Venovo venous stent in the treatment of non-thrombotic or post-thrombotic iliac vein lesions: Results from the Arnsberg venous registry

Michael K. W. Lichtenberg MD, FESC
Arnsberg, Germany
VENOVO® Venous Stent

- Self-expanding nitinol
- Purpose-built for the veins
- Unique flared ends to ensure adequate wall apposition
- Tri-axial delivery system
- Indicated for the treatment of symptomatic iliofemoral venous outflow obstruction
**VENOVO® Stent – Product Design**

**Radial Force/ Crush Resistance**
- Thicker struts than common arterial stents
- Cut from different base tubes for radial force

**Flexibility**
- Alternating ring/strut connectors
- Peak-to-valley design

**Migration Resistance**
- Flared ends
- Minimal foreshortening

**Visibility**
- RO markers

- 3 RO tantalum markers
- 3 non-RO nitinol markers
- 3 nitinol connectors
- Peak to valley connections
- Ends flared 3mm
- 6 nitinol connectors

- Thicker struts

**Purpose-Built Venous Stent Design**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radial Force/ Crush Resistance</td>
<td>Thicker struts than common arterial stents</td>
</tr>
<tr>
<td></td>
<td>Cut from different base tubes for radial force</td>
</tr>
<tr>
<td>Flexibility</td>
<td>Alternating ring/strut connectors</td>
</tr>
<tr>
<td></td>
<td>Peak-to-valley design</td>
</tr>
<tr>
<td>Migration Resistance</td>
<td>Flared ends</td>
</tr>
<tr>
<td></td>
<td>Minimal foreshortening</td>
</tr>
<tr>
<td>Visibility</td>
<td>RO markers</td>
</tr>
</tbody>
</table>

**Table of Features**

- 3 RO tantalum markers
- 3 non-RO nitinol markers
- 3 nitinol connectors
- Peak to valley connections
- Ends flared 3mm
- Thicker struts
Open Cell Stent Design

Open Cell Design

Closed Cell Design

Higher Flexibility Lower
**VENOVO® Stent – Delivery System**

- **Control**
  - Dual-speed thumbwheel
  - 0.035” guidewire compatible

- **Ease of Use**
  - Ergonomic thumbwheel
  - Controlled delivery

- **Accuracy**
  - Tri-axial system
  - Safety lock slider

- **Catheter Lengths**
  - 80 cm
  - 120 cm

**Designed to Facilitate Stent Placement**

**Dual-speed thumbwheel**

**Ergonomic handle**

**0.035” compatible**

**Two catheter lengths**
# VENOVO® Venous Stent System

<table>
<thead>
<tr>
<th>VENOVO® Venous Stent</th>
<th>Stent Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40</td>
</tr>
<tr>
<td>Stent Diameter (mm)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>
# Venous Stent Trials

<table>
<thead>
<tr>
<th></th>
<th>VICI (Veniti/Boston Scientific)</th>
<th>Zilver™ Vena™ (Cook)</th>
<th>VENOVO (Bard)</th>
<th>ABRE (Medtronic)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CE Mark/ FDA Approval</strong></td>
<td>✓/-</td>
<td>✓/-</td>
<td>✓/-</td>
<td>✓/-</td>
</tr>
<tr>
<td><strong>Trial Name</strong></td>
<td>VIRTUS</td>
<td>VIVO</td>
<td>VERNACULAR</td>
<td>ABRE</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Multi-center, single arm</td>
<td>Multi-center, single arm</td>
<td>Multi-center, single arm</td>
<td>Multi-center, single arm</td>
</tr>
<tr>
<td><strong>N</strong></td>
<td>170 (pivotal cohort)</td>
<td>243</td>
<td>170</td>
<td>200</td>
</tr>
</tbody>
</table>

**Efficacy endpoint**

<table>
<thead>
<tr>
<th>VICI Venous Stent</th>
<th>12M Primary patency</th>
<th>Freedom from:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12M Primary patency</td>
<td>Freedom from:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Freedom from:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Freedom from:</td>
</tr>
</tbody>
</table>

- **Primary patency**
- Freedom from:
  - Reintervention
  - Occlusion, thrombosis
  - In-stent restenosis >50%

**Eligibility**

- CEAP “C” ≥3 OR VCSS Pain Score ≥2
- Iliofemoral occlusive disease
- ≥50% reduction in target vessel lumen diameter (venogram)

**clinicaltrials.gov**

- NCT02112877
- NCT01970007
- NCT02655887
- NCT03038438


Primary Patency (12-Months)

Primary patency with the VENOVO® Venous Stent was statistically different compared to a literature-derived performance goal (74%).

