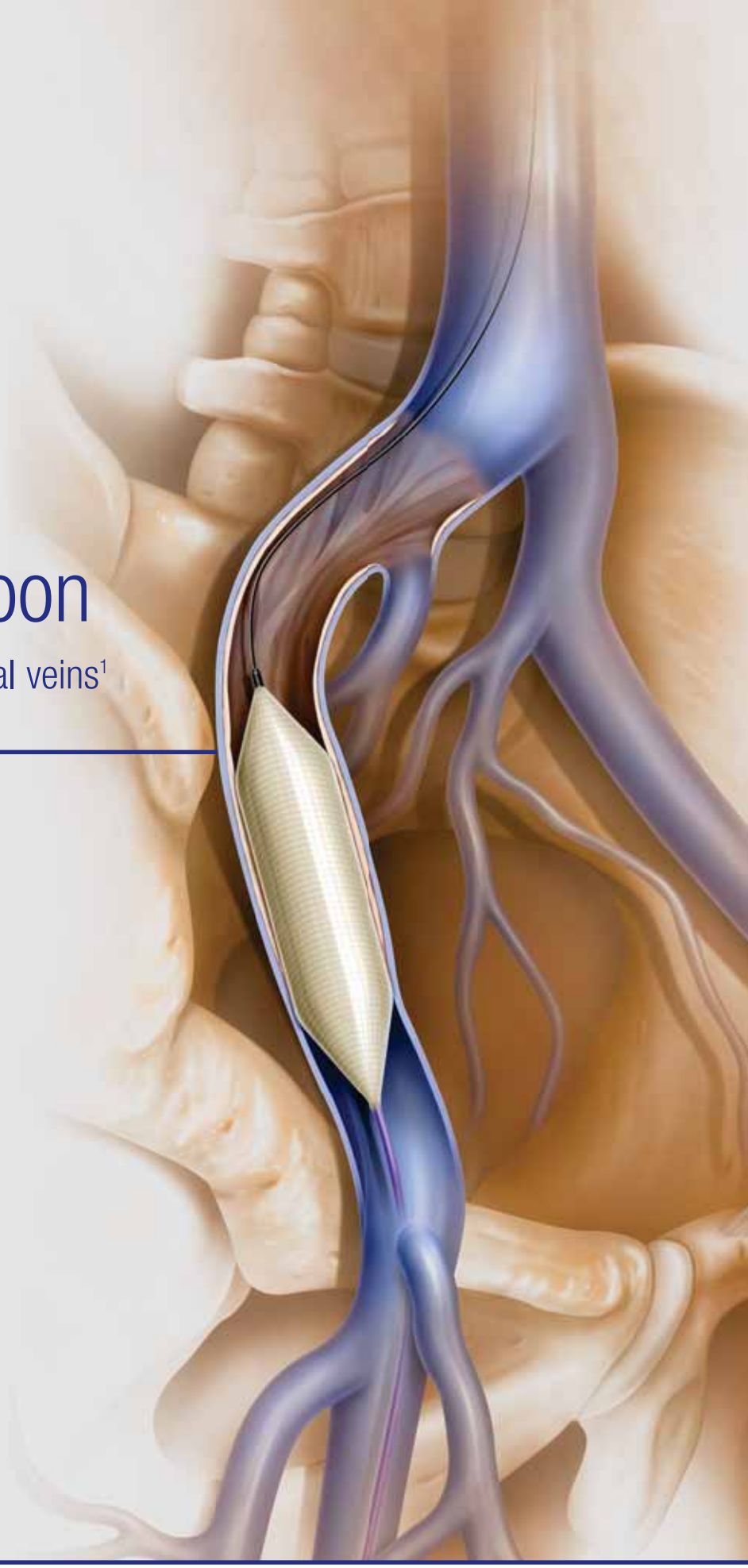
Designed for veins™

The **Only** Venoplasty Balloon

Indicated for use in the iliofemoral veins[1]



ATLAS® GOLD

PTA Dilatation Catheter

BD

BARD

has joined BD

Designed and **Indicated** for Iliofemoral Veins

As an ultra non-compliant balloon providing consistent diameters even at high pressures,[2] the ATLAS® GOLD PTA Dilatation Catheter is designed for iliofemoral veins and is offered in a wide range of large diameters at uniform sizing intervals.

LARGE DIAMETERS

NEEDED TO DILATE ILIAC AND FEMORAL VEINS (UP TO 26MM)

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

TAPERED TIP ENGINEERED FOR

PUSHABILITY AND TRACKABILITY

PREDICTABLE

BALLOON DIAMETERS DESIGNED TO HELP REDUCE RISK OF OVERDILATION OF THE ILIOFEMORAL VEINS[3]

