



Stent Technology Designed Specifically for the **Iliofemoral** **Venous Anatomy**

The VENOVO™ Venous Stent System is the latest in the BARD® stent portfolio that is designed to treat stenoses and occlusions in the iliac and femoral veins.

TRIAxIAL DELIVERY SYSTEM

DUAL-SPEED THUMBWHEEL

VENOVO™
Venous Stent System

80 CM CATHETER LENGTH			
Stent Diameter (mm)	Stent Length (mm)	Sheath Compatibility (F)	Product Code
10	40	8	VENEM10040*
	60	8	VENEM10060
	80	8	VENEM10080
	100	8	VENEM10100
	120	8	VENEM10120
	140	8	VENEM10140
12	160	8	VENEM10160
	40	8	VENEM12040*
	60	8	VENEM12060
	80	8	VENEM12080
	100	8	VENEM12100
	120	8	VENEM12120
14	140	8	VENEM12140
	160	8	VENEM12160
	40	9	VENEM14040*
	60	9	VENEM14060
	80	9	VENEM14080
	100	9	VENEM14100
16	120	9	VENEM14120
	140	9	VENEM14140
	160	9	VENEM14160
	40	10	VENEM16040*
	60	10	VENEM16060
	80	10	VENEM16080
18	100	10	VENEM16100
	120	10	VENEM16120
	140	10	VENEM16140
	160	10	VENEM16160
	40	10	VENEM18040*
	60	10	VENEM18060
20	80	10	VENEM18080
	100	10	VENEM18100
	120	10	VENEM18120
	140	10	VENEM18140
	160	10	VENEM18160
	40	10	VENEM20040*
20	60	10	VENEM20060
	80	10	VENEM20080
	100	10	VENEM20100
	120	10	VENEM20120
	140	10	VENEM20140
	160	10	VENEM20160

120 CM CATHETER LENGTH			
Stent Diameter (mm)	Stent Length (mm)	Sheath Compatibility (F)	Product Code
10	40	8	VENEL10040*
	60	8	VENEL10060
	80	8	VENEL10080
	100	8	VENEL10100
	120	8	VENEL10120
	140	8	VENEL10140
12	160	8	VENEL10160
	40	8	VENEL12040*
	60	8	VENEL12060
	80	8	VENEL12080
	100	8	VENEL12100
	120	8	VENEL12120
14	140	8	VENEL12140
	160	8	VENEL12160
	40	9	VENEL14040*
	60	9	VENEL14060
	80	9	VENEL14080
	100	9	VENEL14100
16	120	9	VENEL14120
	140	9	VENEL14140
	160	9	VENEL14160
	40	10	VENEL16040*
	60	10	VENEL16060
	80	10	VENEL16080
18	100	10	VENEL16100
	120	10	VENEL16120
	140	10	VENEL16140
	160	10	VENEL16160
	40	10	VENEL18040*
	60	10	VENEL18060
20	80	10	VENEL18080
	100	10	VENEL18100
	120	10	VENEL18120
	140	10	VENEL18140
	160	10	VENEL18160
	40	10	VENEL20040*
20	60	10	VENEL20060
	80	10	VENEL20080
	100	10	VENEL20100
	120	10	VENEL20120
	140	10	VENEL20140
	160	10	VENEL20160

For all product codes: 0.035" guidewire. *Please consult your Bard Representative for local availability.

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 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 indeterminate 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/anaphylactoid 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 and instructions for use for indications, contraindications, hazards, warnings and precautions.

Not available for sale in the USA.

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