EVAR secondary interventions with Endoanchors and treatment of type IA endoleaks

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On behalf of the ANCHOR trial collaborators

Critical Issues, Lille
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Disclosures:

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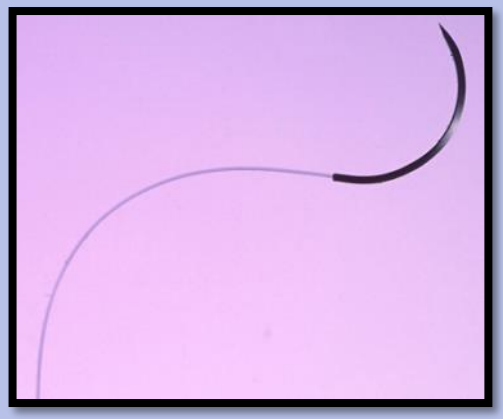
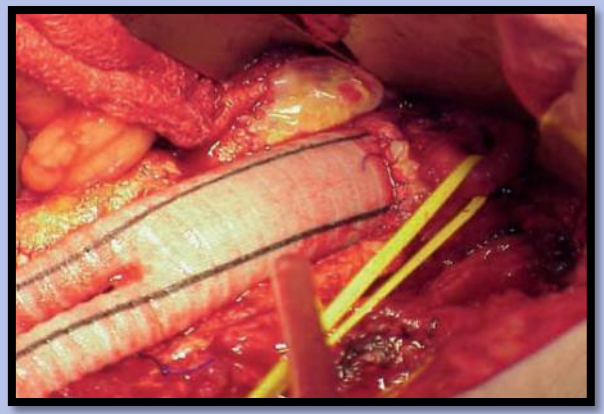
Research grants: Cardionovum, Angiocare, Endologix, BTG, St. Antonius Fund

Tailored Seal and Fixation of EndoAnchors

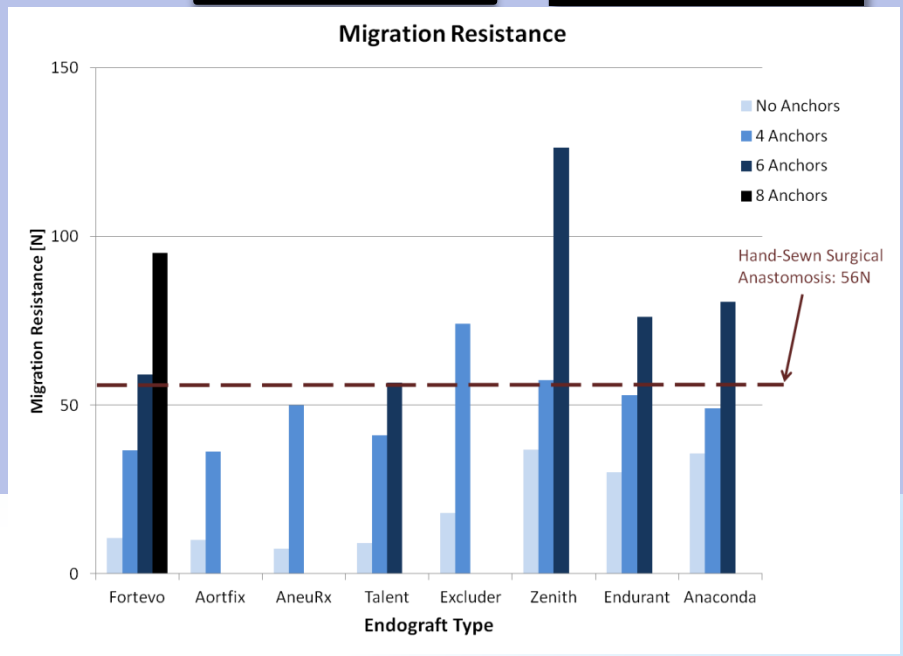
CREATE THE STABILITY OF A SURGICAL ANASTOMOSIS IN EVAR AND TEVAR

Surgical Anastomosis





EndoAnchoring



ANCHOR Registry – Capturing real world-usage

Registry Design	Prospective, observational, international, multi-center, dual-arm Registry
Treatment Arms	"Primary" – Up to 1000 pts, Prophylactic
	"Revision" – Up to 1000 pts, Therapeutic
Enrollment & Duration	Enrollment began 2012 and patients will be followed for 5 years
Follow-up	Per Standard of Care at each center & discretion of Investigator

Registry Principal Investigators	Europe: Dr Jean-Paul de Vries – Chief of Vascular Surgery, St. Antonius Hospital
	US: Dr William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine

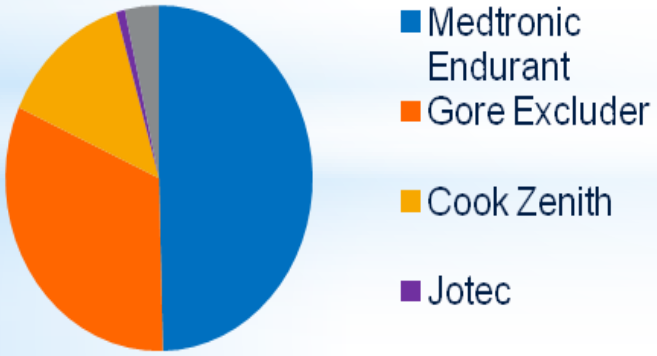
ANCHOR Registry – Enrollment Status (data cut Aug 10, 2015)

ANCHOR Registry
593 Subjects
(74.9% US/25.1% OUS)

