CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
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Technical features of the Cordis investigational INCRAFT® AAA Stent Graft System

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INCRAFT® AAA Stent Graft System is not regulatory approved and is not commercially available

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Disclosures

- Co-PI / research coordinator for thoracic and abdominal aortic stent graft trials (COOK®, Cordis®, Trivascular™, Gore®)

- Participated as a lecturer at symposia hosted by COOK®, Cordis®

INCRAFT® System

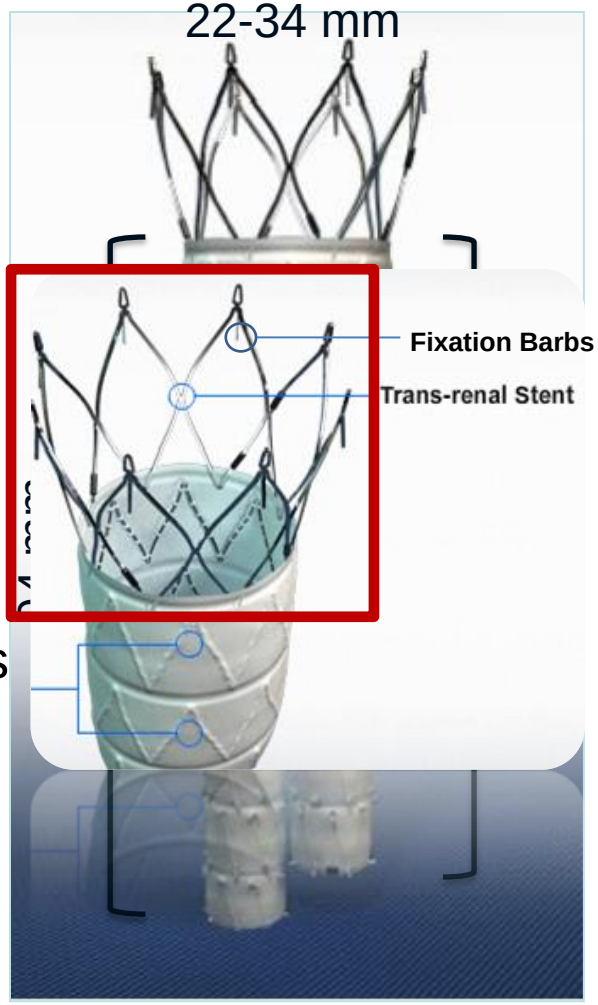
Key features

- 3-piece modular system:
  - ✓ Low porosity polyester graft
  - ✓ Segmented nitinol stents
  - ✓ Supra-renal fixation
- Customization:
  - ✓ "Few-fits-most" surgical graft concept
  - ✓ Partial proximal re-positioning
  - ✓ Bilateral in-situ length adjustment
- Ultra-low Profile:
  - ✓ 13Fr Integrated Delivery System
  - ✓ Catheter-like shaft flexibility

INCRAFT® System Main Body

Design

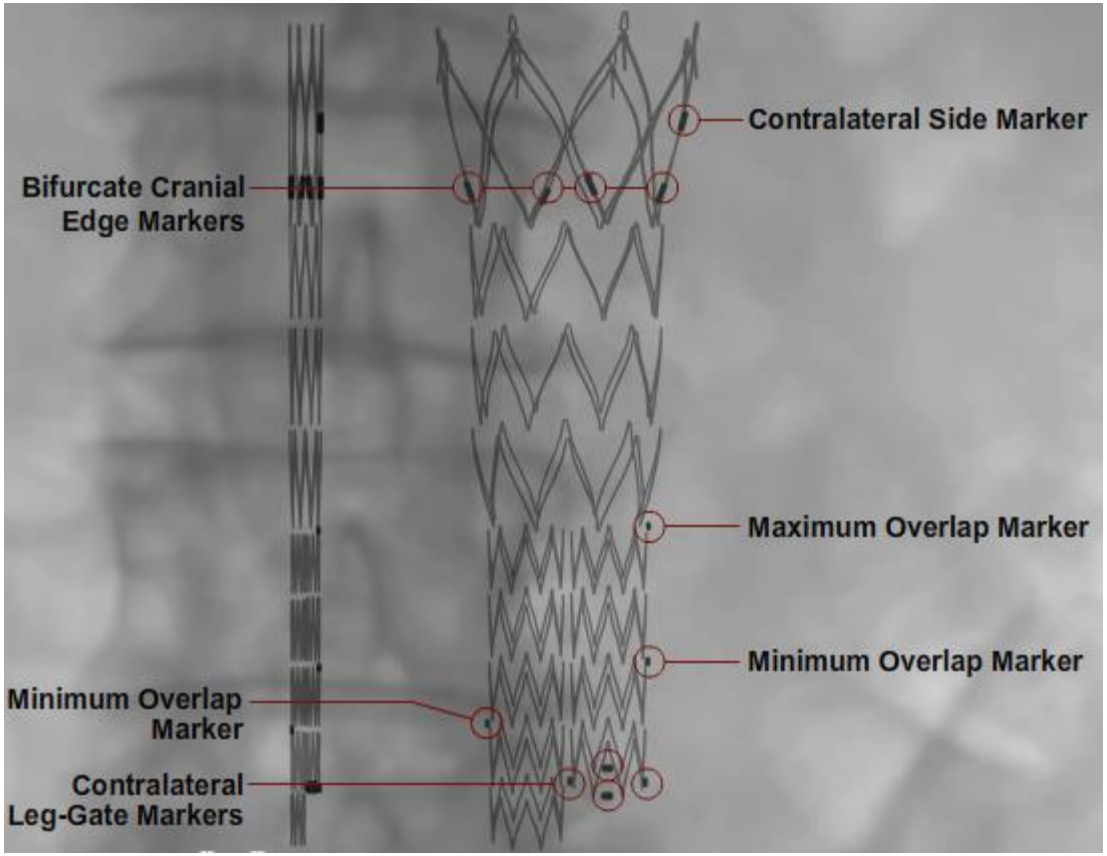
- Flared bare trans-renal stent
  - ✓ Cranial migration resistance
  - ✓ Main Body Stability - Perpendicular deployment
  - ✓ Higher radial force compared to Z-Stent
- Laser-cut supra-renal fixation barbs
  - ✓ Fracture resistance
  - ✓ Corrosion resistance relative to welded barbs
- 4 diameter sizes (22, 26, 30, 34mm)
  - ✓ allowing treatment of proximal aortic neck diameters from 17-31mm



Main Body

Partial proximal re-positioning and placement accuracy

- Accurate Positioning Through Superior Visualization:
  - ✓ 4 Cranial Graft Edge Markerbands
  - ✓ Sheath Tip Marker
  - ✓ Contralateral Side Marker
- **NOTE**: Partial proximal re-positioning possible prior to fixation release



