

# **Use of Aptus Heli-FX EndoAnchor implants with standard endografts to strengthen seal in hostile anatomies: technical tips, case experience and clinical results**

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January 20th, 2017

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Eastern Virginia Medical School  
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# DISCLOSURES:

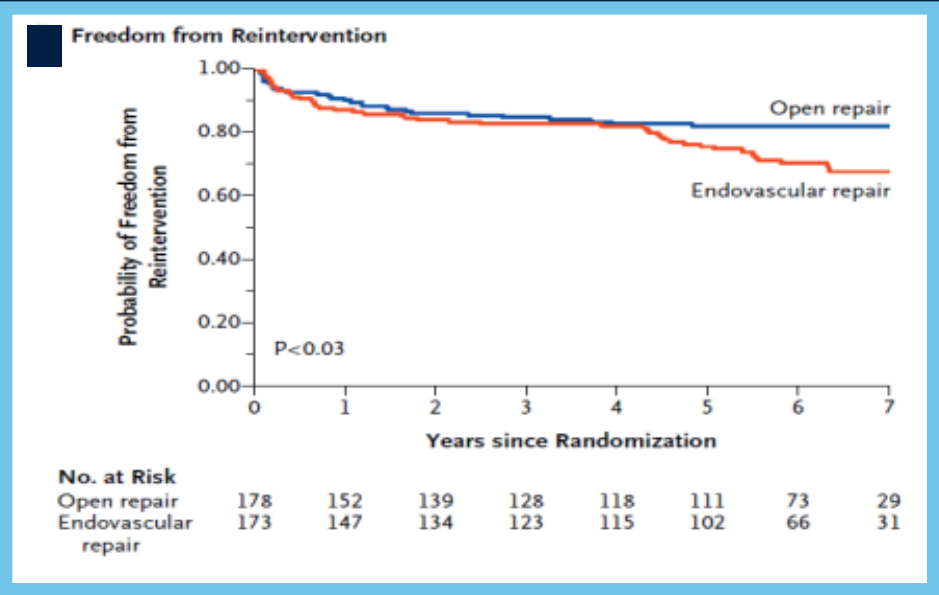
Consultant: Cook Medical  
Bolton Medical,  
Medtronic Inc,  
Volcano,  
WL Gore

Speakers' Bureau: Medtronic Inc.

Grants / Research support: Bolton Medical  
Cook Medical  
Medtronic Inc.  
WL Gore

Scientific Advisory Board: Medtronic Inc.,  
Mellon Medical

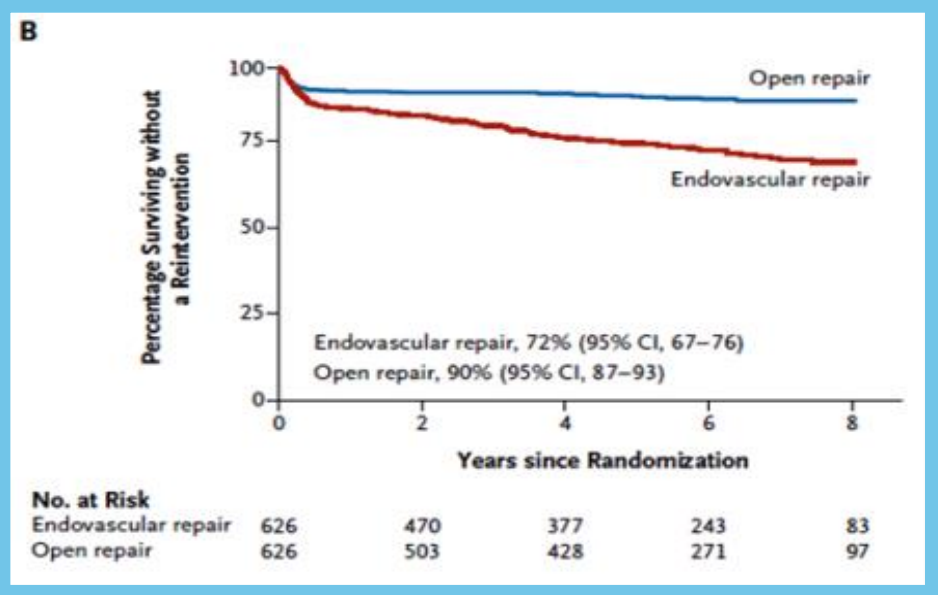
# Legacy studies continue to highlight need for lifelong surveillance in EVAR



## DREAM

De Bruin *et al.* NEJM 2010

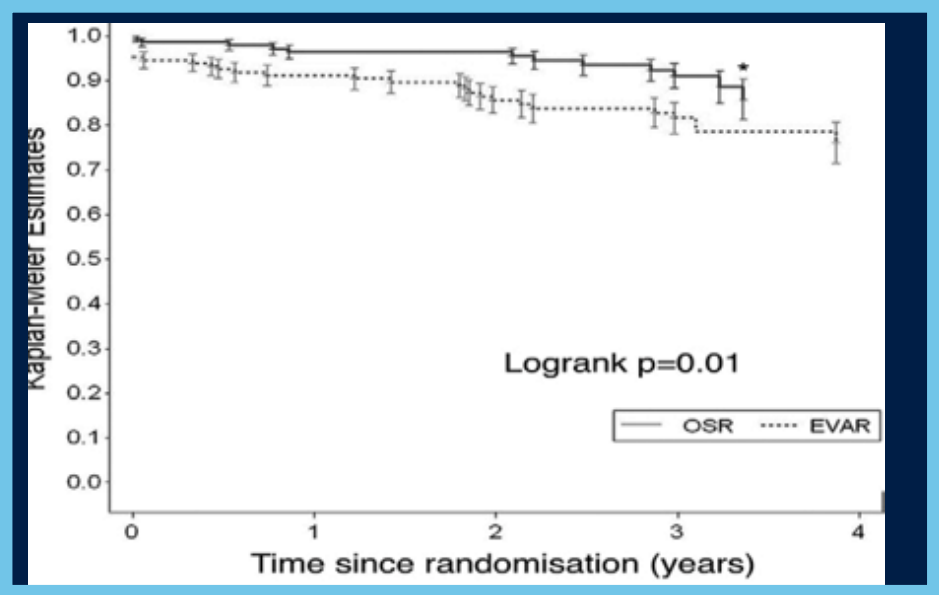
Late ruptures in EVAR,  
none in open surgery



## EVAR-1

Greenhalgh *et al.* NEJM 2010

With evar, predictors for  
rupture (endoleaks and  
migration) increase with time



## ACE

Becquemin *et al.* JVS 2011

In ACE, 16% re-  
interventions in EVAR vs.  
2.4% for open repair at 3 yr  
median f/u

