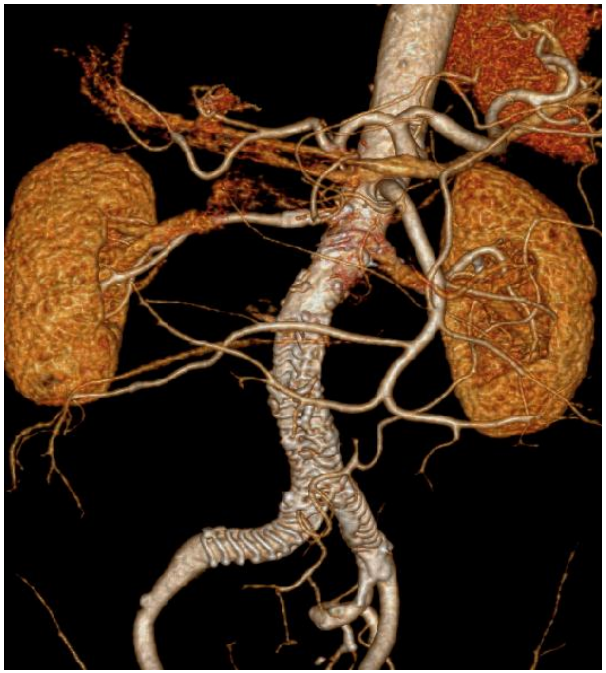
Early Experience of The Fenestrated Anaconda Device

David Gerrard
Vascular Surgeon
Frimley Park Hospital
UK

Anaconda™ Infra-renal Platform

11 000 cases world wide

Phase II FDA trial in progress



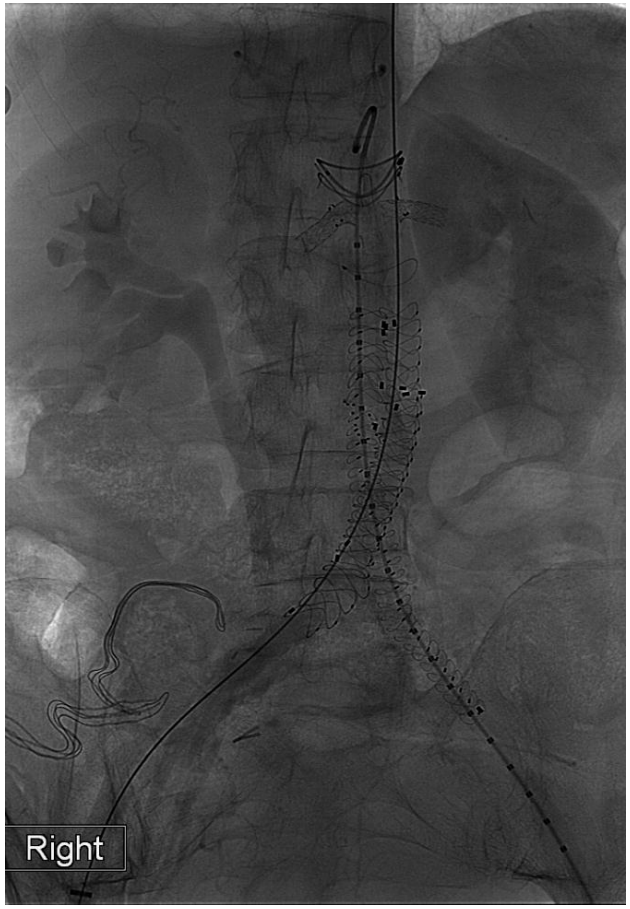
Infrarenal EVAR – Indications / Limitations

IFU standard endgrafts

- neck lengths > 10mm
- neck diameter < 31mm
- angulation < 90°

Use beyond the IFU – short / angulated necks

- increased endoleaks
- increased reinterventions
- increased AAA-related mortality long-term

