Viabahn BX Balloon-Expandable Stent Graft (Gore): Indications, 2-Year Results, Advantages and Limitations

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Balloon Expandable Covered Stents

- Superior to non-covered BE-stents for TASC C and D lesions
- **Many advantages for complex iliac disease**
  - Treats aneurysmal/ectatic disease, perforations
  - Affords embolic and perforation protection
  - Inhibits neointimal hyperplasia (good for ISR)
- **Original covered BE stent limitations**
  - Relatively small available size (L,D) matrix
  - Foreshorten with larger inflations
  - Rigid stent and delivery

Viabahn BX Covered Stents

**Potential Advantages**

- MUCH larger size matrix
  - 11mm stent (can go to 16mm); 11 lengths
  - Conformable, flexible
  - Can be inflated larger w/ less foreshortening
  - “Tailorable” diameters throughout stent
  - Also, “8 Large” - 11mm stent on 8 mm balloon
  - Deliverability, less stent/ balloon issues
  - Proprietary GORE PTFE properties
- These benefits could be studied elsewhere

Available VBX Sizes

<table>
<thead>
<tr>
<th>Stent Labeled / Nominal Diameter (mm)</th>
<th>Channeled Stent Lengths (mm)</th>
<th>Introducer Sheath Size (Fr)</th>
<th>Maximum Over-Dilated Stent Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>15, 19, 29, 39, 49, 79</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>6</td>
<td>15, 19, 29, 39, 49, 79</td>
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<td>8</td>
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<td>11</td>
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<td>29, 39, 79</td>
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<td>29, 39, 79</td>
<td>8</td>
<td>16</td>
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</tbody>
</table>
**Viabahn BX Flex IDE Trial**
(9 month results published)

**Objective**
- Evaluates the safety and efficacy of the VBX Stent Graft for the treatment of arteriovenous fistula in patients with (or nom) or venous lesions in the common and/or external iliac arteries.

**Methodology / Design**
- Prospective, multi-center, single-arm clinical study.
- 134 patients meeting all eligibility criteria enrolled across 27 sites.
- Primary endpoint composite of MAEs at 9 months, patient follow-up through three years.

**Eligible patients included**
- Patients with arteriovenous fistula.
- Patients with venous lesions in the common and/or external iliac arteries.

**Procedural results**
- 100% technical success (device successfully delivered and ≤ 30% residual stenosis).
- 234 devices implanted in 213 lesions.
- 97% acute procedural success (four subjects with procedural-related SAEs that successfully resolved).

**VBX FLEX Study procedural results and primary endpoint**

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**VBX FLEX: 9-month and 12-month RESULTS**

**Measure (Per-patient)**
- Follow-up: 132
- Improvement of ≥ 1 Rutherford category vs. baseline: 94.6% vs. 74.7%.
- ABI improvement vs baseline (mean): 0.20 vs. 0.19.
- Device-related serious adverse event: 0 vs. 1.
- Unanticipated adverse device effect: 0 vs. 0.

* - Due to censoring with loss to follow-up and death.
** - Bilateral femoral access with wire extravasation.

**Secondary Endpoint and Subgroup Analysis**

<table>
<thead>
<tr>
<th>Measure</th>
<th>9-month Kaplan-Meier</th>
<th>12-month Kaplan-Meier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Patency</td>
<td>96.7%</td>
<td>96.5%</td>
</tr>
<tr>
<td>RASC (90%)</td>
<td>95.5%</td>
<td>95.5%</td>
</tr>
<tr>
<td>Requiring procedure</td>
<td>95.5%</td>
<td>94.2%</td>
</tr>
<tr>
<td>EA</td>
<td>97.4%</td>
<td>92.9%</td>
</tr>
<tr>
<td>TEI</td>
<td>92.7%</td>
<td>95.6%</td>
</tr>
<tr>
<td>TENTER</td>
<td>96.8%</td>
<td>97.0%</td>
</tr>
</tbody>
</table>

* - Implant Patency
## VBX FLEX Study Estimates of secondary endpoints

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Primary endpoint</th>
<th>Follow-up endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR</td>
<td>Overall (n = 24)</td>
<td>97.9% (n = 24)</td>
</tr>
<tr>
<td></td>
<td>SVD 0 to 2 vs. 3</td>
<td>97.9% (n = 24)</td>
</tr>
<tr>
<td></td>
<td>Overall (n = 24)</td>
<td>97.9% (n = 24)</td>
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</table>

### fTLR: 24-month results from VBX FLEX Study

#### Change in Rutherford category

- Improved: 50.0% (n = 24)
- Maintained: 33.3% (n = 24)
- Worsened: 16.7% (n = 24)

### Resting ABI

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Pre-procedure</th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
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</thead>
<tbody>
<tr>
<td>Angios for dLCIA PTA</td>
<td>0.75</td>
<td>0.85</td>
<td>0.92</td>
<td>0.93</td>
</tr>
<tr>
<td>Resting ABI</td>
<td>0.75</td>
<td>0.85</td>
<td>0.92</td>
<td>0.93</td>
</tr>
</tbody>
</table>

### WIQ, ABI, and Rutherford: Results from VBX FLEX Study through 24-months

#### “Flush” Ostial CA++ LCIA CTO

### Angios for dLCIA PTA

### NC PTA ostial and mid LCIA
Panel: 50 yo old with 20 year AO CTO?

"CERAB Technique"

Vascular Surgery consult, 3 Consults with me...

PTA with 5X80 balloons

Viabahn BX 8X59 LARGE
Conclusions

- Viabahn BX is a unique balloon-expandable covered stent with significant potential advantages
- The Viabahn BX IDE Trial showed sustained clinical and patency benefits with a favorable safety profile at 9 months (primary endpoint)
- 24 month follow up of Viabahn BX demonstrated excellent freedom from TLR, maintained ABI’s, and sustained clinical objective measures of clinical improvement

Thank You Very Much for Your Attention!