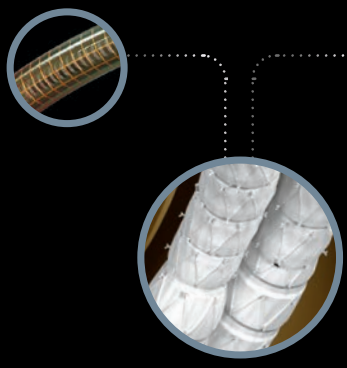
LOW PROFILE, YET DURABLE

ULTRA-LOW PROFILE

DURABLE[1,2]



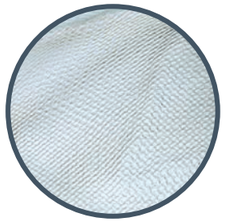
☑ CLINICALLY PROVEN

INCRAFT™

AAA STENT GRAFT SYSTEM

Cordis

CLINICALLY PROVEN DURABILITY

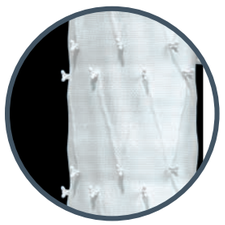


Durable fabric (with proven performance in vascular surgery)

Each prosthesis is constructed of a seamless, low porosity, woven polyester graft to prevent perfusion of the AAA sac [3,4]

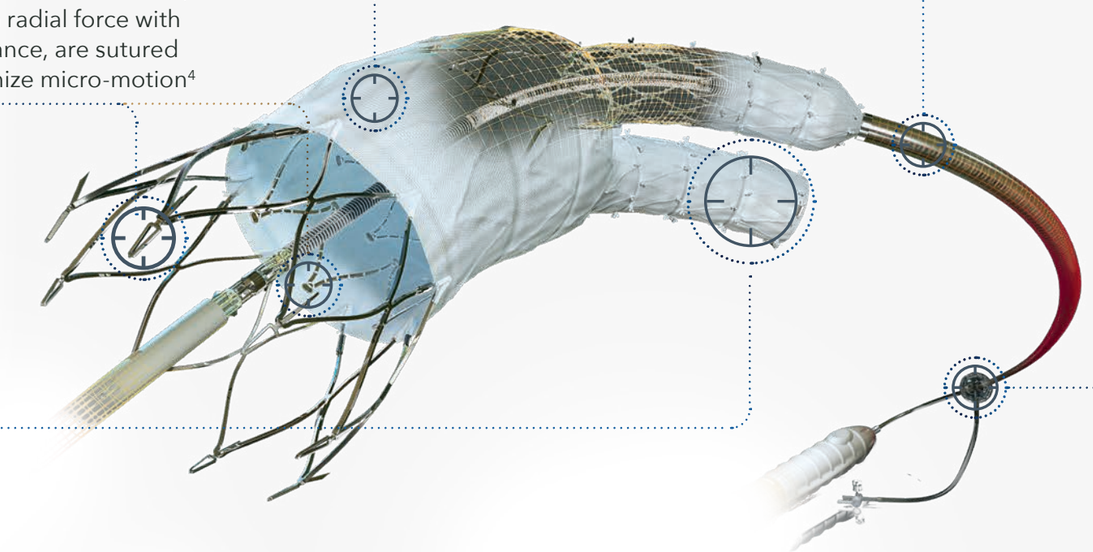
Enhanced Stent Graft Integrity

Biocompatible laser cut nitinol stents, which combine high radial force with stent fracture resistance, are sutured to the graft to minimize micro-motion[4]



Enduring modular junction strength

Durable sealing technology to avoid disconnections and type III endoleaks[4]



LOW PROFILE

Designed for efficient packing into Ultra Low Profile delivery system without sacrificing durability

Advantages of laser-cut, one piece stents with integral barbs for supra- renal fixation