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Study Date:19/08/2010
Study Time:09:46:12
MRN:
[RAF]
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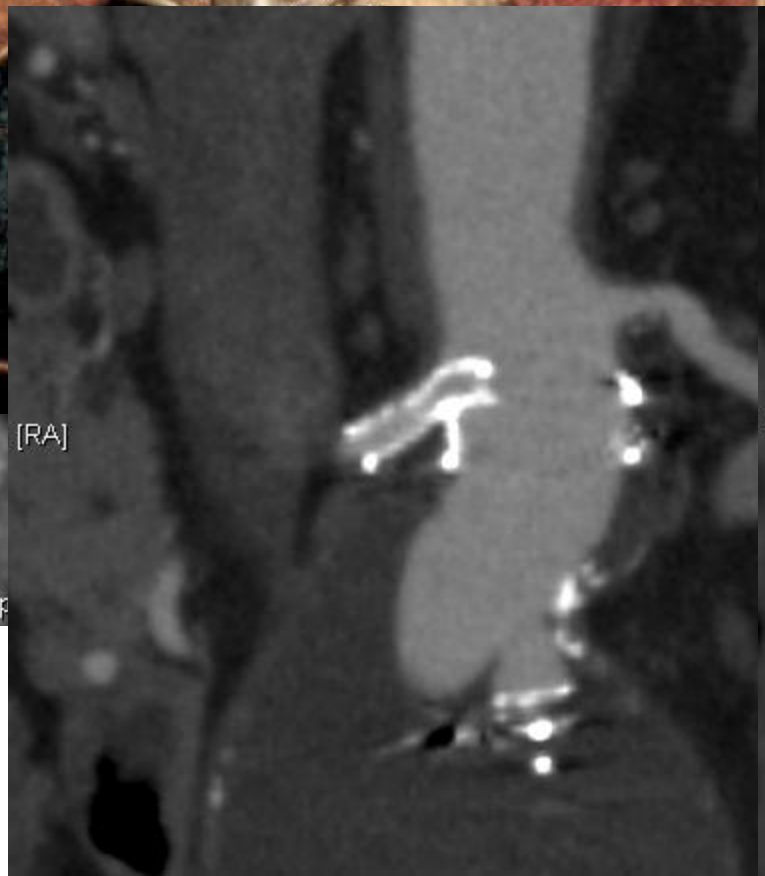
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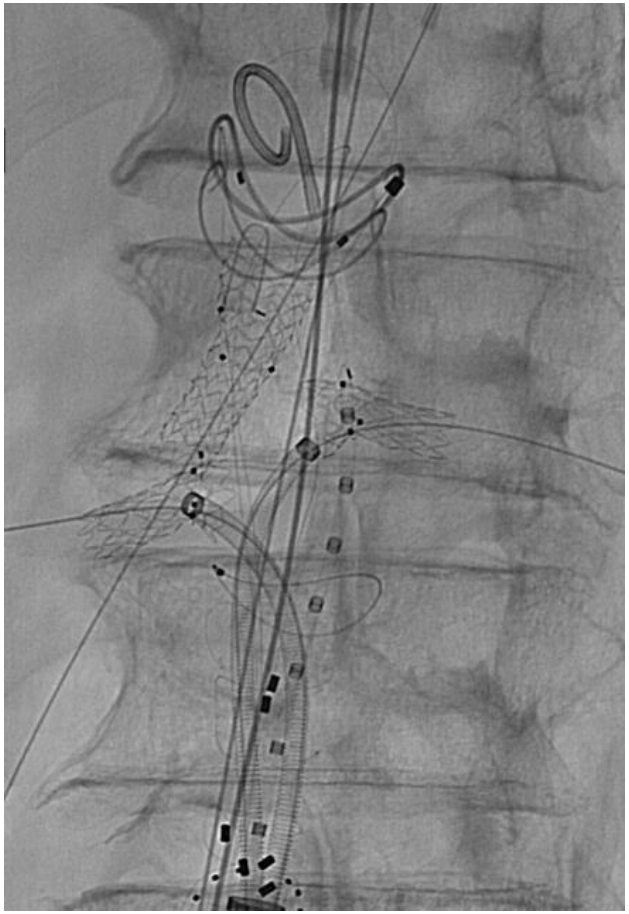
When there is no neck…

BSET Globalstar UK National Registry

- Initial report – 318 patients

- 2 renal fenestration 36%
- 4 fenestration 2.5%

- 30-day mortality - 4.1%
- Generally high risk patients



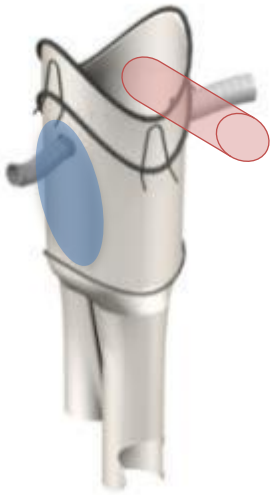
Anaconda Fenestrated - Concept

POTENTIAL ADVANTAGES

- Flexibility
- Accuracy
- Security
- Fenestration size and position
- Cannulation from brachial access

benefits

- Ring stent configuration
  - Ideal for positioning and locating the SMA or CA
- Unsupported fabric region on body
  - Accurate positioning of fenestrations
  - Flexibility of fabric aids alignment
- Re-positioning
  - Can aid in fenestration alignment
  - Retained during cannulation
  - Offers procedural alternatives



fenestrated anaconda™

Custom AAA Stent Graft System

design possibilities

standard

- Based on Anaconda One-Lok platform
- Body lengthened by 15mm
- SMA cradled in anterior valley

augmented valley

- Proximal ring tilted towards anterior
- Anterior valley hook removed or reduced in size
- SMA/celiac artery cradled in augmented anterior valley

long body

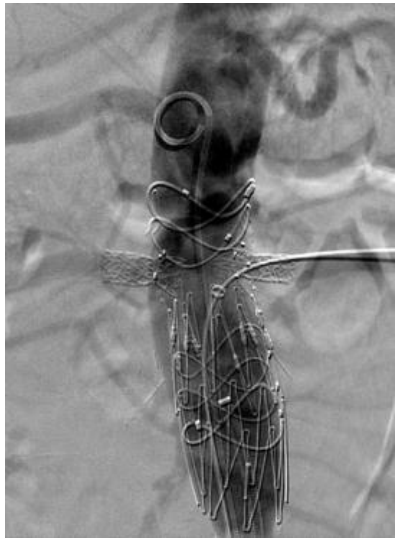
- Body length increased by up to 45mm
- Up to 4 fenestrations positionable in large fabric region
- For 4 fenestration cases, device can be designed with peaks in A-P orientation
- Additional mid-rings can be added if required
- Can feature augmented valley

fenestrated valley

- SMA fenestration between proximal rings
- Celiac artery cradled in anterior valley
- No anterior valley hook