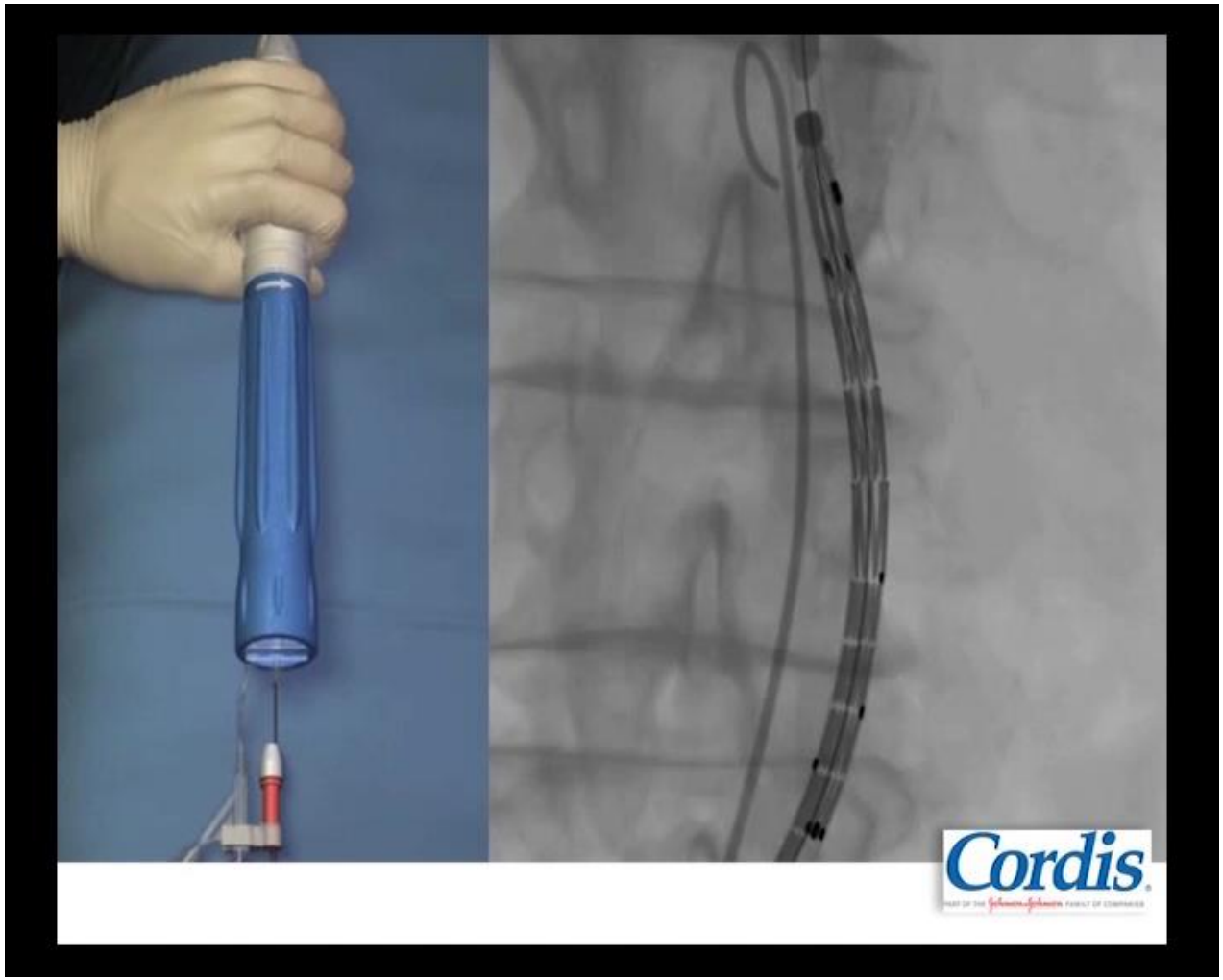
Main Body

Partial proximal re-positioning and placement accuracy

- Accurate Positioning and Fixation Release:

✓ Distal end without top cap allows for fully perpendicular deployment due to sealing stent release prior to fixation release

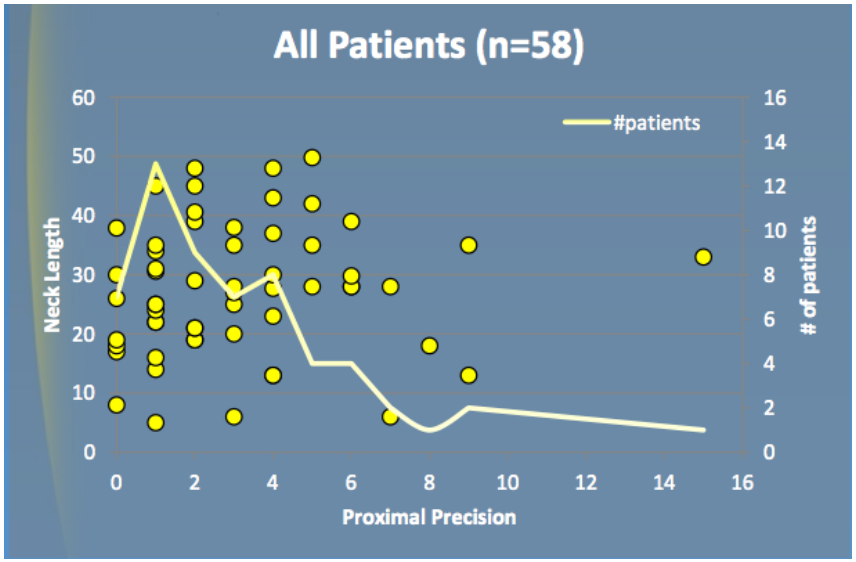
✓ Bifurcate delivery system can be removed <u>without additional top cap “retrieval” step</u>



Main Body

Placement accuracy data - INNOVATION Study

- Median distance from renal artery*: 2 mm (-4†; 15mm)
- †No renal artery coverage