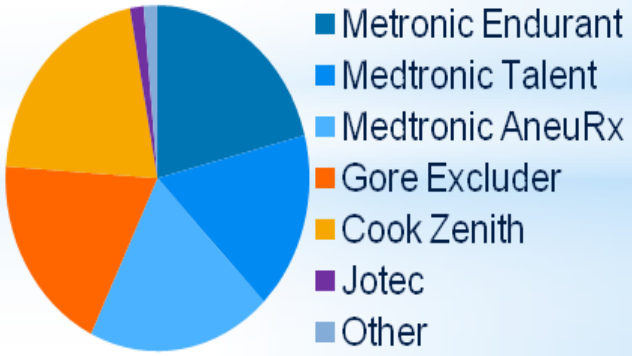
Primary Arm
439 Subjects

Revision Arm
154 Subjects

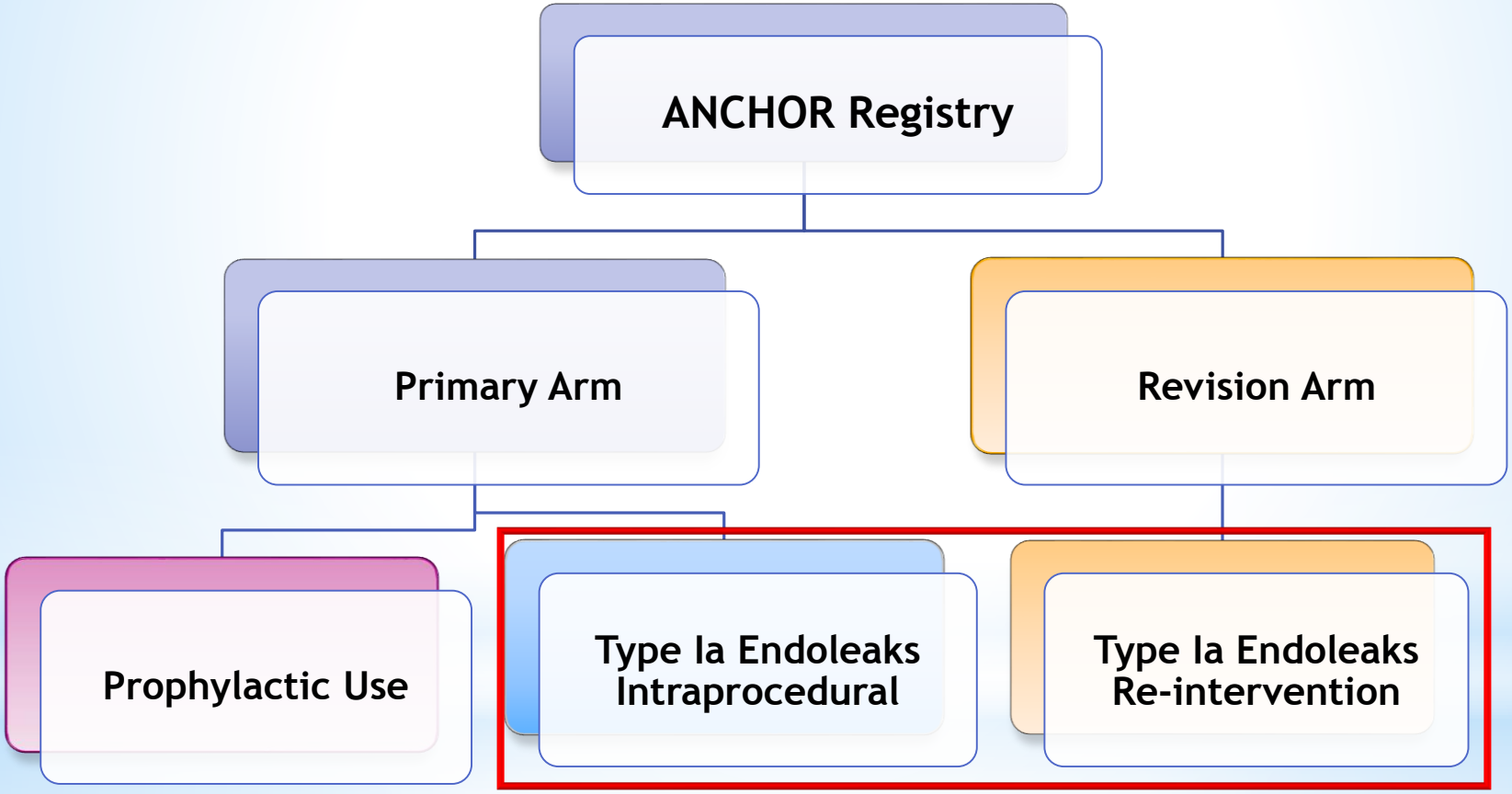
Stent Grafts - Primary Arm



Stent Grafts - Revision Arm



ANCHOR Registry – Therapeutic Use



ANCHOR Registry – Therapeutic Use for Proximal ELs

Location	Sites	%	Subjects	%
United States	35	70.0%	205	77.9%
Europe	15	30.0%	57	22.1%
All	50	100.0%	263	100.0%

Demographics	Primary	Revision
Male (N/N, %)	109/141 77.3%	97/122 79.5%
Urgent Cases	13/141 9.2%	18/122 14.8%
Age (years)	76.3	80.1
Height (cm)	176.0	172.9
Weight (kg)	84.2	84.8
BMI (kg/m^2)	27.1	28.2

ANCHOR Registry – Therapeutic Use for Proximal ELs

Indication	Number	Percent
Primaries	**141**	**53.6%**
Prophylactic	0	0.0%
Endoleak	141	53.6%
Endograft Misdeployment	0	0.0%
Revisions	**122**	**46.4%**
Late Type Ia Endoleak	82	31.2%
Endograft Migration	0	0.0%
Migration and Ia Endoleak	40	15.2%

ANCHOR Registry – Therapeutic Use for Proximal ELs

Anatomic Index	All	Primary	Revision
Number with Baseline CT Scans	161	106	55
Aneurysm Diameter (mm)	61.1	56.6	65.9
Proximal Neck Length (mm)	**16.2**	**16.8**	**14.8**
Suprarenal Diameter (mm)	27.8	27.1	29.1
Infrarenal Diameter (mm)	**27.2**	**26.1**	**29.2**
Suprarenal Angulation (degrees)	16	17.7	12.9
Infrarenal Angulation (degrees)	36	37.8	34.0
Neck Thrombus Thickness (mm)	0.6	0.5	0.9
Neck Calcium Thickness (mm)	1.0	1.3	0.4
Conical Neck (Subjects >10%/10mm)	**42.2%**	**38.7%**	**49.1%**
Hostile Necks	**74.5%**	**73.6%**	**76.4%**