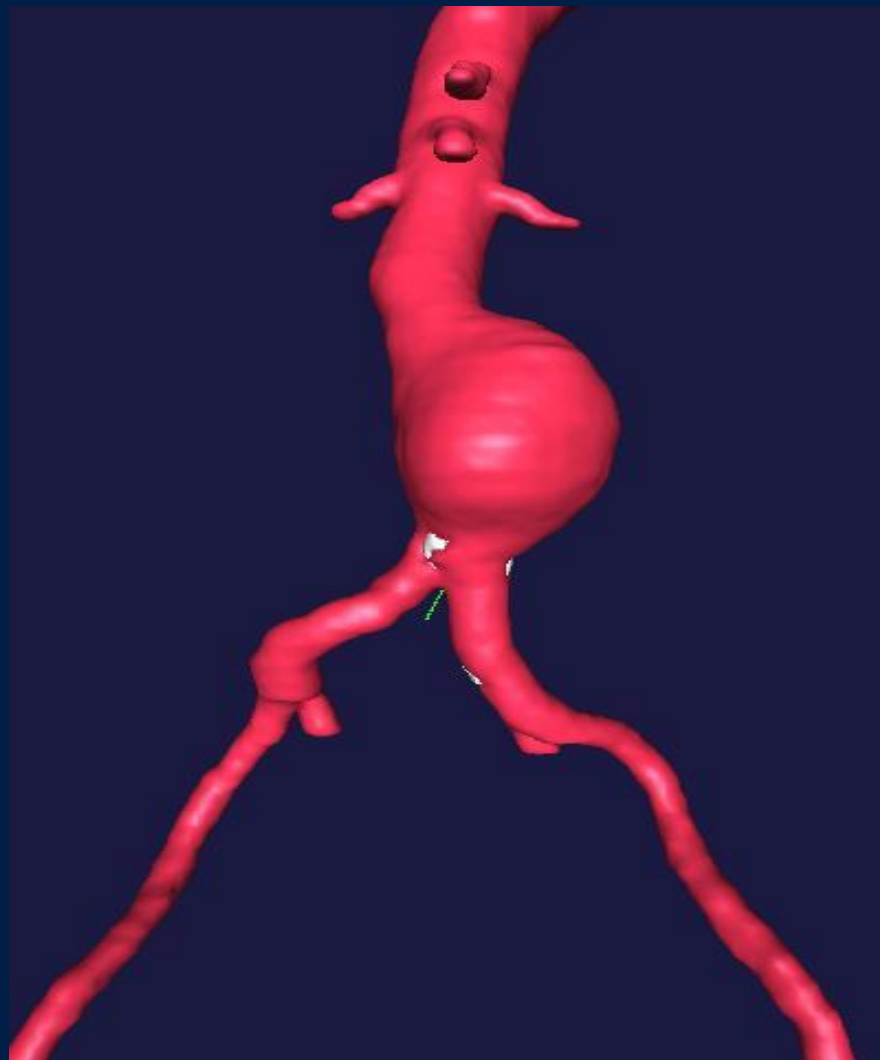
# OBJECTIVES

*The proximal neck is the Achilles' heel of EVAR*

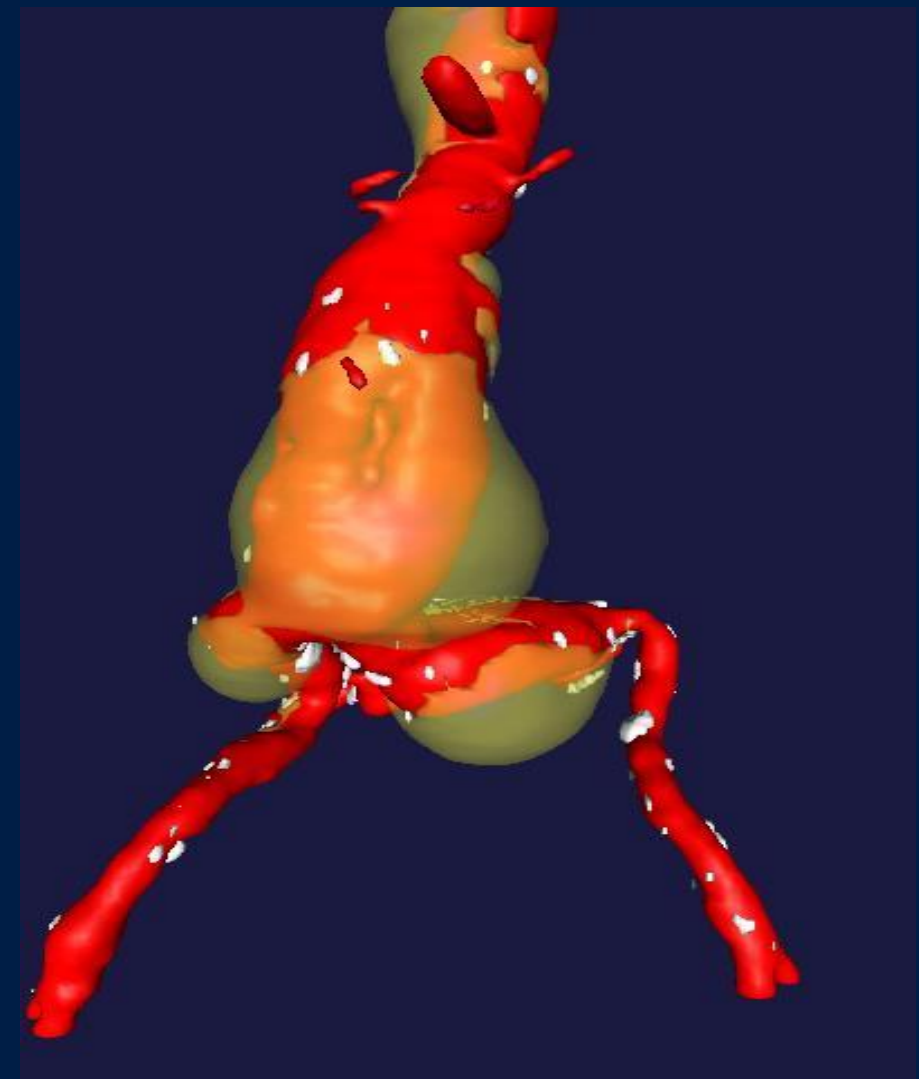


1. To illustrate the technique for EndoAnchors implant in hostile anatomies during EVAR
2. To review the results of the ANCHOR Registry for prophylactic and therapeutic indications

# These attributes qualify or disqualify a neck



1. *Length*
2. *Diameter*
3. *Shape*
4. *Angulation*
5. *Wall ( thrombus or calcification )*



*The success of EVAR depends on fixation and seal at the proximal neck*



# IMPACT OF HOSTILE NECKS ON EVAR OUTCOMES

Meta-Analysis of 7 major studies compared EVAR outcomes in hostile vs. friendly neck anatomies (total patients N = 1559)

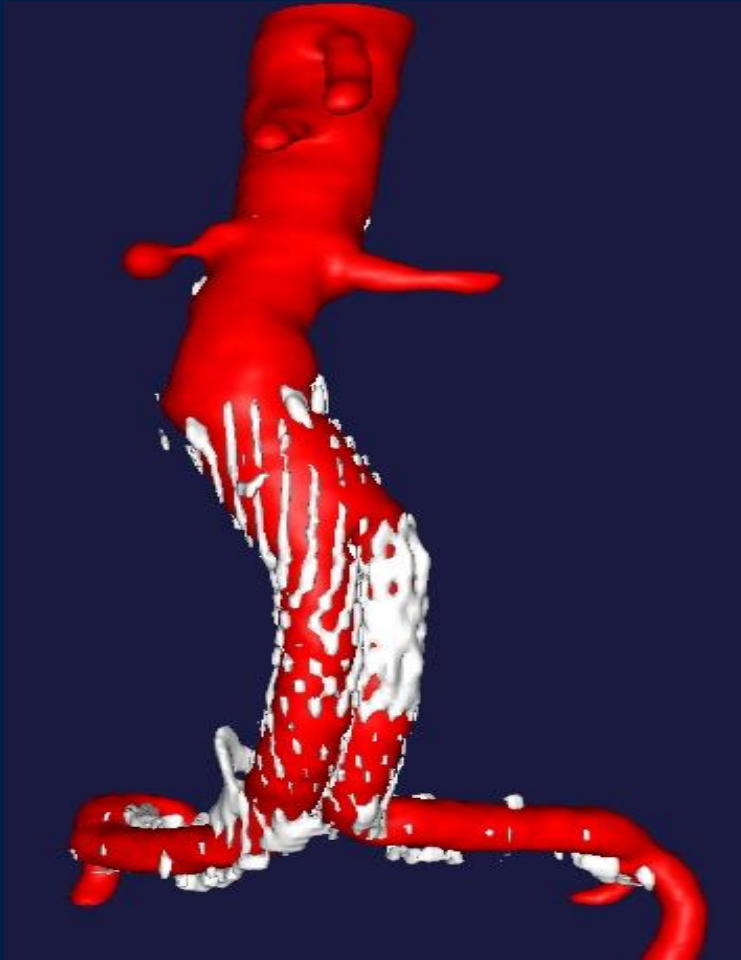
Study	Sample Size	Endografts
Torsello et al, 2011	177	Endurant
AbuRahma et al, 2010	238	AneuRx, Excluder, Zenith, Talent
Hoshina et al, 2010	129	Excluder, Zenith
Abbruzzese et al, 2008	565	AneuRx, Excluder, Zenith
Choke et al, 2006	147	Talent, Zenith, Excluder, AneuRx
Fulton et al, 2006	84	AneuRx
Fairman et al, 2004	219	Talent

