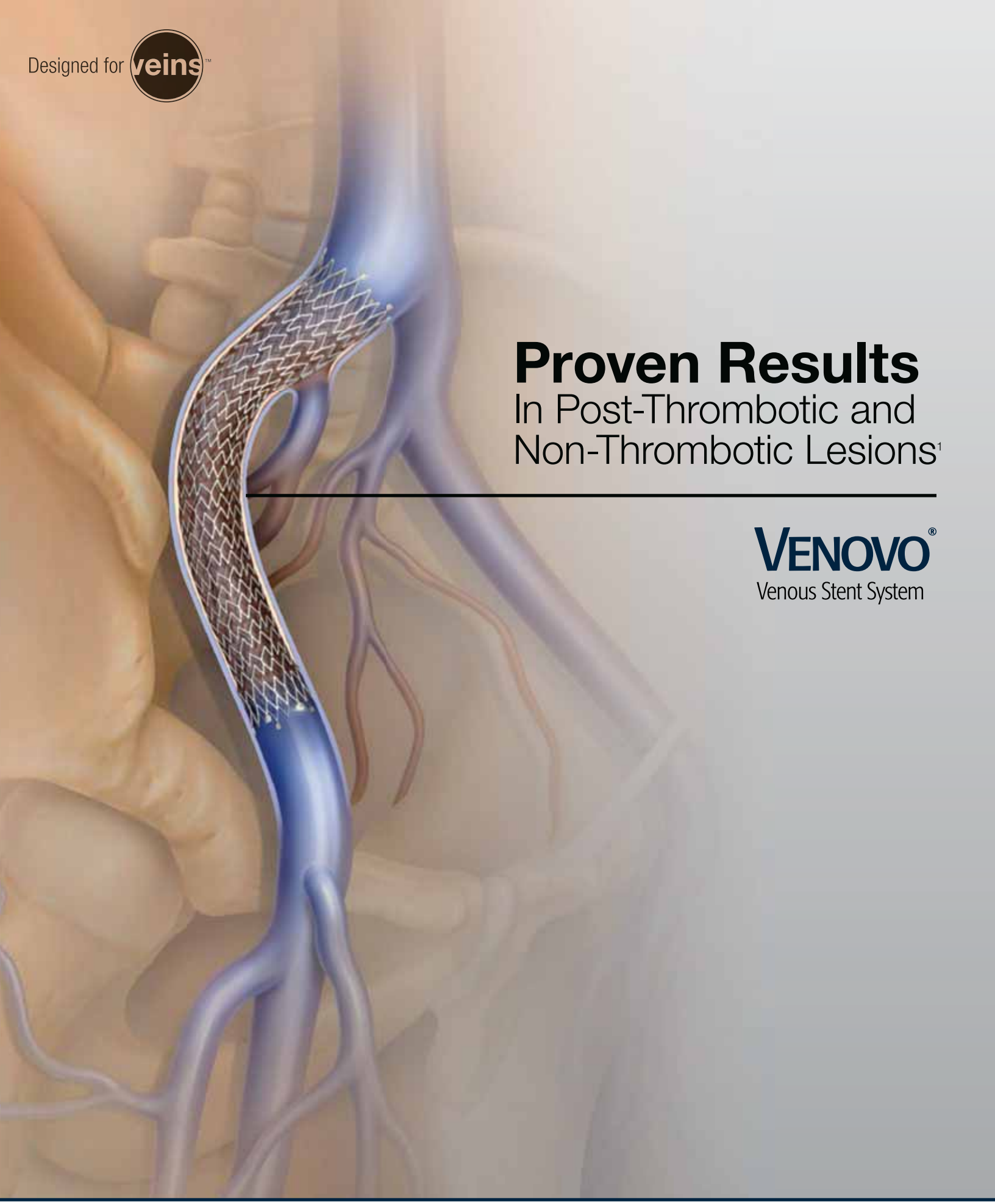
Designed for veins™



Proven Results
In Post-Thrombotic and Non-Thrombotic Lesions[1]

