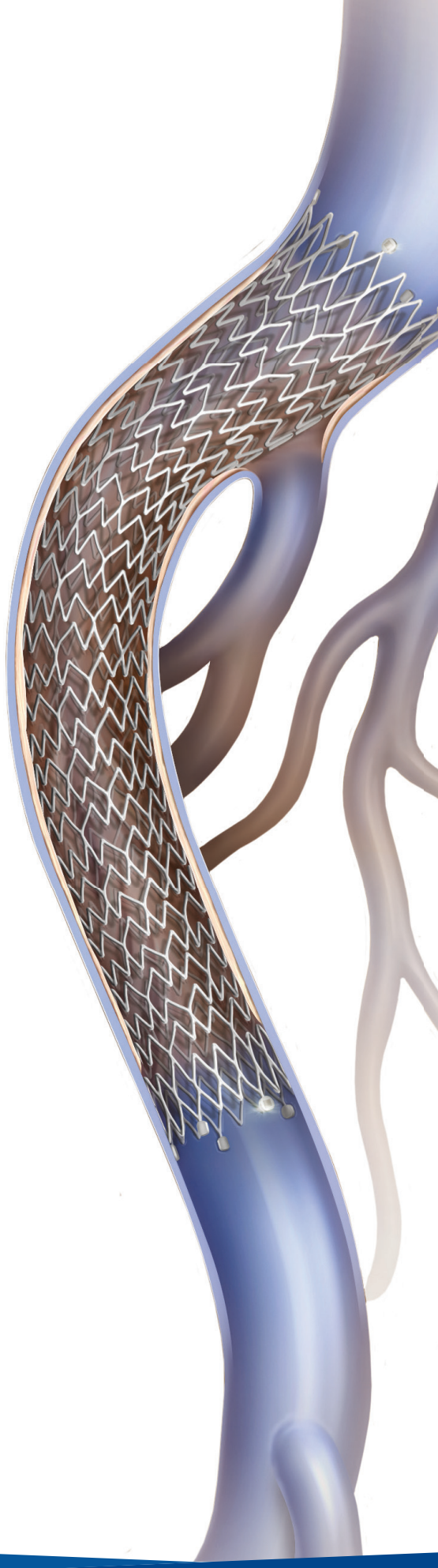
Designed for veins™

Venovo™

Venous Stent System



Proven 36-month results in post-thrombotic and non-thrombotic lesions in the **VERNACULAR** Trial[1].