ANCHOR Registry – Therapeutic Use for Proximal ELs

Details of Index Procedure	Primary	Revision
Duration of Procedure (min)	159	158
Time to Implant EndoAnchors (min)	**20**	**23**
Number of EndoAnchors	**6.1**	**7.7**
Fluoroscopy Time (min)	37	33
Technical Success (Site-Reported)	**95.7%**	**93.4%**
Procedural Success (Site-Reported)	85.1%	82.8%
ICU Admission	25.5%	32.0%
Length of Hospitalization (days)	3.9	6.8

ANCHOR Registry – Therapeutic Use for Proximal ELs

Adjunctive Devices	Primary (N=141)	Revision (N=122)	All (N=263)
Aortic Extender Cuff	25 (17.7%)	62 (50.8%)	87 (33.1%)
Giant bare stent (e.g. Palmaz)	2 (1.4%)	4 (3.3%)	6 (2.3%)
Cuff + Palmaz	0 (0%)	2 (0.8%)	2 (0.8%)
Chimney	0 (0%)	2 (0.8%)	2 (0.8%)
Fenestrated	0 (0%)	1 (0.4%)	1 (0.4%)
Debranching	0 (0%)	1 (0.4%)	1 (0.4%)
EndoAnchors alone	114 (80.9%)	50 (41.0%)	164 (62.4%)

ANCHOR Registry – Therapeutic Use for Proximal ELs

Adverse Events *Mean Follow-Up 18.9m*	Primary (N=141)			Revision (N=122)		
	Events	Subjects With Events		Events	Subjects With Events	
Adverse Events	165	63	45.0%	209	78	63.9%
Serious Adverse Events	93	44	31.4%	107	54	44.3%
Procedure-Related SAE	14	9	6.4%	11	9	7.4%
Endograft-Related SAE	0	0	0.0%	4	3	2.5%
EndoAnchor-Related SAE	0	0	0.0%	3	2	1.6%
Aneurysm-Related SAE	12	3	2.1%	12	9	7.4%
Unrelated SAE	61	32	22.9%	55	36	29.5%
Rupture of AAA	0	0	0.0%	1	1	0.8%
All-Cause Mortality	6	6	4.3%	6	6	4.9%

Persistent / recurrent type IA endoleaks

CORE LAB
MEAN CT FOLLOW-UP 10.4 MONTHS

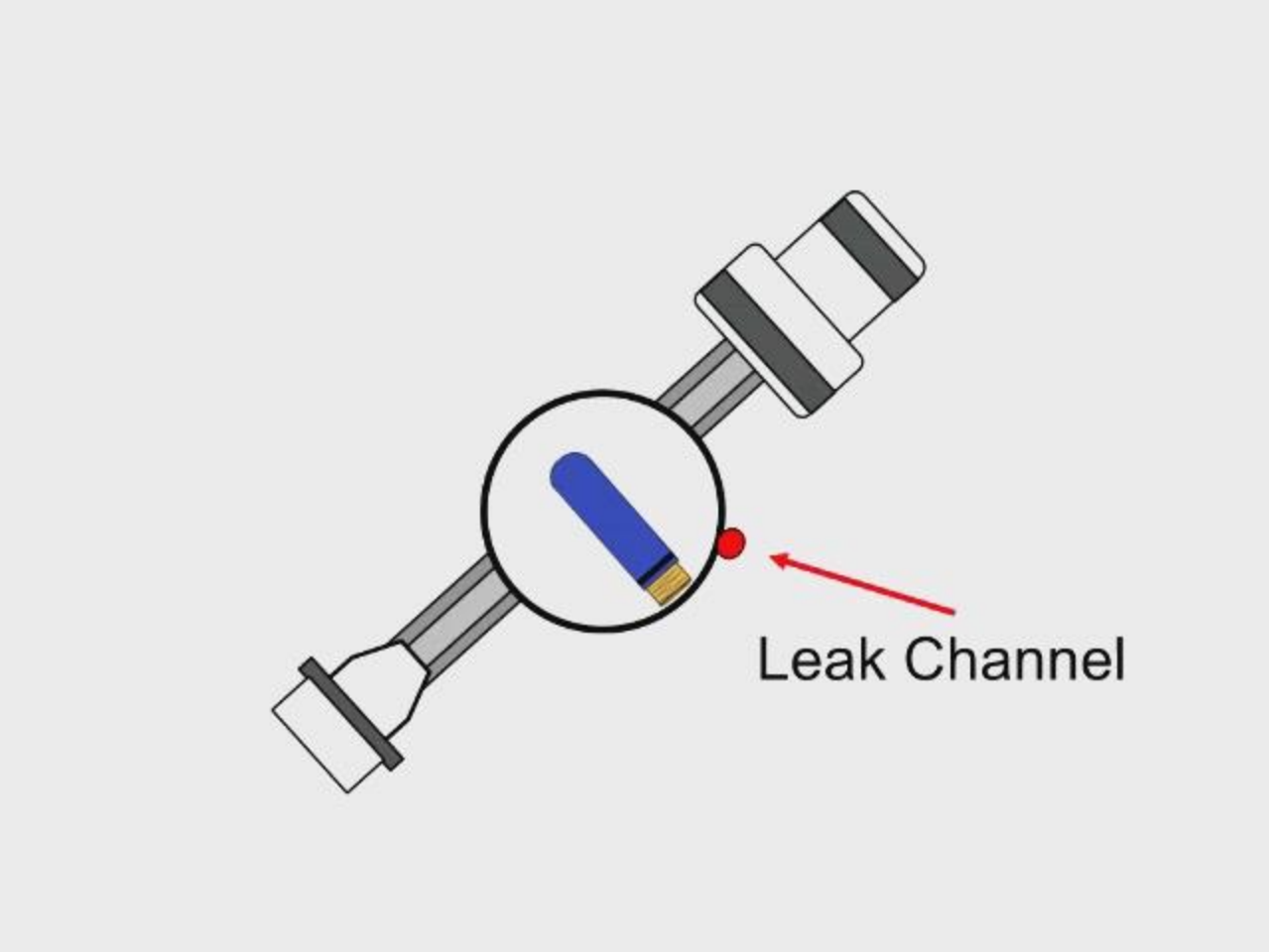
Cohort	All Cases		
	1a ELs	CTs	%
All	24	142	16.9%
Primary	3	76	3.9%
Revision	21	66	31.8%

