VERNACULAR Clinical Study  (12-Month Data Report)

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Design
The VENOVO® Venous Stent System was evaluated through an Investigational Device Exemption (IDE) study in the prospective, multi-center, non-randomized, single-arm VERNACULAR study for the treatment of symptomatic iliofemoral venous outflow obstruction. Safety and effectiveness measures for subjects receiving the VENOVO® Venous Stent are presented with information derived from clinical literature. The study is currently ongoing at 21 investigational sites in the U.S., Europe and Australia, and includes follow-ups at 30-days, 6-, 12-, 24-, and 36-months. The primary safety endpoint was analyzed at 30-days and the primary effectiveness endpoint was analyzed at 12-months. Predetermined secondary endpoints were also reported at the index procedure and at follow-ups.

Patient Demographics

<table>
<thead>
<tr>
<th>Location</th>
<th>Location</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Iliac Vein:</td>
<td>External Iliac Vein:</td>
<td>Common Femoral Vein:</td>
</tr>
<tr>
<td>PTS: 92.1%</td>
<td>PTS: 58.4%</td>
<td>PTS: 14.6%</td>
</tr>
<tr>
<td>NIVL: 97.3%</td>
<td>NIVL: 18.9%</td>
<td>NIVL: 2.7%</td>
</tr>
<tr>
<td>Total: 94.5%</td>
<td>Total: 40.5%</td>
<td>Total: 9.2%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Location</th>
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<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Lesion Length:</td>
<td>Thrombus Present:</td>
<td>No Blood Flow (Occluded):</td>
</tr>
<tr>
<td>PTS: 80.5 mm</td>
<td>PTS: 14.8%</td>
<td>PTS: 38.6%</td>
</tr>
<tr>
<td>NIVL: 55.2 mm</td>
<td>NIVL: 1.4%</td>
<td>NIVL: 4.1%</td>
</tr>
<tr>
<td>Total: 67.8 mm</td>
<td>Total: 8.6%</td>
<td>Total: 22.8%</td>
</tr>
</tbody>
</table>

Lesion Characteristics

Device Characteristics

<table>
<thead>
<tr>
<th>Location</th>
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<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Stent Length:</td>
<td>Mean Stent Diameter:</td>
<td>Mean Stent Overlap²:</td>
</tr>
<tr>
<td>PTS: 100.1 mm</td>
<td>PTS: 15.4 mm</td>
<td>PTS: 21.4 mm</td>
</tr>
<tr>
<td>NIVL: 83.0 mm</td>
<td>NIVL: 16.6 mm</td>
<td>NIVL: 18.9 mm</td>
</tr>
<tr>
<td>Total: 93.5 mm</td>
<td>Total: 15.9 mm</td>
<td>Total: 21.0 mm</td>
</tr>
</tbody>
</table>

N=170

Average Age: 52
Average Stents Per Patient: 1.3
63% Female (n=107)
Target Lesions Per Patient: 1.09

45% NIVL (n=77) Non-thrombotic iliac vein lesion

55% PTS (n=93) Post-thrombotic syndrome

Mean Stent Length:
PTS: 100.1 mm
NIVL: 83.0 mm
Total: 93.5 mm

Mean Stent Diameter:
PTS: 15.4 mm
NIVL: 16.6 mm
Total: 15.9 mm

Mean Stent Overlap²:
PTS: 21.4 mm
NIVL: 18.9 mm
Total: 21.0 mm
Results

### Primary Safety

Freedom from major adverse events (MAE) through 30-days post-index procedure (p-value=0.0322)

- Primary Safety: \(93.5\%\)
  - PTS: \(88.2\%\)
  - NIVL: \(100.0\%\)

\(^{1}\) \text{163 subjects had images evaluable by the core lab (PTS=89, NIVL=74).}

\(^{2}\) \text{49 subjects had overlapping stents (PTS=41, NIVL=8).}

\(^{3}\) \text{162 subject images were analyzed to provide interpolated values.}

\(^{4}\) \text{Stents were evaluated at the 12-month follow-up for fracture analysis. An anteroposterior and lateral x-ray for each evaluated stent were sent to an independent core lab for analysis. 137 subjects’ x-rays were analyzed and no stent fractures were reported. Missing x-ray analyses were recorded as protocol deviations. VERNACULAR Clinical Study: Data on File. Bard Peripheral Vascular Inc., Tempe, AZ.}

### Primary Effectiveness

Freedom from target vessel revascularization, thrombotic occlusion and stenosis <50\% measured by duplex ultrasound at 12-months (p-value <0.0001)

- Primary Patency: \(88.3\%\)
  - PTS: \(81.3\%\)
  - NIVL: \(96.9\%\)

### Secondary Endpoints

- **100\% Lesion Success**
  - Attainment of ≤50\% residual stenosis at the conclusion of the index procedure

- **100\% Acute Technical Success**
  - Successful deployment of stent(s) to the intended target site with adequate lesion coverage assessed by investigator

- **0 Stent Fractures**
  - At 12-month x-ray analysis

### Patient Outcomes

The VENOVO® Venous Stent demonstrated significant improvement in both VCSS pain scores and quality of life (CIVIQ-20) compared to baseline at 12-months. The CIVIQ-20 assessment demonstrated a change from baseline in the total study population of -15.7 and the VCSS pain assessment demonstrated a change from baseline in the total study population of -1.7.

#### VCSS Pain Score (ITT Subjects)

- **All Patients** (n=170)
- **PTS** (n=93)
- **NIVL** (n=77)

\(^{5}\) \text{SUSTAINED PAIN REDUCTION AT 12 MONTHS}