

**CORDIS abdominal endograft:
early experience with a new customizable,
ultra-low profile abdominal aortic
aneurysm stent graft system**

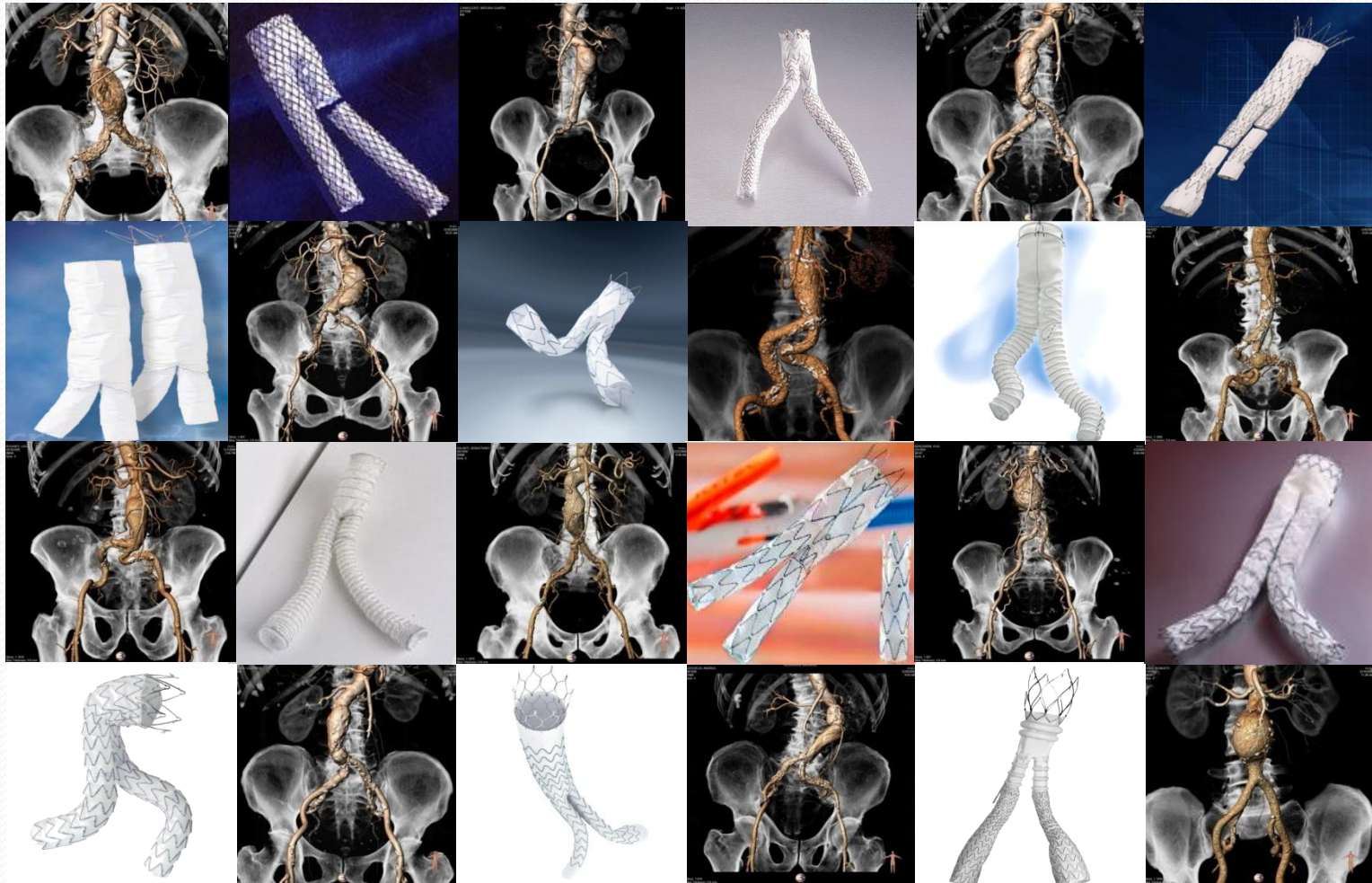
Giovanni Pratesi, M.D.

On behalf of the INNOVATION trial participants

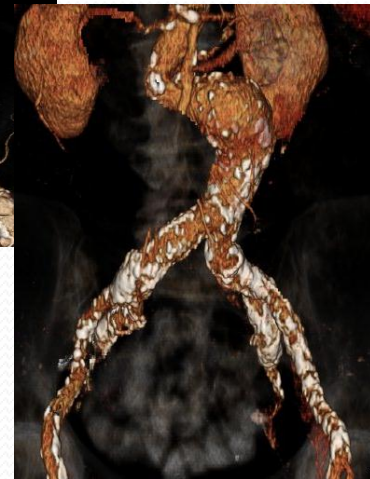
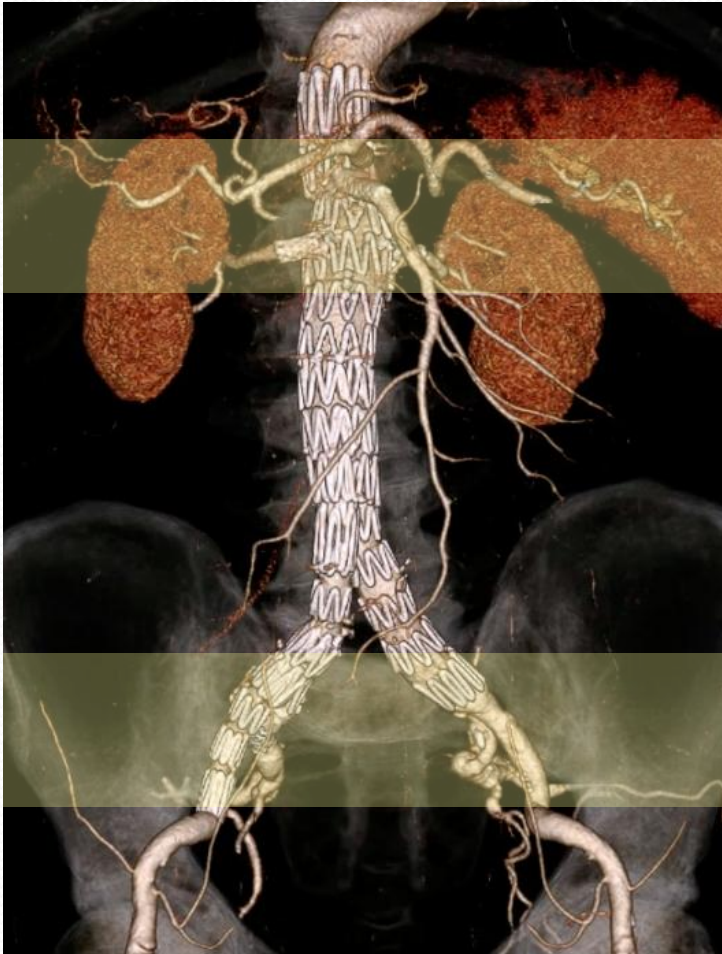
Disclosure