BD

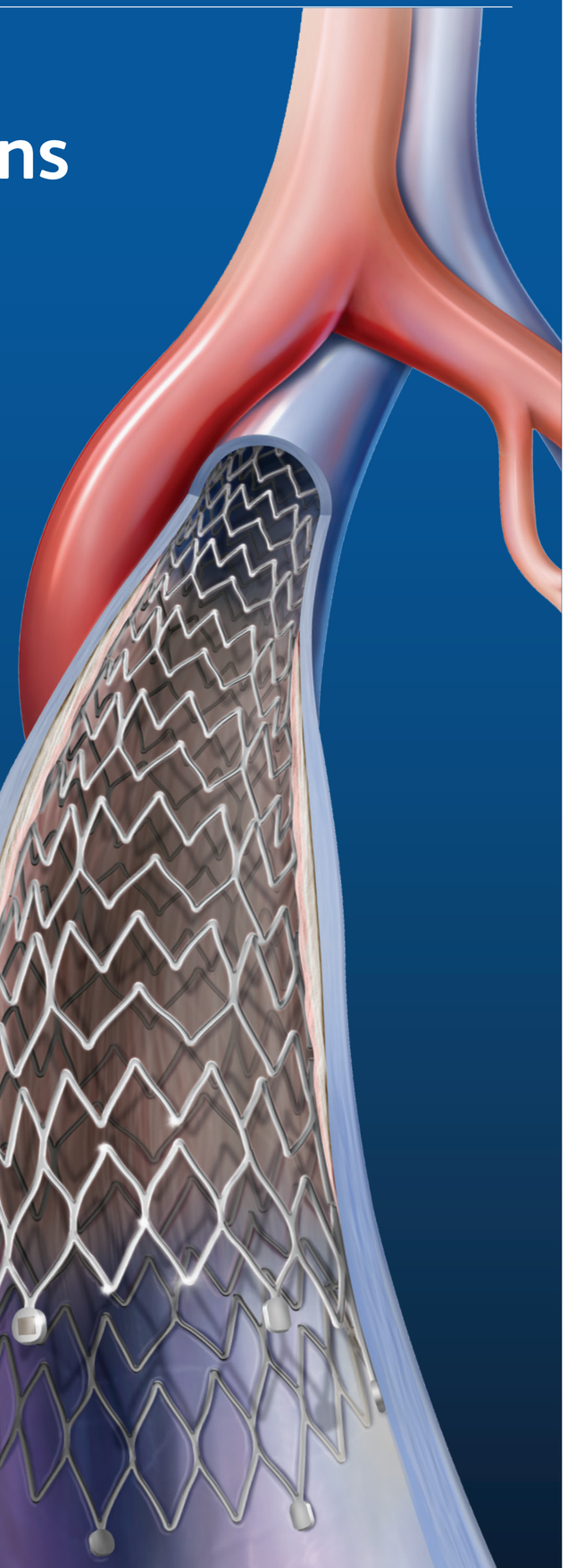
Designed for **veins**

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.

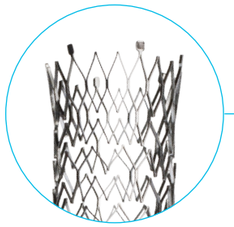
It offers radial force, crush resistance, and flexibility without compromising on delivery accuracy and is available in the sizes needed for the iliofemoral veins.



Proven 36-month results
Venovo™ Venous Stent

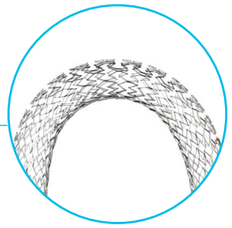
Purpose-built Venous Stent

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 maximise wall apposition

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.

Minimal foreshortening for maximum lesion coverage[3]

100%
Deployment accuracy
in the VERNACULAR Study (n=170)[1]

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

Ergonomic handle and dual-speed thumbwheels for **operator control**

Full range of **sizes**

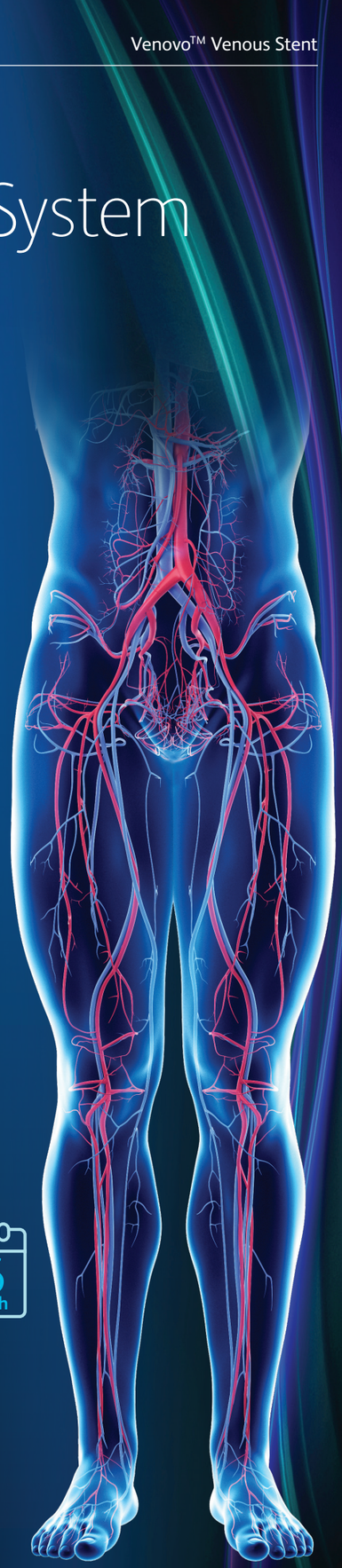
The Venovo™ Venous Stent offers a **broad size range** including 10 mm - 20 mm stent diameters and stent lengths up to 160 mm.

