**Aorfix™ Clinical Results**

**European Multi-Centre Arbiter II study\(^1\) results**
- All AAAs had high-angled infra-renal necks (range 70°– 90°) and placement was well tolerated.
- Low occurrence of device deployment events.
- Incidence of endoleaks at 30 days was superior to that of the comparator historical data set.
- 30-day and 6-month follow ups show no reports of device rupture, migration, stent fracture, loss of patency, vessel perforation, significant obstruction or conversion to open repair.
- All patients at six months follow up had stable or shrinking aneurysm sacs.

**RADAR Registry Results**
- The Retrospective Aorfix™ Data Retrieval (‘RADAR’) voluntary international registry includes data from 931 cases with a follow up range up to 7 yrs (as of March 2010).
- A wide spectrum of patients have been successfully treated including significant numbers having AAAs with severely angled necks and/or tortuous iliacs.
- Despite the challenging nature of many cases, an overall Type Ia endoleak rate of 1.4% has been seen.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Neck angle &lt; 60°</th>
<th>Neck angle ≥ 60°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible cases for 1 year follow up</td>
<td>233</td>
<td>143</td>
</tr>
<tr>
<td>Mean Aneurysm Neck Angle (range 0°-123°)</td>
<td>31°</td>
<td>79°</td>
</tr>
<tr>
<td>Stent migration (&gt; 30 days up to 12 months)</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Wire fracture (&gt; 30 days up to 12 months)</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

The only device labelled* for the highest angulations

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*Registered in England and Wales Reg No. 2588628
*\(^1\) Data on file Lombard Medical Technologies PLC. April 2009
*CE Marked, please refer to current Aorfix™ IFU.
The Anatomy of Technology

Aorfix™ gives you technology that conforms to patient anatomy, optimising both procedure and post-operative performance.

- Fishmouth for optimum neck positioning. Excellent seal from 4 closely aligned nitinol wires maximising radial force.
- Electro-polished nitinol rings adapt to highly angulated necks.
- 8 hooks provide secure fixation.
- Radiopaque markers to assist positioning.
- Nitinol helical constructed legs conform to complex iliac anatomy.
- Radiopaque markers

Durable, Flexible & Adaptable

Aorfix™ gives you the opportunity for single-intervention success by adapting to anatomy during and after the implantation.

- Electro-polished nitinol wire construction gives excellent durability while following the body’s movements.
- Fabric quality gives improved contouring to landing zones.
- Flexible construction maintains patency and resists migration as the aneurysm volume reduces.

“*The device’s flexible design allows safe and accurate aneurysm sac exclusion in patients with highly challenging anatomy.*”


“Aorfix™ is likely to increase the number of patients considered suitable for EVAR who were previously excluded from this type of treatment and also reduce the risk of endoleaks.”

Horrocks, M. Retrospective Aorfix™ Data Retrieval Registry (RADAR) Presentation. Charing Cross Symposium 2009
Precise Positioning

Aorfix™ enhances the clinician’s skills, ensuring it can be positioned optimally for long-term effectiveness.

Radiopaque markers on the graft body and legs allow precise positioning.

The ultra flexible delivery system with its flexible tip allows controlled step-by-step graft deployment in angles up to 90°.

Effective Sealing

Effective sealing as neck angulation increases compared to Z-stent graft design.

"The Aorfix™ stent graft has the potential to decrease the incidence of proximal Type I endoleak in patients with a severely angulated aortic neck."


Aorfix™ stent graft for abdominal aortic aneurysms reduces the risk of proximal Type I endoleak in angulated necks: bench-test study. Vascular, 13, 6, 321-326.

Analysis of Stent Graft Failure Pull Out Forces

Interlocking helical design gives secure iliac limb engagement, as the device changes with anatomy over time resisting dislocation risk for Type III endoleak.


Copyright permission provided from ISES Inc.; J Endovasc Ther, 2006, 13:77-84.
Aorfix™ Step-by-Step Sizing Guide

Use the following steps to assess the most appropriate size of Aorfix™ device for a given CT scan:

Please refer to the Aorfix™ stock list when selecting graft sizes for immediate use. The following steps to assess the most appropriate size of Aorfix™ device:

1. **Access Vessel Size and Quality**: Assess the diameter and quality of the access vessels in relation to the Aorfix™ delivery system sizes; 22Fr outer diameter for the main body, 20Fr outer diameter for the contralateral leg and distal extensions.

2. **Ipsilateral Side**: Determine which side of the patient will be used as the ipsilateral side. Consider factors such as the direction and degree of proximal neck angulation, iliac vessel tortuosity and access vessel dimensions.

3. **Proximal Neck Length**: Measure the length from the inferior margin of the distal renal artery to immediately superior to the start of aneurysmal dilation to determine the length of proximal neck.

4. **Proximal Diameter (D1)**: Measure the aortic diameter at several levels in the proximal neck. Measure diameters from internal wall to internal wall. Determine the largest diameter in the proximal neck. Oversize this diameter to determine the D1 graft diameter. Refer to the IFU for recommended oversized parameters.

5. **SMA to Distal Renal Distance**: Measure the length between the inferior margin of the SMA and the inferior margin of the distal renal artery.

6. **Graft Main Body Length (L1)**: Measure the length from inferior margin of the distal renal artery to the aortic bifurcation. The distal opening of the cannulation socket will usually lie between 10 and 30 mm above the aortic bifurcation. Choose an appropriate L1 length from the lengths available.

7. **Diameter at the Cannulation Socket**: Measure the diameter at the level of the cannulation socket.

8. **Aortic Bifurcation Diameter**: Measure the diameter at the level of the aortic bifurcation.

9. **Ipsilateral Leg Length (L2)**: Measure the length from the level of the cannulation socket to the ipsilateral common iliac artery bifurcation. Choose an appropriate L2 length. The graft limb length should normally result in the distal fishmouth lying proximal to the internal iliac artery origin.

10. **Ipsilateral Leg Diameter (D2)**: Measure the diameter of the selected landing zone at several levels. Oversize appropriately to determine the graft diameter D2.

11. **Contralateral Leg Length (L3)**: Measure the distance from the level of the cannulation socket to the level of the contralateral common iliac artery bifurcation. Choose an appropriate L3 length.

12. **Contralateral Leg Diameter (D3)**: Measure the diameter of the common iliac artery at several levels in the region of the projected landing zone. Oversize appropriately to determine the graft diameter D3.

**Aorfix™ Stock Sizes**

<table>
<thead>
<tr>
<th>Proximal Diameter (D1)</th>
<th>Body Length (L1)</th>
<th>Ipsilateral Leg Diameter (D2)</th>
<th>Distal Diameter (D3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>'81</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

**DISCLAIMER**: It is the responsibility of the doctor to assess the suitability of Aorfix™ for their patient by referring to the Instructions for Use (IFU). The information included in this brochure is intended for the physician and is not intended to replace the IFU. Clinicians should understand the principles related to endovascular grafts and be trained in endovascular techniques prior to commencing any kind of procedure.