I do not have any potential conflict of interest

Is a new AAA stent-graft system really needed?



How to manage anatomical limitations of standard endograft?



InCraft™: a new customizable, ultra-low profile AAA stent-graft system

3-piece modular system:

- ✓ Low porosity polyester graft
- ✓ Segmented nitinol stents
- ✓ Supra-renal fixation



Customization:

- ✓ Bilateral in-situ length adjustment up to 3cm
- ✓ Partial proximal re-positioning
- ✓ “Few-fits-most” surgical graft concept

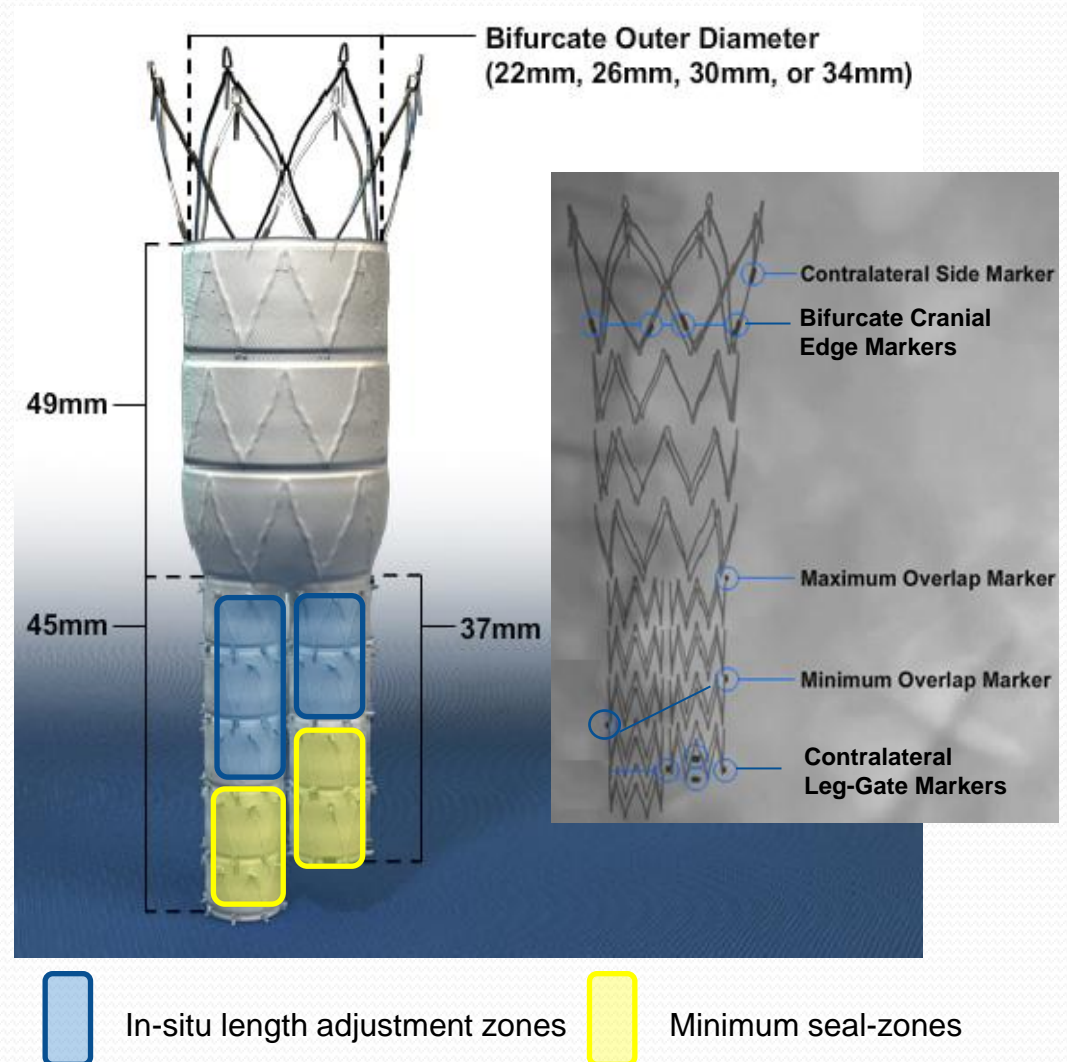
Ultra-low Profile:

- ✓ 13F Integrated Delivery System -14F O.D.
- ✓ Catheter-like shaft flexibility

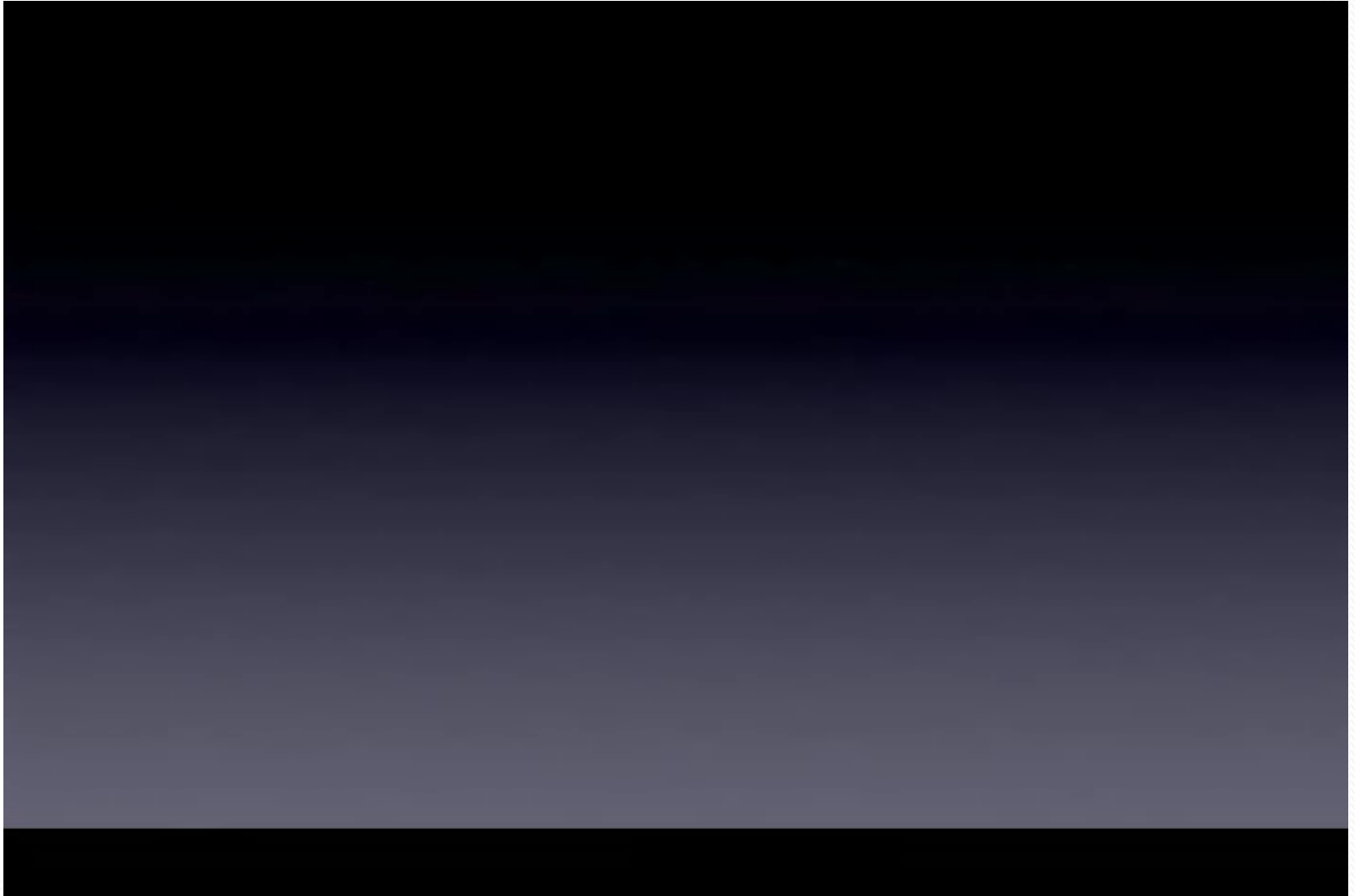


InCraft™ – Aortic Main Body

- Flared bare trans-renal stent with 8 laser-cut barbs (10 for 34 mm AB).
- **4 diameter** sizes (22, 26, 30 and 34mm) allowing treatment of proximal aortic **neck diameters from 17-31mm**.
- Delivery system with a built-in sheath introducer with an outer diameter of **14F** (16F for 34 mm AB).