- ✓ **Type I endoleaks 4.5x more likely at 1-year** after endograft implantation in hostile proximal aortic neck anatomy (P = .010)
- ✓ **Aneurysm-related mortality risk 9x greater** in hostile neck anatomy (P= .013)

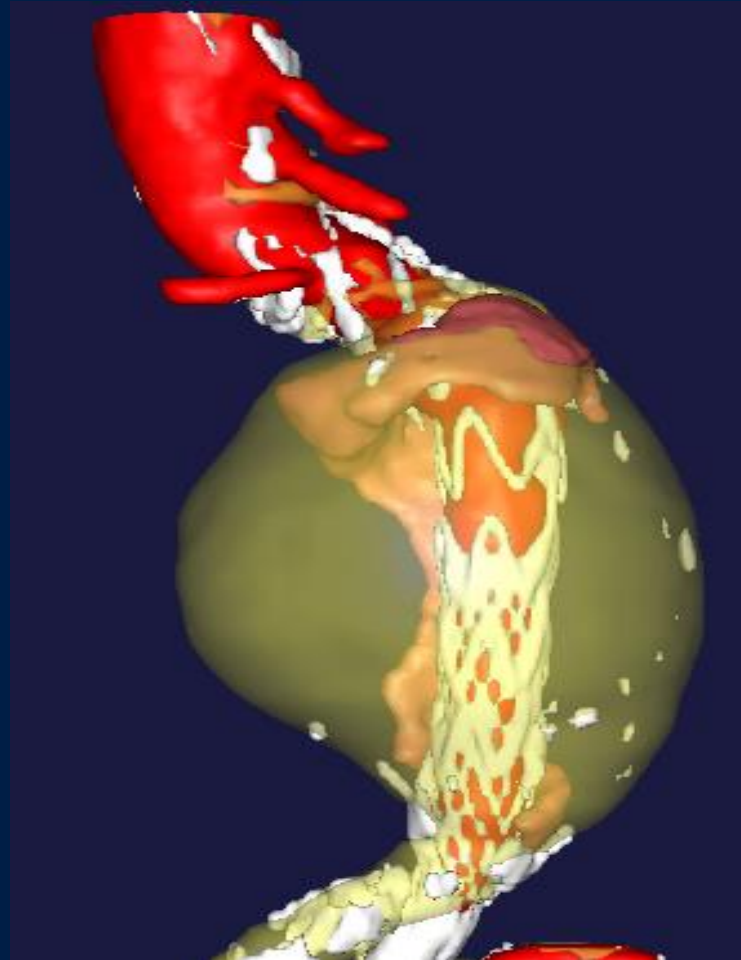
<sup>1</sup>Antoniou GA et al. J Vasc Surg. 2013;57(2):527-38.

# EVAR COMPLICATIONS

*Loss of fixation*



*Loss of seal*



*Ruptured AAA from migration with proximal type I endoleak*



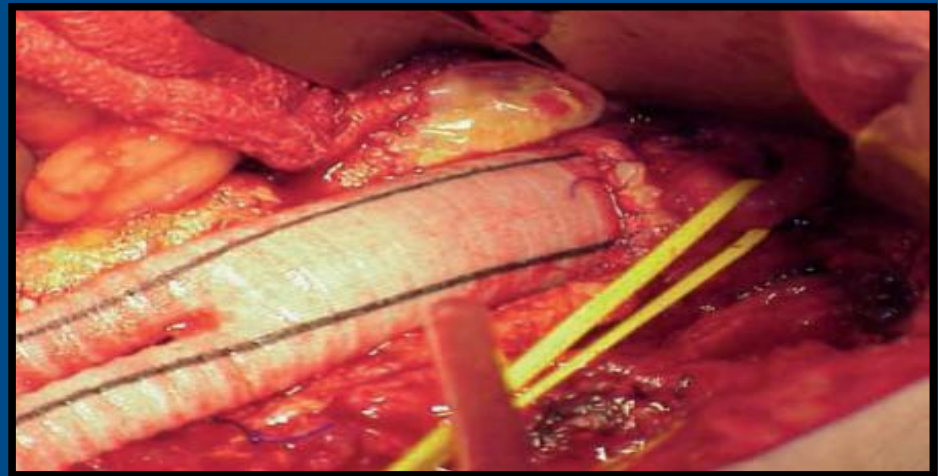
*Graft migration*

*Type I endoleak*

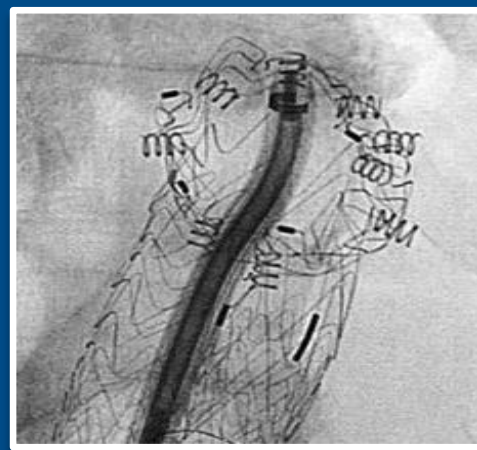
# Tailored seal and fixation of endoanchors

CREATE THE STABILITY OF A SURGICAL ANASTOMOSIS IN EVAR AND TEVAR

Surgical Anastomosis



EndoAnchoring



Displacement force in Newtons

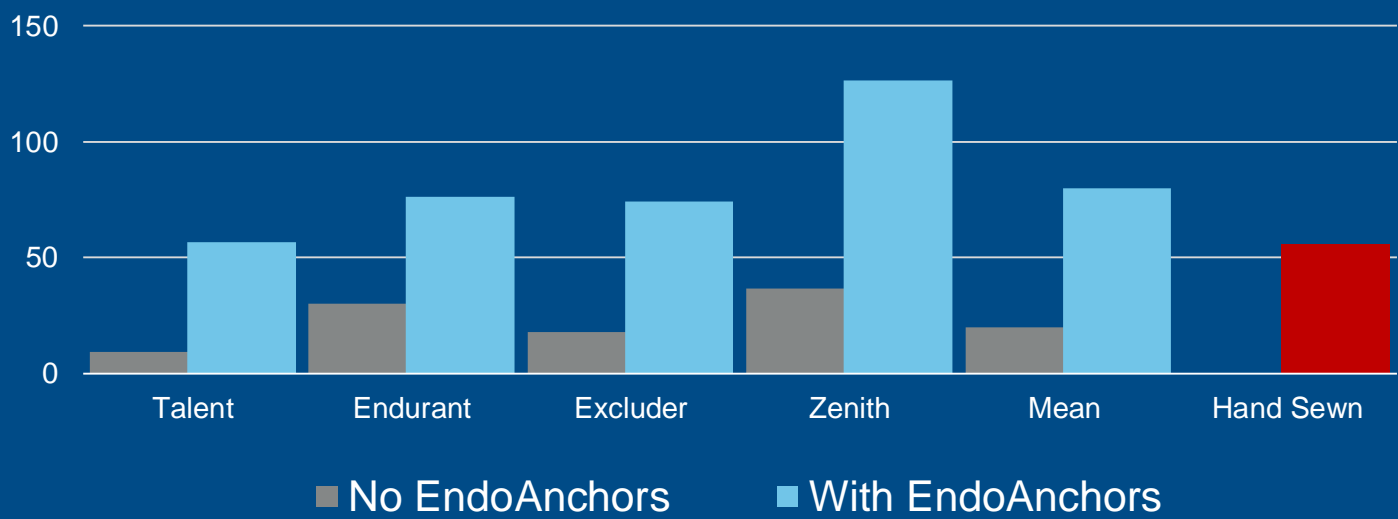


Chart from data published in Melas N, et al. *J Vasc Surg* 2012;55(6):1726-33

Case images courtesy of John Aruny MD, Bart Edward Muhs, MD, PhD.



