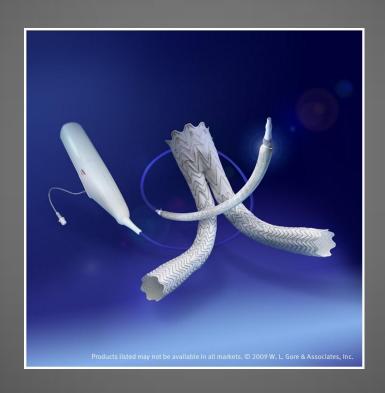
The "new" Redeployable Gore Excluder C3



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On Behalf of all European C3 Investigators

Disclosures

- William Cook Europe/Cook Inc.
 - Consultant
 - Research grant
- W.L. Gore & Associates
 - Consultant
 - Research grant
- Atrium
 - Consultant

Introduction

- Not "new" anymore
 - But still no long-term results
- European C3-Registry
 - 400 Pts within 2 Years (13 Sites)
- Personal experience
 - 76 Pts (74/76 within C3-registry)

C3-concept: Options!

- Step 1: Deployment body
- Step 2:
 - Cathetherization CL limb
 - Re-orientation if needed
 - a-DSA control for proximal position
 - Repositioning if needed
 - Reorientation if desired
- Step 3: Full deployment
 - In cases of adverse anatomy: insertion of contralateral limb before ipsilateral limb deployment
 - Option to adapt the length of ipsilateral limb

European C3 Enrollment

GRT 10-12

Site Number	Site Name	N (%)
203	Nuremberg Hospital	74(18.5%)
209	Cologne University Hospital	26(6.5%)
215	Regensburg University Hospital	13(3.3%)
218	Heidelberg University Hospital	23(5.8%)
263	Hospital Clinic I Provincial de Barcelona	5(1.3%)
264	Orebro University Hopsital	41(10.3%)
278	Aberdeen Royal Infirmary	67(16.8%)
279	Cambridge University Hospitals	32(8.0%)
280	Royal Liverpool University Hospital	38(9.5%)
282	Hull Royal Infirmary	35(8.8%)
283	Weißeritztal Kliniken GmbH	19(4.8%)
284	Azienda Ospedaliera Policlinico Sant'Orsola Malpighi	18(4.5%)
285	Erasmus Medical Center	9(2.3%)
	Total Subjects Enrolled	400

"Real Life" C3 Excluder Registry N = 400

- Neck Length < 1.5 cm: 7.3%
- Neck Angulation ≥ 60°: 11.6%
- Neck Length < 1.5 cm + Angulation ≥ 60°: 2.1%
- Significant Calcification at Landing Zones: 17.6%
- Significant Thrombus at Landing Zones: 11.4%

C3 Repositioning GRT 10-12

	All
Number of Cases Reporting Trunk Repositioning	190/399(47.6%)
Reasons for Repositioning	N=190
Positioning Closer to Renal Arteries	151(79.5%)
Contralateral Gate Positioning	37(19.5%)
Other	29(15.3%)

C3 Repositioning GRT 10-12

Number of Repositions per Case	All
	N=400
0	210(52.5%)
1	123(30.8%)
2	52(13%)
3	12(3%)
4	3(0.8%)

C3 Deployment Accuracy GRT 10-12

Device Deployed Where Planned	385/399 (96.5%)
Deployed within 5mm of intended location	392/399 (98.2%)
Deployed ≥5mm from intended location	7/399 (1.8%)

C3 Extenders Use GRT 10-12

	All
Number of Subjects Enrolled/Devices Implanted	399
Subjects with Aortic Extender(s) Implanted	21(5.3%)
Subjects with Unplanned Aortic Extender(s)	18(4.5%)
Reasons for Unplanned Extender Use	
Increase Seal	8(44.4%)
Increase Radial Force	5(27.8%)
Extend Landing Zone	4(22.2%)
Type I Endoleak	14(77.8%)

C3 Adverse Events and Outcomes GRT 10-12

Number of Enrolled Patients	400	
Any In-Hospital Serious Event	9(2.3%)	
Iliac artery stenosis/occlusion	2(0.5%)	
Pneumonia	2(0.5%)	
Kidney hemorrhage	2(0.5%)	
Retroperitoneal haematoma	1(0.3%)	
Uncoded	2(0.5%)	

Number of Enrolled Subjects	400
Number of Subjects with Devices Implanted	399
30-Day Survival	398/400(99.5%)
30-Day Conversions	2/400(0.5%)

Nürnberg Experience (N=76) Repositioning

No Repositioning: n=33 (43%)

• 1x Repositioning: n=26

– Level only:
n=11

Orientation only: n=11

– Level+Orientation: n=4

More than 1 repositioning: n=17

– Level only:
n=5

— Orientation only: n=1

– Level and Orientation: n=11

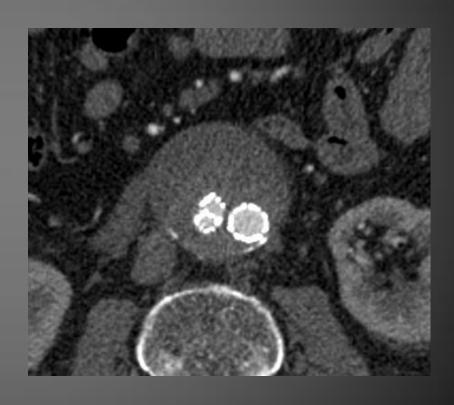
Nürnberg Experience (N=76) Outcome

- Surgical mortality: 0
- Coverage of renal arteries: 1
 - Stent (Express 6x18mm)
- Type I endoleaks: n=2 (#68, #73)
 - CT @ 1 month: No endoleak
- Proximal Landing of the graft:
 - 97.4% intended location
 - 2.6% within 5 mm
- Extender/Cuff use: 0

