Twelve-month outcomes from the Japanese post-market surveillance study of the GORE® VIABAHN® Endoprosthesis as treatment for symptomatic peripheral arterial disease in the superficial femoral arteries

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Disclosure

Speaker name: Osamu Iida, MD

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

☐ I do not have any potential conflict of interest
Background: Initial Japan Experience

12-month patencies:
GORE® VIABAHN® Endoprosthesis Gore Japan IDE Clinical Study

- Primary patency: 88%
- Secondary patency: 98%
- fTLR: 93%

Patency / fTLR (%)

Months post-treatment (months)

- Primary patency
- Secondary patency
- Freedom from TLR

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Study Objectives

Purpose

• To confirm device efficacy and safety in the clinical setting after the launch of the GORE® VIABAHN® Endoprosthesis for the treatment of symptomatic peripheral arterial disease in the superficial femoral arteries (SFA)
Study Device

Ultra-thin wall ePTFE tube
Covers and excludes disease

Single wire nitinol frame
Flexibility; tractability; fracture resistance

Radiopaque markers
Enhances visibility

Contoured proximal edge
Reduces in-folding

CBAS Heparin Surface
Lasting thromboresistance*

Lengths: 2.5 / 5 / 10 / 15 / 25 cm
Diameters: 5–8 mm
Guidewires: .014" / .018" (5–8 mm)

Methods

• Enrollment Period: August 2016 – July 2017
• Pre-specified follow-up: 1 month; 1, 2, 3, 4, 5 years
• Expected Target Patients: SFA lesions ≥10cm in length with reference vessel diameters ranging from 4.0 to 7.5mm
• Effectiveness endpoints:
  ✓ Primary, Primary-assisted and Secondary Patencies
  ✓ Limb salvage: Absence of major amputation (assessed at 12 months) were limb salvage
  ✓ Freedom from target lesion revascularization
  ✓ Clinical improvement: change in ABI relative to baseline assessment
• Device safety: occurrence of device- or procedure-related serious adverse events (SAEs) through the end of the 12 month visit window (395 days) and occurrence of stent fracture at 12-month assessment.
### Patient Population and Limb Characteristics

#### Patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N = 321</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (N=318)</td>
<td>73.9 ± 8.7</td>
</tr>
<tr>
<td>Male (N=321)</td>
<td>248 (77.3)</td>
</tr>
<tr>
<td>Hypertension (N=321)</td>
<td>271 (84.4)</td>
</tr>
<tr>
<td>Diabetes (N=321)</td>
<td>176 (54.8)</td>
</tr>
<tr>
<td>Coronary artery disease (N=321)</td>
<td>138 (43.0)</td>
</tr>
<tr>
<td>Congestive heart failure (N=321)</td>
<td>26 (8.1)</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease (N=321)</td>
<td>25 (7.8)</td>
</tr>
<tr>
<td>Renal failure requiring dialysis (N=321)</td>
<td>74 (23.1)</td>
</tr>
<tr>
<td>Smoking history (N=306)</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>79 (25.8)</td>
</tr>
<tr>
<td>Former smoker</td>
<td>153 (50.0)</td>
</tr>
<tr>
<td>Chronic limb-threatening ischemia</td>
<td>85 (26.5)</td>
</tr>
<tr>
<td>Mean ABPI</td>
<td>0.60 ± 0.16</td>
</tr>
</tbody>
</table>

#### Limb characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N = 324</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior PAD treatment (N=324)</td>
<td>72 (22.2)</td>
</tr>
<tr>
<td>TASC C/D (N=320)</td>
<td>277 (86.6)</td>
</tr>
<tr>
<td>ABI (N=292)</td>
<td>0.60 ± 0.16</td>
</tr>
<tr>
<td>Lesion length, cm (N=324)</td>
<td>23.6 ± 6.6</td>
</tr>
<tr>
<td>Maximum percent stenosis (N=324)</td>
<td>97.2 ± 6.3</td>
</tr>
<tr>
<td>Total occlusion (N=324)</td>
<td>228 (70.4)</td>
</tr>
<tr>
<td>Moderate/severe lesion calcification (N=324)</td>
<td>129 (39.8)</td>
</tr>
<tr>
<td>Reference vessel diameter (proximal to lesion) (N=317)</td>
<td>5.9 ±1.0</td>
</tr>
<tr>
<td>Reference vessel diameter (distal to lesion) (N=317)</td>
<td>5.2±0.8</td>
</tr>
<tr>
<td>Patent tibial runoff vessels (N=324)</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>9 (2.8)</td>
</tr>
<tr>
<td>1</td>
<td>83 (25.6)</td>
</tr>
<tr>
<td>2</td>
<td>113 (34.9)</td>
</tr>
<tr>
<td>3</td>
<td>119 (36.7)</td>
</tr>
</tbody>
</table>
### Procedural Characteristics

