1 Simulated use data on file. Results may not be predictive of actual clinical outcomes. Different test methods may yield different results. BD Peripheral Intervention, Tempe, AZ. Venovo™ Stent (14 mm x 100 mm, N=6) and Medtronic Abre™ Stent (14 mm x 100 mm, N=6). · The maximum pull-out force of an implant from a silicone tubing section at 1 mm oversizing and at an overlap length of 40 mm was measured. A higher pull-out force is interpreted as higher migration resistance. Venovo™ Stent demonstrated higher mean pull-out force (0.107 N/mm) compared to the Medtronic Abre™ Stent (0.095 N/mm). · The length of the stents deployed inside mock vessels at minimum oversize was measured and related to the length of the stents compressed inside their catheter. The Venovo™ Stent demonstrated a mean length change percentage of 0.7% compared to the Medtronic Abre™ Stent which demonstrated a mean length change of -1.9% pre- and post-deployment. Positive percentages indicate stent elongation, and negative percentages indicate stent foreshortening. · Local compression resistance was characterized by evaluating the stent's ability to resist external compression at a single point. Mean implant local compression resistance was 2.82N for the Venovo™ Stent and 2.86N for the Medtronic Abre™ Stent., respectively. Radial force was reported in [N/mm] as hoop force, normalized by measured unconstrained stent length without markers. Radial resistive force (RRF) is measured during compression. The Venovo™ Stent showed higher mean RRF (0.13 N/mm) compared to the Medtronic Abre™ Stent (0.08 N/mm) at minimum oversize per product IFU.

2 The Venovo™ Venous Stent offers the broadest size matrix of iliofemoral indicated venous stents available in the U.S. as of April 2022. 3 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, defined as: freedom from TVR and freedom from thrombus occlusion and stenosis > 50% as measured by DUS. Patients who received a Venovo™ Venous Stent had a weighted PP rate of 88.6%, demonstrating a statistically significant difference from a literature-derived performance goal (PG) of 74%, with an 81.7% PP rate for subjects with post-thrombotic syndrome (PTS) (n=93) and 97.1% PP rate for subjects with non-thrombotic iliac vein lesions (NIVL) (n=77). The primary safety endpoint was freedom from major adverse events (MAE), including stent migration, through 30 days post-index procedure. Freedom from MAE was 93.5%, demonstrating a statistically significant difference from a literature-derived PG of 89%. At 36 months, patients who received the Venovo™ Venous Stent had an unweighted PP of 79.5% (84.0% K-M) (N=141), with a 70.0% PP rate for PTS (74.8% K-M) (n=79) and 93.6% PP for NIVL (95.5% K-M) (n=62). Dake, Michael D, et al. "Three-Year Results from the Venovo Venous Stent Study for the Treatment of Iliac and Femoral Vein Obstruction." Cardiovasc Intervent Radiol, vol. 44, no. 12, Dec. 2021, https://doi.org/10.1007/s00270-021-02975-2. Epub 2021 Sep 20. BD Peripheral Intervention, Tempe, AZ. Venovo™ Venous Stent System

Indication 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.
- Patients who cannot receive recommended antiplatelet and/or anti-coagulation therapy.
- Patients 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 can not 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 Complications and Adverse Events
Complications and Adverse Events which may occur include, but are not limited to the following:
- Allergic/anaphylactic reaction
- Amputation
- Aneurysm
- Arteriovenous fistula
- Death related to procedure
- Death unrelated to procedure
- Dissection
- Embolization, venous
- Embolization, stent
- Extravasation
- Fever
- Hemorrhage/bleeding requiring a blood transfusion
- Hematoma, remote site
- Hematoma, puncture site
- 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, remote from puncture site
- Venous occlusion/thrombosis, near the puncture site
- Venous occlusion/restenosis of the treated vessel

Please consult product labels, package insert and instructions for use for all indications, contraindications, hazards, warnings and precautions.
- These products are to be used by Health Care Professionals only.