# ENDOANCHORING: A NEW MODALITY TO IMPROVE PROXIMAL FIXATION AND SEALING

- Heli-FX Aortic Securement System
  - Heli-FX Guide
  - Heli-FX Applier
  - Cassette with EndoAnchors
- EndoAnchor dimensions:
  - 4.5mm length
  - 3.0mm diameter



# EndoAnchor Deployment

Controlled

Tactile

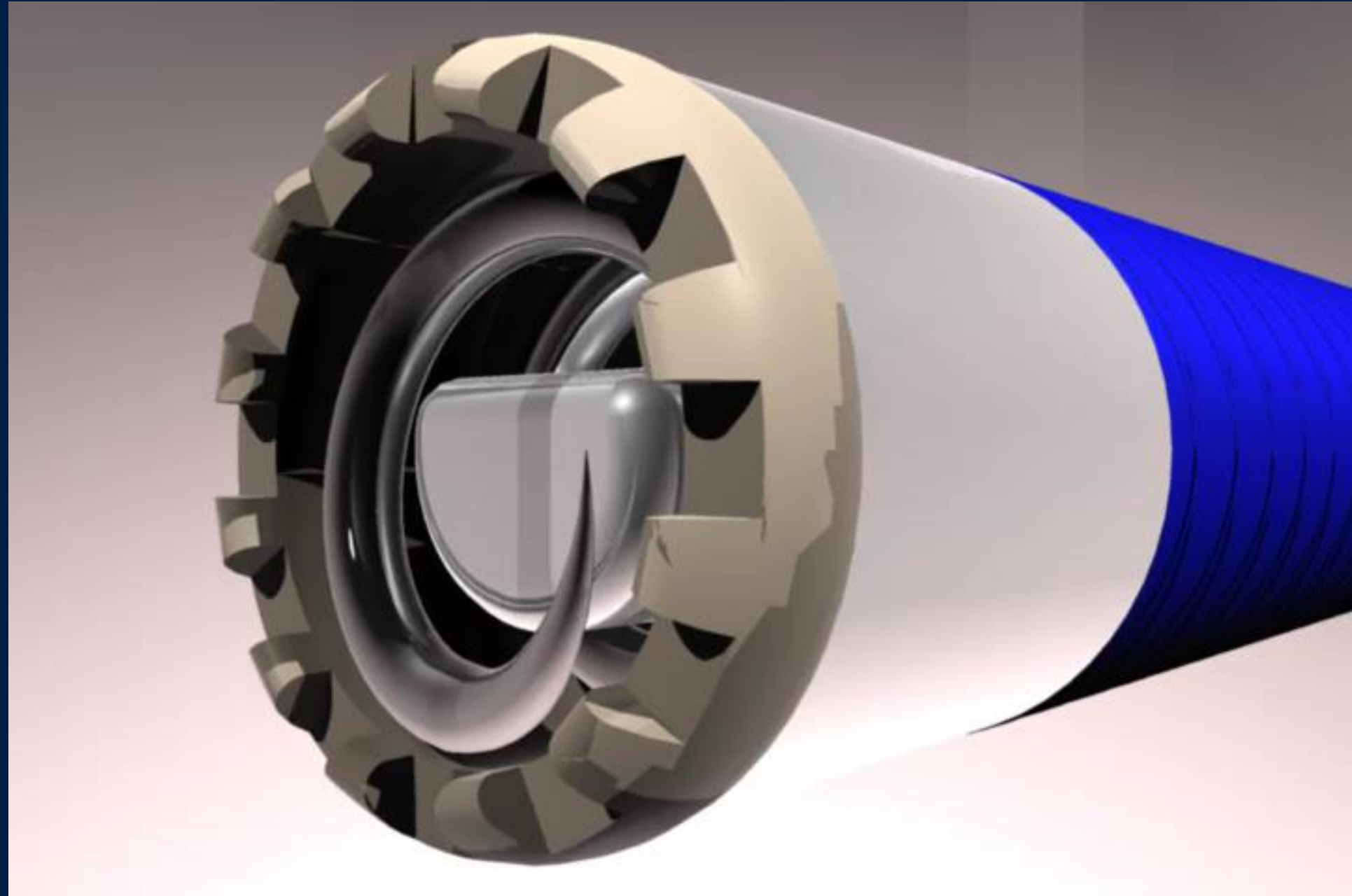
Intuitive

Safe

2 steps process

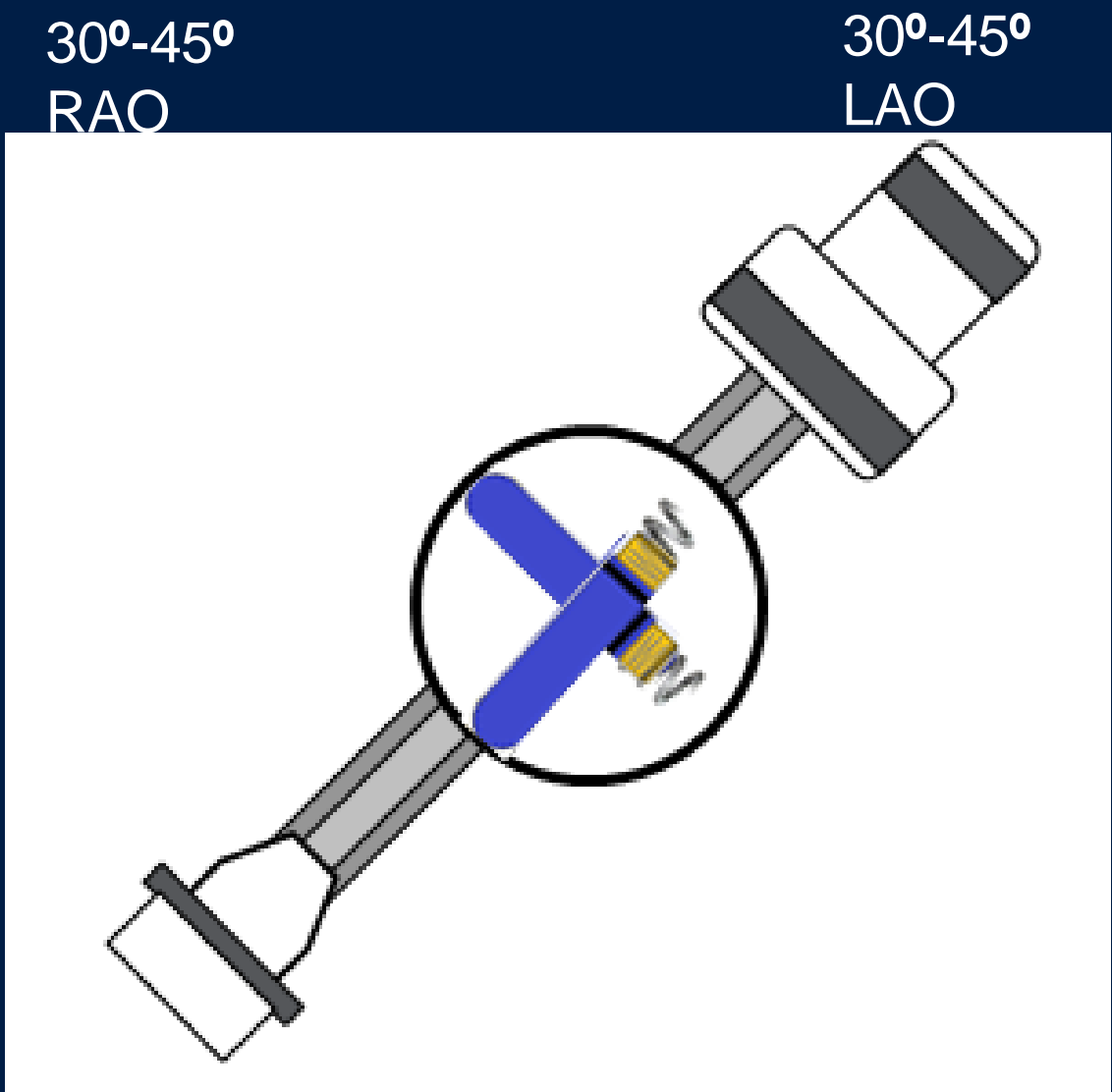
Recapture

Release



# Technique for EndoAnchors Deployment

Minimum 4 EndoAnchors recommended



Note: C-arm positions above show just one possible combination

## Tips for EndoAnchor implantation:

- C-arm positioning critical for proper spacing, visualization & implantation
- Min 4 EndoAnchors recommended
  - For prox neck dia. > 29mm, min 6 EndoAnchors recommended
- Strive for even spacing around neck circumference
- EndoAnchors should penetrate vessel wall
  - Select positions lacking excessive thrombus/calcium