Treatment of persistent / recurrent type IA endoleaks

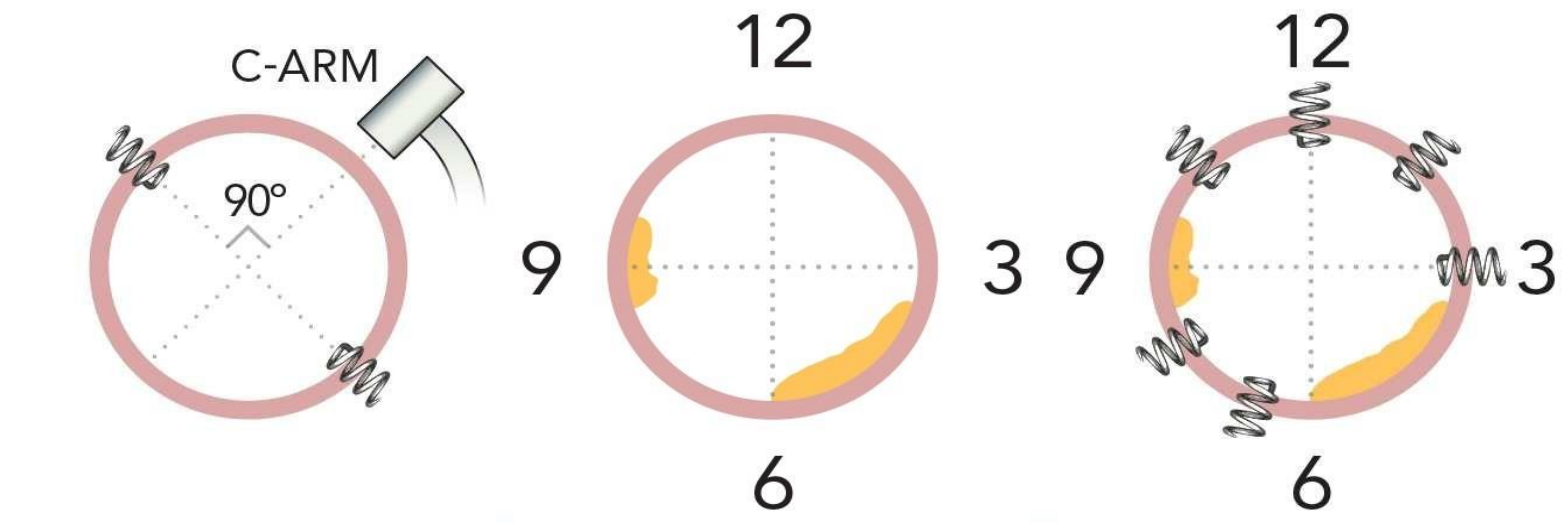
Reinterventions*	Number (%)	Successful**
Open surgical conversion	2/24 (8%)	2/2
Fenestrated graft	2/24 (8%)	0/2
Additional EndoAnchors	1/24 (4%)	0/1
Aortic extension cuff	1/24 (4%)	No Imaging
No additional procedures reported	18/24 (75%)	N/A

**Data from 24 patients with persistent Type Ia endoleaks reported by the Core Laboratory.*
***Successful is defined by no type Ia endoleak on imaging studies after the reintervention.*

C-arm position for type IA endoleaks/ revisions



What We've Learned: C-arm position

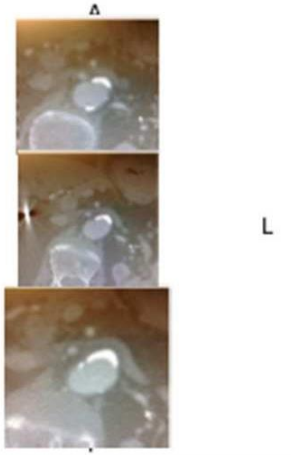
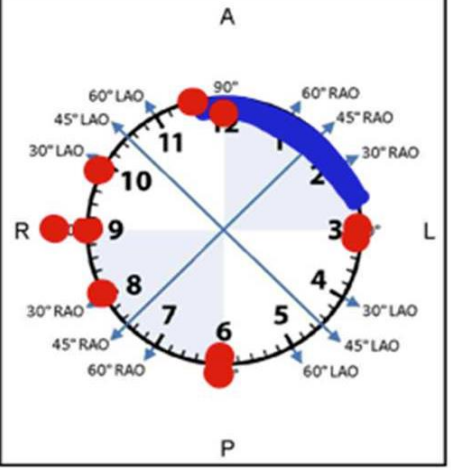


Pre-op planning C-arm crucial

HELIFX – AORTIC SECUREMENT SYSTEM

Pre- Case Planning Worksheet

Patient Initials / ID:	L.R.	Physician:	Dr. Jordan	Prepared By:	Charmaine Hunt
DOB / Gender:		Hospital:	UAB	Date Prepared:	6/25/13

Coronal View	Axial View	C-Arm Angle Reference
(Measure proximal neck length, diameters, & angle)	(Note thrombus/calcium – plan EndoAnchor locations)	(Adjust C-Arm for desired EndoAnchor location)
10 anchors 2 at 9:00, one top, one beneath 2 at 3:00, one on top, one beneath 2 at 6:00, one on top, one beneath Last anchor deployed at 90 LAO w/slight posterior "C" - miss deployed or hit calcium & didn't appear to penetrate wall; however did not move from place it was implanted		

