Complex ilio-caval revascularization in chronic venous obstruction with the Venovo® Stent

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**Affiliation/Financial Relationship**  **Company**

1. Honoraria for lectures: CR Bard, Veniti, AB Medica, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan

2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific

3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow

4. Research funding: Biotronik, Boston Scientific, Veryan, Veniti, AB Medica

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Current Regulatory Status

• The VENOVO® Venous Stent has CE Mark approval for sale and distribution in Europe. The VENOVO® Venous Stent is currently undergoing an investigational device exemption (IDE) in the United States.

• This device is limited by United States law to investigational use only. This device is not available for sale or distribution in the U.S.
BARD DISCLAIMER

- The speakers’ presentation today is on behalf of Bard Peripheral Vascular, Inc. Any discussion regarding Bard products during the presentation today is limited to information that is consistent with the Bard labeling for those products. Please consult Bard product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use. The opinions and clinical experiences presented herein are for informational purposes only. The results from these case studies may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes. These physicians have been compensated by Bard Peripheral Vascular.
Venous Stent Attributes

- Self-expandable
- Crush resistant across length of stent
- Sufficient chronic outward force
- Sufficient wall coverage
- Flexibility sufficient to resist kink at physiological angles
- Durability allowing repeated shortening, twisting, and bending at the groin
- Minimal foreshortening on deployment and balloon dilation
- Predictable, consistent deployment
Stent options!

Boston Wallstent
Optimed
Cook Zilver Vena
VIVO (EU) Trial
Veniti Vici
Optimed Sinus obliquus
Sinus Obliquus-01-NIS
Bard Venovo
VIRTUS Trial
VERNACULAR Trial

Upcoming: Medtronic, Gore, ab Medica, INTACT, Abbott Vascular
Venovo® Stent 14 x 120 mm and 14 x 80 mm on both CIV and EIV

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Stent Design

- Self expanding nitinol
- Flexible, fine tubular mesh prosthesis
- Design alternates between 3 and 6 nitinol connectors in the main body of the stent
- 6 markers at each end, 3 are radiopaque tantalum, 3 are nitinol
- Ends flared 3mm to ensure adequate wall apposition
- Outward radial force established vessel patency

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Venovo™ Venous Stent

- Tri-axial system
- 0.035”, over-the-wire
- Dual speed thumbwheel
  - Large thumbwheel for slow deployment
  - Small thumbwheel for fast deployment
- Shaft Length: 80 & 120 cm

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**Venovo™ Venous Stent**

<table>
<thead>
<tr>
<th>Stent Lengths</th>
<th>20 mm</th>
<th>40 mm</th>
<th>60 mm</th>
<th>80 mm</th>
<th>100 mm</th>
<th>120 mm</th>
<th>140 mm</th>
<th>160 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stent Diameters</strong></td>
<td><strong>10 mm</strong></td>
<td><strong>12 mm</strong></td>
<td><strong>14 mm</strong></td>
<td><strong>16 mm</strong></td>
<td><strong>18 mm</strong></td>
<td><strong>20 mm</strong></td>
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<td>8F</td>
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</tbody>
</table>
Visibility

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Images presented above are from a Bard GLP animal study in an ovine model.
Stent Strength Attributes

**FOCAL LOAD**

- Ability to withstand non-uniform **FOCAL** load.
- More closely represents condition of diseased veins.

**CIRCUMFERENTIAL LOAD**

- Ability to withstand uniform **CIRCUMFERENTIAL** load
- Not closely representative of diseased veins.

**Crush Resistance**

- Ability to withstand non-uniform **FOCAL** load.
- More closely represents condition of diseased veins.

**Radial Resistive Force**

- Ability to withstand uniform **CIRCUMFERENTIAL** load
- Not closely representative of diseased veins.
Bench testing may not be indicative of clinical performance. Different test methods may yield different results. Competitive testing samples represent commercially available venous stents with CE mark as of June 2014.
Stent Flexibility

Bard N=20
Optimed Sinus Venous N=3
Cook Zilver Vena N=3

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This product is not available for sale in the US.
“Choose wisely”
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C6, 58 year female with chronic outflow obstruction
2 Sinus XL Stent (22 x 80 mm)
4 x Venovo® Stent (16 x 120 mm + 14 x 60 mm)

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34 y, male, PTS, CEAP IV
Venovo® Stent  16 x 100 mm + 14 x 60 mm

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Take home message

General

• Use dedicated venous stents!
• Choose wisely - based on lesion morphology
• Choose wisely – based on stent technology

Venovo Stent

• Flexibility: proven
• Strength: proven
• Lumen quality: proven
Thank you for your attention
VENOVO® Venous Stent

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.

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VENOVO® Venous Stent

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 package insert for more detailed safety information and instructions for use.

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