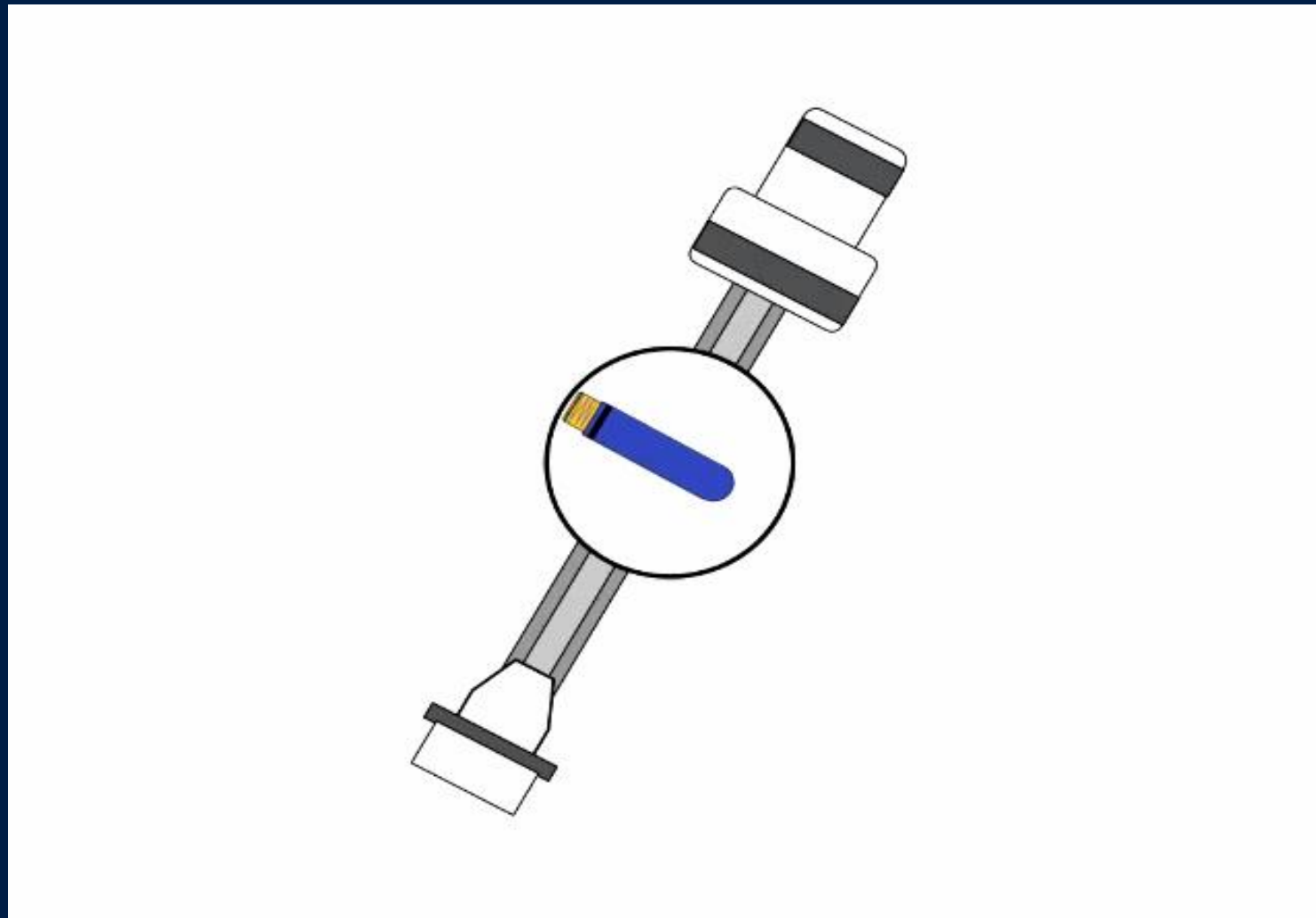
EndoAnchors	# of C-arm positions	Recommended angular offset
4 EndoAnchors	2	~90°
6 EndoAnchors	3	~60°