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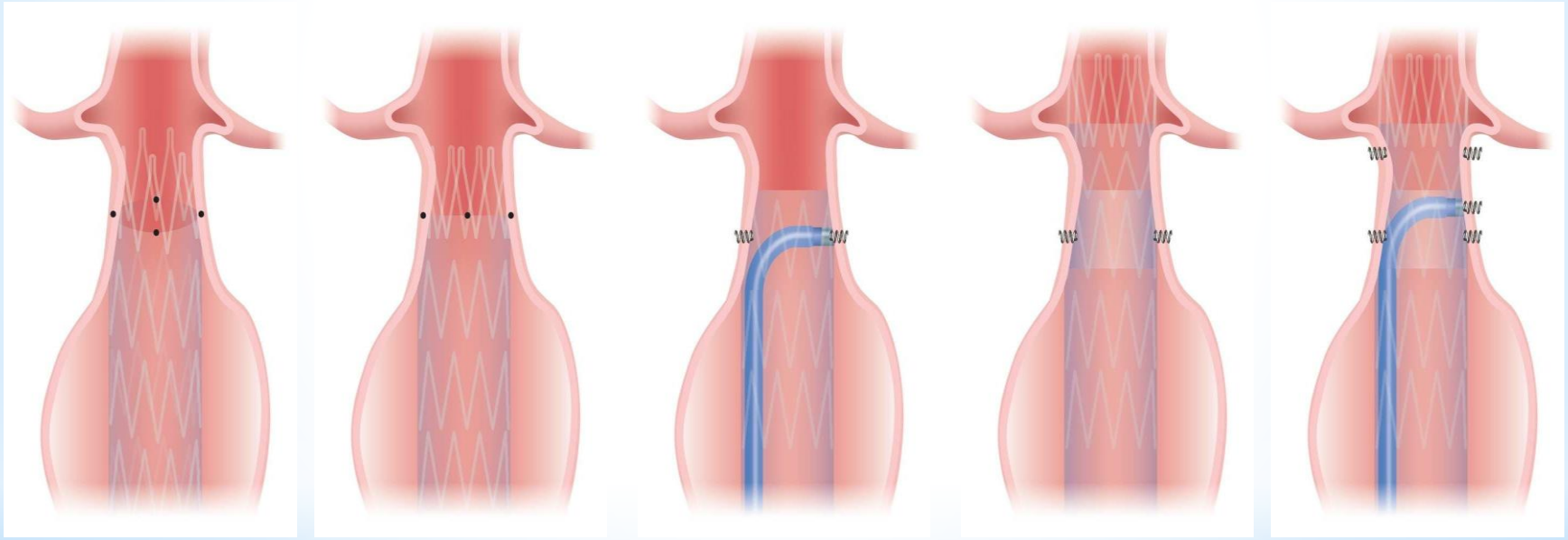
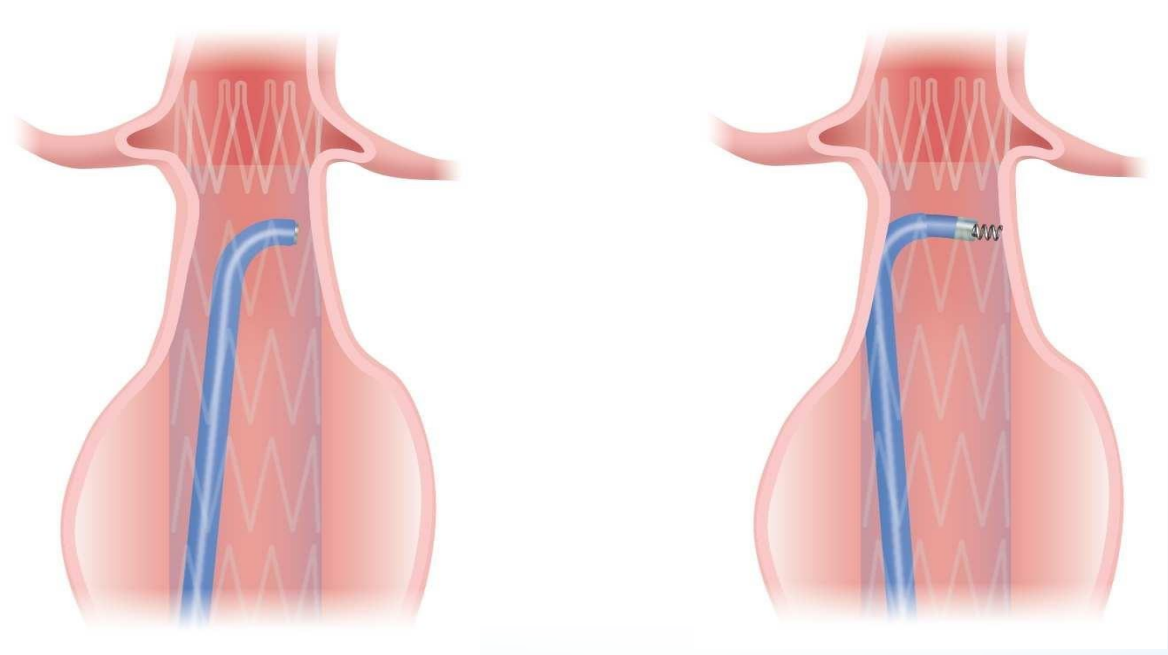
Courtesy dr. W. Jordan jr.

