

# EVERY ANGLE COVERED

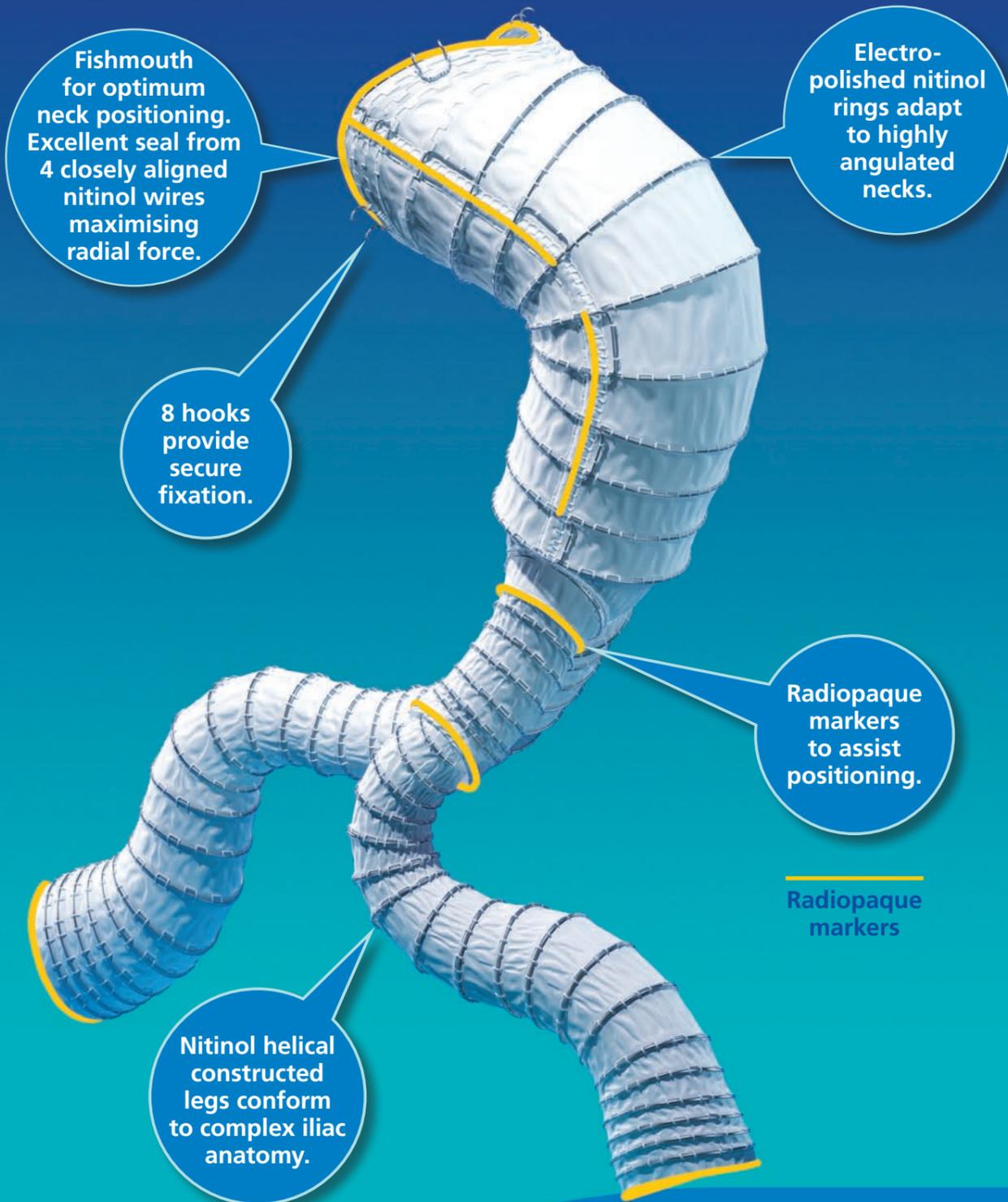
THE  
**ONLY**  
DEVICE LABELLED™  
FOR THE HIGHEST  
ANGULATIONS



**aorfix**™  
Endovascular Stent Graft

# The Anatomy of Technology

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



# Durable, Flexible & Adaptable

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



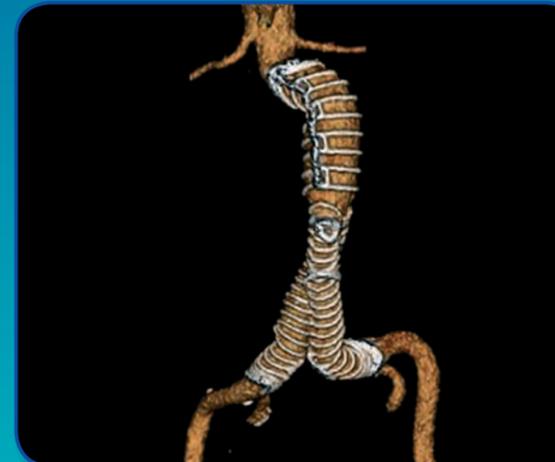
Electro-polished nitinol wire construction gives excellent durability while following the body's movements.

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."*