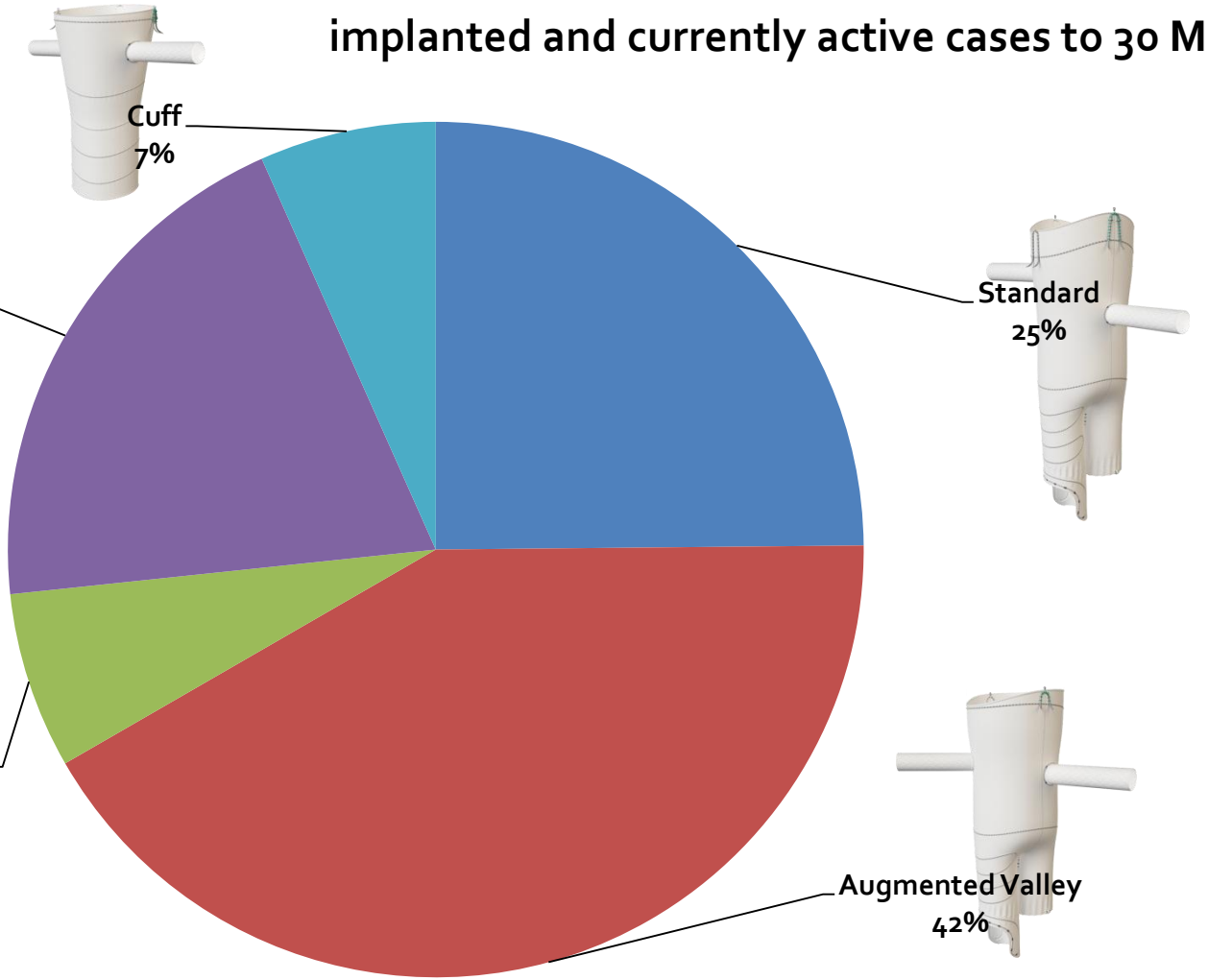
fenestrated cuff

- Proximal end re-positionable
- Distal end docked inside existing device
- Can have up to 4 fenestrations
- Can feature augmented valley
- Can be tapered or flared to suit specific anatomy