<table>
<thead>
<tr>
<th>ITT Population</th>
<th>PTS N=93 (90% CI)</th>
<th>NIVL N=77 (90% CI)</th>
<th>Total N=170 (90% CI)</th>
<th>p-value³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency (Proportional Analysis)</td>
<td>81.3% (72.6%, 88.1%)</td>
<td>96.9% (90.6%, 99.5%)</td>
<td>88.3%¹ (82.4%, 94.2%)²</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

¹ Weighted combined patency rate of PTS and NIVL with 55% and 45% weight, respectively. The combined patency was tested against the performance goal of 74%.

² 90% confidence intervals from the weighted Z statistics.

³ One-sided p-value calculated from the weighted Z statistics.
Patients’ pain symptoms decreased from moderate/severe to **mild/no pain** post-stent placement with a 1.7 point decrease in mean VCSS Pain score.

P-value calculated from a two-sided paired t-test
ARNSBERG VENOUS REGISTRY
## Venovo Cohort (n = 80)

<table>
<thead>
<tr>
<th><strong>Objective</strong></th>
<th>Assess safety &amp; effectiveness in achieving patency of target venous lesion through 36 months post stent placement in patients with non-thrombotic iliac vein lesions and post thrombotic iliac vein lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness</strong></td>
<td>Primary Patency @ 24-Months / Clinical outcome @ 24-Months</td>
</tr>
<tr>
<td><strong>Principle Investigators</strong></td>
<td>Dr. Michael Lichtenberg &amp; Dr. Rick de Graaf – this study is not sponsored by BD</td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
<td>Ongoing prospective, single arm, single center non-randomized registry</td>
</tr>
<tr>
<td><strong>Follow-Up</strong></td>
<td>4 weeks, 6 months, 12 months, 24 months, 36 months</td>
</tr>
<tr>
<td><strong>Patient Population</strong></td>
<td>Subjects with clinically significant chronic non-malignant obstruction of the iliofemoral venous segment</td>
</tr>
</tbody>
</table>

# Clinical Assessment

http://www.veinforum.org/uploadDocs/1/Revised-VCSS---June-2010.pdf

<table>
<thead>
<tr>
<th>NAME:</th>
<th>LEFT</th>
<th>RIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>DATE:</td>
<td>Initial</td>
<td>Pre-Cp</td>
</tr>
<tr>
<td>CEAP (0-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue (Y/N)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VCSS (0-3 Each)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicose Vein</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venous Edema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pigmentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inflammation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insuration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Ulcers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulceration Duration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Ulcer Size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compressive Therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complications: Blank (none) to 3 (severe)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperpigmentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phlebitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraneuropathy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erythema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eczematous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermal injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Satisfaction: (None/Party/Slight)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venous Veins (None/Residual/New/Repair)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcome: (Not Successful/Success/NA)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

www.veinforum.org
### Demographics


<table>
<thead>
<tr>
<th>Demographics</th>
<th>N=80 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong> (Median [Range]) in years (n=80)</td>
<td>57 (19-89)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>44 (56%)</td>
</tr>
<tr>
<td>Male</td>
<td>35 (44%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>79 (100%)</td>
</tr>
</tbody>
</table>
Medical History