# Technique: C-Arm positioning for 6 EndoAnchors

30° RAO

30° LAO

90°  
Lateral



Note: C-arm positions above show just one possible combination



# PROPHYLACTIC ENDOANCHORS WITH INDEX EVAR

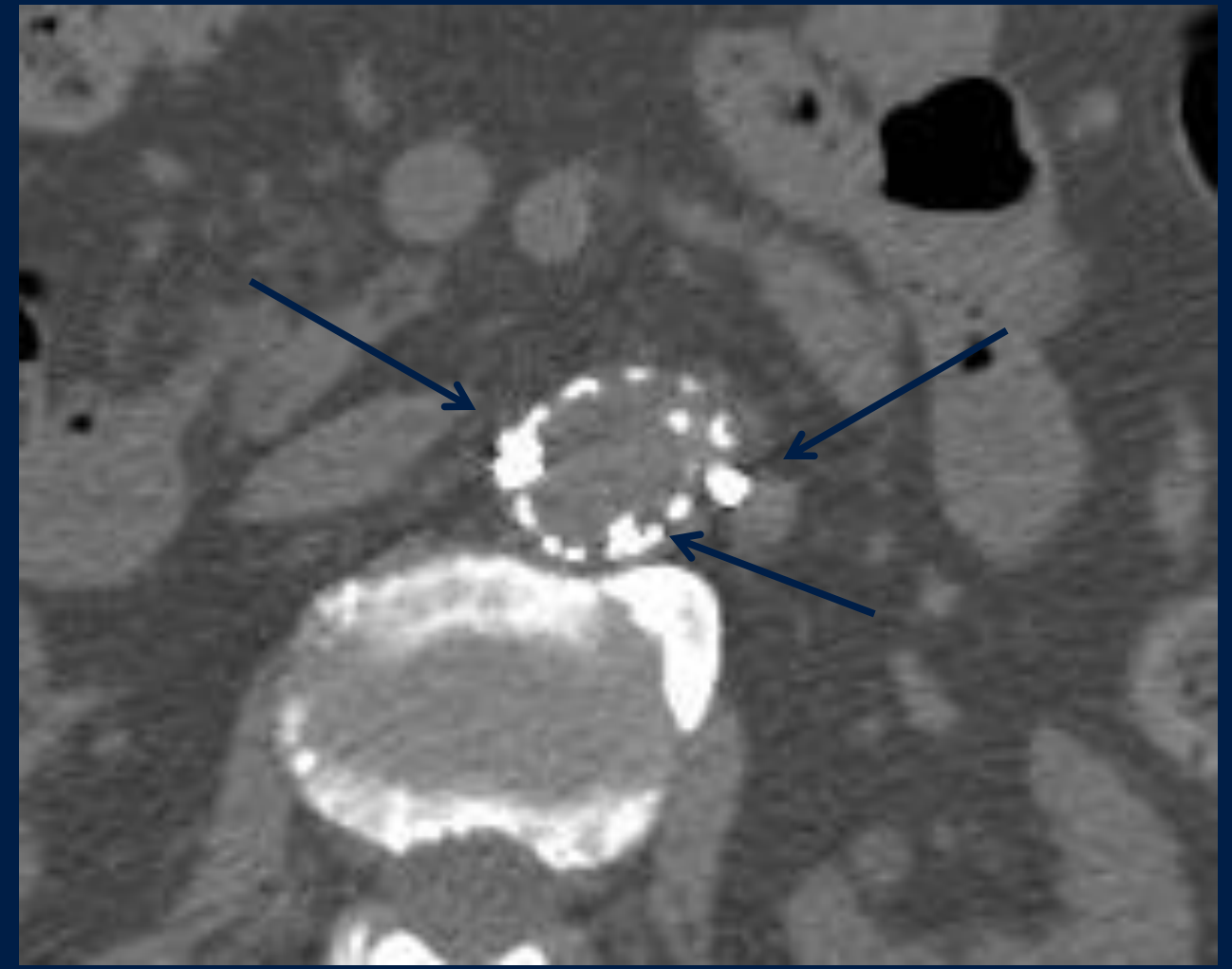
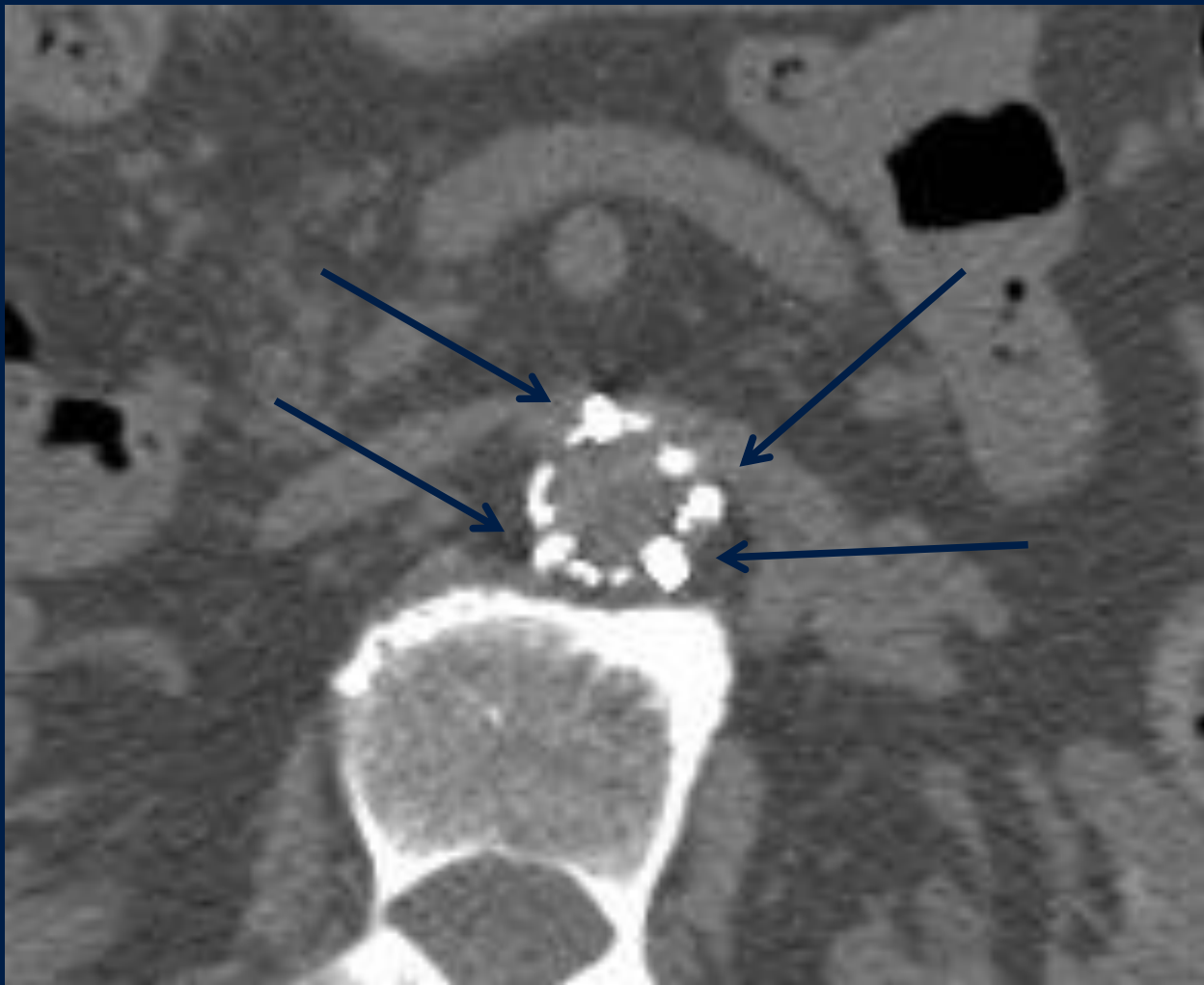
84 y.o female patient with rapidly expanding AAA

CTA: short, conical angulated neck



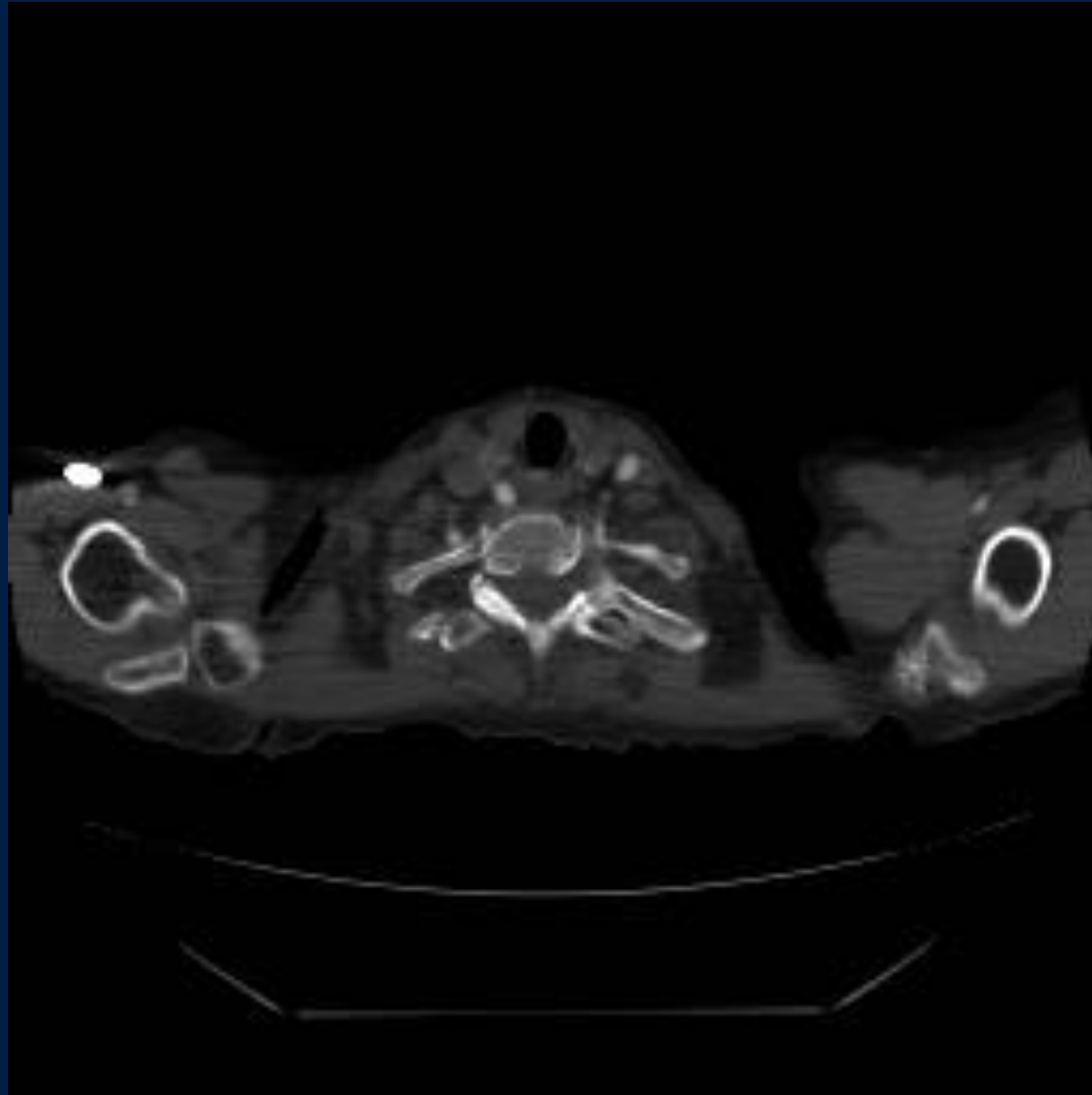
# PROPHYLACTIC ENDOANCHORS WITH INDEX EVAR

CTA: Circumferential placement of endoanchors  
No endoleaks, AAA decreased to 4.5cm over 1yr