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

Venovo™ Venous Stent System 36-month review[1]

Results of VENOVO™ Venous Stent VERNACULAR Clinical Study for treatment of Symptomatic Iliofemoral Venous Outflow

Study design: prospective, multi-center, non-randomised, single-arm study



170 Intent-to-treat population

93 with Post-thrombotic syndrome (PTS)

77 with non-thrombotic iliac vein lesions (NIVL)

21 sites in Europe, U.S. and Australia*

30 day · **12 month** · **24 month** · **36 month**
Subjects followed through 36 months

*22 sites enrolled subjects; 21 active sites at end of study

Proven **safe** and **effective**

VERNACULAR study design	Prospective, multi-center, non-randomised, 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)
Key secondary endpoints	· VCSS Pain Score/QoL assessment · Procedure/technical success at index procedure	· Freedom from TVR/TLR at 30 days, 6, 12, 24 and 36 months post index procedure · Primary patency at 24 and 36 months · X-ray analysis of stent fracture

* 22 sites enrolled subjects; 21 active sites at end of study

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

Patency rate

93.6% Primary patency in non-thrombotic lesions at 36 months[1]

70.0% Primary patency in post-thrombotic lesions at 36 months[1]

11.9% TRL rate at 36 months[1]

Device performance

100% Placement accuracy and lesion coverage

Zero Stent fractures through 36 months

Zero stent migrations through 36 months

Proven 36-month results Venovo™ Venous Stent

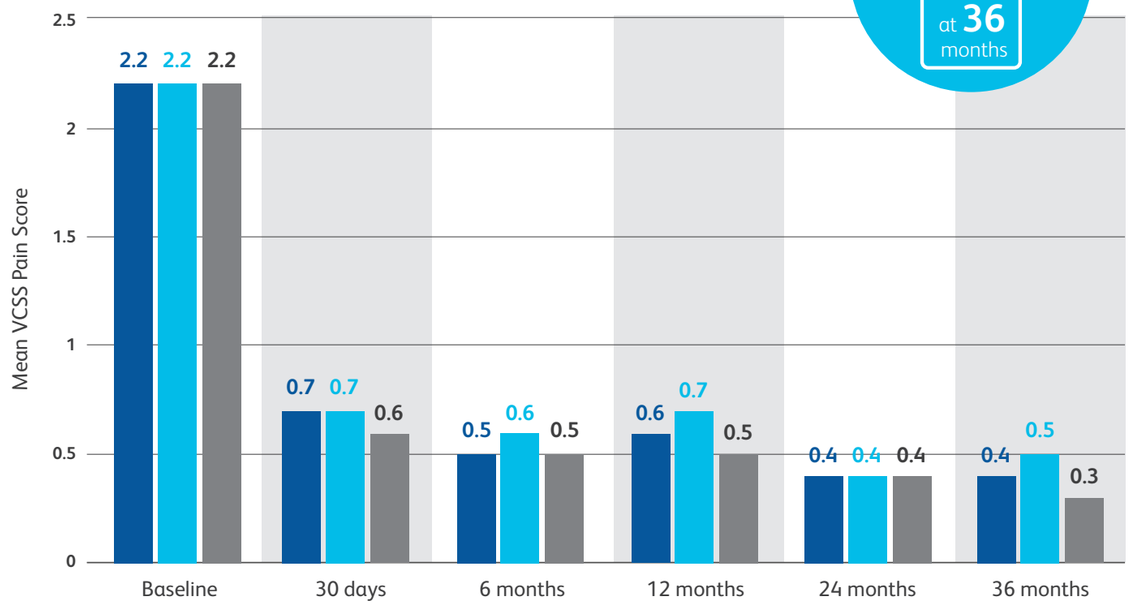
Patient-reported **improvements**

In the VERNACULAR Clinical Study, the Venovo™ Venous Stent demonstrated **significant improvement** in VCSS pain scores and quality of life (CIVIQ-20) at 36 months compared to baseline[1].

VCSS pain score through 36 months

Significant Shift to Lower Pain Scores
Mean Pain Score Improvement from Baseline*: -1.9 (95% CI: -1.95, -1.66)

Sustained pain reduction at **36** months



*Paired mean difference in pain score at 36 months compared to baseline (95% CI).

VCSS pain score measures discomfort in the treated leg:
0 – Absent
1 – Mild
2 – Moderate
3 – Severe

ITT Population
PTS Subgroup
NIVL Subgroup

Venovo™ Venous Stent System

Ordering information

Venovo™
Venous Stent System

120cm Shaft Length	80cm Shaft Length	Stent diameter (mm)	Stent length (mm)	Sheath compatibility (F)