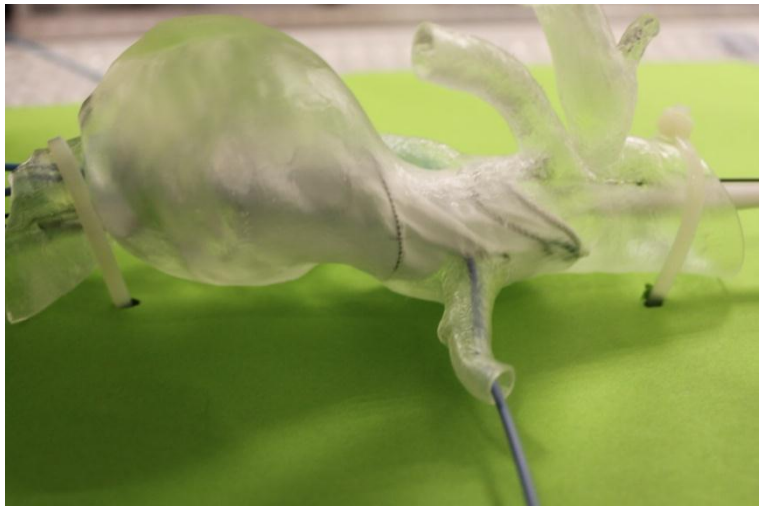


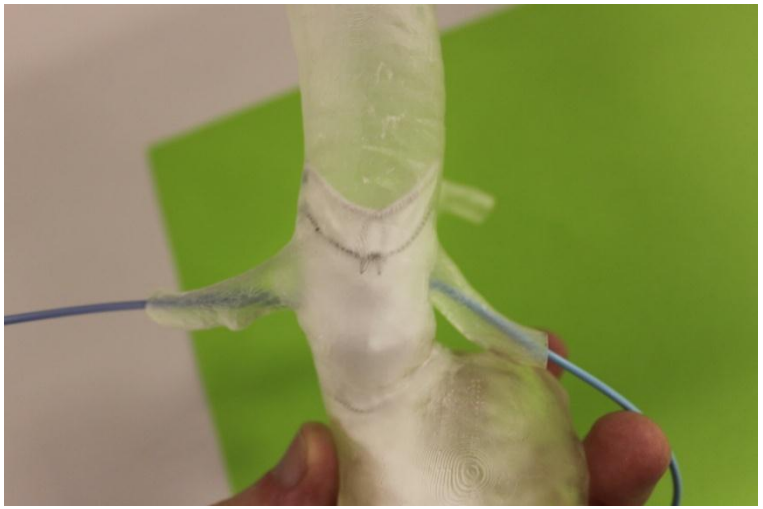
device type breakdown

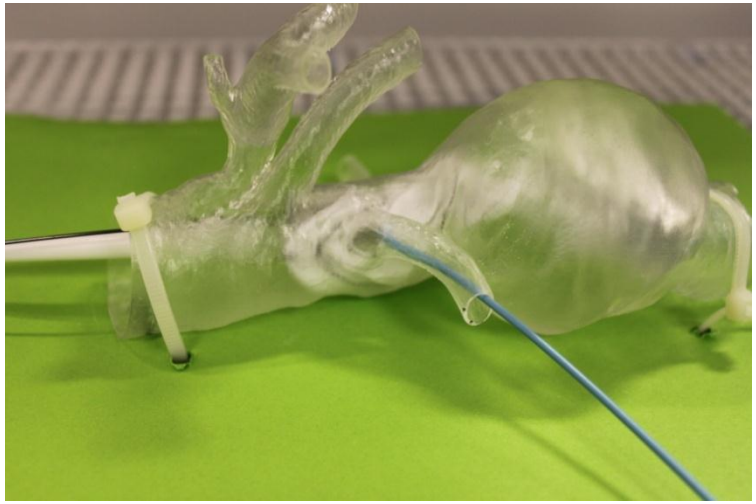
implanted and currently active cases to 30 May 2012