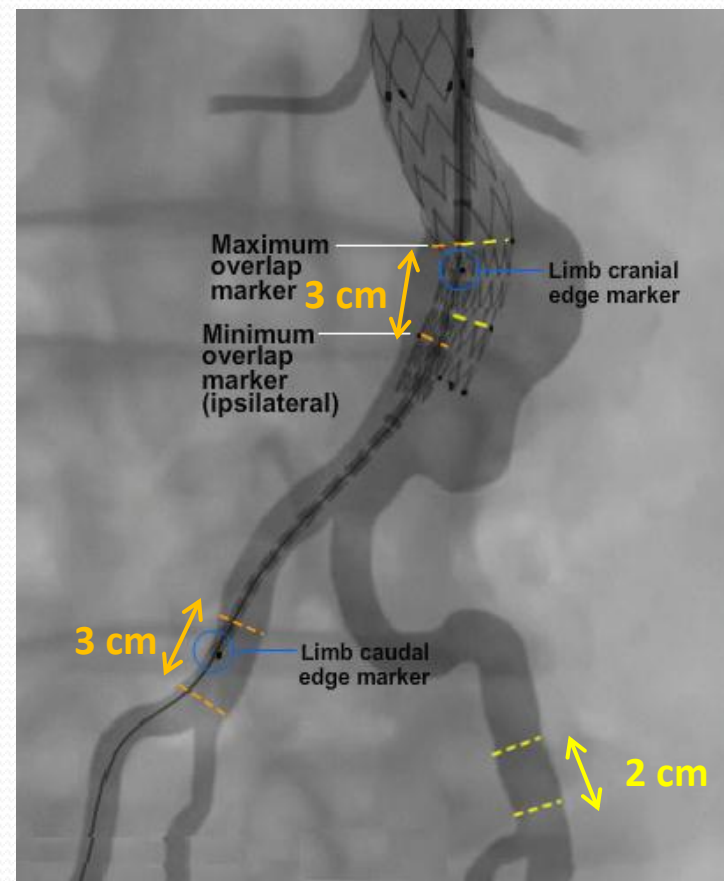
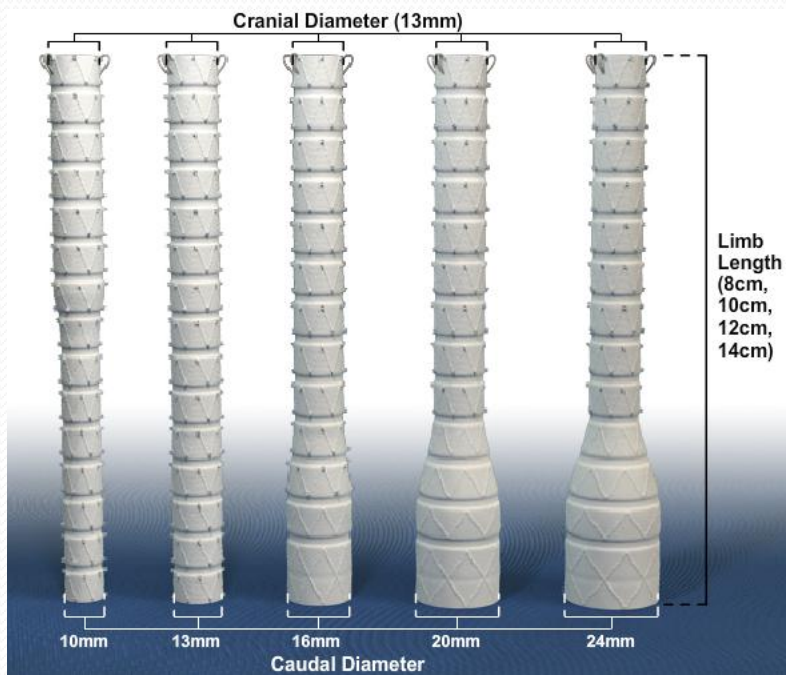