Balasubramaniam, K., Hardman, J., Horrocks, M., Bulbulia, R. 2009. The advantages of Aorfix™ for endovascular repair of abdominal aortic aneurysm. *Journal of Cardiovascular Surgery*, 50, 2, 139-143.



High-Angled Neck

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



Tortuous Iliacs

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

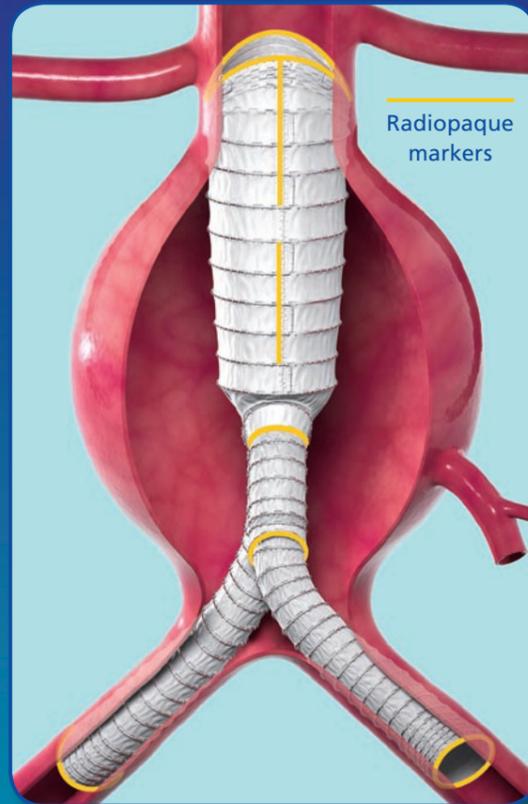
# Precise Positioning

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.

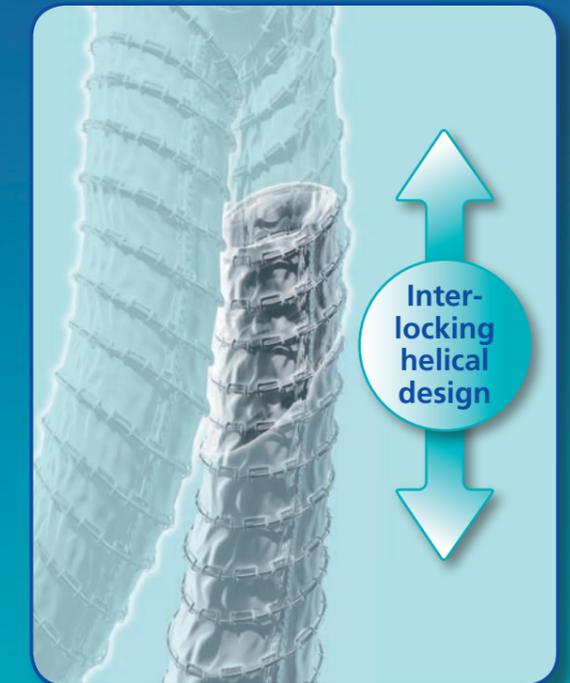
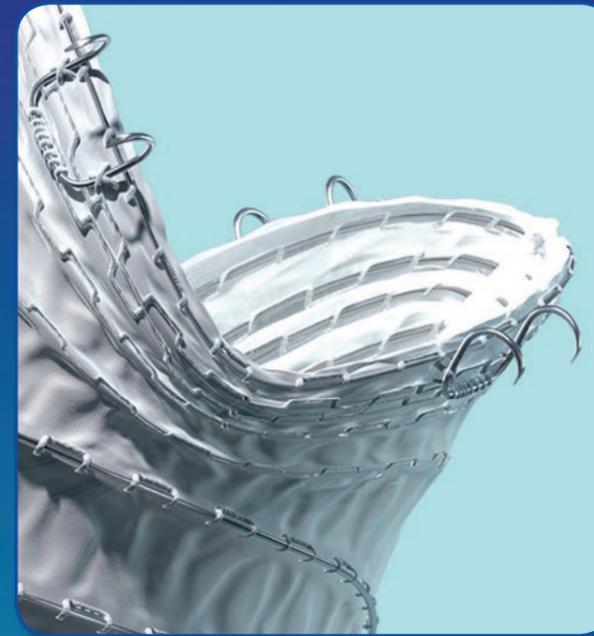


