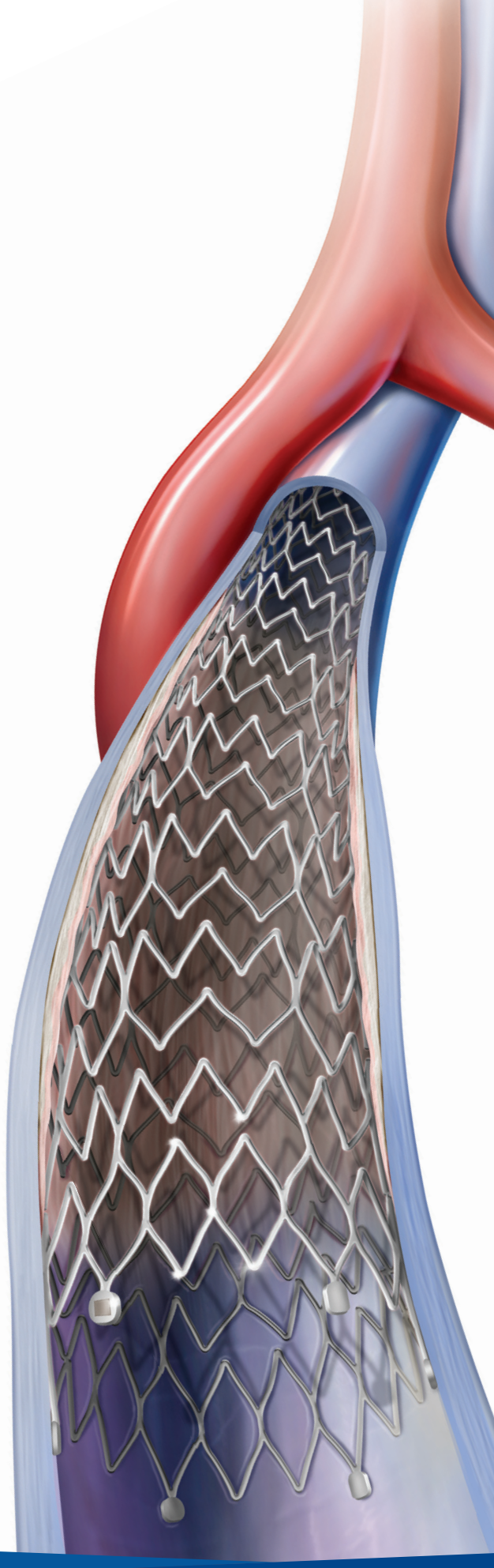
Venovo™

Venous Stent System

Stent technology designed specifically for the **Iliofemoral Venous Anatomy**



Technical data and specifications	
Stent material	Nitinol
Stent diameters	10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm
Stent lengths	40 mm, 60 mm, 80 mm, 100 mm, 120 mm, 140 mm, 160 mm
Catheter working lengths	80 cm, 120 cm
Guidewire compatibility	0.035 inch (0.89 mm)
Introducer sheath compatibility	10 mm and 12 mm: 8F 14 mm: 9F 16 mm, 18 mm, and 20 mm: l0F
Delivery system catheter design	Triaxial, over-the-wire
Deployment action	Dual-speed thumbwheel
Indication	Treatment of stenoses and occlusions in the iliac and femoral veins

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Venovo™ Venous Stent System

Ordering information

Venovo™
Venous Stent System

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

0.035" guidewire compatible

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

Units per case: 1

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 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.

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