InCraft™ – Aortic Main Body

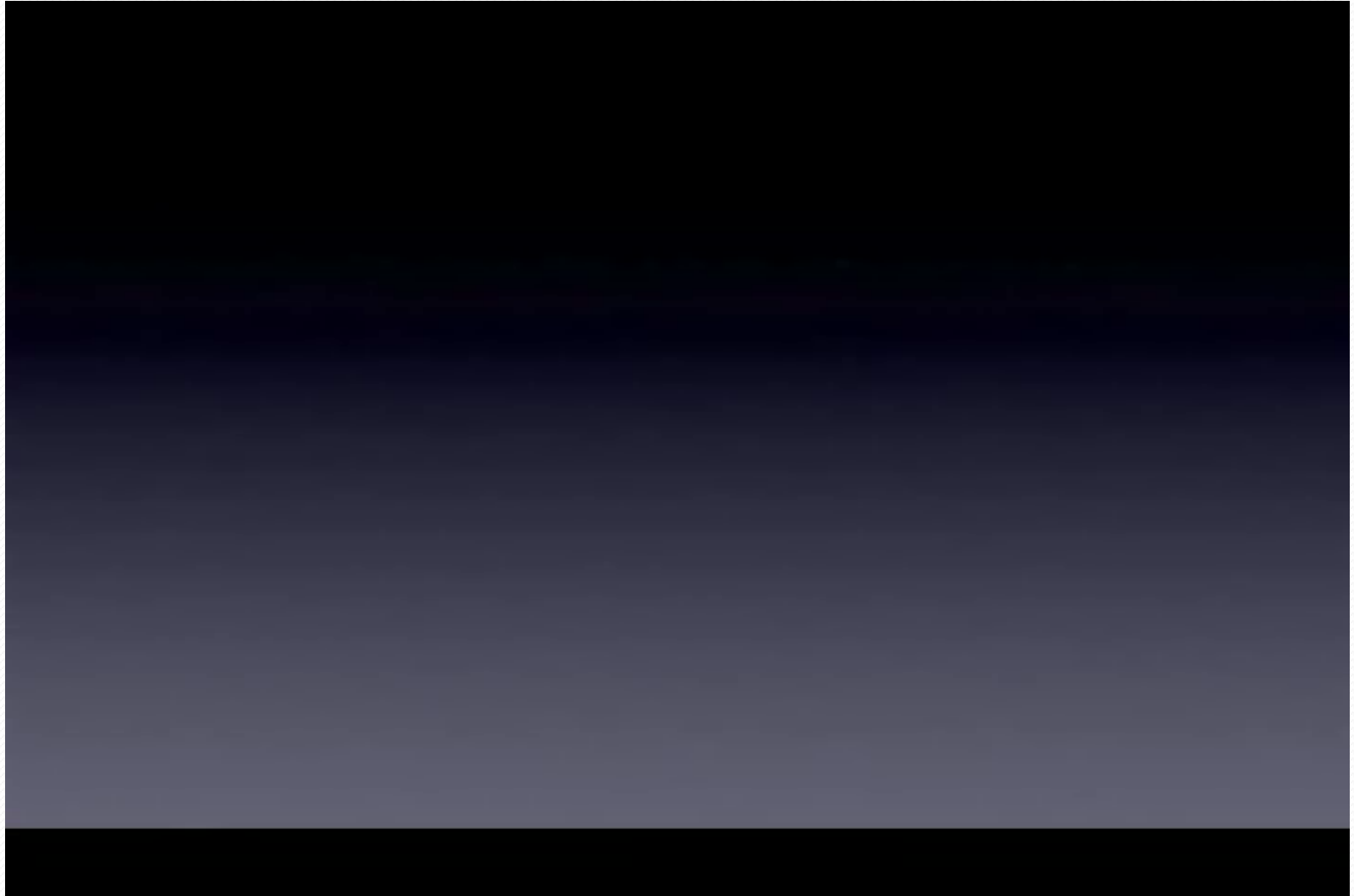


InCraft™ – Iliac Limbs

- Iliac Limb Prostheses available in **5 diameters distally** (10, 13, 16, 20 and 24mm) accommodating iliac arteries ranging from **7-22mm**.
- **4 limb lengths** (8, 10, 12, and 14mm) to treat a overall treatment length range of **12-21 cm**.
- Profile of delivery system for the Iliac Limbs is 12F O.D. (12.5 F for 24 mm IL) .



InCraft™ – Iliac Limbs



The INNOVATION Study

Study Design

- FIH, multi-center prospective, open label, non-randomized investigation of INCRAFT in subjects with AAA.
- 60 patients have been included in 6 German and Italian centers

Objective

- To assess the technical success and safety of the Cordis INCRAFT™ Stent Graft System in subjects with AAA

Primary Endpoints

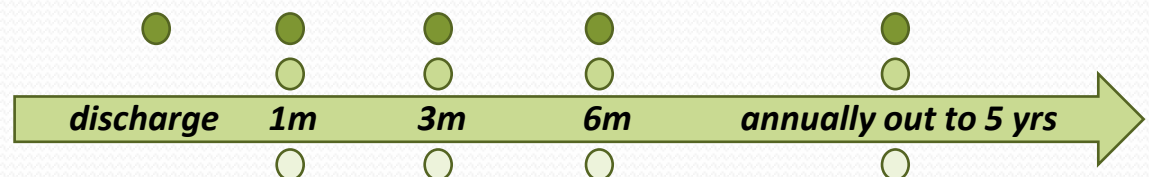
- Successful deployment at desired location and absence of Endoleaks (I, III or IV) post-procedure
- Absence of Endoleaks and device or procedure related major adverse events (MAE) at 30 days

Investigators (enrollement)

- **D:** Prof. D. Scheinert (10); Prof. G.Torsello (17); Prof J. Brunkwall (4)
- **IT:** Prof. G. Coppi (7); Prof. C. Pratesi (14); Prof. R. Chiesa (8)

Follow- up

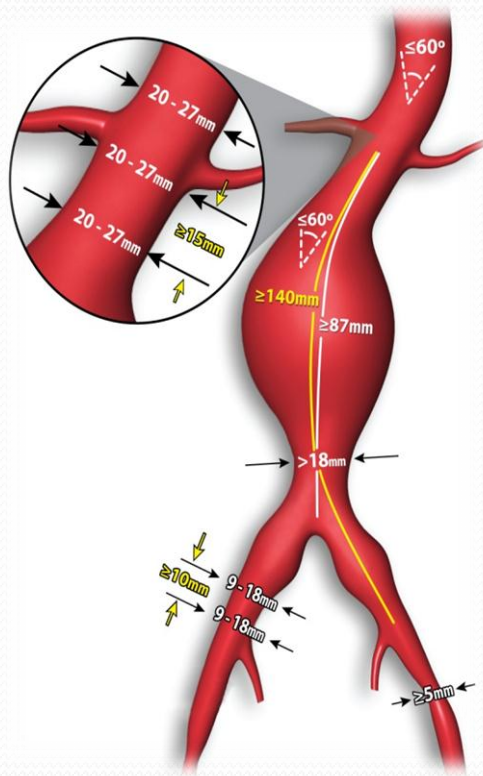
AE assessment
CT scan and X-ray
QOL questionnaire



Pre-Procedural Measurements

Inclusion Criteria

Anatomical Measurements (Core Lab)



	Mean (N=60)	Range (N=60)	% pts with severe morphology *
Infra-renal angle	34.4°	6.9-67.3°	5%
Proximal neck Ø	22.3mm	17-29.5	2%
Neck Length	26.9 mm	5-50	17%
AAA maximum Ø	52.6 mm	35-101	NA
Min. Aortic bifurcation Ø	20.5 mm	11-33	33% [†]
Left iliac seal zone Ø	13.3mm	9-20	13%
Right iliac seal zone Ø	13.7mm	8.7-23	10%
Left min. access Ø	7.1mm	3.6-10	46% [‡]
Right min. access Ø	7.2mm	4.3-10	44% [‡]

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

† Proportion of patients with <18mm Ø (diameter)

‡ Proportion of patients with <7mm Ø (diameter)