<table>
<thead>
<tr>
<th>Medical History</th>
<th>N=80 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTD</td>
<td>Yes 62 (78%)</td>
</tr>
<tr>
<td>Pulmonary Embolism</td>
<td>Yes 8 (10%)</td>
</tr>
<tr>
<td>Deep vein thrombosis (DVT)</td>
<td>Yes 38 (48%)</td>
</tr>
<tr>
<td>DVT Legs</td>
<td>Both 6 (8%)</td>
</tr>
<tr>
<td></td>
<td>Left 25 (31%)</td>
</tr>
<tr>
<td></td>
<td>Right 5 (6%)</td>
</tr>
<tr>
<td></td>
<td>Unknown 2 (3%)</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td>Yes 40 (50%)</td>
</tr>
<tr>
<td>High Blood Pressure Control</td>
<td>Yes 36 (45%)</td>
</tr>
<tr>
<td>Renal Disease</td>
<td>Yes 6 (8%)</td>
</tr>
<tr>
<td>PVD</td>
<td>No 80 (100%)</td>
</tr>
<tr>
<td>Coagulopathy</td>
<td>Yes 3 (4%)</td>
</tr>
<tr>
<td>CVA</td>
<td>Yes 4 (5%)</td>
</tr>
<tr>
<td>Cancer</td>
<td>Yes 9 (11%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medical History (Contd.)</th>
<th>N=80 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma</td>
<td>No 80 (100%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Yes 11 (14%)</td>
</tr>
<tr>
<td>Diabetes Control</td>
<td>Yes 10 (13%)</td>
</tr>
<tr>
<td>Allergy</td>
<td>Yes 17 (21%)</td>
</tr>
<tr>
<td></td>
<td>Unknown 61 (76%)</td>
</tr>
<tr>
<td>Smoking</td>
<td>Yes 13 (16%)</td>
</tr>
<tr>
<td></td>
<td>No 66 (83%)</td>
</tr>
<tr>
<td></td>
<td>Missing 1 (1%)</td>
</tr>
<tr>
<td>Smoking Status</td>
<td>Current 11 (14%)</td>
</tr>
<tr>
<td></td>
<td>Former 2 (3%)</td>
</tr>
<tr>
<td>NIVL</td>
<td>Yes 29 (36%)</td>
</tr>
<tr>
<td></td>
<td>No 50 (63%)</td>
</tr>
<tr>
<td></td>
<td>Missing 1 (1%)</td>
</tr>
</tbody>
</table>
### Overview of Target Vessel Lesions

#### Target limb per intervention

<table>
<thead>
<tr>
<th>Target vessel</th>
<th>Both limbs</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 6 (8%)</td>
<td>N = 18 (22%)</td>
<td>N = 56 (70%)</td>
</tr>
<tr>
<td>CIV</td>
<td>N = 3 (4%)</td>
<td>N = 3 (4%)</td>
<td>N = 30 (38%)</td>
</tr>
<tr>
<td>CIV + EIV + CFV</td>
<td>n/a</td>
<td>N = 14 (17%)</td>
<td>N = 18 (22%)</td>
</tr>
<tr>
<td>EIV + CFV</td>
<td>N = 3 (4%)</td>
<td>N = 1 (1%)</td>
<td>N = 5 (6%)</td>
</tr>
<tr>
<td>CFV</td>
<td>n/a</td>
<td>n/a</td>
<td>N = 3 (4%)</td>
</tr>
</tbody>
</table>

CIV: common iliac vein; EIV: external iliac vein; CFV: common femoral vein
24-Months Overall Patency Results

96.1% mean 661 days

N=3 events:
Pat. #86 – 34 days (complete)
Pat. #19 – 59 days
Pat. #45 – 156 days

Case Processing Summary

<table>
<thead>
<tr>
<th>Total N</th>
<th>N of Events</th>
<th>Censored</th>
</tr>
</thead>
<tbody>
<tr>
<td>77</td>
<td>3</td>
<td>74</td>
</tr>
</tbody>
</table>
NIVL vs. PTS Primary Patency After 24-Months

NIVL: 96.8%
PTS: 95.8%
Mean 661 days
Mean VCSS score (±SD)

- Baseline (N=79)
- FU1 (N=77)
- FU2 (N=40)
- FU3 (N=47)
- FU4 (N=44)

Significance levels:
- p<0.001
- p<0.05
Case Review # 1
Case Review # 2

44 years, female, subacute iliofemoral DVT
After mechanical thrombectomy (Aspirex 10F)
and Venovo 14 x 160 mm stent implantation
Questions
Venovo venous stent in the treatment of non-thrombotic or post-thrombotic iliac vein lesions: Results from the Arnsberg venous registry

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