARD
has joined BD

BD now offers a line of products for **treating iliofemoral venous lesions** including:







- **Only** iliofemoral venous stent with the broadest size range needed for the treatment of iliofemoral venous obstruction[1]

- **Only** venoplasty balloon indicated for use in the iliofemoral veins[1]

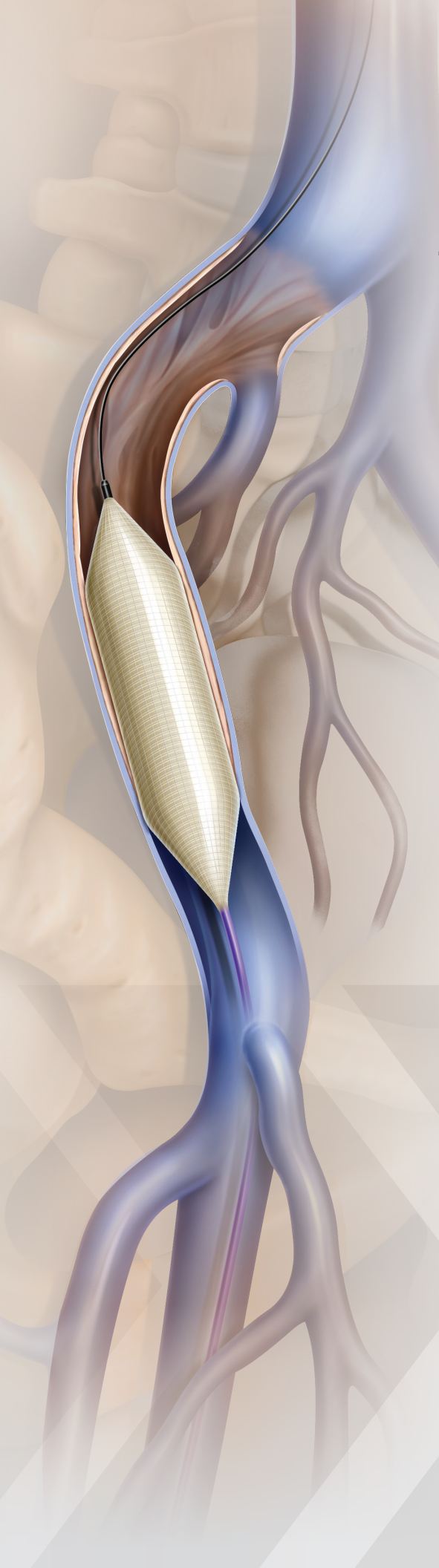
- Inflation device for high pressure PTA balloons

Prep

The PRESTO® Inflation Device offers a single solution treatment option.[2]

- Designed to inflate large or small balloons with a **single fill of the device**
- Large barrel allows for **rapid and easy deflation**
- **Ergonomic design** allows for comfortable handling
- Inflate across the range of atmospheres needed for **venoplasty balloons**