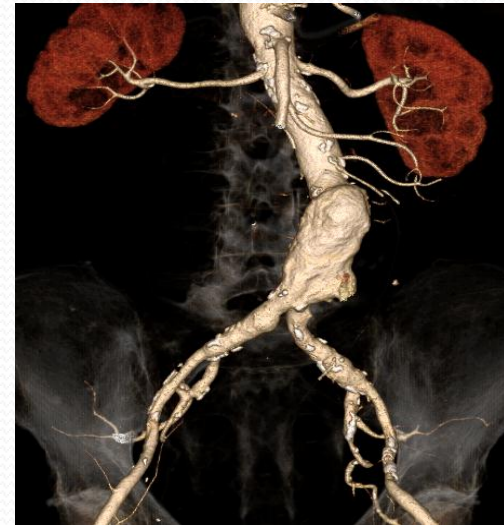
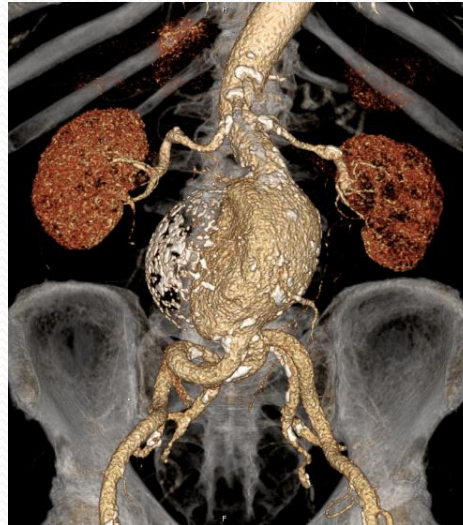
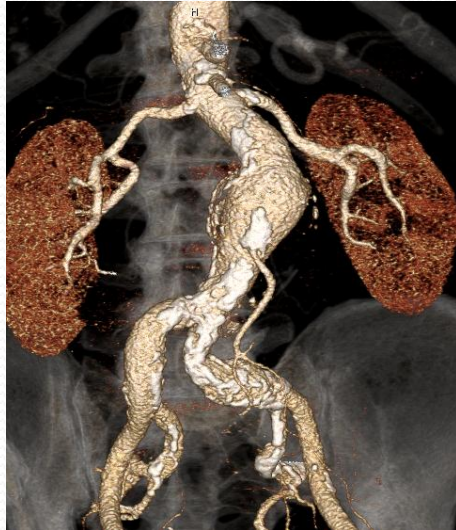
Severe Morphologies in Innovation

Challenging Necks

Challenging Iliacs

Small Access Vessels

Screening CT



Follow-up CT



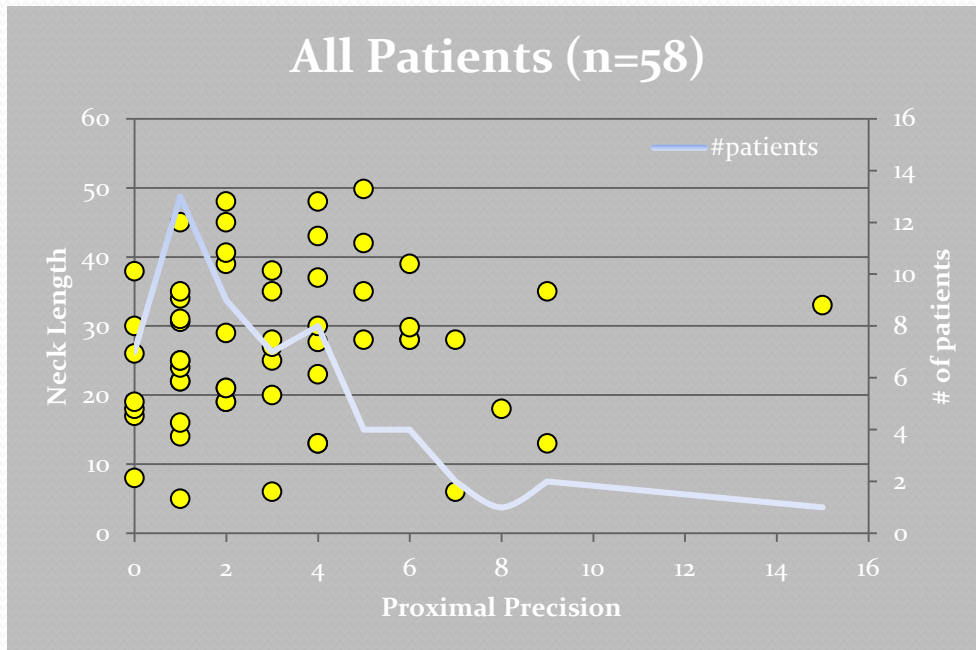
Proximal Accuracy - *Repositioning*

Definition:

distance from lowest renal to bottom of first two cranial graft edge markers

Results:

Median distance from renal artery*
2 mm (-4; 15mm)



* No renal artery coverage



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Distance to the Lower RA:

1M FU = 0 mm; 1Y FU = 0 mm

Distal Accuracy – Customization

Definition:

% of common iliac length covered by graft starting from aortic bifurcation till caudal graft edge marker

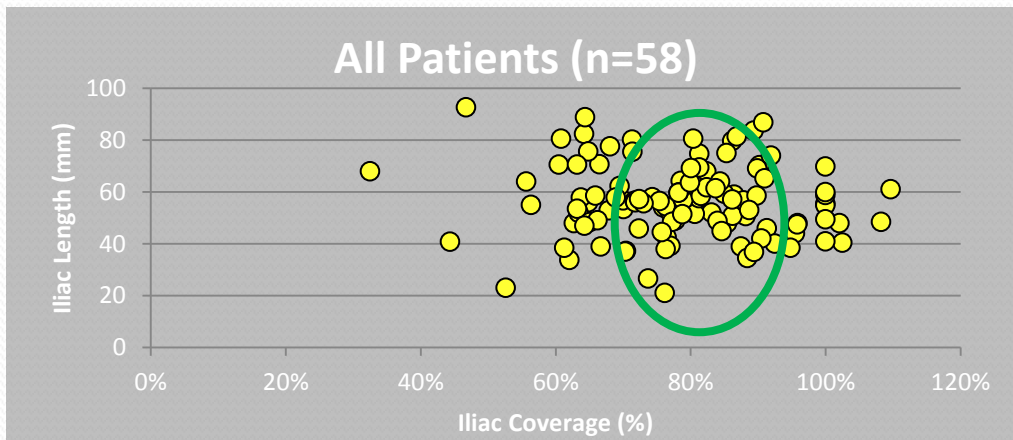
Results:

Median distance from IIA origin*

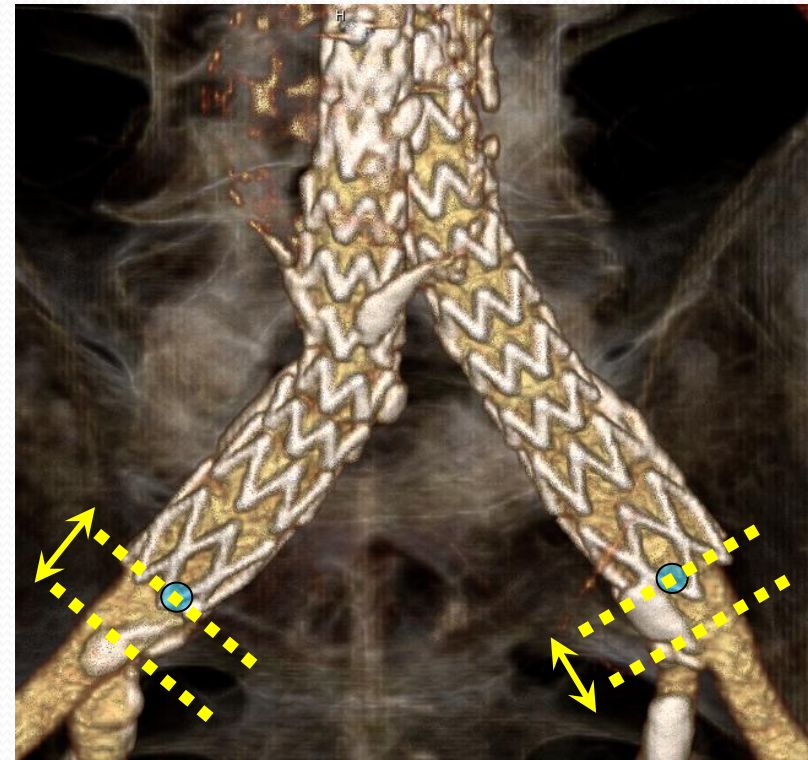
12.2 mm (-5.9; 49.4)

Mean iliac artery coverage:

79% (30-110%)



* No unintentional hypogastric coverage;
no iliac extension required



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Distance to the Rt/Lt CIA: 1M FU = 7 mm