The ultra flexible delivery system with its flexible tip allows controlled step-by-step graft deployment in angles up to 90°.



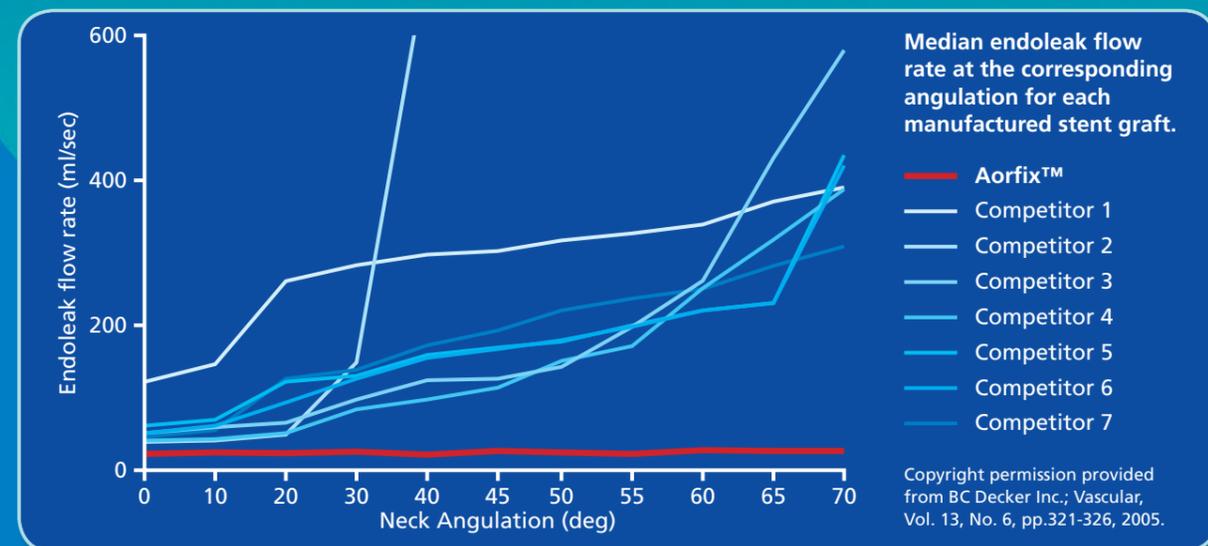
# Aorfix™ Stays Where You Place It

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

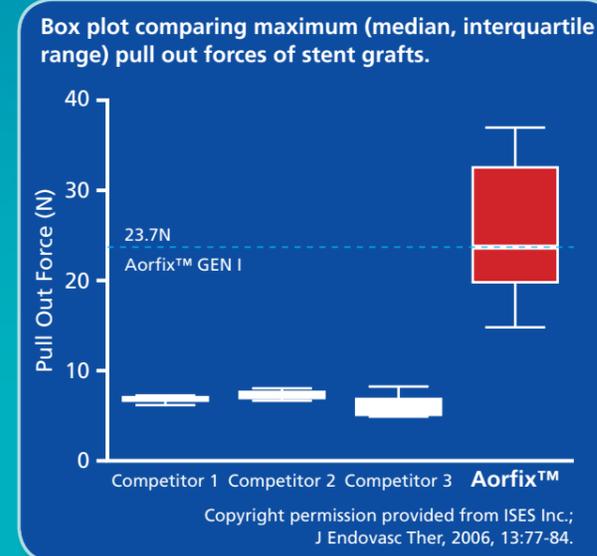


# Effective Sealing

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



# 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.

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

Albertini, J. N., DeMasi, M. A., Macierewicz, J., El Idrissi, R., Hopkinson, B. R., Clément, C., Branchereau, A. 2005. 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.

Hinchliffe, R. J., Natarajan, S., Hopkinson, B. R. 2006. In vitro analysis of modular aortic stent graft failure. Journal of Endovascular Therapy, 13, 77-84.