What We've Learned: Sequence of Steps



What We've Learned: Don't undersize the Applier

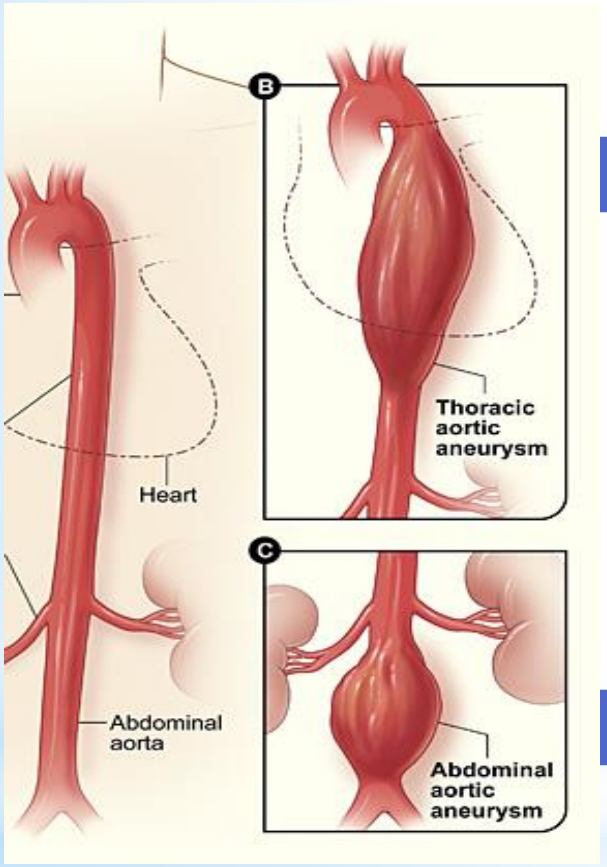


Support of the Applier at the opposite wall

Pushing the endograft towards the aortic wall

Prevent wiggling of EndoAnchors

Length of endoguide tip = diameter aortic neck



Aptus™ Heli-FX™ Thoracic EndoAnchor ™System

18Fr OD,
90cm working length

Aptus™ Heli-FX™ Abominal EndoAnchor™ System

16Fr OD,
62cm working length

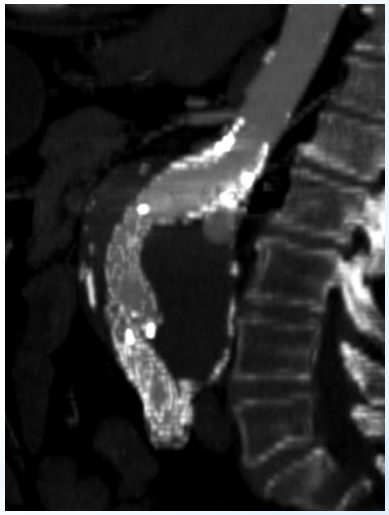
When Endoanchors not to use

Lack of EndoAnchor penetration in aortic tissue may increase risk of developing/re-developing type I endoleaks

CoreLab assessment of etiology of residual type 1A after EndoAnchor placement (N =17)

Reason for persistent type 1a endoleak	Number of cases
Calcified Rim	5
Gap between graft and aortic wall	6
EndoAnchor deployed above graft fabric	3
EndoAnchor deployed in aneurysm sac	4
EndoAnchor not oriented perpendicular to graft wall	2

4 subjects had two reasons identified for persistent type 1a endoleak



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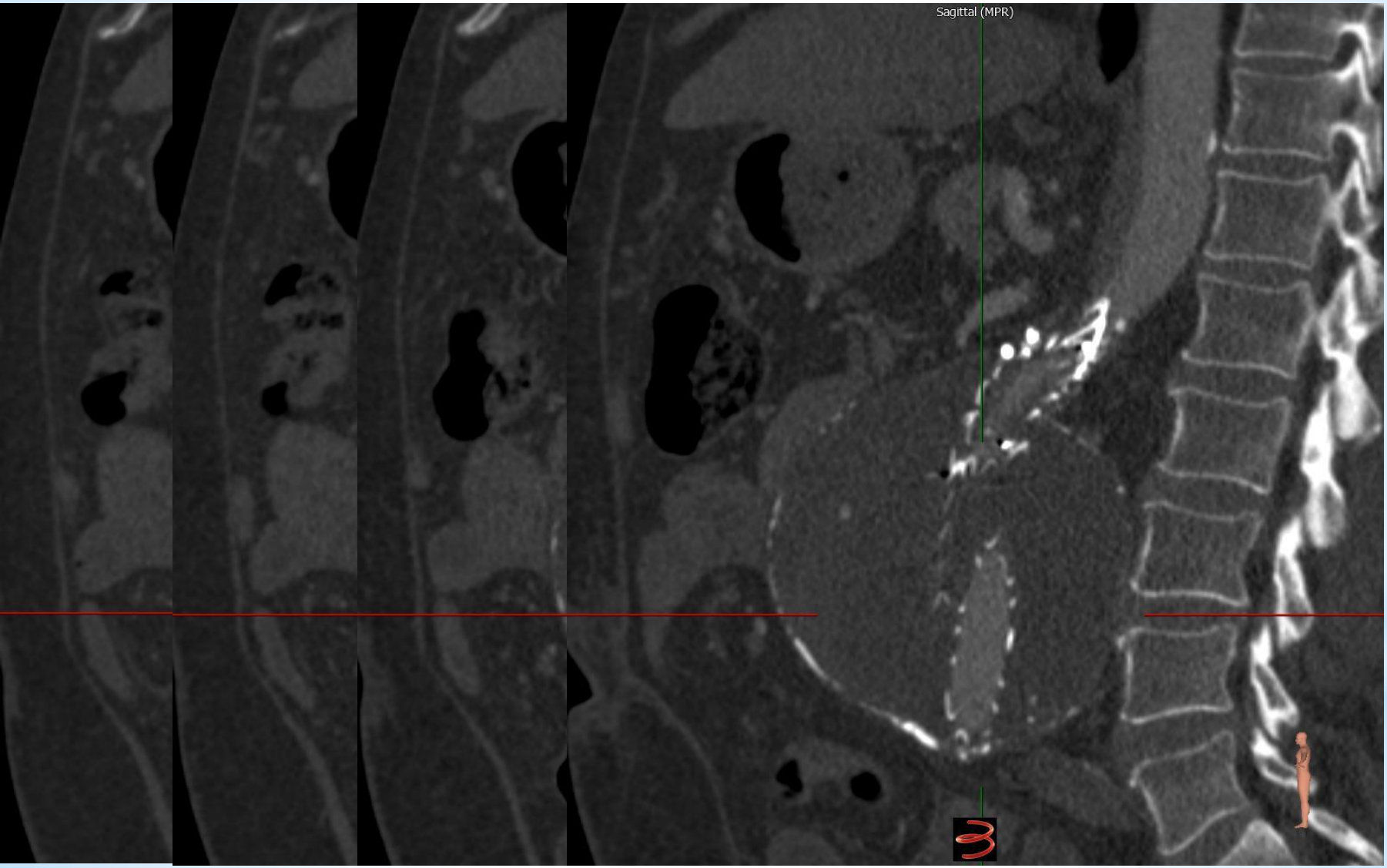