Rt/Lt CIA Coverage: 1M FU = 90%

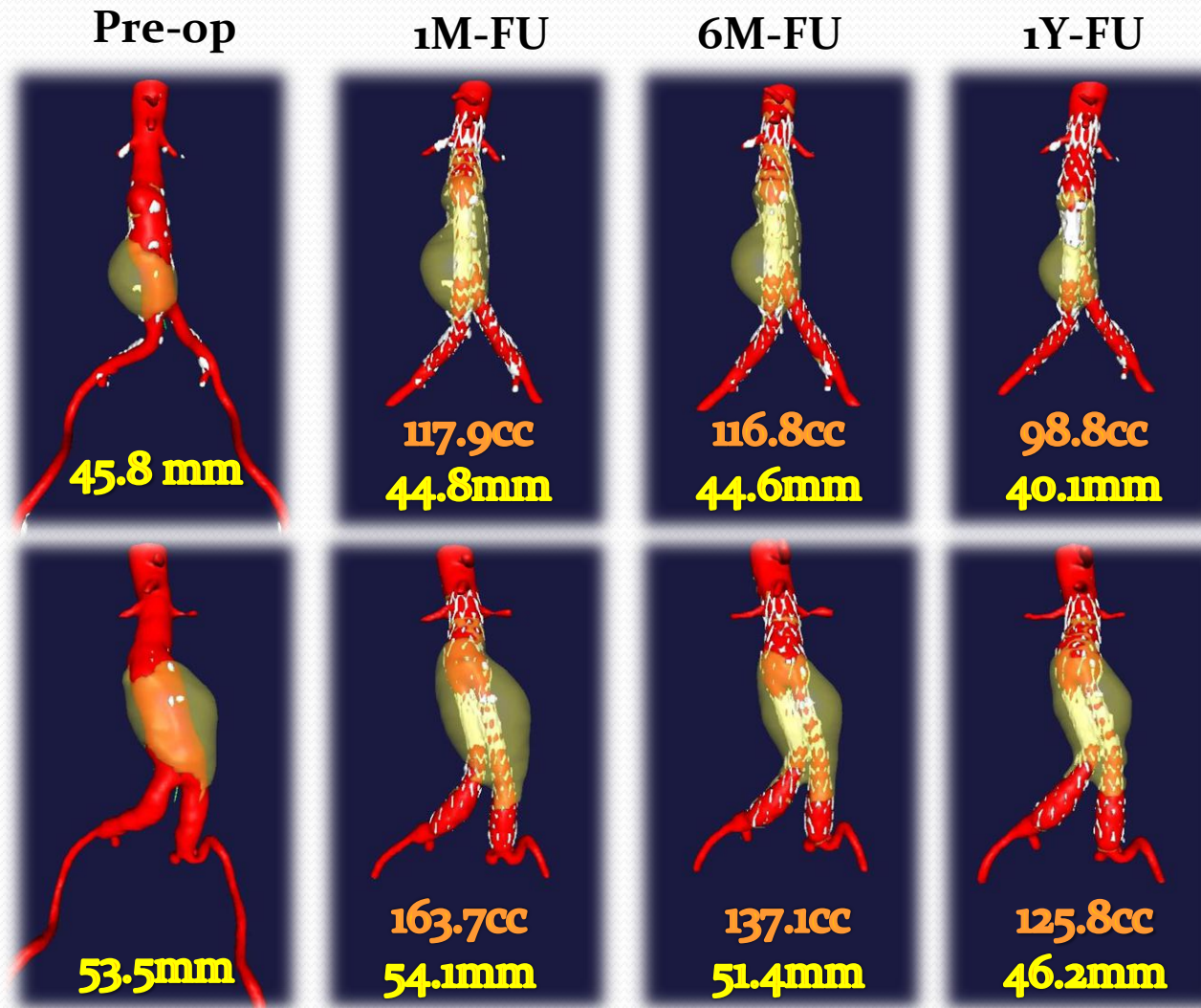
Innovation: 6 months outcomes

	Operative	30 days (58/60)	6 M (56/60)
Successful deployment at desired location	98.3%	NA	NA
Freedom from Endoleak			
Type I	98.3%*	96.6%†	98.2%
Type III	100%	100%	100%
Type IV	93.3%	100%	NA
Stent Graft Patency	100%	100%	100%
Freedom from Migrations	NA	100%	100%
Freedom from Fracture	NA	100%	100%
Freedom from Sac Enlargement	NA	100%	100%
Freedom from MAE (death, QMI, CVA, renal failure)	100%	100%	100%

* Type I EL due to severe calcification in aortic neck, resolved after additional endovascular intervention on day 61

† Second Type I EL was present at 30 day follow-up and resolved after additional endovascular intervention on day 278

Florence experience: 1 year follow-up (n=6/14)

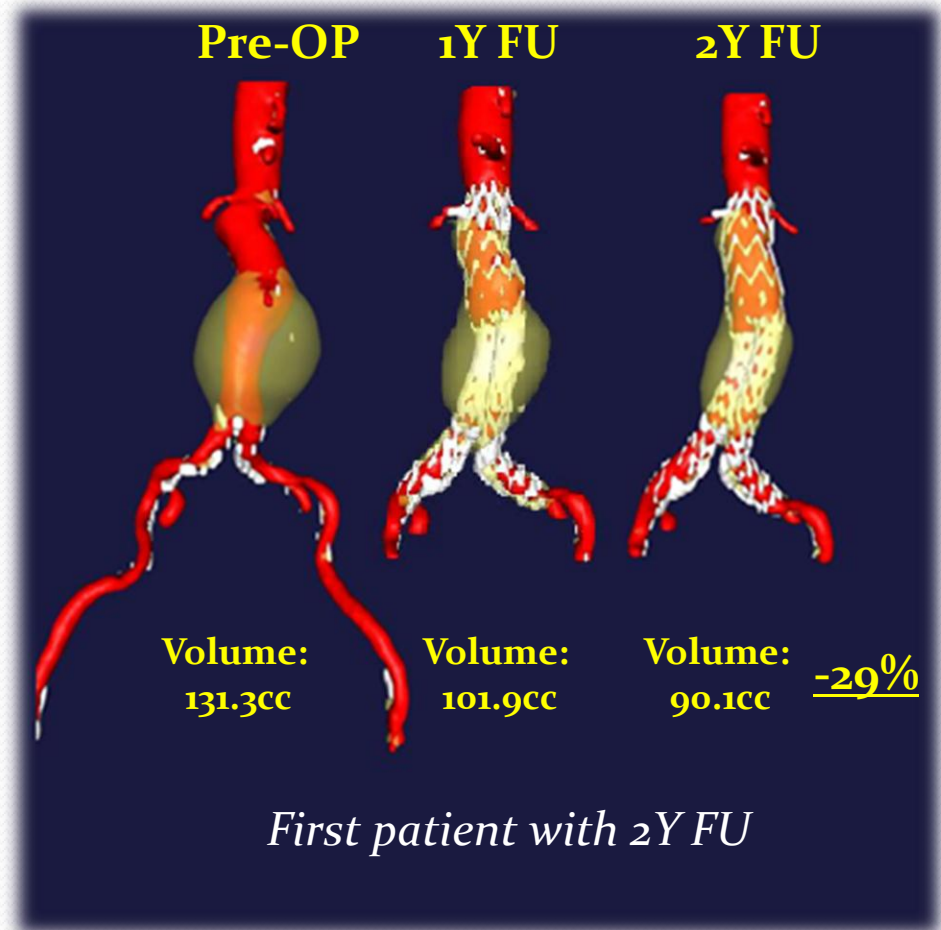


Shrinkage:
- 16.2 %

Shrinkage:
- 23.2%

Conclusions

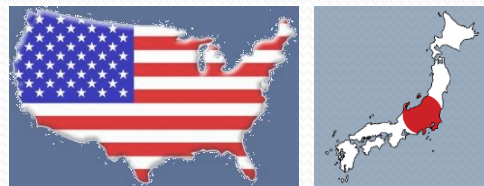
- InCraft™, ultra-low profile abdominal aortic aneurysm stent graft system demonstrated to be:
 - easy to use
 - accurate in placement
 - effective in navigational challenges
- Initial experience and preliminary mid-term results with this new customizable, ultra-low profile AAA stent graft system is encouraging



InCraft™: more data are coming...



150 subjects will be enrolled at up to **25 sites** in Europe, Australia and New Zealand



190 subjects will be enrolled at up to **50 sites** in North America and Japan