VENOVO®
Venous Stent System

BD

BARD
has joined BD

Designed for veins™

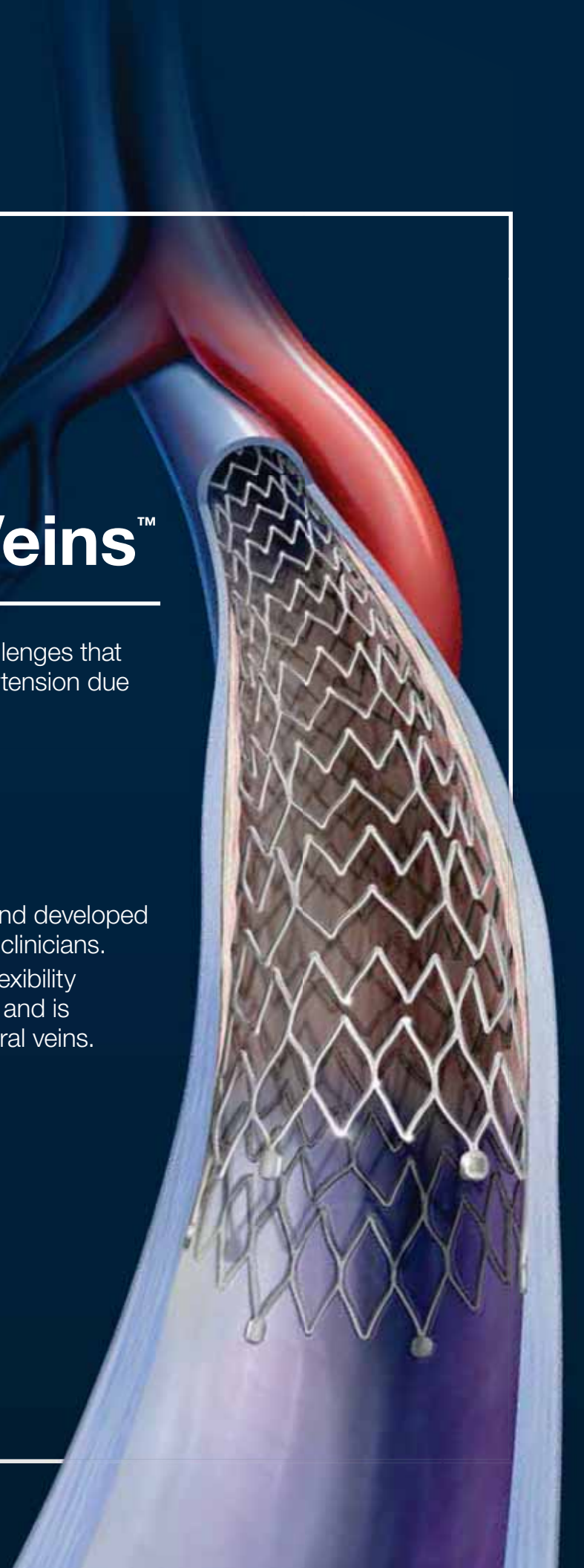
Designed for Veins™

The iliac and femoral veins have unique challenges that must be addressed to reduce venous hypertension due to occlusive disease:

- Large caliber
- Diffuse and focal lesions
- Extrinsic compression
- Post-thrombotic change
- Complex curvature

The VENOVO® Venous Stent was designed and developed for the iliofemoral veins in collaboration with clinicians.

It offers radial force, crush resistance, and flexibility without compromising on delivery accuracy and is available in the sizes needed for the iliofemoral veins.



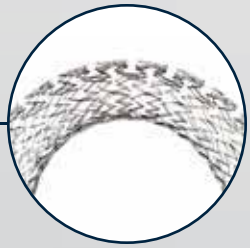
Purpose-Built Venous Stent

The VENOVO® Venous Stent was designed to treat non-thrombotic and post-thrombotic iliofemoral lesions with a balance between **radial strength**, **compression resistance**, and **flexibility**.

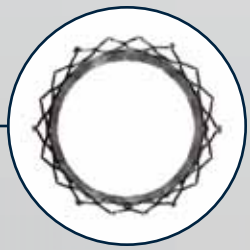
Unique 3 mm flared ends designed to **reduce stent migration** and maximize wall apposition

Compression of stent with 50 gram weight

Designed for use in **high compression** iliofemoral venous obstructions



Open-cell, **flexible design** to conform to vessel curvature while maintaining lumen diameter



Designed to have **high radial force**[2]

Tantalum markers for **high visibility** under fluoroscopy[2]

Placement Accuracy

The VENOVO® Venous Stent System is designed to provide accurate deployment for **optimal stent placement** and lesion coverage.

100% DEPLOYMENT ACCURACY
In the VERNACULAR Study (n=170)[1]

Minimal foreshortening for maximum lesion coverage[3]

Ergonomic handle and dual-speed thumbwheels for operator control

Triaxial delivery system designed for:
- **Ease of use**
- **Deployment control**
- **Precise placement accuracy**

Full Range of Sizes

The VENOVO® Venous Stent offers a **broad size range** including 10 mm - 20 mm stent diameters and stent lengths up to 160 mm.

Stent Length (mm)

Stent Diameter (mm)	40	60	80	100	120	140	160
10	8F						
12							
14	9F						
16	10F						
18							
20							

Proven Safe and Effective

VERNACULAR Study Design	Prospective, multi-center, non-randomized, single-arm; Core lab & DSMB	
Purpose	To assess the safety and effectiveness of the VENOVO® Venous Stent for the treatment of iliofemoral occlusive disease.	
As Treated Population	170 subjects at 21 sites in the U.S., Europe, and Australia/NZ	
Primary Endpoint[5]*	· Primary patency* (12 months)	· Freedom from MAE* (30 days)
Secondary Endpoints	· VCSS Pain Score/QoL assessment at 30 days, 6 and 12 months · Procedure/technical success at index procedure	· Freedom from TVR/TLR at 30 days, 6 and 12 months · X-ray analysis of stent fracture at 12 months

