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

**The Anatomy of Technology**

- **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 and 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.”


High-Angled Neck

Tortuous Iliacs

Source: Mr A. D. McLain, Consultant Vascular Surgery, Royal Gwent Hospital, UK.

Source: Mr D. Morrow, Consultant Vascular Surgery, Norfolk & Norwich Hospital, UK.

“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.

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™ stays where you place it

8 coplanar hooks are designed to maximise fixation security and resist graft migration.

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

Box plot comparing maximum (median, interquartile range) pull out forces of stent grafts.

<table>
<thead>
<tr>
<th>Pull Out Force (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competitor 1</td>
</tr>
<tr>
<td>Competitor 2</td>
</tr>
<tr>
<td>Competitor 3</td>
</tr>
<tr>
<td>Aorfix™ GEN I</td>
</tr>
</tbody>
</table>

23.7N

Aorfix™ GEN I

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.

# Aorfix™ Sizing Guide

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Measurement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Access Vessel Size and Quality</td>
<td>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.</td>
</tr>
<tr>
<td>2</td>
<td>Ipsilateral Side</td>
<td>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.</td>
</tr>
<tr>
<td>3</td>
<td>Proximal Neck Length</td>
<td>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.</td>
</tr>
<tr>
<td>4</td>
<td>Proximal Diameter (D1)</td>
<td>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 oversizing parameters.</td>
</tr>
<tr>
<td>5</td>
<td>SMA to Distal Renal Distance</td>
<td>Measure the length between the inferior margin of the SMA and the inferior margin of the distal renal artery.</td>
</tr>
<tr>
<td>6</td>
<td>Graft Main Body Length (L1)</td>
<td>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 from the lengths available.</td>
</tr>
<tr>
<td>7</td>
<td>Diameter at the Cannulation Socket</td>
<td>Measure the diameter at the level of the cannulation socket.</td>
</tr>
<tr>
<td>8</td>
<td>Aortic Bifurcation Diameter</td>
<td>Measure the diameter at the level of the aortic bifurcation.</td>
</tr>
<tr>
<td>9</td>
<td>Ipsilateral Leg Length (L2)</td>
<td>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.</td>
</tr>
<tr>
<td>10</td>
<td>Ipsilateral leg distal diameter (D2)</td>
<td>Measure the diameter of the selected landing zone at several levels. Oversize appropriately to determine the graft diameter D2.</td>
</tr>
<tr>
<td>11</td>
<td>Contralateral leg length (L3)</td>
<td>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.</td>
</tr>
<tr>
<td>12</td>
<td>Contralateral leg distal diameter (D3)</td>
<td>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.</td>
</tr>
</tbody>
</table>
Aorfix™ Sizing

Measure a range of diameters in the neck. Oversize largest diameter by 10%.

Graft length from decided proximal landing zone to aortic bifurcation minus approx. 10-30 mm.

Position cannulation socket 10-30 mm above level of aortic bifurcation.

Diameter at cannulation socket and aortic bifurcation should be ≥ 24 × 12 mm.

Cannulation socket to distal landing zone position (see note on step-by-step guide).

SMA to distal origin of renal artery with 10% oversizing fishmouth is 7-12 mm deep. Take care if SMA is ≤ 10 mm from int. renal artery.

D1

L1

L2

D2

L3

D3

Diameter at distal landing zone. Oversize by 10%.

Cannulation socket to distal landing zone position (see note on step-by-step guide).

DISCLAIMER It is the responsibility of the clinician to assess the suitability of Aorfix™ for their patient by referring to the Instructions for Use (IFU). The information included in this brochure should not be used as an EVAR training tool and does not replace clinical expertise. Clinicians should understand the principles related to endovascular stent grafts and be trained in EVAR techniques prior to commencing any EVAR procedure.
Aorfix™ Clinical Results

European Multi-Centre Arbiter II study† 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 1236 cases with a follow up range up to 8 yrs (as of March 2011).
› A wide spectrum of patients have been successfully treated including significant numbers having AAAs with severely angled necks and/or tortuous iliacs.

<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>294</td>
<td>215</td>
</tr>
<tr>
<td>Endoleaks Type 1</td>
<td>0.0%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Stent migration (&gt; 30 days up to 12 months)</td>
<td>0.0%</td>
<td>1.9%</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>

Customer Value Added Support
› International training workshops.
› Case planning:
  › 3D TeraRecon imaging software technology for learning curve case sizing reports.
  › Field sizing support via specialists and sizing guide.
  › Clinical and technical proctors case attendance.
› ‘Pick from stock’ wide range of graft sizes.
› ‘Special’ (SP) non-stock graft sizes built by request.

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*CE Marked, please refer to current Aorfix™ IFU. †Data on file Lombard Medical Limited, April 2009.
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