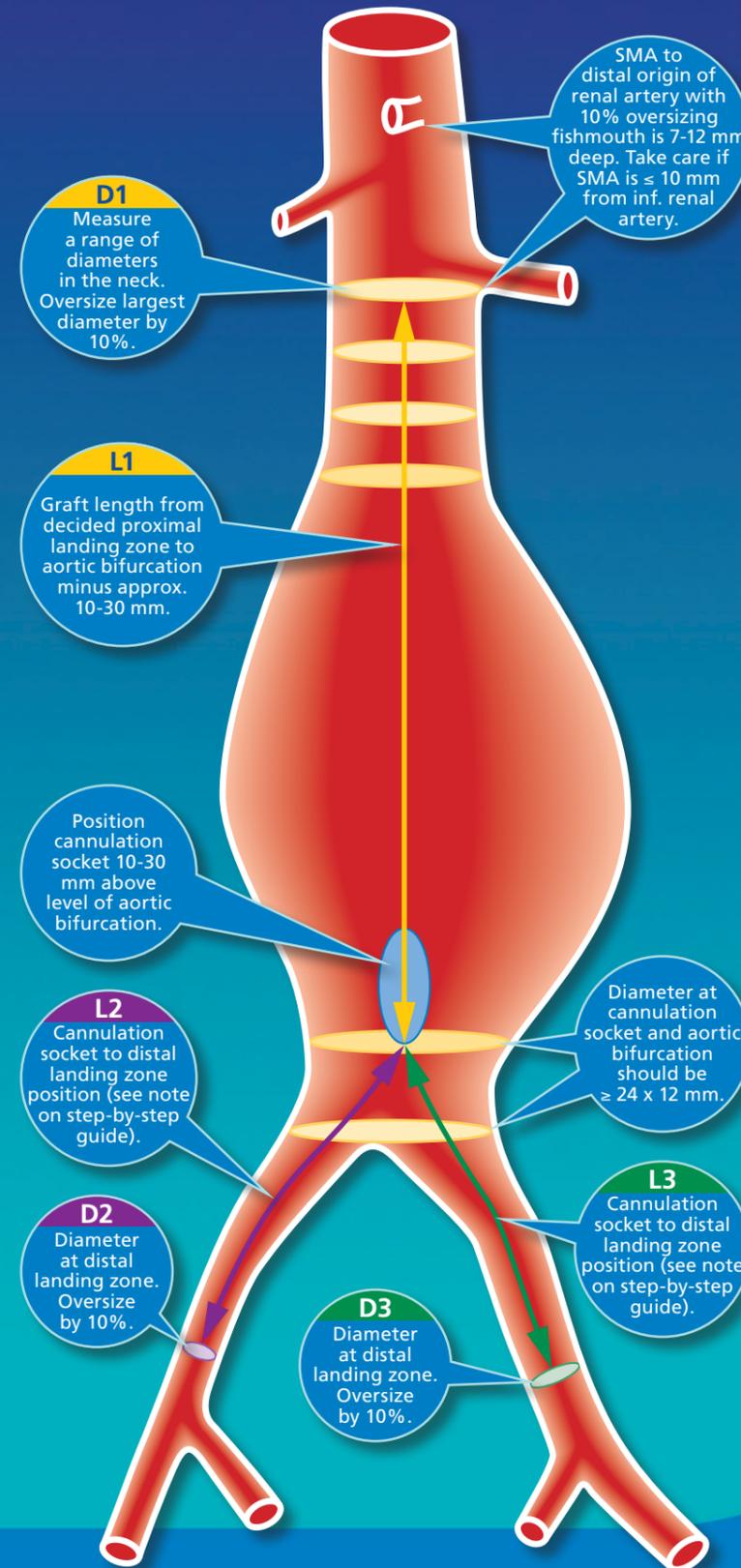
# Aorfix™ Step-by-Step Sizing Guide

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 ordering. Special (SP) non stock sizes may be ordered with a lead time of approximately 4 weeks.

- 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 oversizing 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 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 distal 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 distal 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



Proximal Diameter D1	24												
Body Length L1	*81			96			111			126			
Ipsilateral Length L2	63	80	97	63	80	97	63	80	97	63	80		
Distal Diameter D2	12	✓	✓	✓	✓	✓	✓	✓	✓	SP	✓	✓	
	14	✓	✓	SP	✓	✓	SP	✓	✓	SP	✓	SP	
	16	✓	✓	✓	✓	✓	✓	✓	✓	SP	✓	✓	
	20	✓	✓	SP	✓	✓	SP	✓	✓	SP	✓	✓	
Proximal Diameter D1	26												
Body Length L1	*81			96			111			126			
Ipsilateral Length L2	63	80	97	63	80	97	63	80	97	63	80		
Distal Diameter D2	12	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	14	✓	✓	SP	✓	✓	SP	✓	✓	SP	✓	SP	
	16	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	20	✓	✓	SP	✓	✓	SP	✓	✓	SP	✓	✓	
Proximal Diameter D1	28												
Body Length L1	*81			96			111			126			
Ipsilateral Length L2	63	80	97	63	80	97	63	80	97	63	80		
Distal Diameter D2	12	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	14	✓	✓	SP	✓	✓	SP	✓	✓	SP	✓	SP	
