Venovo™ Venous Stent & Clinical Data

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Galway, Ireland
Disclosure

Speaker name:
Gerry O’Sullivan ....................................................

I have the following potential conflicts of interest to report:

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☐ Employment in industry
☒ Stockholder of a healthcare company Marvao Medical, Orthosensor, Vetex
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
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Venovo™ Venous Stent System

- Self-expanding nitinol stent designed for veins
- Flared ends designed for vein wall apposition
- Tri-axial, 0.035” over-the-wire delivery system
- 6 radiopaque tantalum markers (3 on each end)

FDA Approved March 13, 2019: For the treatment of symptomatic iliofemoral venous outflow obstruction

**Stent Sizes**
- Diameters: 10 – 20 mm (2 mm increments)
- Lengths: 40 – 160 mm (20 mm increments)
- 8F – 10F
Objective: Assess the performance of the Venovo™ Venous Stent for the treatment of iliac & femoral vein outflow obstructions

Design: Prospective, Multicenter, Non-Randomized, Single-Arm

Patient Population: 170 patients

21 International Sites: USA, Europe, and Australia

Independent Analysis:
- Venographic & radiographic assessment: Yale Core Lab
- Duplex Ultrasound (DUS) evaluation: VasCore
- Clinical Events Committee (CEC): adjudicated serious adverse events
- Data Safety Monitoring Board (DSMB): assessed overall patient safety
# VERNACULAR Study Criteria

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unilateral disease of common femoral, common/external iliac</td>
<td>Contralateral disease and lesions that extend into IVC or below lesser trochanter</td>
</tr>
<tr>
<td>Symptomatic venous outflow obstruction &gt;50% by venography</td>
<td>Uncorrectable bleeding diathesis or active coagulopathy</td>
</tr>
<tr>
<td>CEAP “C” &gt;3 or VCSS (Pain Score) &gt;2</td>
<td>Prior stent placement in the target vessel</td>
</tr>
<tr>
<td>Reference vessel diameter 7 mm - 19 mm</td>
<td>Cannot cross occlusion</td>
</tr>
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</table>
## Patient Demographic

### ITT Population

<table>
<thead>
<tr>
<th>Demographic Criteria</th>
<th>Total (N=170)</th>
<th>Mean Age, years ± SD</th>
<th>52.1 ± 15.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age, years ± SD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male/Female, %/%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean BMI, kg/m² ± SD</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Co-Morbidities/Medical History, % (n)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Varicosis</td>
<td>78.2 (133)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>May-Thurner Syndrome</td>
<td>60.0 (102)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoker (Current &amp; Former)</td>
<td>34.1 (58)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>32.4 (55)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>27.6 (47)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes (Type 2)</td>
<td>10.6 (18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral Artery Disease</td>
<td>10.6 (18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTS¹ (N=93)</td>
<td></td>
<td>49.8 ± 15.0</td>
<td>55.0 ± 15.4</td>
</tr>
<tr>
<td>NIVL² (N=77)</td>
<td></td>
<td>45.2/54.8</td>
<td>27.3/72.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28.6 ± 6.4</td>
<td>29.1 ± 7.7</td>
</tr>
</tbody>
</table>

¹ Post-Thrombotic Syndrome  
² Non-Thrombotic Iliac Vein Lesion
## Lesion Characteristics & Procedural Data

<table>
<thead>
<tr>
<th>Lesion Criteria</th>
<th>Total (N=170)</th>
<th>PTS (N=93)</th>
<th>NIVL (N=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion Location</strong>, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common Iliac Vein</td>
<td>94.5</td>
<td>92.1</td>
<td>97.3</td>
</tr>
<tr>
<td>External Iliac Vein</td>
<td>40.5</td>
<td>58.4</td>
<td>18.9</td>
</tr>
<tr>
<td>Common Femoral Vein</td>
<td>9.2</td>
<td>14.6</td>
<td>2.7</td>
</tr>
<tr>
<td><strong>Lesion Morphology</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Lesion Length, mm ± SD</td>
<td>67.8 ± 40.0</td>
<td>80.5 ± 42.8</td>
<td>55.2 ± 32.0</td>
</tr>
<tr>
<td>Thrombus Present, % (n/N)</td>
<td>8.6 (14/162)</td>
<td>14.8 (13/88)</td>
<td>1.4 (1/74)</td>
</tr>
<tr>
<td>No Blood Flow (Occluded), % (n/N)</td>
<td>22.8 (37/162)</td>
<td>38.6 (34/88)</td>
<td>4.1 (3/74)</td>
</tr>
<tr>
<td>Number of Stents, N</td>
<td>219</td>
<td>134</td>
<td>85</td>
</tr>
<tr>
<td>Number of Stents per Patient</td>
<td>1.3</td>
<td>1.4</td>
<td>1.1</td>
</tr>
<tr>
<td>Mean Stented Length, mm ± SD</td>
<td>100.6 ± 49.1</td>
<td>109.2 ± 49.8</td>
<td>86.0 ± 45.2</td>
</tr>
<tr>
<td>Acute Technical Success, % (n/N)</td>
<td>100 (170/170)</td>
<td>100 (93/93)</td>
<td>100 (77/77)</td>
</tr>
<tr>
<td>Acute Procedure Success, % (n/N)</td>
<td>98.8 (168/170)</td>
<td>97.8 (91/93)</td>
<td>100 (77/77)</td>
</tr>
</tbody>
</table>

1. One hundred and sixty-three (163) patients had images evaluable by the core lab.
2. Lesions could occur in more than one vein per patient.
3. Technical success plus no MAE's through discharge. Two patients in the PTS group had minor detection requiring a DVT (investigator assessment).
4. Technical success plus no MAE's through discharge. Two patients in the NIVL group had minor detection requiring a DVT (investigator assessment).