PRESTO®
Inflation Device



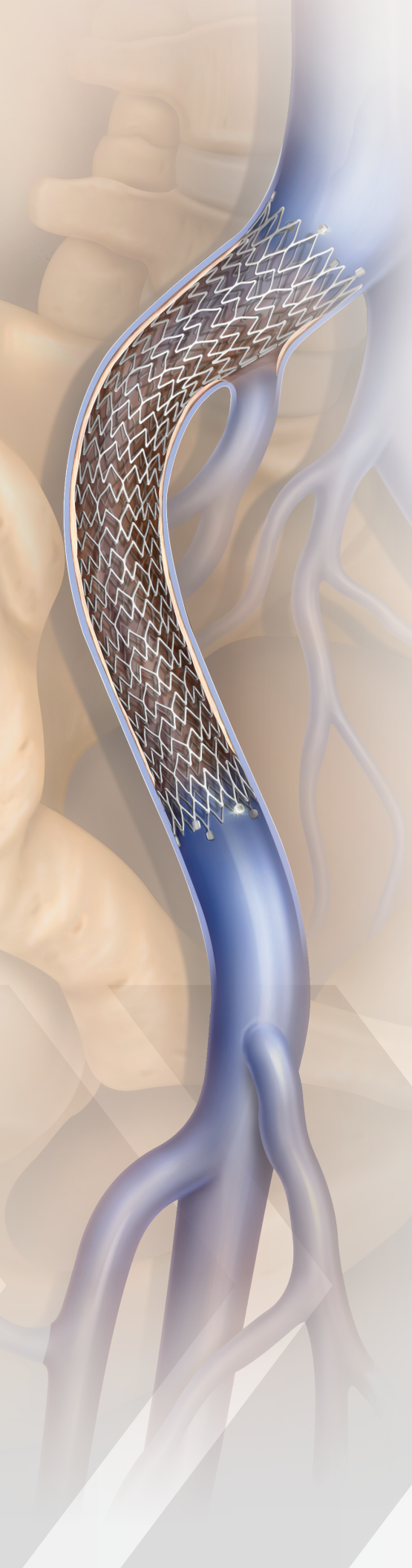
Dilate

The ATLAS® GOLD PTA Balloon is the only PTA balloon indicated for the iliofemoral veins.[1,3] Its ultra non-compliant balloon technology offers unique features suitable for venous applications including:

- **High pressure** dilatation up to 18 ATM
- **Predictable** balloon diameters to help reduce risk of overdilation[3]
- **Short shoulders** to allow high pressure dilatation at stent edges
- **Large diameters** needed for the iliofemoral veins

ATLAS® GOLD
PTA Dilatation Catheter

Diameters (mm)	Lengths (mm)		
	20	40	60
12	●	●	●
14	●	●	●
16	●	●	●
18	●	●	●
20	●	●	
22	●	●	
24	●	●	
26	●	●	



Treat

The VENOVO® Venous Stent is a self-expanding nitinol stent specifically designed for the treatment of non-thrombotic and post-thrombotic iliofemoral vein lesions.

The VENOVO® Venous Stent offers:

- **Balance** between radial force, compression resistance and flexibility
- Tri-axial delivery system designed for **precise placement accuracy**
- **Proven results** in post-thrombotic and non-thrombotic lesions[4]
- Broadest range of stent sizes indicated for iliofemoral venous obstruction with lengths up to **160 mm and diameters up to 20 mm**[1]

VENOVO®
Venous Stent System

Diameters (mm) \ Lengths (mm)	40	60	80	100	120	140	160
10	●	●	●	●	●	●	●
12	●	●	●	●	●	●	●
14	●	●	●	●	●	●	●
16	●	●	●	●	●	●	●
18	●	●	●	●	●	●	●
20	●	●	●	●	●	●	●

PRESTO® Inflation Device | 40 ATM, 30 CC barrel

Description	Quantity	Product Code
PRESTO® Inflation Device	5/Box	☐ ID4030

ATLAS® GOLD PTA Dilatation Catheter

Balloon Size		80 cm Shaft Length / .035" Guidewire Compatible			
Diameter (mm)	Length (cm)	Nominal* (ATM)	RBP † (atm)	Sheath Size (Fr)	Order Codes
12	2	6	18	7	☐ ATG80122
	4	6	18	7	☐ ATG80124
	6	6	18	7	☐ ATG80126
14	2	6	18	7	☐ ATG80142
	4	6	18	7	☐ ATG80144
	6	6	18	8	☐ ATG80146
16	2	6	18	8	☐ ATG80162
	4	6	18	8	☐ ATG80164
	6	6	16	8	☐ ATG80166
18	2	6	16	8	☐ ATG80182
	4	6	16	8	☐ ATG80184
	6	6	16	9	☐ ATG80186
20	2	6	16	9	☐ ATG80202
	4	6	16	9	☐ ATG80204
22	2	4	14	10	☐ ATG80222
	4	4	14	10	☐ ATG80224
24	2	4	14	10	☐ ATG80242
	4	4	14	10	☐ ATG80244
26	2	4	12	12	☐ ATG80262
	4	4	12	12	☐ ATG80264
Balloon Size		**120 cm Shaft Length / .035" Guidewire Compatible**			
Diameter (mm)	Length (cm)	Nominal* (ATM)	RBP † (atm)	Sheath Size (Fr)	Order Codes
12	2	6	18	7	☐ ATG120122
	4	6	18	7	☐ ATG120124
	6	6	18	7	☐ ATG120126
14	2	6	18	7	☐ ATG120142
	4	6	18	7	☐ ATG120144
	6	6	18	8	☐ ATG120146
16	2	6	18	8	☐ ATG120162
	4	6	18	8	☐ ATG120164
	6	6	16	8	☐ ATG120166
18	2	6	16	8	☐ ATG120182
	4	6	16	8	☐ ATG120184
	6	6	16	9	☐ ATG120186
20	2	6	16	9	☐ ATG120202
	4	6	16	9	☐ ATG120204
22	2	4	14	10	☐ ATG120222
	4	4	14	10	☐ ATG120224
24	2	4	14	10	☐ ATG120242
	4	4	14	10	☐ ATG120244
26	2	4	12	12	☐ ATG120262
	4	4	12	12	☐ ATG120264