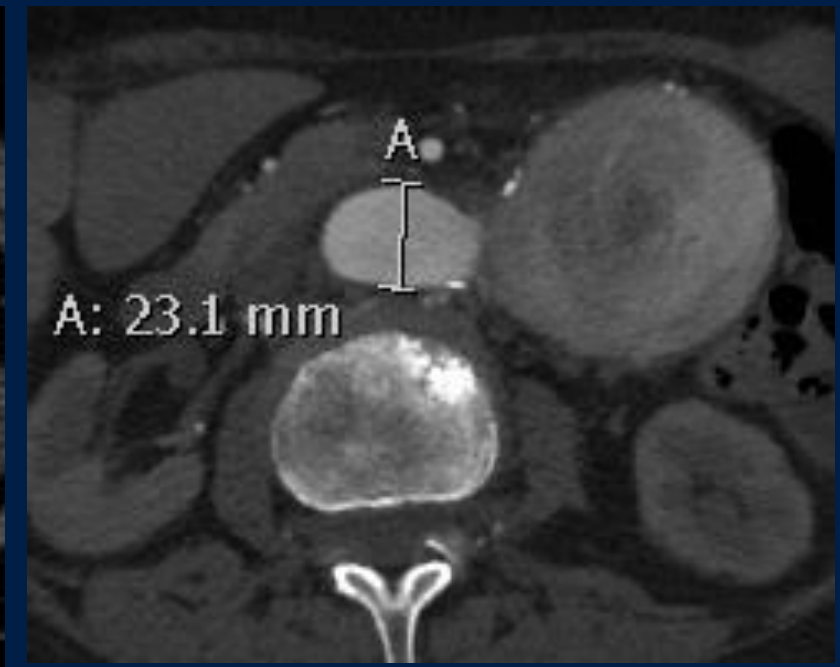


# PROPHYLACTIC ENDOANCHORS WITH INDEX EVAR

Patient information: 79 yr old female patient



CTA: 7 cm AAA & 4.5 cm DTA  
Aortic neck: diameter 23 mm  
length 37 mm





# PROPHYLACTIC ENDOANCHORS WITH INDEX EVAR

## 3 D CTA

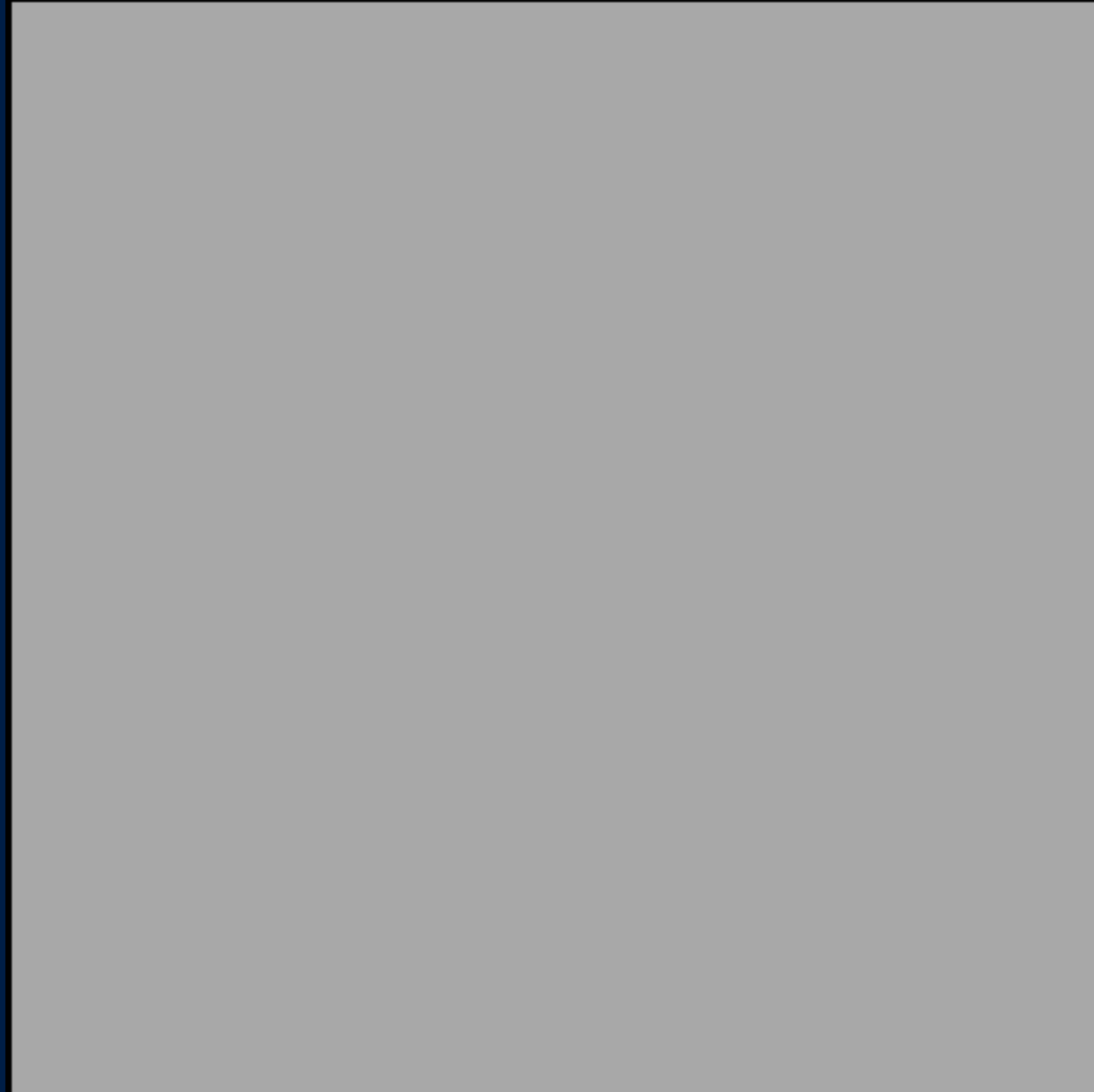


Should you place  
EndoAnchors ?



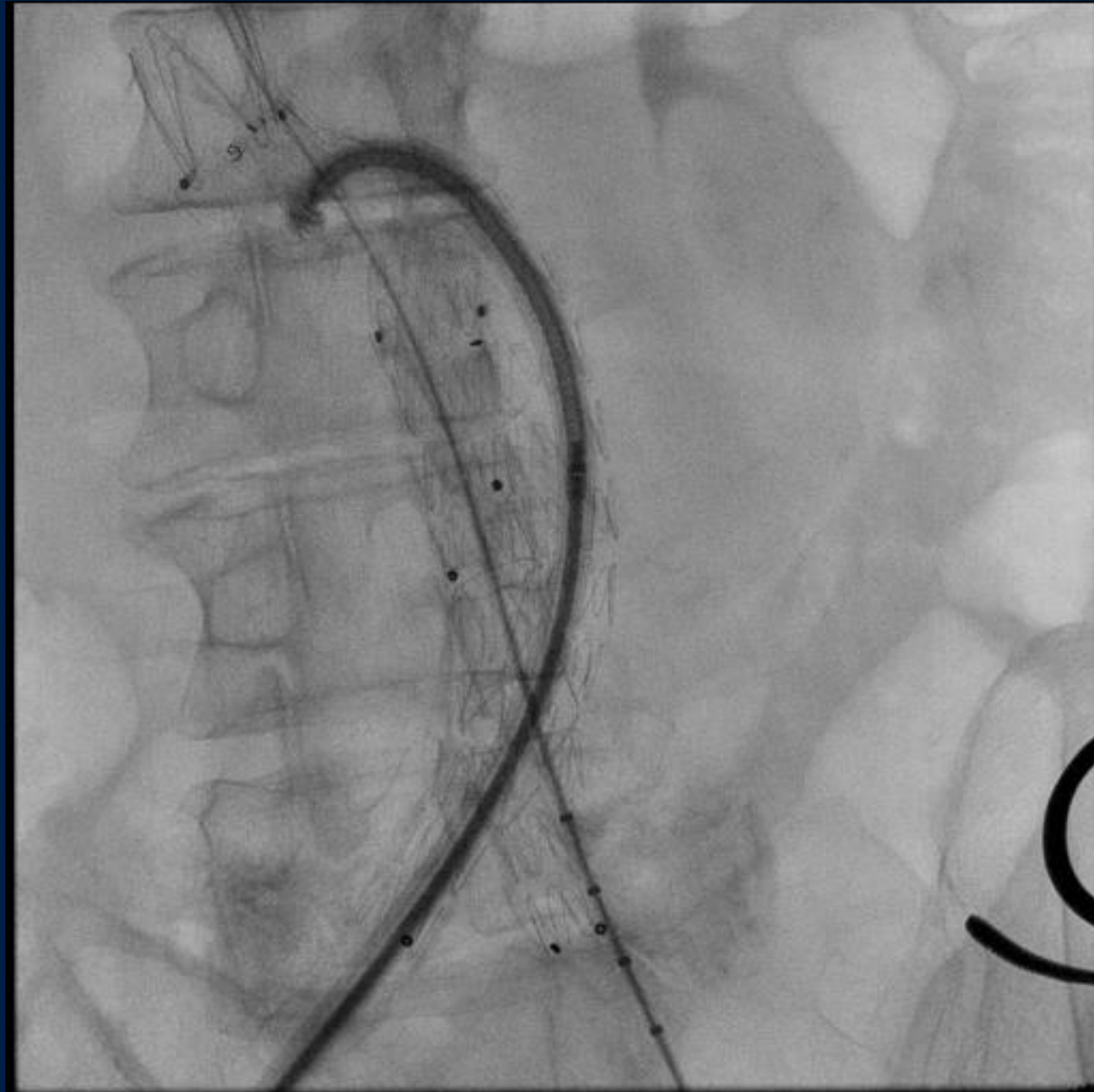
# PROPHYLACTIC ENDOANCHORS WITH INDEX EVAR