<table>
<thead>
<tr>
<th>Procedural Characteristic</th>
<th>N=324</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target lesions fully covered by VIABAHN</td>
<td>314 (96.9)</td>
</tr>
<tr>
<td>Number of devices</td>
<td>562</td>
</tr>
<tr>
<td>Device diameter, mm</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>190 (33.8)</td>
</tr>
<tr>
<td>6</td>
<td>289 (51.4)</td>
</tr>
<tr>
<td>7</td>
<td>74 (13.2)</td>
</tr>
<tr>
<td>8</td>
<td>9 (1.6)</td>
</tr>
<tr>
<td>Device length, cm</td>
<td></td>
</tr>
<tr>
<td>2.5</td>
<td>4 (0.7)</td>
</tr>
<tr>
<td>5</td>
<td>47 (8.4)</td>
</tr>
<tr>
<td>10</td>
<td>107 (19.0)</td>
</tr>
<tr>
<td>15</td>
<td>204 (36.3)</td>
</tr>
<tr>
<td>25</td>
<td>200 (35.6)</td>
</tr>
</tbody>
</table>
## Safety Outcomes

### Serious Adverse Events (SAE)

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Number of SAEs</th>
<th>Patients Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudoaneurysm (1 popliteal, 1 femoral, 1 unspecified)</td>
<td>3 pts (0.9)</td>
<td>[3]</td>
</tr>
<tr>
<td>Access site hemorrhage</td>
<td>1 pt (0.3)</td>
<td>[1]</td>
</tr>
<tr>
<td>Arterial injury</td>
<td>1 pt (0.3)</td>
<td>[1]</td>
</tr>
<tr>
<td>Peripheral embolism</td>
<td>1 pt (0.3)</td>
<td>[1]</td>
</tr>
<tr>
<td>Popliteal artery occlusion</td>
<td>1 pt (0.3)</td>
<td>[1]</td>
</tr>
<tr>
<td>Femoral artery occlusion</td>
<td>1 pt (0.3)</td>
<td>[1]</td>
</tr>
<tr>
<td>Inflammatory reaction</td>
<td>1 pt (0.3)</td>
<td>[1]</td>
</tr>
<tr>
<td>Plaque shift</td>
<td>1 pt (0.3)</td>
<td>[1]</td>
</tr>
<tr>
<td>Device occlusion</td>
<td>13 pts (4.0)</td>
<td>[16]</td>
</tr>
<tr>
<td>Vascular stent-graft restenosis</td>
<td>8 pts (2.5)</td>
<td>[10]</td>
</tr>
<tr>
<td>Superficial femoral arterial restenosis</td>
<td>2 pts (0.6)</td>
<td>[2]</td>
</tr>
<tr>
<td>In-stent arterial stenosis</td>
<td>1 pt (0.3)</td>
<td>[1]</td>
</tr>
<tr>
<td>Intermittent claudication</td>
<td>1 pt (0.3)</td>
<td>[1]</td>
</tr>
</tbody>
</table>

Number of patients with SAE (Patients rate of enrolled patient number* 321) [total number of SAEs]

Event names were classified with MedDRA/J
Effectiveness Outcomes

![Graph showing patency rates over time for different stages of patency.]

<table>
<thead>
<tr>
<th>No. as risk, % (C.I.)</th>
<th>Days (0-37)</th>
<th>Days (37-121)</th>
<th>Days 121-212</th>
<th>Days (212-365)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Secondary Patency</strong></td>
<td>304, 99.6% (97.5-99.9%)</td>
<td>274, 98.5% (96.2-99.4%)</td>
<td>265, 96.7% (93.7-98.3%)</td>
<td>259, 94% (90.9-96.6%)</td>
</tr>
<tr>
<td><strong>Primary Assisted Patency</strong></td>
<td>304, 99.3% (97.3-99.8%)</td>
<td>272, 97.8% (95.2-99.0%)</td>
<td>262, 95.6% (92.4-94.5%)</td>
<td>255, 91.7% (87.7-94.5%)</td>
</tr>
<tr>
<td><strong>Primary Patency</strong></td>
<td>304, 99.3% (97.3-99.8%)</td>
<td>273, 97.1% (94.3-98.5%)</td>
<td>261, 94.1% (90.6-96.4%)</td>
<td>252, 85.2% (80.3-89.0%)</td>
</tr>
</tbody>
</table>
Freedom from Target Lesion Revascularization