VENEL10040	VENEM10040		40	8
VENEL10060	VENEM10060		60	8
VENEL10080	VENEM10080		80	8
VENEL10100	VENEM10100	10	100	8
VENEL10120	VENEM10120		120	8
VENEL10140	VENEM10140		140	8
VENEL10160	VENEM10160		160	8
VENEL12040	VENEM12040		40	8
VENEL12060	VENEM12060		60	8
VENEL12080	VENEM12080		80	8
VENEL12100	VENEM12100	12	100	8
VENEL12120	VENEM12120		120	8
VENEL12140	VENEM12140		140	8
VENEL12160	VENEM12160		160	8
VENEL14040	VENEM14040		40	9
VENEL14060	VENEM14060		60	9
VENEL14080	VENEM14080		80	9
VENEL14100	VENEM14100	14	100	9
VENEL14120	VENEM14120		120	9
VENEL14140	VENEM14140		140	9
VENEL14160	VENEM14160		160	9
VENEL16040	VENEM16040		40	10
VENEL16060	VENEM16060		60	10
VENEL16080	VENEM16080		80	10
VENEL16100	VENEM16100	16	100	10
VENEL16120	VENEM16120		120	10
VENEL16140	VENEM16140		140	10
VENEL16160	VENEM16160		160	10
VENEL18040	VENEM18040		40	10
VENEL18060	VENEM18060		60	10
VENEL18080	VENEM18080		80	10
VENEL18100	VENEM18100	18	100	10
VENEL18120	VENEM18120		120	10
VENEL18140	VENEM18140		140	10
VENEL18160	VENEM18160		160	10
VENEL20040	VENEM20040		40	10
VENEL20060	VENEM20060		60	10
VENEL20080	VENEM20080		80	10
VENEL20100	VENEM20100	20	100	10
VENEL20120	VENEM20120		120	10
VENEL20140	VENEM20140		140	10
VENEL20160	VENEM20160		160	10

0.035" guidewire compatible

Units per case: 1

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 36-month follow-up, the CIVIQ-20 assessment demonstrated a change from baseline in the total study population of -16.8 with 95% confidence interval of -20.07 to -13.54 (P<.0001) and for the VCSS Pain score, a change from baseline in the total population of -1.9 with 95% confidence interval of -1.95 to -1.66 (P<.0001).of -1.9. Stents were evaluated at the 36-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. 98 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 stenoses and occlusions in the iliac and femoral veins.

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. Reuse, resterilization, reprocessing and/or repackaging may create a risk to the patient or user, may lead to infection or compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness, or death of the patient. 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 or death. 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.

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