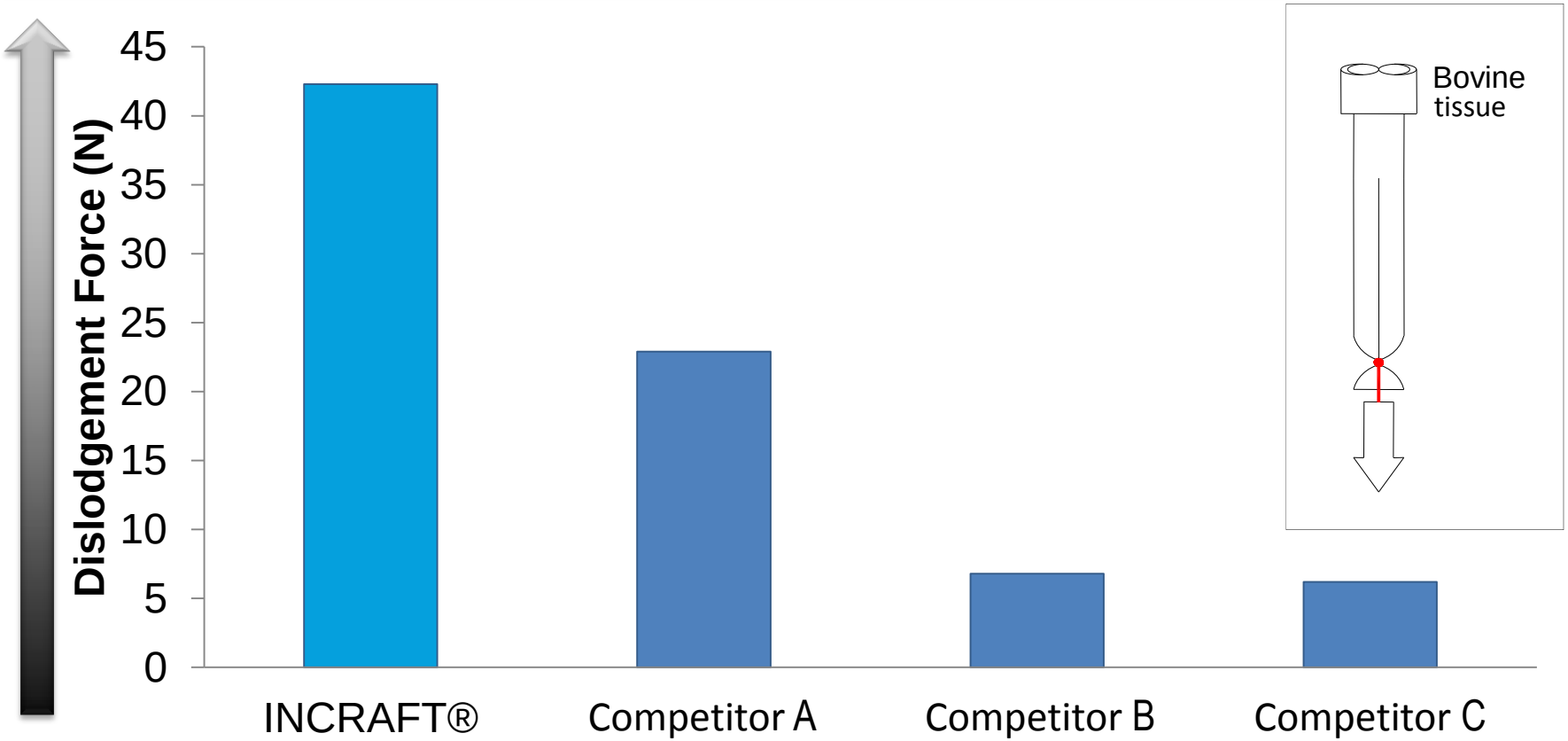


*Accuracy Definition: distance from lowest renal to bottom of first two cranial graft edge markers

D. Scheinert et al; J Vasc Surg 2013; 57(4)):906-914

Main Body

Migration resistance



Endograft migration resistance based on In vitro bench marking

**VEITH 2007-2013*

Main Body

Migration resistance – INNOVATION Study

Stent migration (vs 1 month, mm)*	24 Month
Mean ± SD (N)	1.38 ± 2.04 (50)
Stent migration (> 10mm)	**0% (0/50)**

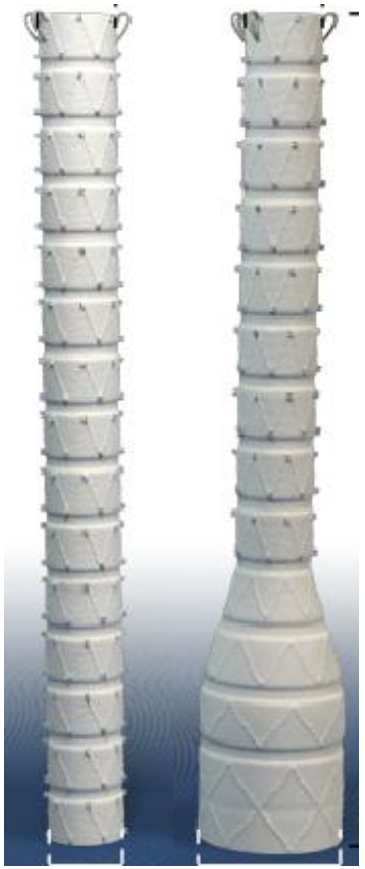
**Notes:*

- *Compared to 1-month measurement as baseline*
- *Core Lab CT Assessment Parameter.*

INCRAFT® System Iliac limbs

Design

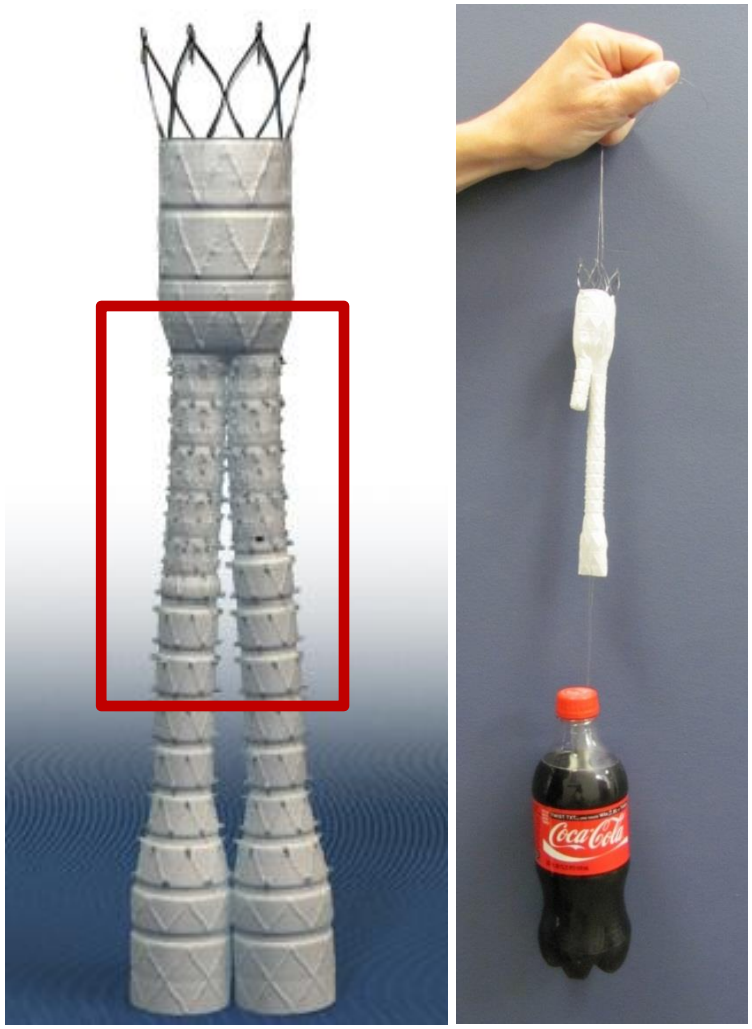
- 5 diameters distally (10, 13, 16, 20, 24mm)
  - ✓ accommodating iliac arteries ranging from 7-22mm.
- 4 lengths (8, 10, 12, 14mm)
  - ✓ to treat a overall treatment length range of 128-212 mm



