Stephen Black, MD

VERNACULAR Trial & Clinical Experience with the VENOVO® Venous Stent
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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.
VENOVO® Venous Stent System

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.

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.

VENOVO® Venous Stent 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 recommended antiplatelet and/or 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.
Consequences of DVT/PE

- 60,000-100,000 in U.S. die each year\(^1,2\)
  - 10-30% die within 1 month of diagnosis\(^1\)
- 33% recurrence over 10 years\(^1\)
- 50% develop post thrombotic syndrome (PTS)\(^1,2\)
  - Swelling, pain, skin discoloration, varicose veins, chronic ulcers
- Avg. 548,000 hospitalizations each year due to VTE\(^3\)

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# VTE Risk Factors

<table>
<thead>
<tr>
<th>Trauma</th>
<th>Surgery</th>
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<tbody>
<tr>
<td>Obesity</td>
<td>Cancer</td>
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</table>
| Pregnancy    | Oral
Contraceptives |
| Hormone Therapy | Smoking   |
| Age          | Genetic Clotting Disorders |
| Prolonged Immobility | Hospitalization |
| Nursing Home | Prolonged Travel |

Costs of VTE

• Hospital claims from 30 hospitals over 7 years\(^1\)
• 8.96% patients had readmission within 1 year\(^1\)
  – Costs 21% higher for readmission
  – Stays longer
• Annual cost for DVT - $9,321\(^1\)
  – Avg. stay 5.6 days
• Annual cost for PE - $15,655\(^1\)
  – Avg. stay 7.0 days
• Avg. cost for DVT + PE - $27,909\(^1\)

Annual US healthcare cost of $2-$10 Billion\(^2\)

Venous Stenting in the Literature

- Meta analysis of 37 studies, 2,869 patients
- Analyzed stent placement for treatment of iliofemoral venous outflow
- Primary Patency at 12 months
  - Nonthrombotic lesions: 96% (95% CI, 93%–98%)
  - Acute DVT: 87% (95% CI, 80%–92%)
  - Chronic DVT: 79% (95% CI, 76%–83%)
- High technical success (94-96%)
- Low complication rate (<1% bleeding, PE, and mortality)

VERNACULAR Trial

- The BARD® VENOVO® Venous Stent Study - A Prospective, Non-Randomized, Multi-Center, Single-Arm Study of the Treatment of Iliofemoral Occlusive Disease – an Assessment for Effectiveness and Safety

- **Design**: Prospective, multi-center, non-randomized, single-arm
  - Core lab & DSMB

- **Purpose**: to assess the safety and effectiveness of the VENOVO® Venous Stent for the treatment of iliofemoral occlusive disease including Acute or Chronic Deep Vein Thrombosis (DVT), May-Thurner Syndrome, or any combination of the above.

- **Investigative Sites**: 35 sites in the US, Europe, and Australia/NZ

- **Subjects**: 170 subjects
Key Inclusion/Exclusion

**Inclusion**
- Unilateral disease of common femoral, common/external iliac
- Symptomatic venous outflow obstruction $\geq 50\%$ by venography
- CEAP $\geq 3$ or VCSS $\geq 2$
- RVD 7 mm - 19 mm

**Exclusion**
- Contralateral disease and lesions that extend into IVC or below lesser trochanter
- Uncorrectable bleeding diathesis or active coagulopathy
- Previous venous stents
- Can’t cross occlusion
VERNACULAR Trial

• **Primary endpoints:**
  - Primary patency (12 months)
  - Freedom from MAE (30 days)
  - Evaluated against literature derived performance goals

• **Key secondary endpoints:**
  - VCSS/ CEAP/ QoL assessment
  - Procedure/technical success
  - Freedom from TVR/TLR
  - Primary patency at 24 and 36 mo.
  - Stent fracture
VERNACULAR:
VENOVO® Stent IDE Clinical Study

• 10 US Sites
• 7 OUS sites
• Enrollment at 77 patients
The ATTRACT Study

Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis

• NIH-funded, Phase III, multicenter, open-label, assessor-blinded, randomized controlled trial
• Randomized to receive PMT + standard therapy vs. standard therapy alone
• 692 patients with symptomatic proximal iliofemoral DVT
• 58 study sites, enrollment closed
• Primary endpoints:
  – Cumulative incidence of PTS (Villalta Scale) at 24 months
• Secondary endpoints:
  – Severity of PTS, DVT symptoms, valve reflux, residual thrombus, clot lysis, cost effectiveness
  – Major bleeding, symptomatic PE, recurrent VTE, death


ClinicalTrials.gov NCT00790335
May-Thurner Syndrome

- Compression of left iliac vein by right iliac artery
- 22-24% of lower extremity DVT cases
- Prevalence may be underestimated

VENOVO® Stent Delivery System
Deployment
Clinical Use

• Visibility is good
• Deployment is easy with minimal foreshortening
• Long term data will come from the VERNACULAR Study
• Key points:
  – May-Thurner
  – Pelvis
  – Ligament
Flexibility
VTE and PTS are major health and economic concerns

Current clinical guidelines vary on appropriate treatment algorithms

Multiple endovascular treatment options needed

VENOVO® Venous Stent is being investigated for treatment of iliofemoral disease
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**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 recommended antiplatelet and/or anticoagulation 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. 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 Complications and 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 more detailed safety information and instructions for use.

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