- More efficient packing = lower profile
- Fracture resistance

Low Profile Stent Graft - reengineering established technology

14F (OD) Delivery System

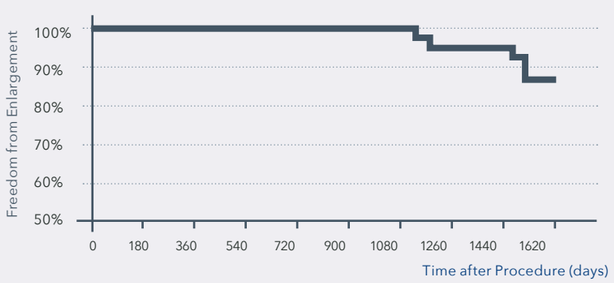
Ultra low profile delivery system
Integrated Introducer Sheath

LONG TERM CLINICAL DATA

INCRAFT™ AAA Stent Graft System Long-term outcomes

INNOVATION 5-year results[2]

Event	4 Years	5 Years
Freedom from Endoleak*		100% (39/39)
Type Ia	100% (39/39)	97.4% (38/39)
Type Ib	97.4% (38/39)	100% (39/39)
Type III	100% (39/39)	
Stent Graf Patency	97.6% (40/41)	97.4%§ (38/39)
Freedom from Migrations	100% (38/38)	100% (37/37)
Freedom from Fracture	97.5% (39/40)	97.4%¥ (38/39)
Freedom from Sac Enlargement	89.7% (35/39)	92.1%# (35/38)
Freedom from MAE (death, QMI, CVA, renal failure)	82.4% (42/51)	76%£ (38/50)



* Any Endoleak contains Type I and III endoleaks that are site-reported and CEC adjudicated.
§ Endoleg non-patency occurred in one subject at 3YFU and is going at 5YFU.
#Both aneurysm enlargement and main body stent-graft migration are defined as being compared to the 30 days baseline CT assessment. One subject did not have 30 days CT and therefore could not be evaluated.
¥ Stent-graft fracture is dedined as stent skeleton fracture and barb separation and identified through X-ray. Fracture occured in one subject at 3YFU and is ongoing at 5YFU. For 7 subjects, X-rays were missing however no fratures were reported through other site imaging.
£ 1 death occured within up to 1 year, 5 within the 2 years timeframe, 2 within 4 years timeframe, 3 within 5 years timeframe, all non-AAA related.

INNOVATION 4 years Publication:

"One of the most important features of the INCRAFT™ AAA Stent Graft System is the precision (proximal and distal) with which it can be deployed. High proximal placement accuracy was achieved during the study"

- "The design of the device permits a high level of deployment precision proximally and distally, maintaining stability with a low rate of migration over long-term follow-up"
- "Durability is maintained despite design attributes that allow reductions in profile comparable to that of a 12F sheath[5]"

INCRAFT™ AAA Stent Graft Post Market Clinical Experience (Muenster)

"Our single center experience has indicated that the INCRAFT™ AAA Stent Graft System achieved generally favorable results although it has been chiefly applied to challenging cases with smaller iliac vessels[6]"

Factors	Group IT *n* = 17	Group CM *n* = 24	*P*
Technical success	17 (100)	24 (100)	
Femoral access			
Cut down/percutaneous	0 (0)/17 (100)	2 (8.3)/22 (91.7)	0.34
Mode of anesthesia			
Regional/spinal	17 (100)/0 (0)	16 (66.7)/8 (33.3)	***0.01***
Adjunctive iliac intervention	0 (0)	8 (33.3)	***0.01***
Fluoroscopy time (min)	21 [18 - 31]	19 [16 - 23]	0.11
Contrast (min)	109 [95 - 140]	105 [94 - 115]	0.32
Intraoperative endoleak			
Type I	0 (0)	0 (0)	
Type II	3 (17.6)	6 (25.0)	0.44
Type III	0 (0)	0 (0)	
Type IV	0 (0)	0 (0)	

Categorical data are expressed as numbers (%).
Continuous data are expressed as the means ± standard deviation or median [interquartile range].
"Bolded italic" ***P***-values < 0.05 are considered to be significant.