Iliac limbs

Interlocking modular connection

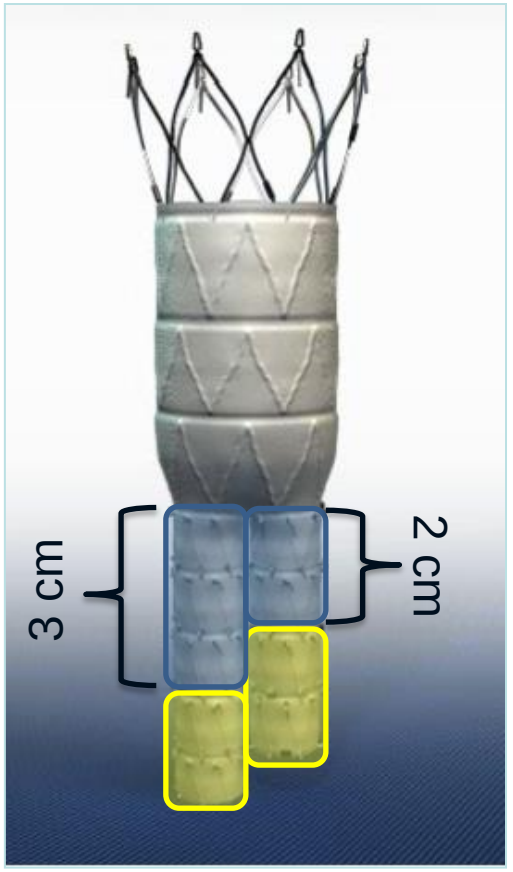
- Aortic Bifurcate-Limb interlocking system:
  - ✓ Suture knots on the limb graft interlock with the Z-stents on the inside of the aortic bifurcate legs
  - ✓ Leads to increased modular junction strength



Iliac limbs

Bilateral in-situ length adjustment

- The varying overlaps (“in-situ sizing”) allow for length adjustment up to 3 cm of assembled implant during the procedure:
  - ✓ 3 cm ipsilateral
  - ✓ 2 cm contralateral



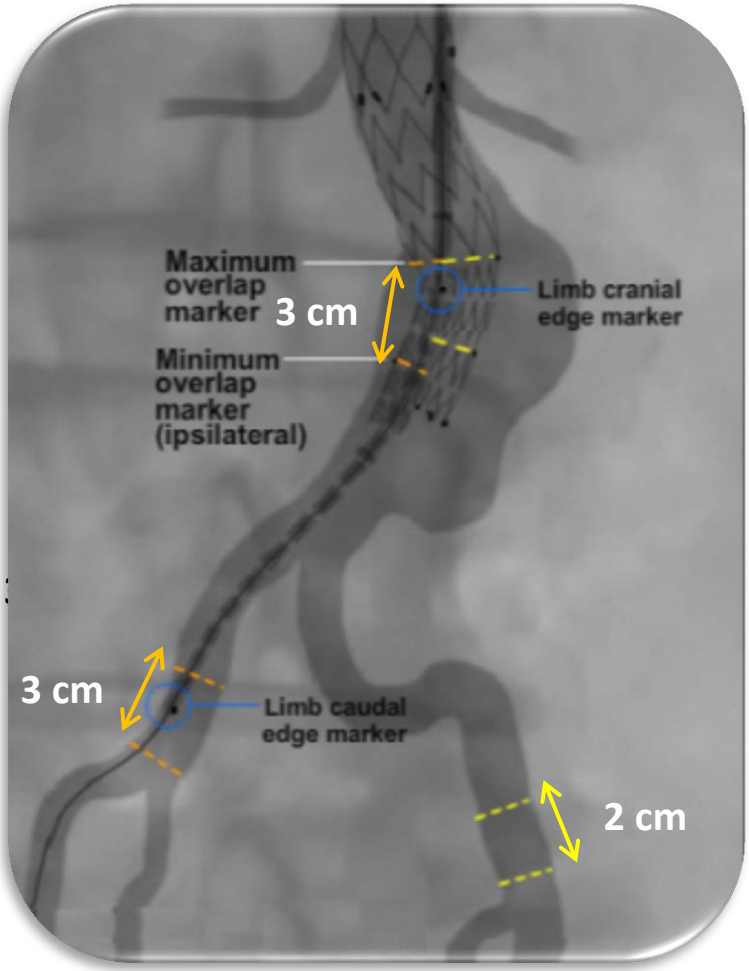
Minimum seal-zones

In-situ length adjustment zones

Iliac limbs

Bilateral in-situ length adjustment

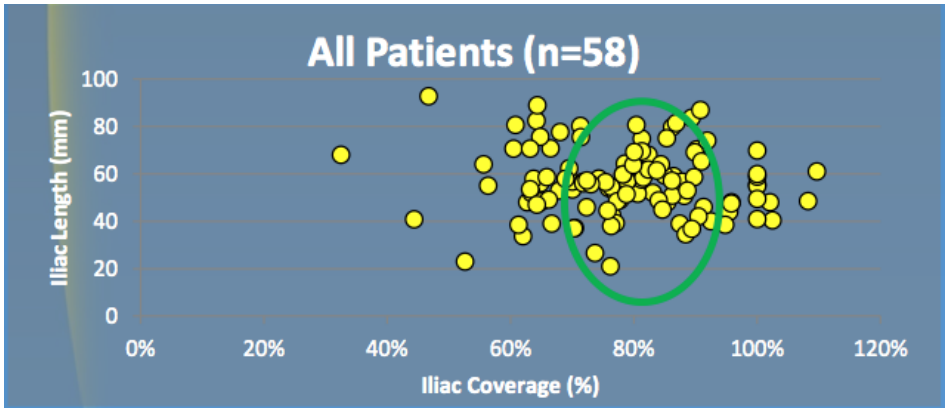
During procedure each limb can be telescoped into the respective aortic bifurcate leg

