Horizon™ EVAR

‘Endo-anastomosis’
## Horizon™ AAA Modules

<table>
<thead>
<tr>
<th>Module</th>
<th>Description</th>
<th>Dimensions [mm]</th>
<th>Delivery system crossing profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>iliac to iliac module limb length</td>
<td>Ø 12-18, L 30-40</td>
<td>14F</td>
</tr>
<tr>
<td>II</td>
<td>Primary aortic limb</td>
<td>Ø 24, L 79-90</td>
<td>14F</td>
</tr>
<tr>
<td>III</td>
<td>Aortic extension limb featuring supra-renal bare stent with barbs</td>
<td>Ø 22-31, L 87-109</td>
<td>14F</td>
</tr>
<tr>
<td>Ext.</td>
<td>21mm iliac cuff extension limb</td>
<td>Ø 21, L 40</td>
<td>14F</td>
</tr>
</tbody>
</table>
Step by step deployment

- Accurate placement and orientation of iliac module prior to and during unsheathing
- Accurate alignment of “hourglass” into gateway – step-wise deployment
- Balloon dilatation – ensures complete expansion and orientation
- 3-4 stent overlap of modules 2 and 3
“Endo-anastomosis”

- Un-sheath to hour-glass
- Accurate alignment
- Resistance on “pull-down”
- Release hour-glass
- Balloon dilatation to complete deployment / alignment?
# Horizon™ Features

<table>
<thead>
<tr>
<th>Current devices</th>
<th>Horizon™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical cut down/groin complications</td>
<td>True 14F catheter</td>
</tr>
<tr>
<td>Failed iliac passage</td>
<td></td>
</tr>
<tr>
<td>Two sided access required</td>
<td>Single sided access possible</td>
</tr>
<tr>
<td></td>
<td>Bilateral access – increases</td>
</tr>
<tr>
<td></td>
<td>deployment options</td>
</tr>
<tr>
<td>Anchoring at proximal neck only</td>
<td>Anchored at the proximal neck</td>
</tr>
<tr>
<td>Neck dilatation/migration</td>
<td>Stabilized at the aortic bifurcation</td>
</tr>
<tr>
<td></td>
<td>Long body</td>
</tr>
<tr>
<td>Cannulation of the contralateral limb</td>
<td>No cannulation required</td>
</tr>
<tr>
<td>Iliac seal options may be limited</td>
<td>Accurate iliac seal options</td>
</tr>
<tr>
<td></td>
<td>CIA aneurysm option</td>
</tr>
</tbody>
</table>
“Zenith” Composite Endovascular Graft

Improving Endograft Stability by Accommodation onto the Aortic Bifurcation

Perdikides, TP; Avgerinos, ED; Lagios, K; Ziegler, P; Stelter, W

J.E.V.T. Oct 2007

---------------------------------------------------------------

Composite implantations N= 456 – complex anatomy
Av. Follow up – 39 months
Primary Type 1 endo-leak - 4.6%.
Secondary Type 1 endo-leak - 0.22%
Migration rate 1.75%
FIM Clinical Evidence

- Prospective, open-label, non-randomized, single-arm FIM study
- 10 AAA patients
- 2 years follow up (still being generated & collected)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Rate of success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful implantation</td>
<td>9/10*</td>
</tr>
<tr>
<td>Mortality</td>
<td>0/10</td>
</tr>
<tr>
<td>MAEs</td>
<td>0/10</td>
</tr>
<tr>
<td>Endoleak (type I,III)</td>
<td>0/10</td>
</tr>
<tr>
<td>Rupture</td>
<td>0/10</td>
</tr>
<tr>
<td>Migration</td>
<td>0/10</td>
</tr>
<tr>
<td>Sac growth</td>
<td>0/8**</td>
</tr>
<tr>
<td>Max aneurysm diameter decreased</td>
<td>8/8**</td>
</tr>
</tbody>
</table>

**5 to 12 months follow-up

*Conversion- premature iliac wire displacement-rotation of iliac limb
Horizon™ /EVAR options

Device limitations

• Iliac tortuosity/ angulation, narrow bifurcation - single groin access

Device versatility

• Bilateral groin access- contralateral wire / catheter / device
  
  **6F.** orientation/aortic access/ aorto-iliac stability /imaging
  
  **14F.** deployment options modules 2 & 3
**Horizon™ clinical indications**

- **Neck anatomy – risk of migration**
  - short, conical, angled necks

- **Compromised external iliac conduit with patent common/internal iliac**
  - avoids fem/fem bypass

- **Compromised contralateral groin**
  - disease/stent/ bypass

- **Ruptured aneurysm**
  - no contralateral limb cannulation
  - bifurcate repair without fem/fem.
Iliac Extension Options

• Iliac limb extensions with more *conforming* wires
  – Accurate iliac bifurcation seal
  – Accurate external iliac seal
  – Antegrade or retrograde delivery

• Iliac bifurcation extension for CIAA
Final procedure after aortic deployment, balloon dilatation etc completed

Wire + device to internal iliac artery

?pre-loaded wire to external iliac

Covered stent seals in external iliac artery
Accreditation Programme

CE Marking – Pivotal Study

• Europe – Eindhoven and Modena
  - approved and functioning
• Israel – One site approved, awaiting MOH
• Europe – Five sites in process of approval
• Israel – One site in process of approval
Conclusions

• Low profile EVAR device

• Single or bilateral groin access

• Resistance to migration

• “Niche” and wider clinical indications

• Concepts and technology applicable to other areas
Potential Clinical Indications

Short "Asian" common iliac artery / aneurysm

CT / angios  ethnic Chinese - EVAR
N= 65   Mean age = 74

• Mean RCA length  = 29.9mm
• Mean LCA length  = 34.2mm
• Average RCA diameter = 20.2mm
• Average LCA diameter  = 17.9mm
  Stephen Cheng et al  JEVT Dec 2004

? Role for Iliac +/- iliac bifurcation extensions