testing: prototype deployment

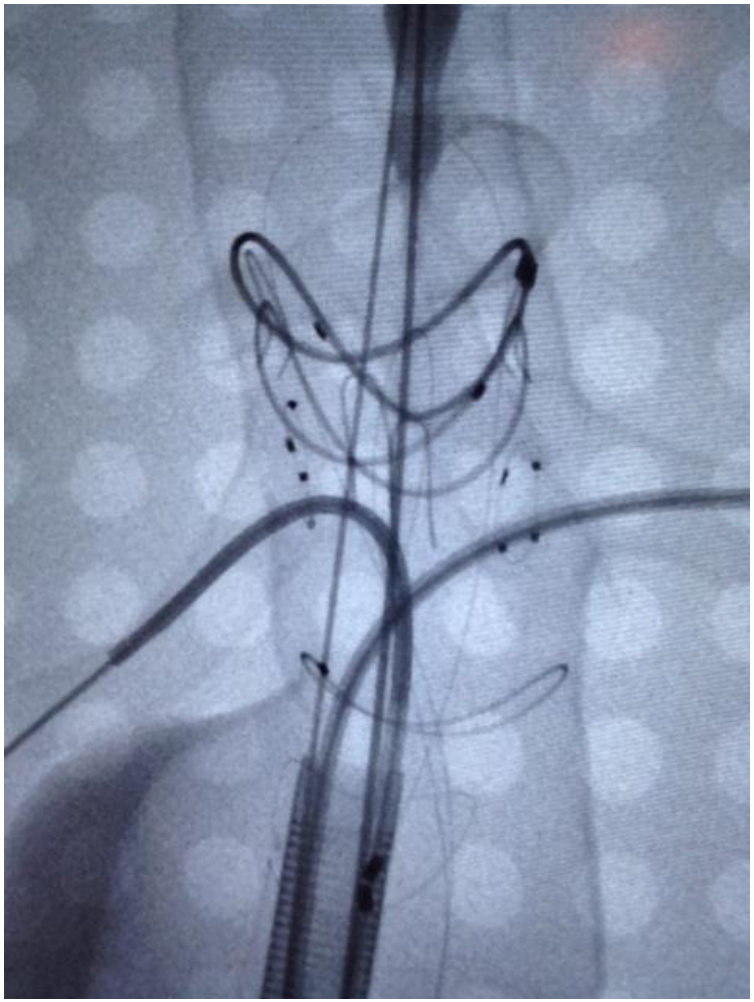




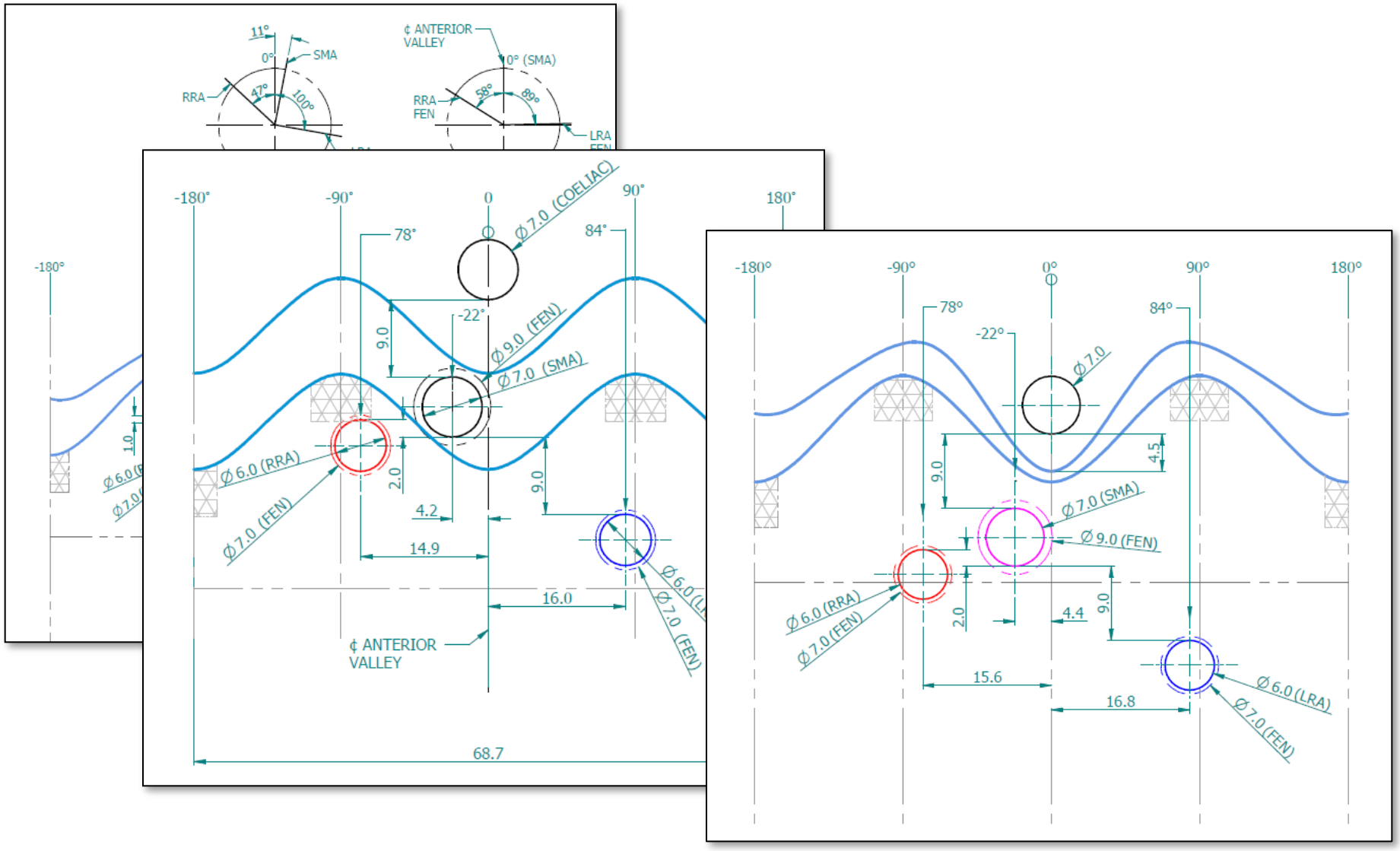


- Test re-positioning in anatomy
- Check alignment of fenestrations
- Check ability to cannulate fenestrations
- Check for suitable SMA to proximal ring clearance
- Check device landing zone in aorta