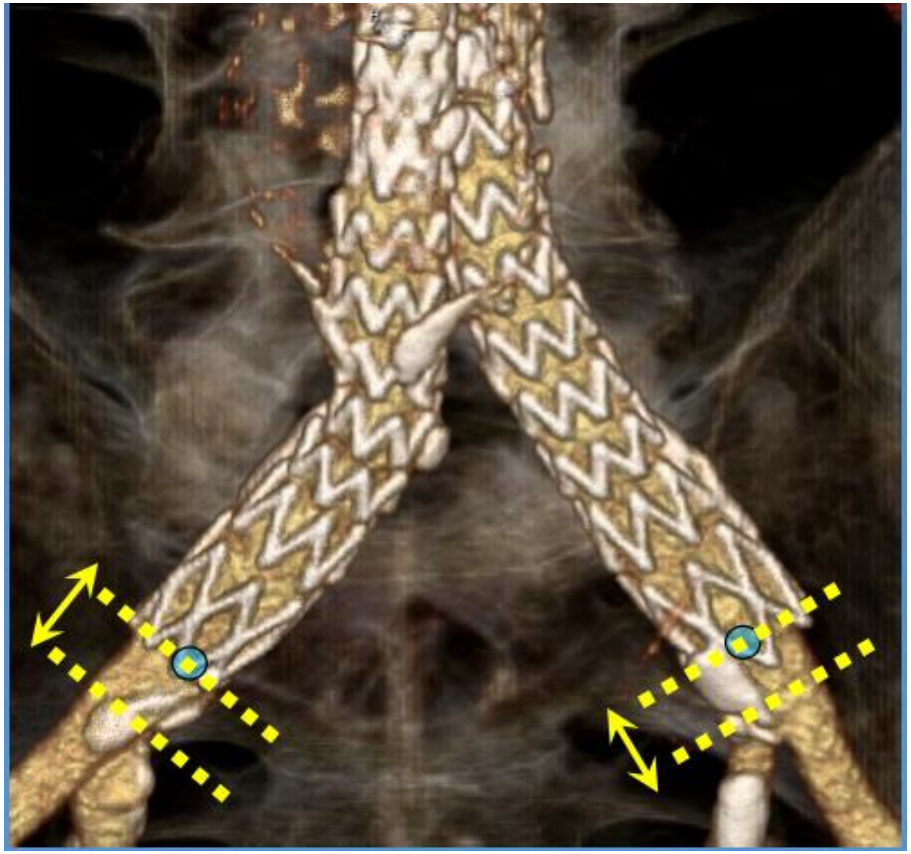


Iliac limbs

In-situ length adjustment - INNOVATION Study

- Median distance from Internal Iliac Artery origin*:
  12.2 mm (-5.9; 49.4)
- Mean iliac artery coverage:
  79% (30-110%)
- Unplanned limb extensions: 0%

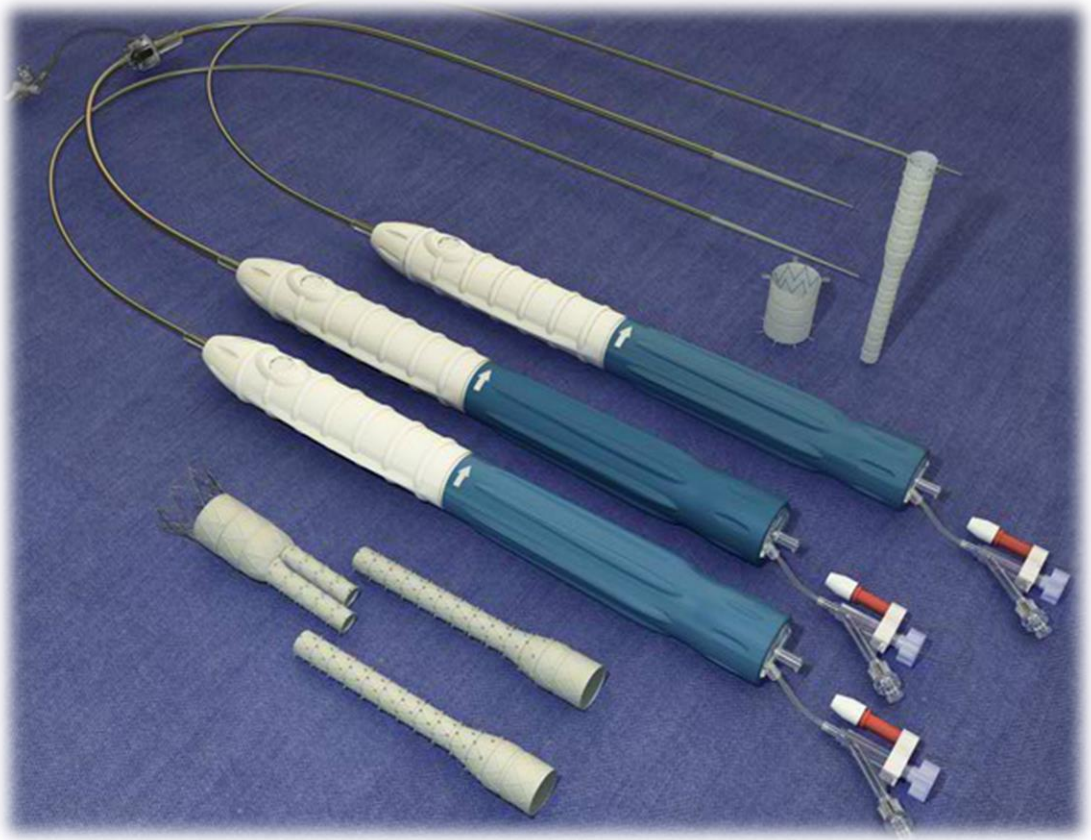




*Charing Cross 2013

INCRAFT® System

"Few-Fits-Most"



4 Main Bodies

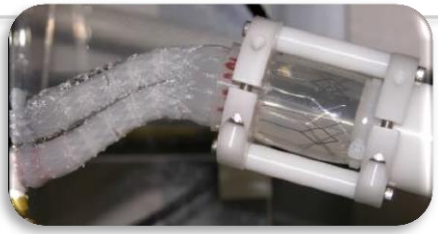
19 Limbs

= 23 product codes

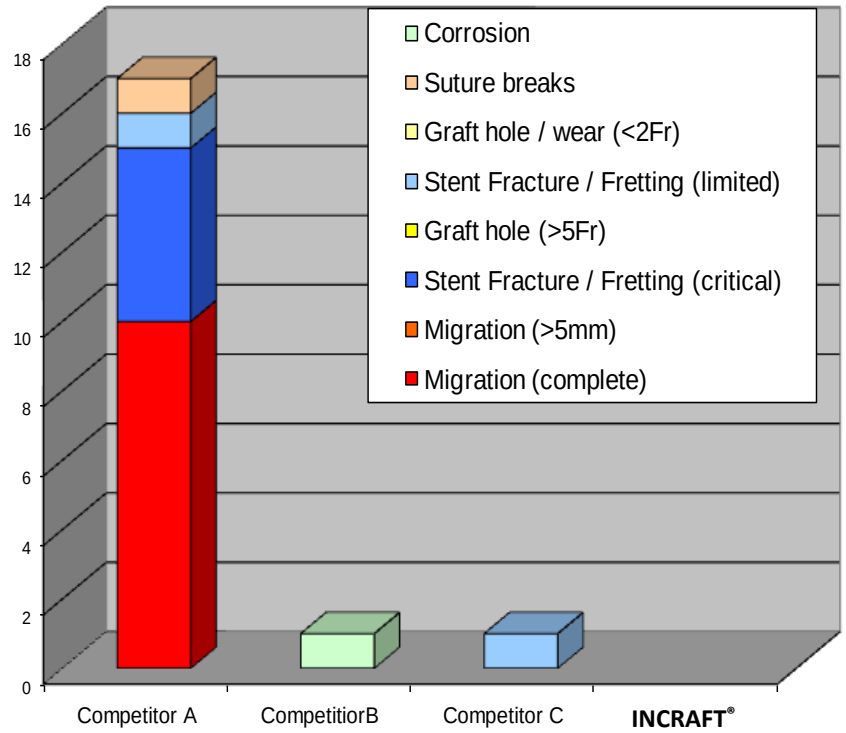
		# of products required	
		High	Low
Anatomy coverage	Broad		***23 product codes***
	Limited		