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>No. as risk, %, (C.I.)</th>
<th>Days (0-30)</th>
<th>Days (30-90)</th>
<th>Days (90-180)</th>
<th>Days (180-365)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>324, 99.7% (97.8-100%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>313, 99.4% (97.5-99.8%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>302, 97.4% (94.8-98.7%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td>295, 92.3% (88.6-94.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td>295, 92.3% (88.6-94.8%)</td>
<td></td>
</tr>
</tbody>
</table>
Subgroup primary patency analyses stratified by number of run-off vessels

Stratified by number of patent runoff vessels post procedure

Log-rank P value = 0.073

<table>
<thead>
<tr>
<th>No. as risk, % (C.I.)</th>
<th>Days (0-37)</th>
<th>Days (37-121)</th>
<th>Days (121-212)</th>
<th>Days (212-365)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Vessel</td>
<td>6, 100% (100-100%)</td>
<td>5, 100% (100-100%)</td>
<td>5, 100% (100-100%)</td>
<td>5, 80.0% (20.4-96.9%)</td>
</tr>
<tr>
<td>1 Vessel</td>
<td>77, 100% (100-100%)</td>
<td>67, 93.8% (84.2-97.6%)</td>
<td>60, 89.1% (78.4-94.6%)</td>
<td>56, 89.1% (78.4-94.6%)</td>
</tr>
<tr>
<td>2 Vessels</td>
<td>108, 99.1% (93.6-99.9%)</td>
<td>97, 99.1% (93.6-99.9%)</td>
<td>96, 96.0% (89.6-98.5%)</td>
<td>93, 91.7% (84.1-95.8%)</td>
</tr>
<tr>
<td>3 Vessels</td>
<td>113, 99.1% (93.5-99.1%)</td>
<td>103, 97.1% (91.3-99.1%)</td>
<td>99, 95.2% (88.7-98.0%)</td>
<td>97, 76.9% (67.3-84.0%)</td>
</tr>
</tbody>
</table>

* 0 vessel run off days 322-365 is 18% Standard Error (SE). All others have SE <10%.
Effectiveness in Real-World Patient Populations

### A. Hemodialysis vs Non-Hemodialysis

<table>
<thead>
<tr>
<th>Disease</th>
<th>Days (0-37)</th>
<th>Days (37-121)</th>
<th>Days (121-365)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>264 (94.1%)</td>
<td>261 (96.7%)</td>
<td>260 (93.6%)</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>70 (100%)</td>
<td>61 (95.3%)</td>
<td>57 (94.0%)</td>
</tr>
</tbody>
</table>

Log-rank P value = 0.514

### B. CLI (Rutherford 4-6) vs IC (Rutherford 1-3)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Days (0-37)</th>
<th>Days (37-121)</th>
<th>Days (121-365)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLI</td>
<td>76 (100%)</td>
<td>61 (98.7%)</td>
<td>57 (96.0%)</td>
</tr>
<tr>
<td>IC</td>
<td>208 (99.1%)</td>
<td>211 (99.7%)</td>
<td>209 (99.1%)</td>
</tr>
</tbody>
</table>

Log-rank P value = 0.906

### C. Moderate-Severe Calcification vs None/Mild

<table>
<thead>
<tr>
<th>Disease</th>
<th>Days (0-37)</th>
<th>Days (37-121)</th>
<th>Days (121-365)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>165 (100%)</td>
<td>167 (100%)</td>
<td>164 (100%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>115 (98.2%)</td>
<td>97 (97.1%)</td>
<td>93 (95.2%)</td>
</tr>
</tbody>
</table>

Log-rank P value = 0.767

### D. Lesion Length

<table>
<thead>
<tr>
<th>Length</th>
<th>Days (0-37)</th>
<th>Days (37-121)</th>
<th>Days (121-365)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 20cm</td>
<td>74 (98.8%)</td>
<td>66 (97.1%)</td>
<td>62 (92.4%)</td>
</tr>
<tr>
<td>≥ 20cm</td>
<td>230 (99.5%)</td>
<td>206 (97.1%)</td>
<td>198 (94.6%)</td>
</tr>
</tbody>
</table>

Log-rank P value = 0.815
Viabahn implantation for SFA-CTO and BTK angioplasty

Initial

Final

Viabahn 5.0*250mm, 6.0*100mm

Plain angioplasty 3mm*300mm
Follow-up angiography

1-year F/U angiography
- SFA: Viabahn patent
- BTK: BTK restenosis

2-year F/U angiography
- SFA: Viabahn patent
- BTK: BTK occlusion
Conclusions

In a real-world Japanese patient population characterized by long SFA lesions and complex PAD:

• The VIABAHN® Device was associated with excellent patency rates through 12 months with an acceptable safety profile

• Patency outcomes were consistent across varying lesion lengths and patient baseline characteristics

• Outcomes with the VIABAHN® Device appear similar in the real-world to those seen in the original investigational study, which is a unique observation vs. other treatment modalities
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