* Evaluated against literature derived performance goal of 74% for efficacy (p<.0001) and 89% for safety (p=.032)

96.9% PRIMARY PATENCY IN NON-THROMBOTIC LESIONS at 12 months[1]

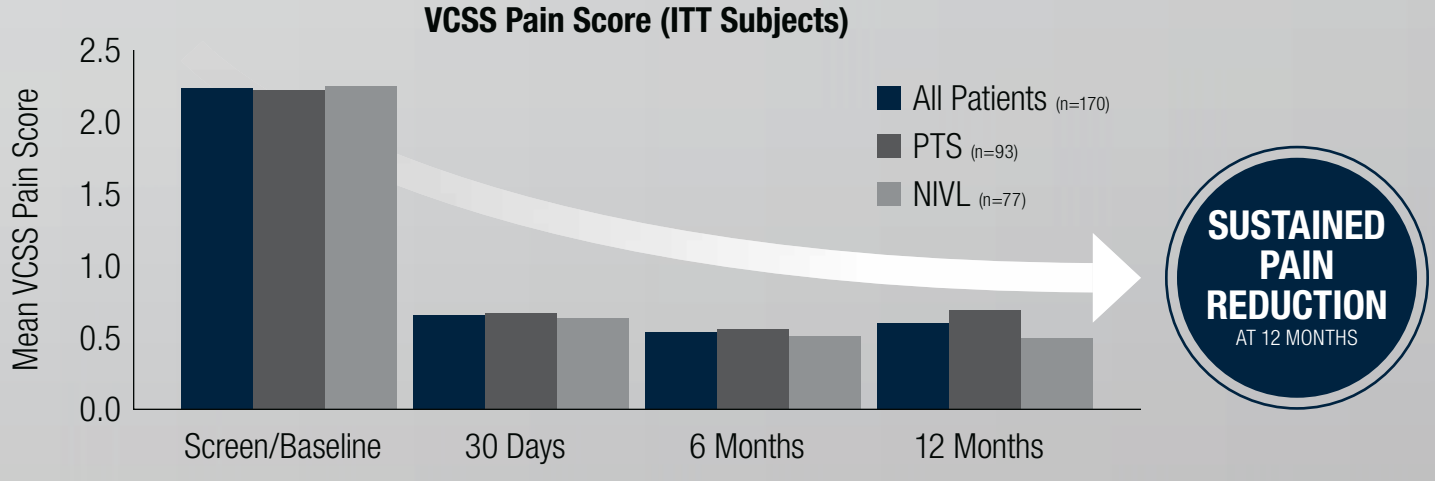
81.3% PRIMARY PATENCY IN POST-THROMBOTIC LESIONS at 12 months[1]

ZERO STENT FRACTURES at 12 months[1]

Weighted Primary Patency 88.3%

Patient-Reported Improvements

In the VERNACULAR Clinical Study, the VENOVO® Venous Stent demonstrated **significant improvement** in VCSS pain scores and quality of life (CIVIQ-20) at 12 months compared to baseline[1].



PTS = Post-Thrombotic Syndrome
NIVL = Non-Thrombotic Iliac Vein Lesion

VENOVO®
Venous Stent System

VENOVO® Venous Stent System Product Codes

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

[1] 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%. Secondary endpoints included acute technical success, Quality of Life (QoL) assessment, Venous Clinical Severity Score (VCSS – Pain score) and stent fractures. Results demonstrated 100% acute technical success, defined as successful deployment of stent(s) to intended target with adequate lesion coverage as assessed by the Investigator at the time of the index procedure. At the 12-month follow-up, the CIVIQ-20 assessment demonstrated a change from baseline in the total study population of -15.7 with 95% confidence interval of -18.41 to -12.96 ($P < .0001$) and, for the VCSS Pain score, a change from baseline in the total population of -1.7 with a 95% confidence interval of -1.81 to -1.49 ($P < .0001$). Stents were evaluated at the 12-month follow-up for fracture analysis. An anteroposterior and lateral x-ray for each evaluated stent were sent to an independent core lab for analysis. 137 subjects' x-rays were analyzed and no stent fractures were reported. Missing x-ray analyses were recorded as protocol deviations. VERNACULAR Clinical Study. Data on File. Bard Peripheral Vascular Inc., Tempe, AZ.

[2] Results shown in bench testing. Data on file, Bard Peripheral Vascular Inc., Tempe, AZ. Bench tests may not be indicative of clinical performance. Different test methods may yield different results.

[3] Results shown in bench testing. Average foreshortening = 2.9% (values based on mathematical calculations). Data on file, Bard Peripheral Vascular Inc., Tempe, AZ. Bench tests may not be indicative of clinical performance. Different test methods may yield different results.

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. Bard Peripheral Vascular, Inc. | www.bardpv.com | 1 800 321 4254 | 1625 W. 3rd Street Tempe, AZ 85281
BPV/VEDI/0319/0067

I authorize the purchase of these products.

PHYSICIAN NAME

PHYSICIAN SIGNATURE

REPRESENTATIVE NAME

CONTACT PHONE NO.

BD

BARD
has joined BD