INCRAFT® System

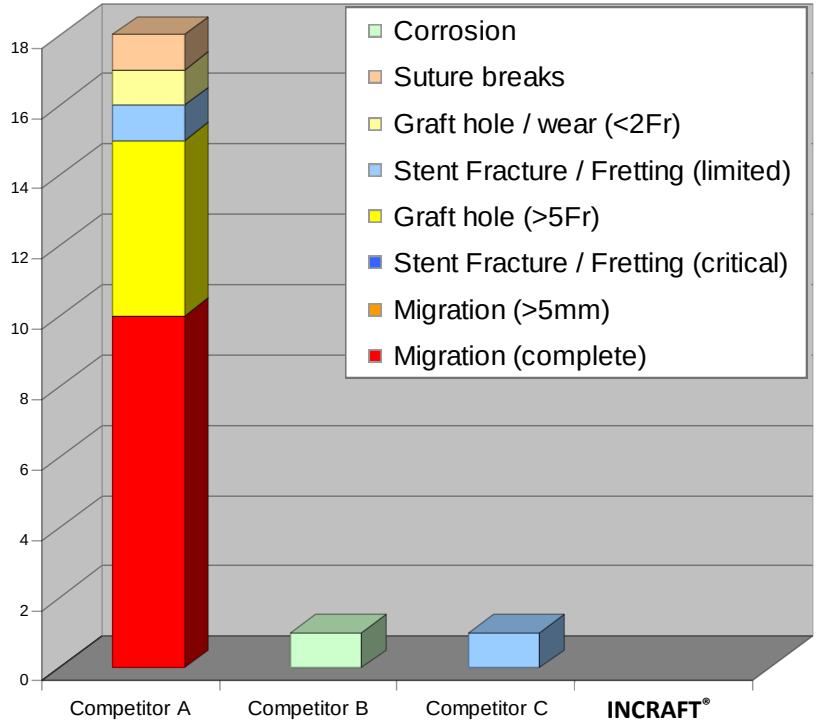
Stent/Fabric Durability



*Pulsatile Fatigue**



*Axial Fatigue**

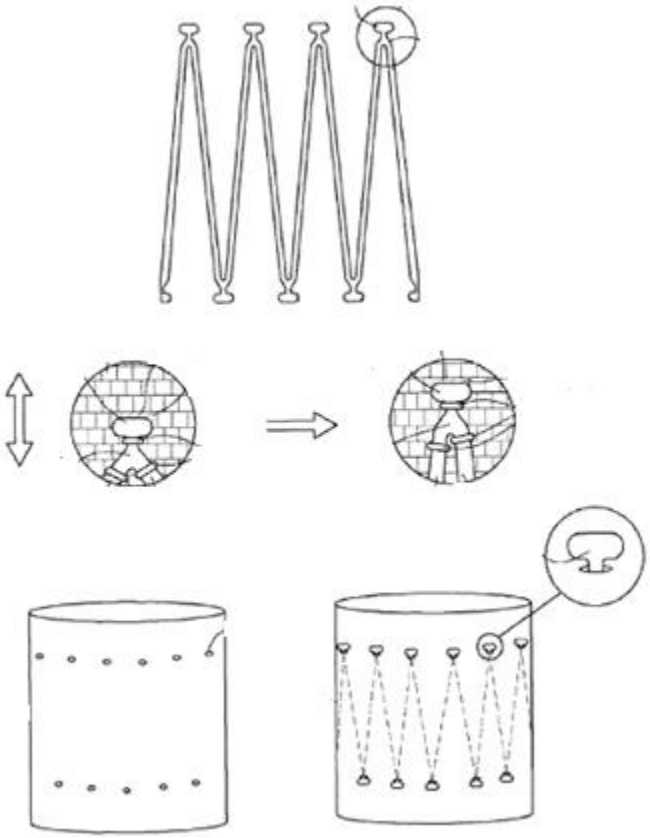


Note: Y-axis based on weighting. See "AAA Program Update Project Ambition" presentation at Veith Symposium November 14th-16th, 2007
Endograft durability based on In vitro bench marking
VEITH 2007-2013

Stent-Graft System

Stent/Fabric Durability

- Delta stitch and tab to prevent micro-motion of the stent strut against the graft material
  - ✓ Improves the durability of the device by limiting the “fraying” of the graft material caused by the constant motion of the pulsating material against the harder surface of the Nitinol alloy



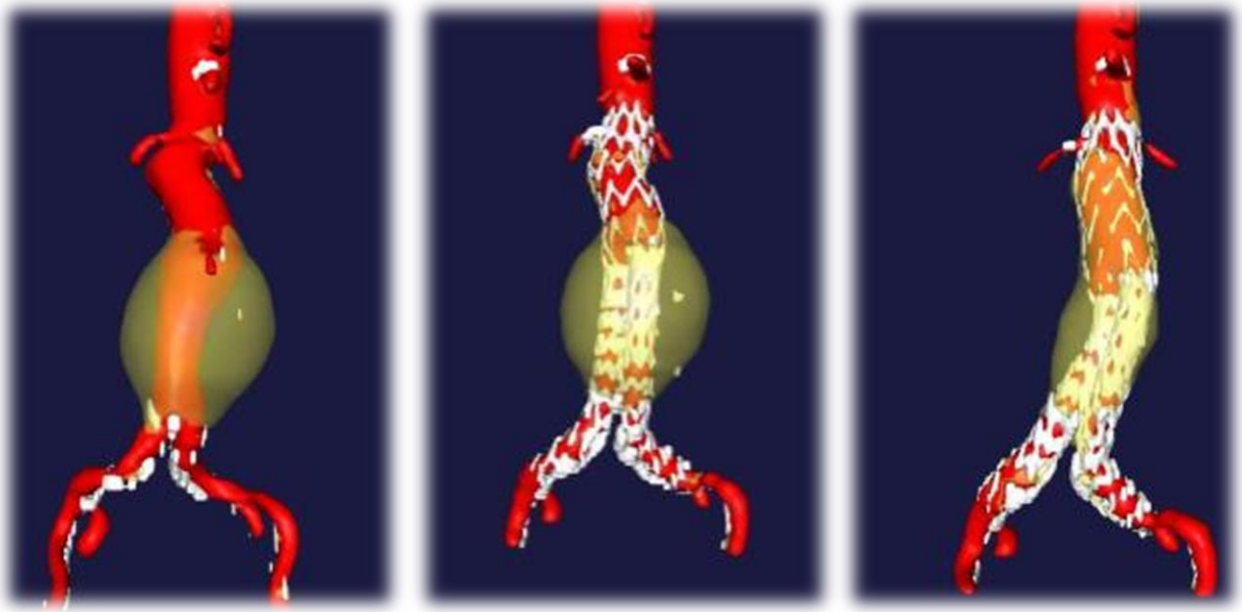
Stent-Graft System

Stent/Fabric Durability – INNOVATION Study

INCRAFT® Stent Graft was designed with an understanding of the biomechanical requirements for a AAA stent-graft and surgical principles, resulting in a durable design[1]

- The 1 year FIM results [2] show (n=56) :
  - ✓ No stent fractures
  - ✓ No graft migrations
  - ✓ No endoleak type I, III
  - ✓ No sac enlargement
- Data on long term durability will need confirmation by larger number of patient with long-term follow up.