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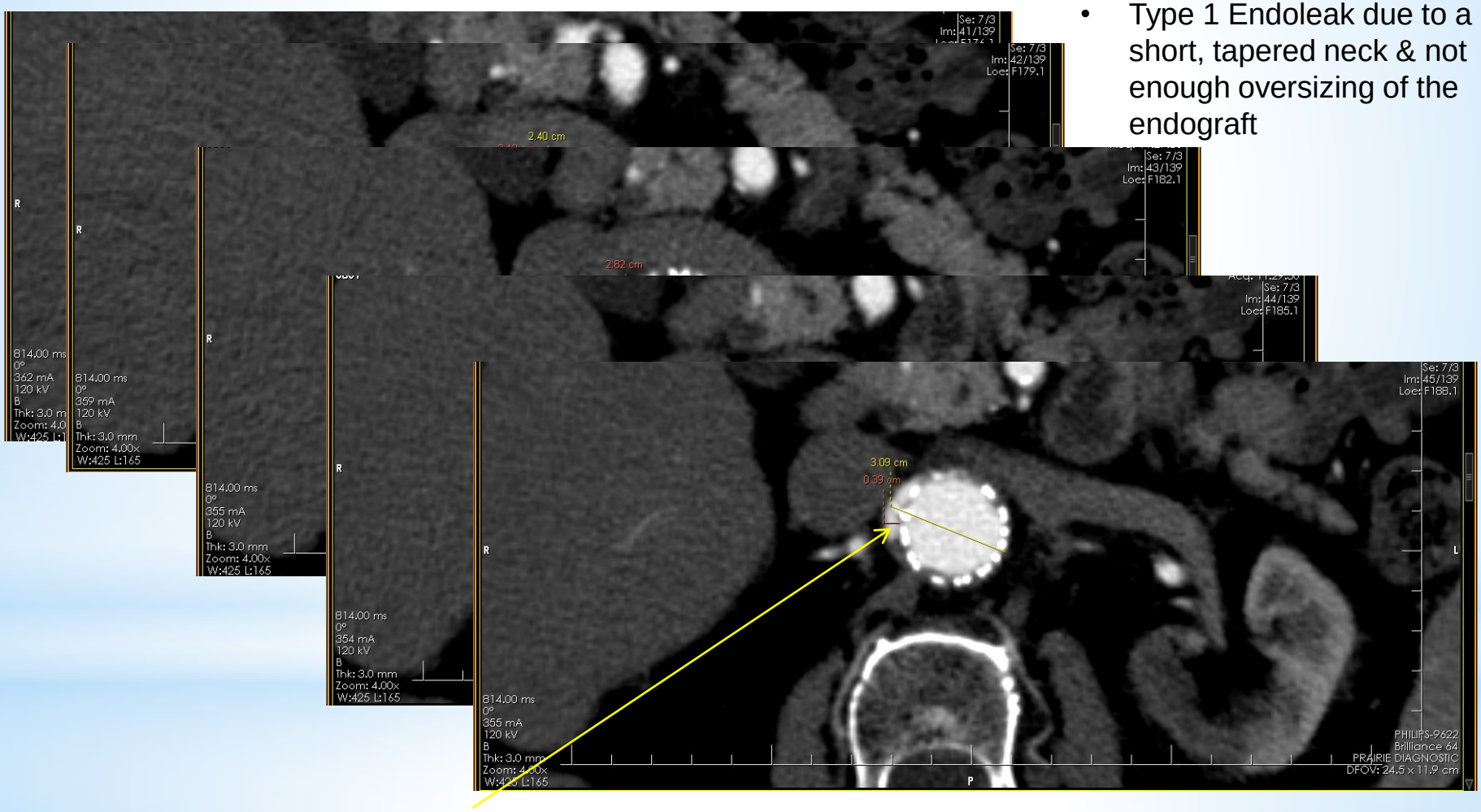

- Type 1 Endoleak due to a short, tapered neck & not enough oversizing of the endograft

- A 4mm gap where the neck is dilated beyond the graft. Anchors were not used because the gap was too wide for the anchors to penetrate the adventitia

Case #1: type IA endoleak 2 years post-implant

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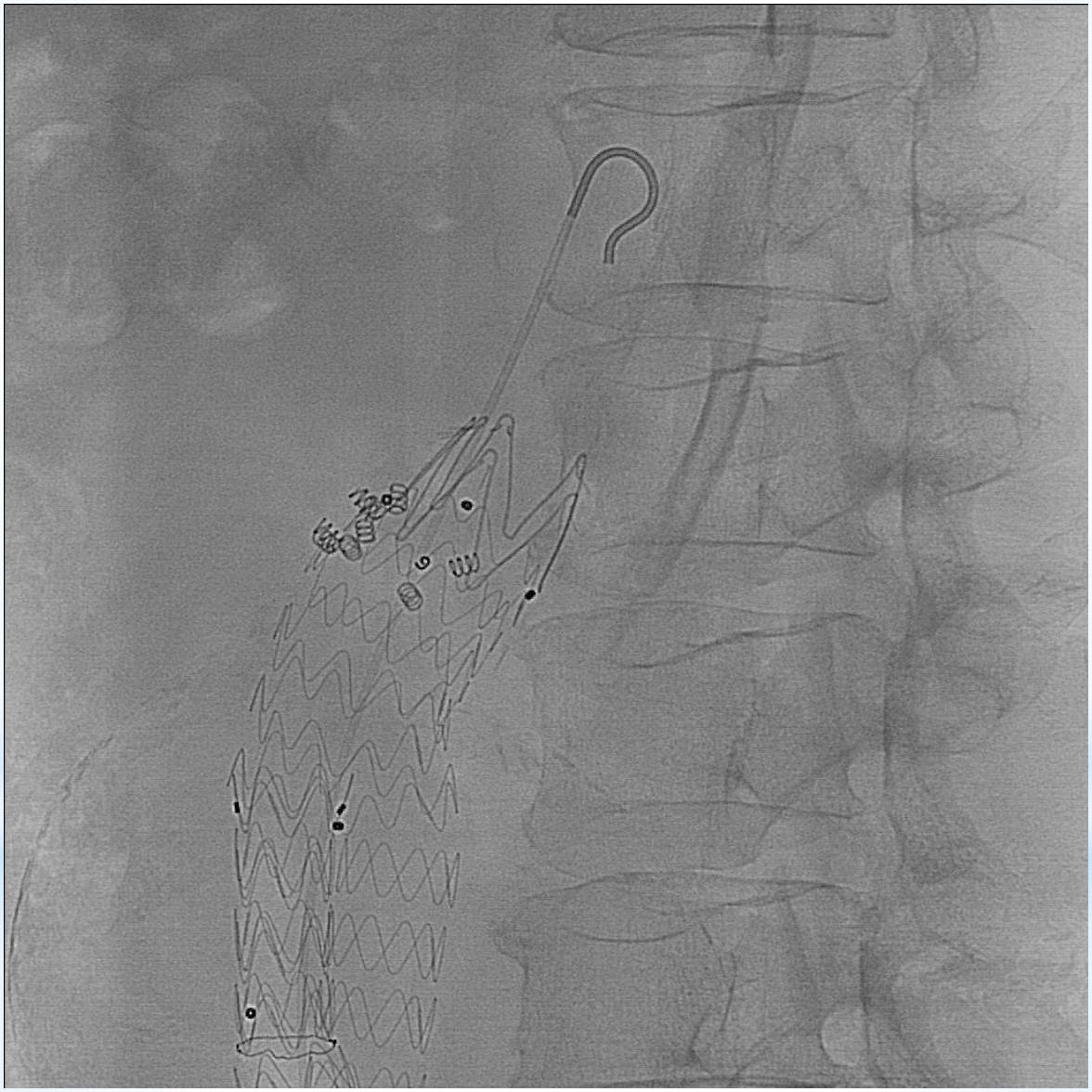