VENOVO® Venous Stent System Product Codes

Diameter (mm)	Length (mm)	Sheath Size (Fr)	80 cm Catheter Length	120 cm Catheter Length
10	40	8	☐ VENUM10040	☐ VENUL10040
	60	8	☐ VENUM10060	☐ VENUL10060
	80	8	☐ VENUM10080	☐ VENUL10080
	100	8	☐ VENUM10100	☐ VENUL10100
	120	8	☐ VENUM10120	☐ VENUL10120
	140	8	☐ VENUM10140	☐ VENUL10140
	160	8	☐ VENUM10160	☐ VENUL10160
12	40	8	☐ VENUM12040	☐ VENUL12040
	60	8	☐ VENUM12060	☐ VENUL12060
	80	8	☐ VENUM12080	☐ VENUL12080
	100	8	☐ VENUM12100	☐ VENUL12100
	120	8	☐ VENUM12120	☐ VENUL12120
	140	8	☐ VENUM12140	☐ VENUL12140
	160	8	☐ VENUM12160	☐ VENUL12160
14	40	9	☐ VENUM14040	☐ VENUL14040
	60	9	☐ VENUM14060	☐ VENUL14060
	80	9	☐ VENUM14080	☐ VENUL14080
	100	9	☐ VENUM14100	☐ VENUL14100
	120	9	☐ VENUM14120	☐ VENUL14120
	140	9	☐ VENUM14140	☐ VENUL14140
	160	9	☐ VENUM14160	☐ VENUL14160
16	40	10	☐ VENUM16040	☐ VENUL16040
	60	10	☐ VENUM16060	☐ VENUL16060
	80	10	☐ VENUM16080	☐ VENUL16080
	100	10	☐ VENUM16100	☐ VENUL16100
	120	10	☐ VENUM16120	☐ VENUL16120
	140	10	☐ VENUM16140	☐ VENUL16140
	160	10	☐ VENUM16160	☐ VENUL16160
18	40	10	☐ VENUM18040	☐ VENUL18040
	60	10	☐ VENUM18060	☐ VENUL18060
	80	10	☐ VENUM18080	☐ VENUL18080
	100	10	☐ VENUM18100	☐ VENUL18100
	120	10	☐ VENUM18120	☐ VENUL18120
	140	10	☐ VENUM18140	☐ VENUL18140
	160	10	☐ VENUM18160	☐ VENUL18160
20	40	10	☐ VENUM20040	☐ VENUL20040
	60	10	☐ VENUM20060	☐ VENUL20060
	80	10	☐ VENUM20080	☐ VENUL20080
	100	10	☐ VENUM20100	☐ VENUL20100
	120	10	☐ VENUM20120	☐ VENUL20120
	140	10	☐ VENUM20140	☐ VENUL20140
	160	10	☐ VENUM20160	☐ VENUL20160

* 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 BDPI Sales Representative for availability of sizes.

1. In the U.S. market. As of August 2019.

2. Warning: Do not exceed rated burst pressure for the ATLAS® GOLD PTA Dilatation Catheter between 12 ATM and 18 ATM. The rated inflation pressure of the PRESTO® Inflation Device is 40 ATM with a 30 cc syringe volume. In the U.S. market. As of August 2019.

3. Caution: During dilation, do not expand the balloon such that dissection complication or perforation could occur. Bench testing (n=45; 15 samples each of 12mmx2mmx80cm, 20mmx4mmx80cm, 26mmx4mmx120cm) may not be indicative of clinical performance. ATLAS® GOLD Catheter demonstrated less than 2% mean compliance between nominal pressure and rated burst pressure. Data on file, Bard Peripheral Vascular, Inc, Tempe, AZ. Different test methods may yield different results.

4. The VENOVO® Venous Stent System was studied in the global VERNACULAR clinical trial, which was a prospective, multi-center, non-randomized, single-arm study of 170 patients. The primary effectiveness endpoint of the study was primary patency (PP) at 12 months post-index procedure. Patients who received a VENOVO® Venous Stent had a weighted PP rate of 88.3%, demonstrating a statistically significant difference from a literature-derived performance goal (PG) of 74%, with an 81.3% PP rate for subjects with post-thrombotic syndrome and 96.9% PP rate for subjects with non-thrombotic iliac vein lesions. The primary safety endpoint was freedom from major adverse events (MAE) through 30 days post-index procedure. Freedom from MAE was 93.5%, demonstrating a statistically significant difference from a literature-derived PG of 89%. VERNACULAR Clinical Study. Data on File. Bard Peripheral Vascular Inc., Tempe, AZ.