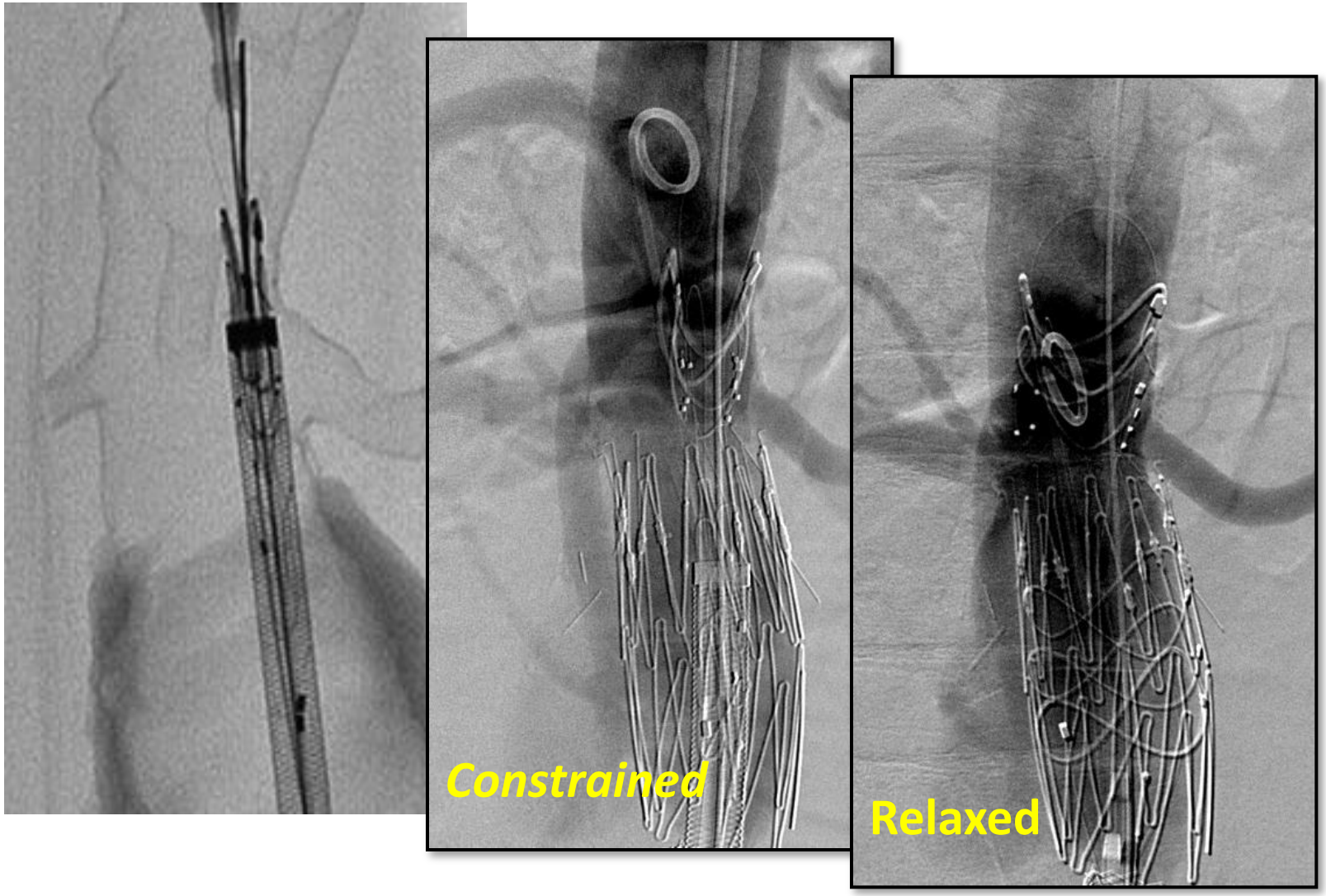
Clinician testing: under fluoroscopy



Effect of vessel origin angle on heights



Deployment sequence



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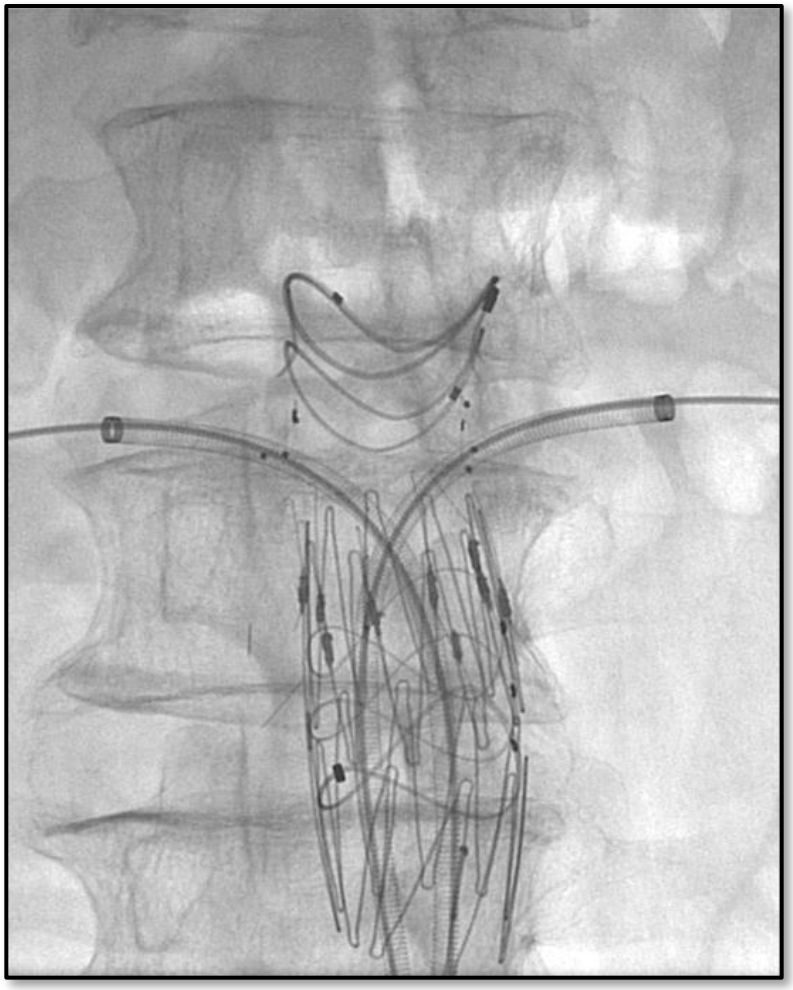