OPTIMIZED DEPLOYMENT

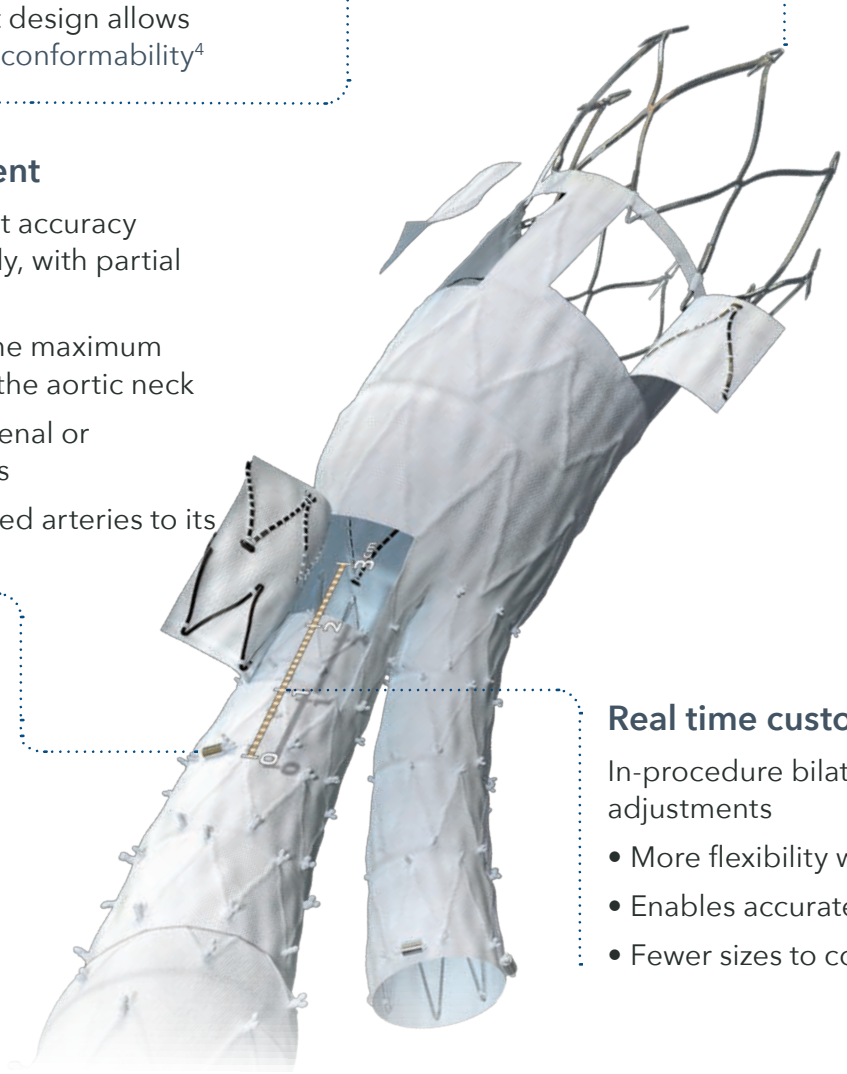
Advanced graft stability

The suprarenal stent design allows optimal fixation and conformability[4]

Accurate placement

Optimized placement accuracy proximally and distally, with partial repositioning

- To be able to use the maximum available length of the aortic neck
- To avoid covering renal or hypogastric arteries
- To cover the diseased arteries to its maximum



Real time customization

In-procedure bilateral in situ adjustments

- More flexibility with sizing
- Enables accurate anatomy coverage
- Fewer sizes to cover more anatomies[4]

References:

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. INNOVATION 5-year results. Torsello G. LINC, 2017.
3. Kannan RY1, Salacinski HJ, Butler PE, et al. Current status of prosthetic bypass grafts: a review. J Biomed Mater Res B Appl Biomater. 2005;74(1):570-581.
4. Pratesi G. INCRAFTTM AAA Stent Graft System 2-year clinical data from the INNOVATION Trial. Presented at: Charing Cross International Symposium. April, 2014. London, UK.
5. INNOVATION: Four-year safety and effectiveness of the INCRAFTTM AAA Stent Graft for endovascular repair of abdominal aortic aneurysms. Prof. Pratesi. JCVS.
6. Post Market clinical experience with the INCRAFTTM AAA Stent Graft System for challenging access routes. Torsello G. Elsevier.