DESIGNED TO PROVIDE

HIGH PRESSURE

DILATION UP TO 18 ATM

SHORT SHOULDERS

TO ALLOW HIGH PRESSURE DILATATION AT STENT EDGES

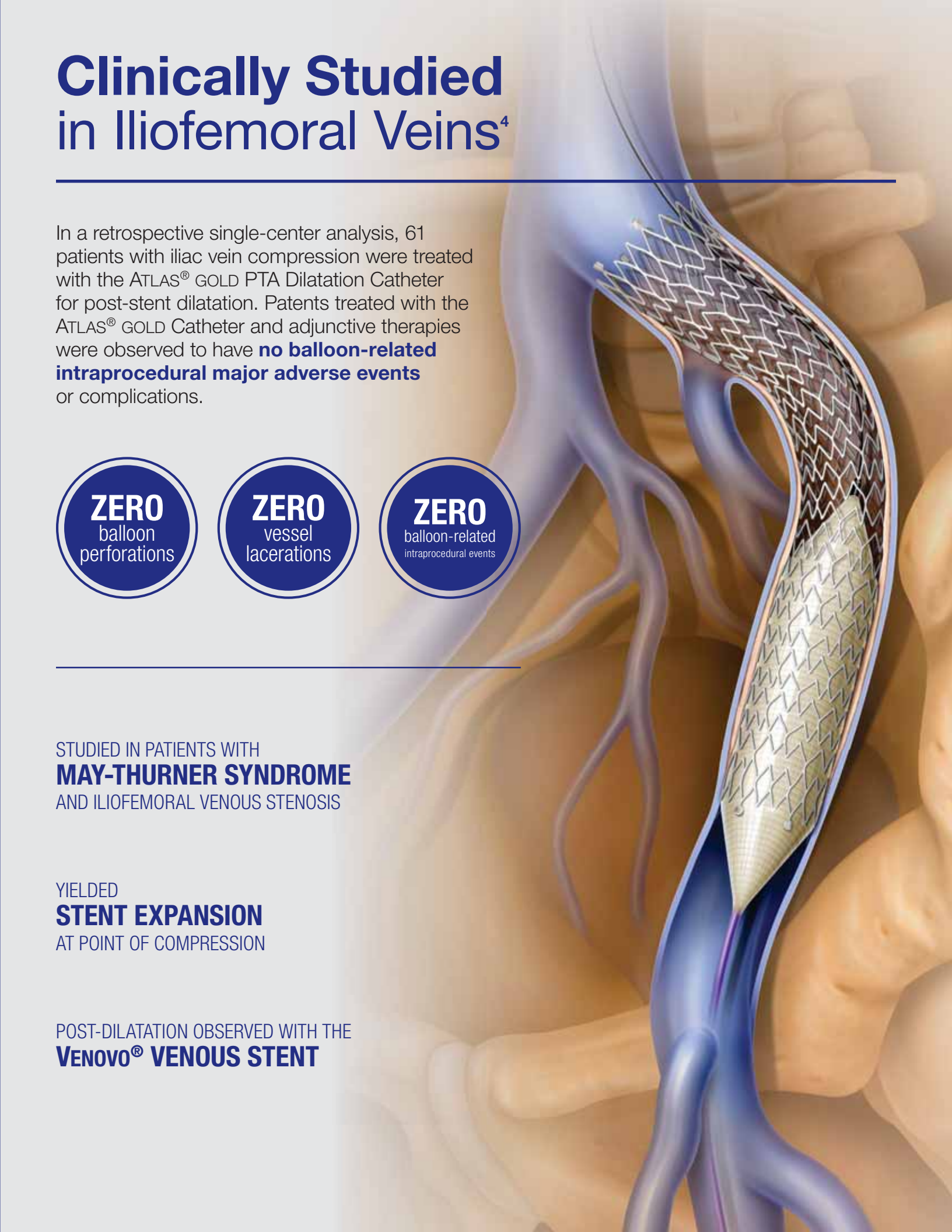
Clinically Studied in Iliofemoral Veins[4]

In a retrospective single-center analysis, 61 patients with iliac vein compression were treated with the ATLAS® GOLD PTA Dilatation Catheter for post-stent dilatation. Patents treated with the ATLAS® GOLD Catheter and adjunctive therapies were observed to have **no balloon-related intraprocedural major adverse events** or complications.

ZERO balloon perforations

ZERO vessel lacerations

ZERO balloon-related intraprocedural events



STUDIED IN PATIENTS WITH
MAY-THURNER SYNDROME
AND ILIOFEMORAL VENOUS STENOSIS

YIELDED
STENT EXPANSION
AT POINT OF COMPRESSION

POST-DILATATION OBSERVED WITH THE
VENOVO® VENOUS STENT

ATLAS® GOLD PTA Dilatation Catheter

Large Diameter Ultra Non-Compliant PTA Dilatation Catheter - Ordering Information

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

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

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

Do not exceed RBP. Balloon diameters 12-26mm offered; nominal pressure 4-6 atm, RBP 18 atm. See Instructions for use.

1 U.S. market only. As of February 2019

2 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.

3 Based on a simulated finite element analysis comparing ATLAS® GOLD Catheter to a nylon (POBA) balloon at 5 atm. Data on file, Bard Peripheral Vascular, Inc, Tempe, AZ. Computer simulated models may not be indicative of clinical performance. Different test methods may yield different results.

4 Shammas NW, Shammas GA, Jones-Miller S, Radaideh Q. Safety of the ATLAS® GOLD Balloon in Treating Iliofemoral Veins: Experience From a Single Center. J Invasive Cardiol 2018;30:401-405. MAE defined as acute thrombosis, peroration, or device-related complications when ATLAS® GOLD Catheter was used. 85.2% of observed patients had May-Thurner Syndrome of the left iliac vein. Lesions were evaluated with venogram and IVUS pre- and post-stent placement. 28 patients were implanted with VENOVO® Venous Stent. Bard Peripheral Vascular, Inc. has purchased the rights to use the data from this study.

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

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

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions and instructions for use.

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