BD-18811
### VERNACULAR Study: Primary Endpoints

**Safety: Freedom from MAEs (30 Days)**

<table>
<thead>
<tr>
<th>ITT (N=170)</th>
<th>90% CI</th>
<th>Performance Goal</th>
<th>p-value&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from MAEs % (n/N)</td>
<td>93.5% (159/170)</td>
<td>(89.5%, 96.3%)</td>
<td>89%</td>
</tr>
</tbody>
</table>

**Efficacy: 12-Month Primary Patency**<sup>*</sup>

<table>
<thead>
<tr>
<th>ITT (N=170)</th>
<th>90% CI</th>
<th>Performance Goal</th>
<th>p-value&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency% (n/N)</td>
<td>88.3% (128/145)</td>
<td>(82.4%, 94.2%)</td>
<td>74%</td>
</tr>
</tbody>
</table>

<sup>1</sup> Freedom from target vessel revascularization (TVR) and thrombotic occlusion and stenosis >50% measured by DUS Core Lab

<sup>2</sup> One-sided p-value calculated from the weighted Z statistic

Freedom from MAEs with Venovo™ Venous Stent was statistically significant when compared to the literature-derived performance goal.

Primary Patency with Venovo™ Venous Stent was statistically significant when compared to the literature-derived performance goal.
## VERNACULAR Study: 24-Month Results

### ITT Population

<table>
<thead>
<tr>
<th>Observations</th>
<th>12 Month (n= 170)</th>
<th>24 Months (n=147)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from TLR, (95% CI)</td>
<td>92.6% (87.5, 96.1)</td>
<td>89.4% (83.6, 93.7)</td>
</tr>
<tr>
<td>Freedom from TVR, (95% CI)</td>
<td>92.6% (87.5, 96.1)</td>
<td>89.4% (83.6, 93.7)</td>
</tr>
<tr>
<td>Primary Patency¹, (90% CI)</td>
<td>88.3% (82.4, 94.2)</td>
<td>83.2% (77.3, 89.1)</td>
</tr>
<tr>
<td>Stent Fractures, (n/N)</td>
<td>0% (0/137)</td>
<td>0% (0/128)²</td>
</tr>
</tbody>
</table>

### Subgroups (24 Months)

<table>
<thead>
<tr>
<th></th>
<th>PTS (n=79)</th>
<th>NIVL (n=62)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from TLR</td>
<td>82.8%</td>
<td>97.3%</td>
</tr>
<tr>
<td>Freedom from TVR</td>
<td>82.8%</td>
<td>97.3%</td>
</tr>
<tr>
<td>Primary Patency</td>
<td>73.4%</td>
<td>95.2%</td>
</tr>
<tr>
<td>Stent Fractures</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Descriptive Statistics - No formal hypothesis testing at 24 months

¹ Weighted primary patency rate (proportional analysis) - 90% CI from weighted Z-statistics
² 128 patients had AP and lateral radiographs that could be evaluated by the Yale core lab at 24 months
### Study
Assess safety and effectiveness of venous stent placement through 36 months in patients with non-thrombotic iliac vein lesions (NIVL) and post-thrombotic (PTS) iliac vein lesions

### Design
Investigator-initiated, ongoing prospective, single arm, single center, non-randomized registry

### Endpoints
Primary patency at 12 months; Clinical outcome at 12 months

### Primary Investigators
Dr. Michael Lichtenberg  
Dr. Rick de Graaf

### Subjects
80 subjects; 50 (63%) PTS and 30 (37%) NIVL

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Nearly 50% of the lesions had a CEAP score ≥ 4 (complex lesions) and more than 20% involved the entire iliofemoral segment.
Patency Results by Duplex

### All Patients

<table>
<thead>
<tr>
<th></th>
<th>Primary</th>
<th>Secondary</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-M (77/80)</td>
<td>98%</td>
<td>100%</td>
</tr>
<tr>
<td>6-M (59/80)</td>
<td>97%</td>
<td>100%</td>
</tr>
<tr>
<td>12-M (52/80)</td>
<td>96%</td>
<td>97%</td>
</tr>
</tbody>
</table>

### By Etiology at 12 Months (n=52)

<table>
<thead>
<tr>
<th></th>
<th>Primary</th>
<th>Secondary</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIVL</td>
<td>97%</td>
<td>100%</td>
</tr>
<tr>
<td>PTS</td>
<td>96%</td>
<td>95%</td>
</tr>
</tbody>
</table>

Data courtesy of Dr. Michael Lichtenberg
Conclusion:

• Venovo™ Venous Stent, IDE trial summary at 24-months
  – Primary Patency: 84.3% (K-M analysis)
  – ftLR/ftVR : 89.4%
  – Stent fractures (Core Lab Analyzed): 0%
  – Improvement in both VCSS pain score and CIVIQ-20
• Venovo™ Venous Stent, Arnsberg Registry*
  – Adequate patency rates at 6 months
  – VCSS improve in 51% patients
  – CEAP decrease from 4.3 → 2.7

THANK YOU
The Venovo™ Venous Stent is indicated for the treatment of symptomatic iliofemoral venous outflow obstruction.

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.

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.