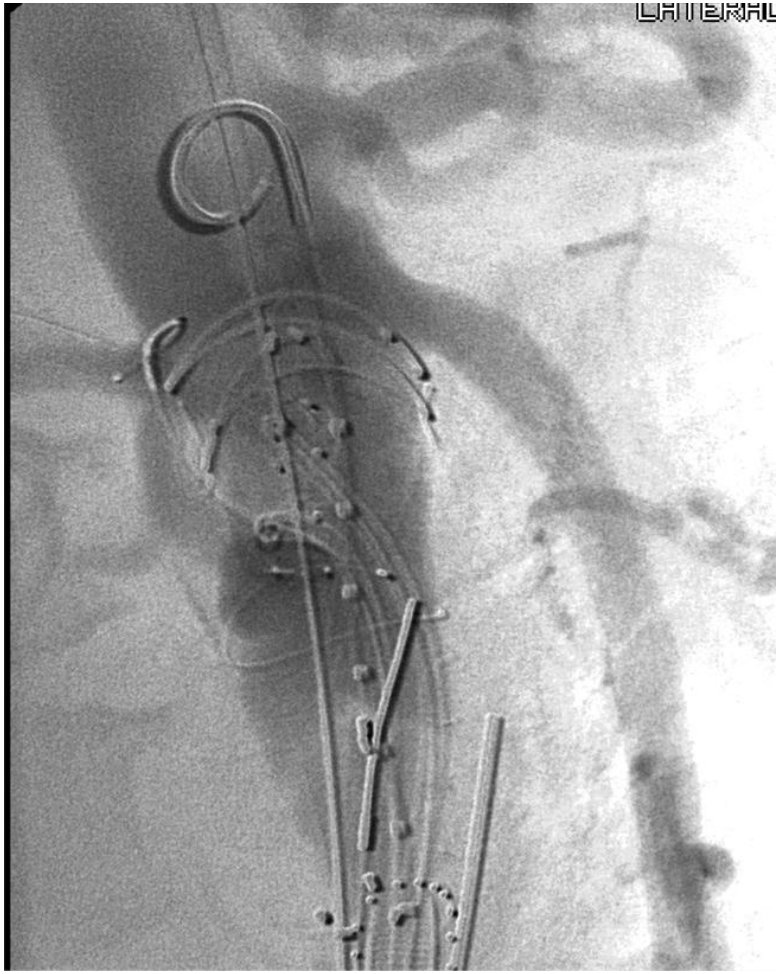

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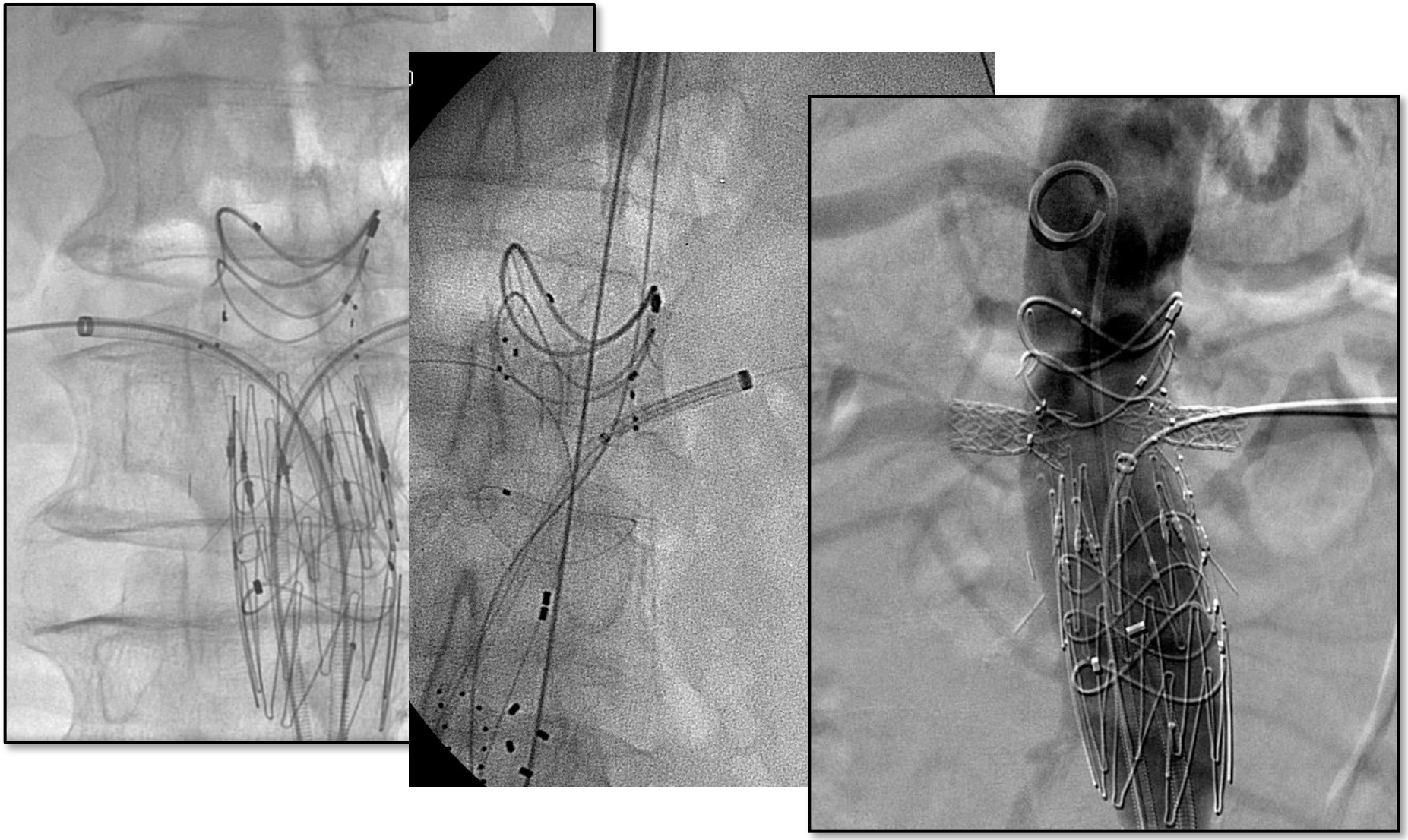
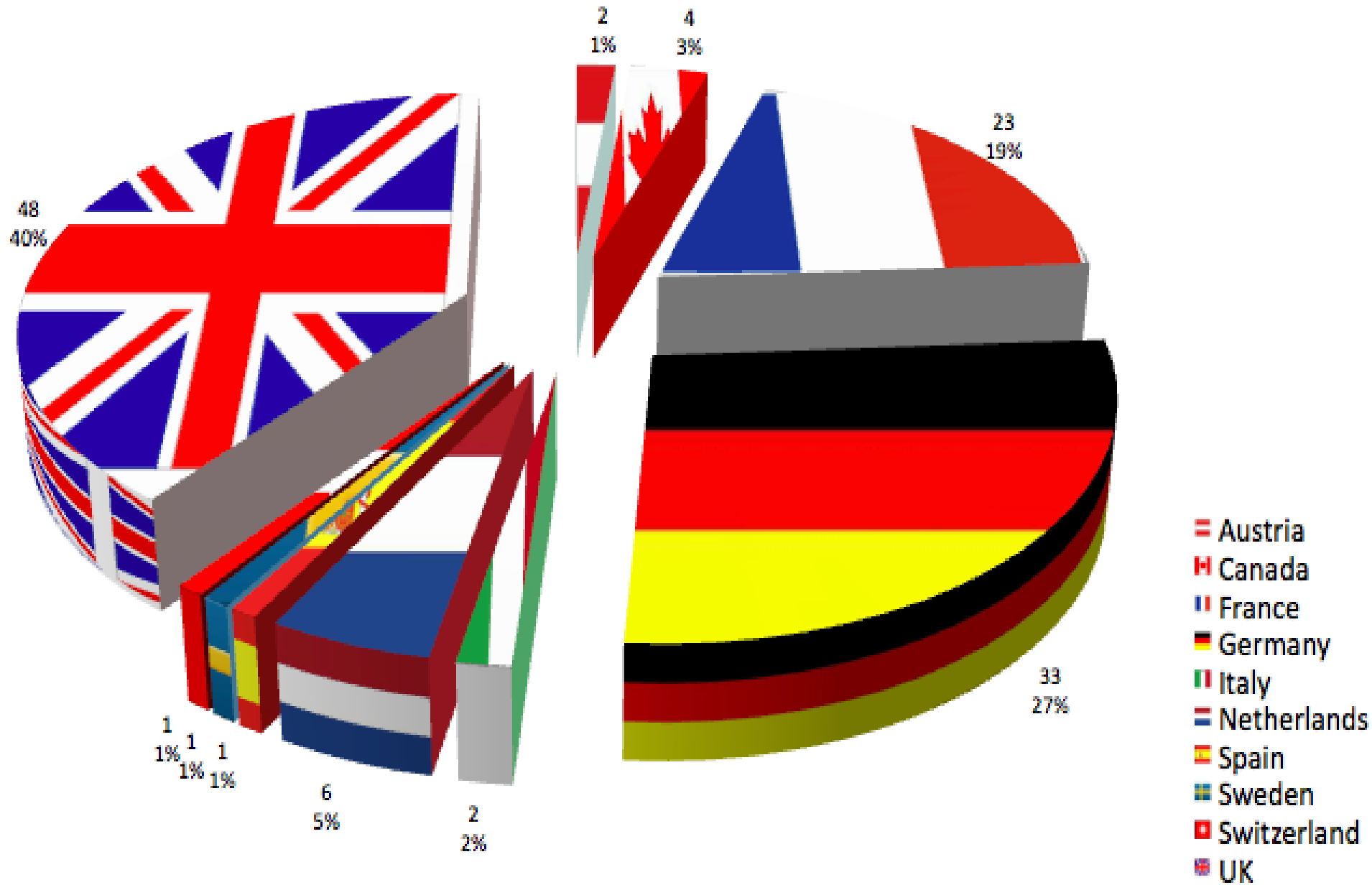
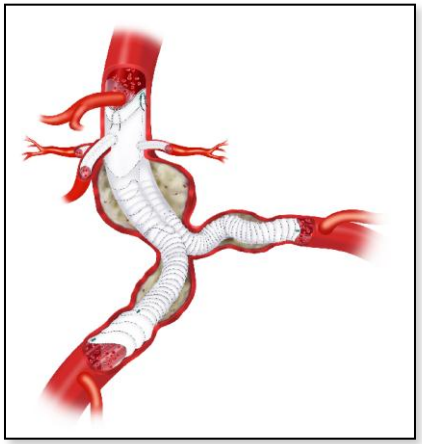