	16	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	20	✓	✓	SP	✓	✓	SP	✓	✓	SP	✓	✓	
Proximal Diameter D1	31												
Body Length L1	*81			96			111			126			
Ipsilateral Length L2	63	80	97	63	80	97	63	80	97	63	80		
Distal Diameter D2	12	✓	✓	SP	✓	✓	✓	✓	✓	✓	✓	✓	
	14	SP	SP	SP	✓	✓	SP	✓	✓	SP	✓	SP	
	16	SP	✓	SP	✓	✓	✓	✓	✓	✓	✓	✓	
	20	SP	SP	SP	✓	✓	SP	✓	✓	SP	✓	✓	
Contralateral Leg Length L3	56	64	73	81	90	98	106						
Distal Diameter D3	10	✓	✓	✓	✓	✓	✓	✓					
	12	✓	✓	✓	✓	✓	✓	✓					
	14	✓	✓	✓	✓	✓	✓	✓					
	16	✓	✓	✓	✓	✓	✓	✓					
	18	✓	✓	✓	✓	✓	✓	✓					
20	✓	✓	✓	✓	✓	✓	✓						

\*For a device that uses an 81mm long body please mark both leg lengths to get correct product code for ordering on the Aorfix™ Order Form.  
 \*Special (SP) non-stock graft sizes built by request



# EVERY ANGLE COVERED

## 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 **R**etrospective **A**orfix™ **D**at**A** **R**etrieval ('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.

Feature	Neck angle < 60°	Neck angle ≥ 60°
Eligible cases for 1 year follow up	233	143
Mean Aneurysm Neck Angle (range 0°-123°)	31°	79°
Stent migration (> 30 days up to 12 months)	0.0%	0.0%
Wire fracture (> 30 days up to 12 months)	0.0%	0.0%



### 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 Technologies PLC. April 2009

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