1st INCRAFT® Stent Graft patient with 3Y Follow up



Screening | 1 month | 3 year

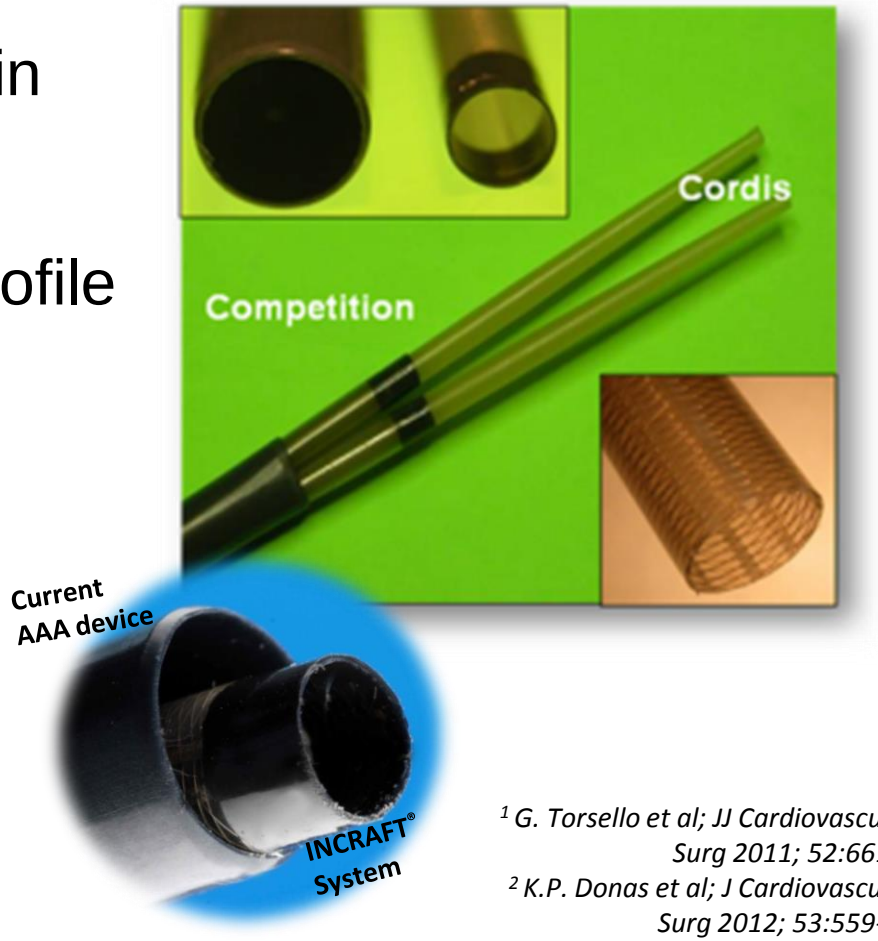
[1] *Torsello G, Brunkwall J, Scheinert D. Cordis incraft ultra-low profile aaa stent-graft system. J Cardiovasc Surg (Torino). 2011;52(5):661-667.*

[2] *G. Coppi; VEITH conference, New York November 2012*

INCRAFT® System

Ultra Low Profile Delivery system

- Delivery system with a built-in 13Fr sheath introducer
- Advantages of Ultra-Low Profile in minimally invasive endovascular surgery[1,2]
  - ✓ Increased applicability
  - ✓ Reduced trauma
  - ✓ Percutaneous access
  - ✓ Local anesthesia
  - ✓ Early discharge



[1] G. Torsello et al; JJ Cardiovascular Surg 2011; 52:661-7
[2] K.P. Donas et al; J Cardiovascular Surg 2012; 53:559-69