Case #2: migrated Talent endograft

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Case #3: type IA endoleak: cuff → Endoanchors

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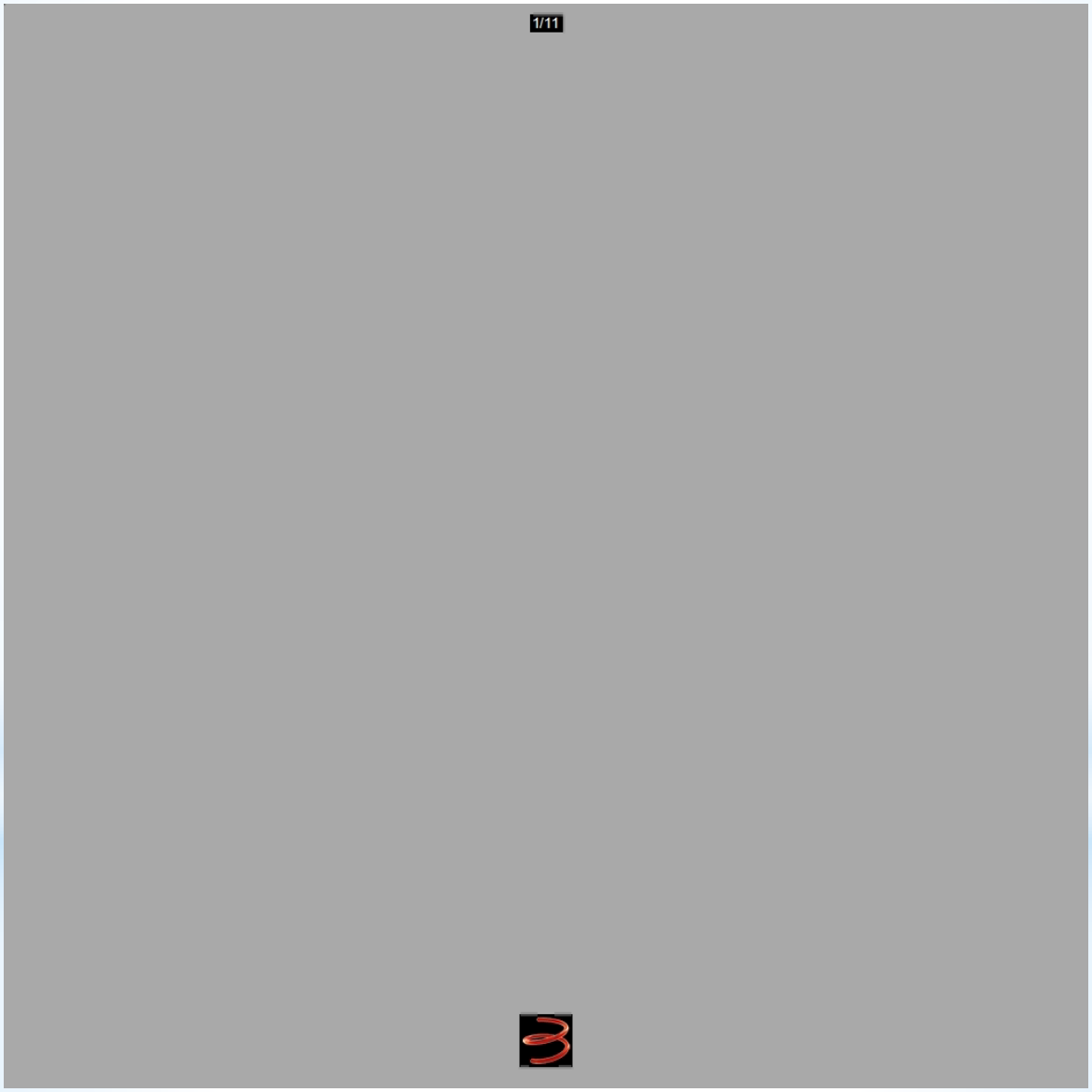

Case #3: type IA endoleak: cuff → Endoanchors

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Conclusions

Use of EndoAnchors for treatment of acute type IA endoleaks is associated with excellent results (96% freedom of renewed type IA endoleaks at 1 year FU)

Use of EndoAnchors for treatment of type IA endoleak remote from an EVAR procedure successful in 68% of patients (75% of patients with persistent leaks do not undergo further interventions)

40% of type IA endoleaks in the revision group can be treated with Endoanchors alone

Planning and sizing essential for technical success (endovascular suture)

Be aware of the limitations of the use of the Endoanchors