Left
ADVANTA V12
85336
ABB/ET
W: 683, C: 50

Fenestrated Anaconda Implants To Date



Global Registry



- Web site: www.fenestratedanaconda.com
- Participants: **Global**
- Patients recruitment: **prospective and retrospective for early cases**

End Points

- *Primary*
  - Technical success
  - AAA exclusion
  - Target vessel patency
- *Secondary*
  - Mortality
  - Type I or III endoleaks
  - Stentgraft migration

Current Registry Status

Cases:	121 patients implanted
Males:	103 (85%)
Females:	18 (15%)
Mean age:	73 years (range 51-91 years)

*none or incomplete data for 24/121 patients

Current Status Device Type

Fenestrations	No. of cases
1 vessel	5
2 vessels	87
3 vessels	27
4 vessels	2

(7 fenestrated cuffs)

121 cases completed

Average Screening and Procedure Time

Category	Time in minutes
Average fluoroscopy time	75
Length Total Procedure	217

Technical Success

Outcome	Percentage
Conversion to open repair	0%
Additional endovascular procedure	6.4%
Additional surgical procedure	4.8%

Details of the 30 day deaths*

Case	Post op day of death	Comments
1	12	Myocardial infarction
2	6	Myocardial infarction
3	29	Cerebral hemorrhage
4	1	Colonic Ischemia
5	21	Multi organ failure
6	6	Colonic Ischemia

*3 post discharge deaths, 3 procedural related

Evolution of Aneurysm Sac

Followed at 12 months*	Percentage
Stable	28.6%
Increase	0
Decreased	71.4%

* 24 patients with 12 months follow up

Summary Current Status

Technical success : 99%

(356 target vessel, 3 failed stenting, all achieved initial wire access)

No persistent type Ia or type III endoleak

Target vessel patency at follow up : 98.4%

2 renal artery occlusion at follow up

24 patients at 1yr

No migration, No type Ia or type III endoleak

CONCLUSION

- Versatility of Anaconda graft ideal for FEVAR
- Technically complex procedure
- Expertise and teamwork required

CONCLUSION

- Satisfactory immediate and short-term results
- Long term follow up required
- Publication of results from analysis of Registry