Stent-Graft System

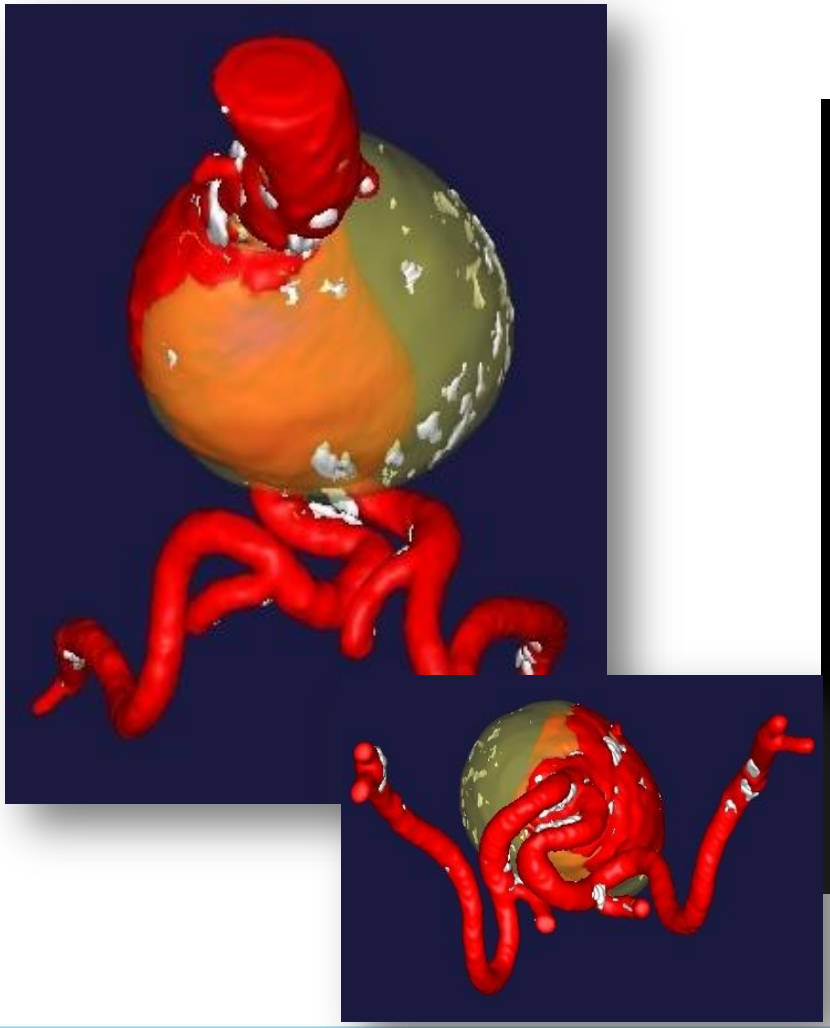
Ultra Low Profile Delivery system

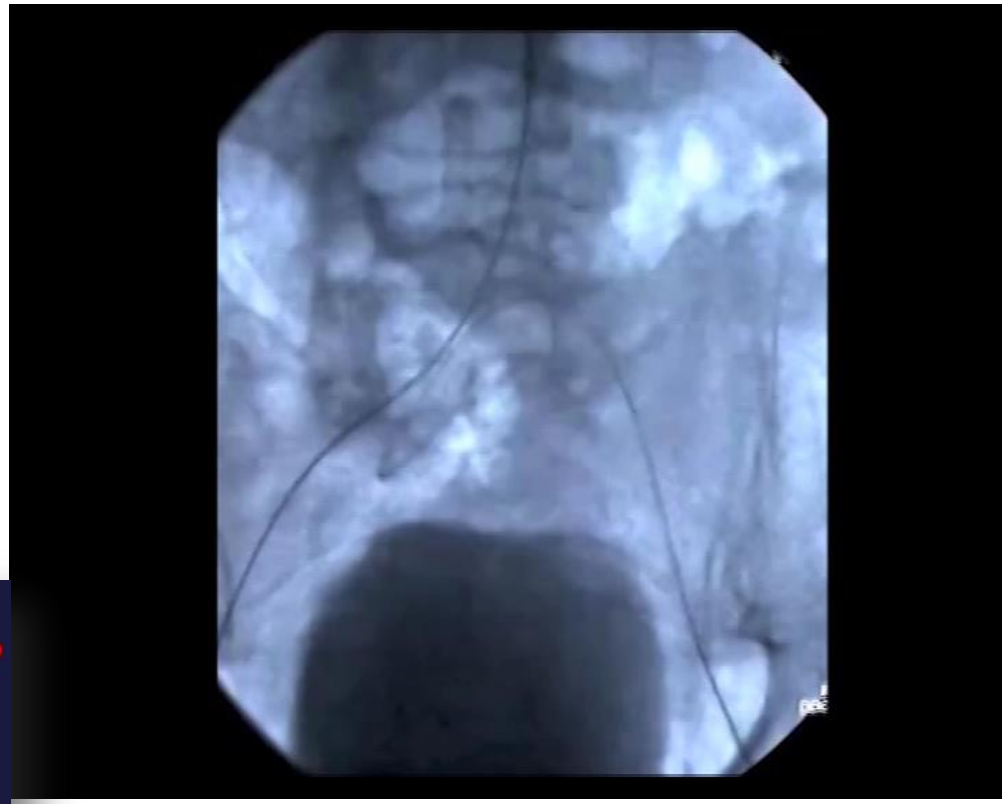
Catheter-like shaft flexibility

[1] *G. Torsello et al; JJ Cardiovascular Surg 2011; 52:661-7*

Stent-Graft System

Ultra Low Profile Delivery system – INNOVATION Study

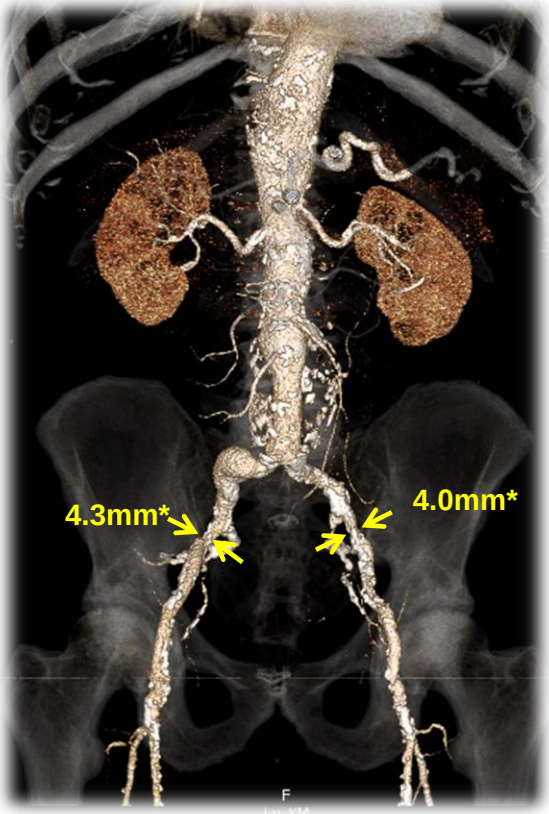


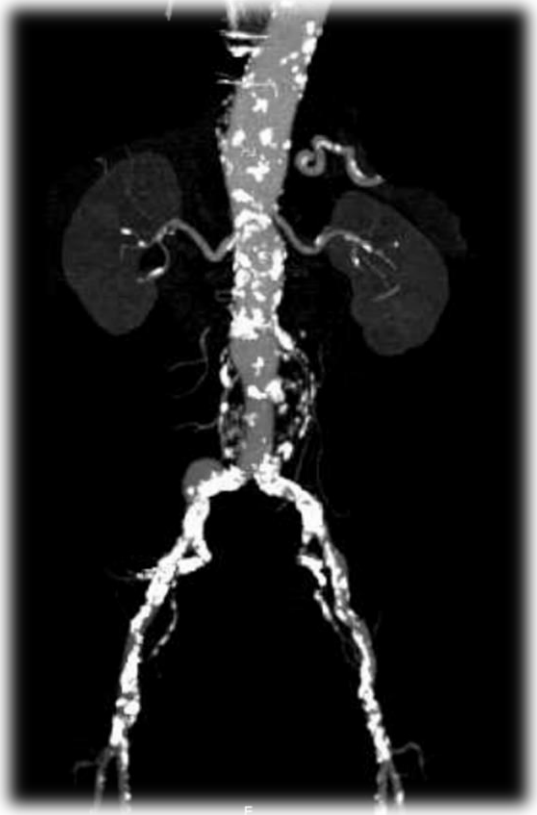


Stent-Graft System

Ultra Low Profile Delivery system – INNOVATION Study

More than 44% of patients with small access* but all treated with 100% Technical success





**Small access define as <7mm*

Chaikof et al. J Vasc Surg 2002;35:1061-6

D. Scheinert et al; J Vasc Surg 2013; 57(4)):906-914

Conclusions

Despite advancement in EVAR stent-graft technology, the INCRAFT® AAA Stent Graft System could improve current commercially available devices and introduce unique new features

Initial experience and preliminary mid-term results with the new customizable, ultra-low profile AAA stent graft system are encouraging