PRESTO® Inflation Device

Indications for Use:
The PRESTO® Inflation Device is indicated for use with angioplasty balloon dilatation catheters to create and monitor the pressure in the angioplasty balloon dilatation catheter and to deflate the angioplasty balloon dilatation catheter.

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 device 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) After use, this device may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations. 5) To reduce the potential risk of air embolism, never use air or other gaseous medium to inflate angioplasty balloon dilatation catheters. Ensure all air has been purged from the entire fluid path prior to patient use. 6) Do not exceed 40 atm when inflating the device. Damage to the device or user injury may result. 7) Refer to the angioplasty balloon dilatation catheter instructions for use for additional warnings.

Precautions:
1) Carefully inspect the device prior to use to verify that it has not been damaged during shipment. Do not use if device damage is evident. 2) Discontinue use of the device if damage, malfunction or contamination is suspected during use. 3) For experienced physician use only. 4) Refer to the angioplasty balloon dilatation catheter instructions for use for additional precautions.

ATLAS® Gold PTA Dialation Catheter

Indications for Use: ATLAS® GOLD PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the peripheral vasculature, including the iliac arteries and iliac and femoral veins, 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). 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. 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. The 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: • Acute thrombotic occlusion • Additional intervention • Allergic reaction to drugs or contrast medium • Aneurysm or pseudoaneurysm • Arrhythmias • Balloon rupture • Balloon getting stuck on stent • Distal embolization (PE) • Hematoma • Hemorrhage, including bleeding at the puncture site • Hypotension/hypertension • Inflammation • Leg edema • Occlusion • Pain or tenderness • Pneumothorax or hemothorax • Sepsis/infection • Shock • Short term hemodynamic deterioration • Stent disruption or dislodgement with balloon insertion • Stroke • Thrombosis • Vessel dissection, perforation, rupture, or spasm

VENOVO® Venous Stent System

Indications for Use: The VENOVO® Venous Stent System is indicated for the treatment of symptomatic iliofemoral venous outflow obstruction.

Contraindications: The VENOVO® Venous Stent System is contraindicated for use in patients with a known hypersensitivity to nitinol (nickel-titanium) and tantalum, who cannot receive intraprocedural anti-coagulation therapy, or who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system.

Warnings: The VENOVO® Venous Stent System is supplied sterile and is intended for single use only. Do not resterilize and/or reuse the device. Do not use in patients with total venous occlusion that cannot be dilated to allow passage of the guidewire. Do not use the device with contralateral access. Do not use if pouch is opened or damaged. Do not use the device after the "Use By" date specified on the label. Persons with allergic reactions to nitinol (nickel-titanium) alloy and/or tantalum may suffer an allergic response to this implant. Do not expose the delivery system to organic solvents, e.g., alcohol. The stent is not designed for repositioning or recapturing. Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures. If a long lesion needs to be stented consider using the longest available stent rather than overlapping stents. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol). The long-term outcomes following repeat dilatation of endothelialized stents are unknown. The safety and effectiveness of this device for use in the arterial system have not been established.

Precautions: The device is intended for use by physicians who have received appropriate training. During system flushing, observe that saline exits at the catheter tip. The delivery system is not designed for use with power injection systems. Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution. Prior to stent deployment, remove slack from the delivery system catheter outside the patient. If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit. Store in a cool, dark, dry place. Do not attempt to break, damage, or disrupt the stent after placement.

Potential Adverse Events: Allergic/anaphylactic reaction · Amputation · Aneurysm · Arteriovenous fistula · Death related/unrelated to procedure · Dissection · Embolization · Extravasation · Fever · Hemorrhage/bleeding requiring a blood transfusion · Hematoma · Hypotension/hypertension · Incorrect positioning of the stent requiring further stenting or surgery · Intimal injury/dissection · Ischemia/infarction of tissue/organ · Local infection · Malposition (failure to deliver the stent to the intended site) · Open surgical repair · Pain · Pulmonary embolism · Pseudoaneurysm · Renal failure · Respiratory arrest · Restenosis · Rupture · Septicemia/bacteremia · Stent Fracture · Stent Migration · Vasospasm · Venous occlusion/thrombosis/restenosis

Please consult package insert for all indications, contraindications, hazards, warnings, precautions, and information for use. | www.bardpv.com | 1 800 321 4254 | 1625 W. 3rd Street Tempe, AZ 85281 **BD-11187**

BD BARD has joined BD