Venovo™ Venous Stent System Product Codes

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

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bd.com

Comparison of iliofemoral venous stents

BD Venovo™ Venous Stent System vs. Medtronic Abre™ Venous Self-Expanding Stent System

Venovo™
Venous Stent System

Designed for iliofemoral veins

The Venovo™ Venous Stent was developed for the iliofemoral veins in collaboration with clinicians. It was designed to offer the optimal balance between radial force, crush resistance, and flexibility[1] without compromising on delivery accuracy. The Venovo™ Venous Stent is offered in the broadest size matrix of iliofemoral indicated venous stents available in the U.S.[2]

Greater Migration Resistance

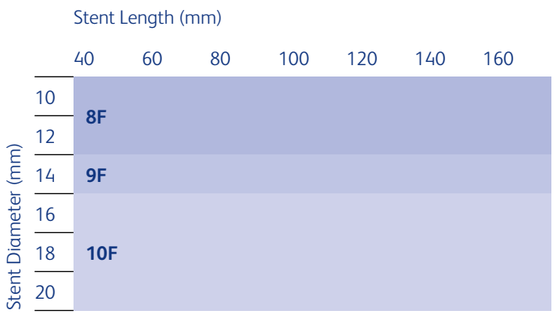
12.6% GREATER
MEAN MIGRATION RESISTANCE

The Venovo™ Venous Stent was engineered with flared ends to help reduce stent migration and maximize wall apposition. It showed higher mean pull force, interpreted as migration resistance, compared to the Medtronic Abre™ Stent in simulated use testing.[1]

More Stent Sizes with Longer Lengths

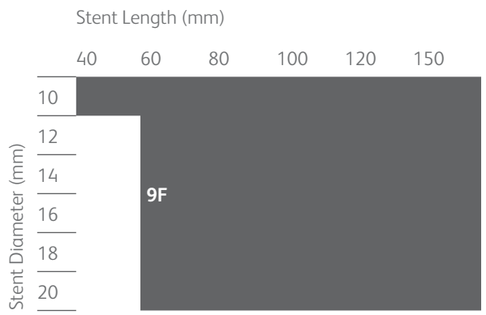
Venovo™ Venous Stent

· Total of **42** sizes ·Longer stent lengths up to **160 mm**



Medtronic Abre™ Stent

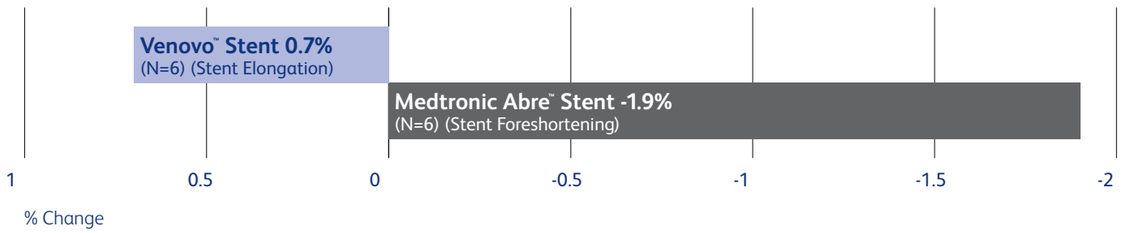
· Total of 31 sizes ·Lengths up to 150 mm



More Accurate Lesion Coverage

The Venovo™ Venous Stent had a lower mean percent change in stent lengths during pre- and post-stent deployment compared to the Medtronic Abre™ Stent in simulated use testing.[1]

Mean Change in Stent Length



Note: Positive percentages indicate stent elongation, and negative percentages indicate stent foreshortening.

Greater Radial Resistive Force

The Venovo™ Venous Stent was designed with high radial force and compression resistance to maximize luminal gain. It showed comparable mean local compression resistance and higher mean radial resistive force compared to the Medtronic Abre™ Stent in simulated use testing.[1]

68.5%
GREATER
MEAN RADIAL
RESISTIVE FORCE[1]

Proven Long-Term Results

At 36 Months in the VERNACULAR Trial[3]

84.0%
PRIMARY PATENCY
AT 36 MONTHS
KAPLAN-MEIER ESTIMATES

95.5%
NIVL
AT 36 MONTHS

74.8%
PTS
AT 36 MONTHS