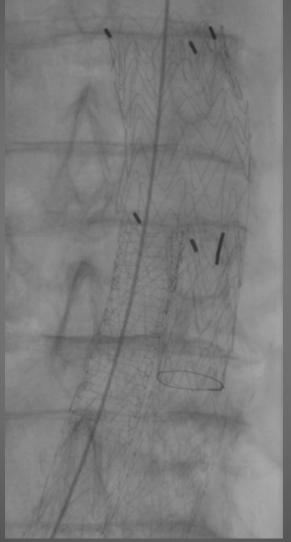
Cave-ats

Over-excessive reorientation (#39)









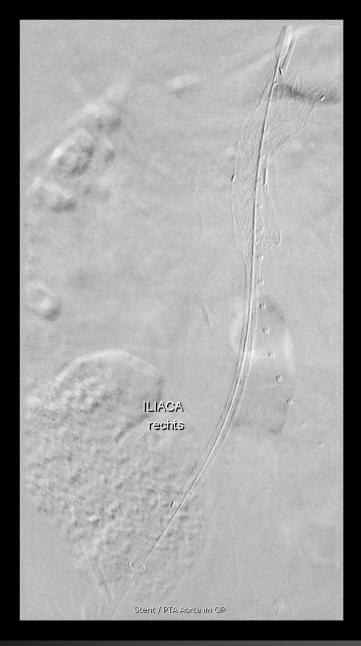


Risk of pushing up Ipsi Limb? (#51)



HGZ Nürnberg AXIOM-Artis

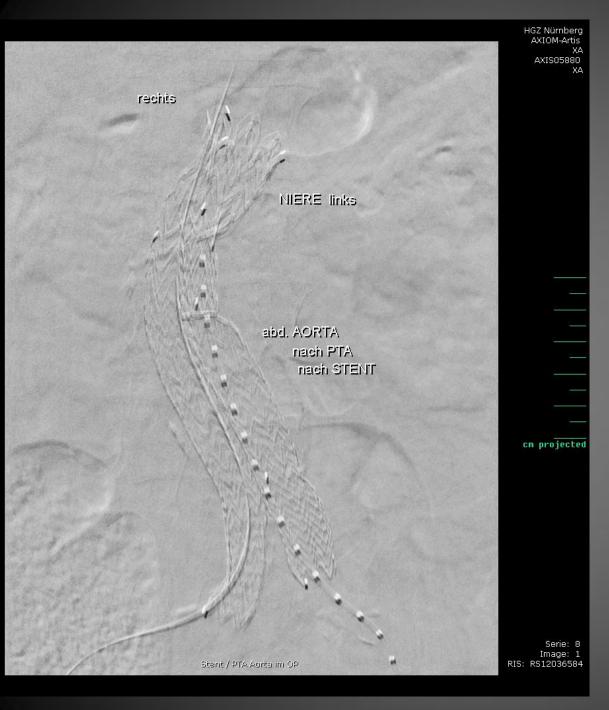
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ILIACA rechts Stent / PTA Aorta im OP

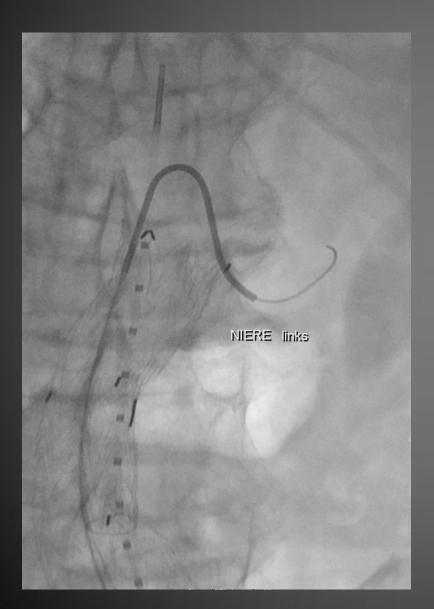
kV: 77.1 DAP: 44.9 mA: 335 FOV(mm) 420.0

9.1925 149



- C3 over LRA
- Ipsi Limb too high!!!!

#51



- Treatment
 - Express 6mm x 18mm
 - Sidewinder fell into LRA

#51



- Treatment
 - Express 6mm x 18mm
 - Sidewinder fell into LRA

Conclusions

- C3 Excluder is a safe and effective device!
- Deployment system allows for aggressive positioning & repositioning
- Lower number of cuffs needed.

 Does make a difference in standard cases and probably even more in difficult anatomy...





17th International Experts Symposium

CRITICAL ISSUES in aortic endografting 2013

June 21 & 22 – Nürnberg, Germany