Pre deployment angiogram



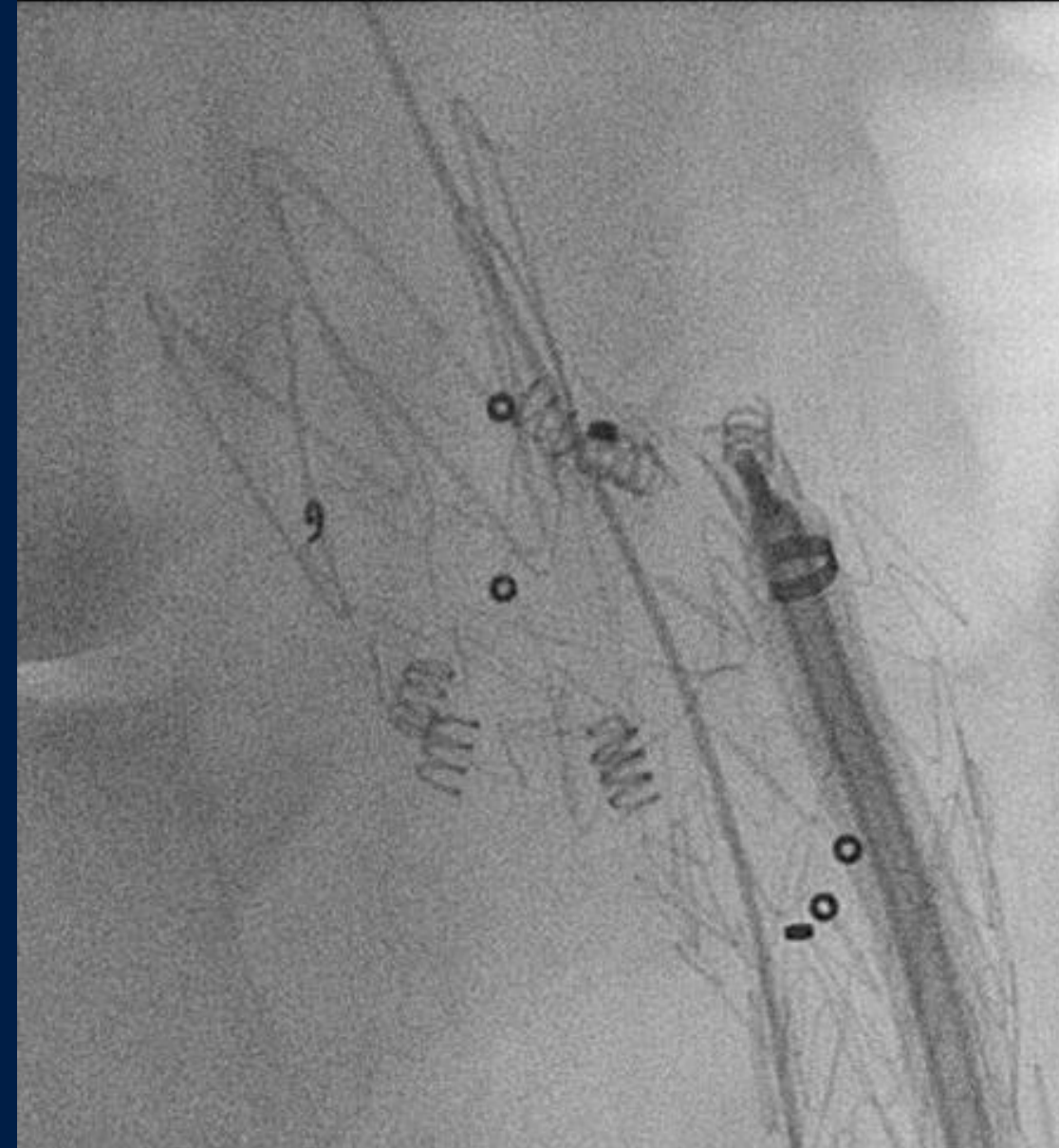
# PROPHYLACTIC ENDOANCHORS WITH INDEX EVAR

## EndoAnchor deployment



# PROPHYLACTIC ENDOANCHORS WITH INDEX EVAR

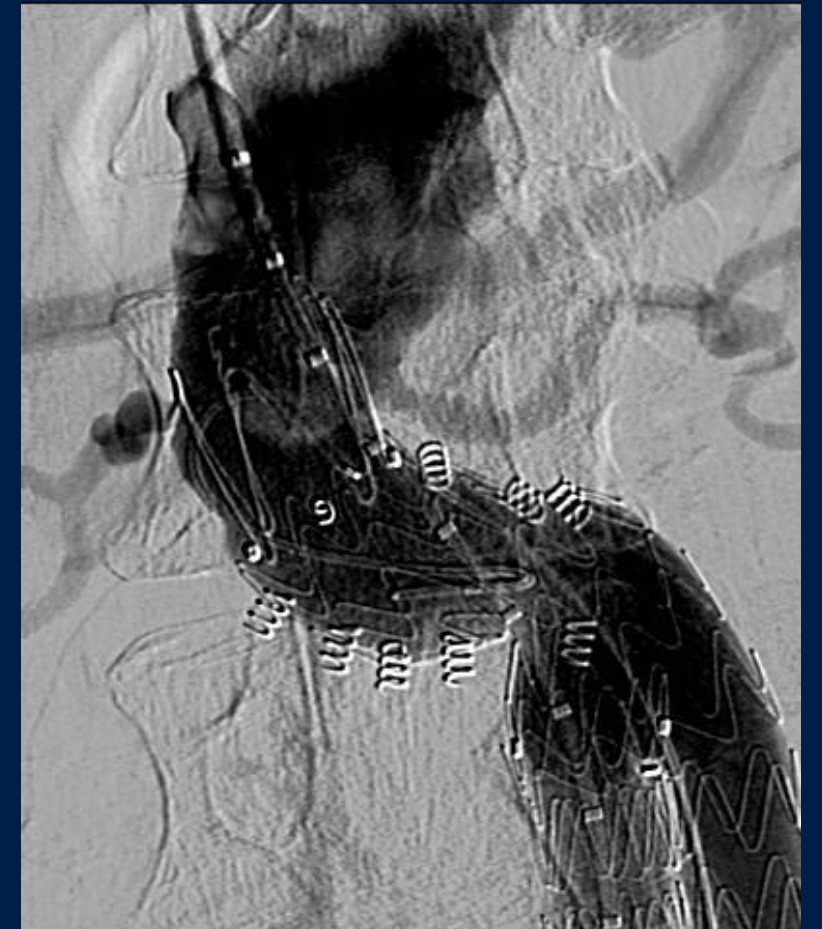
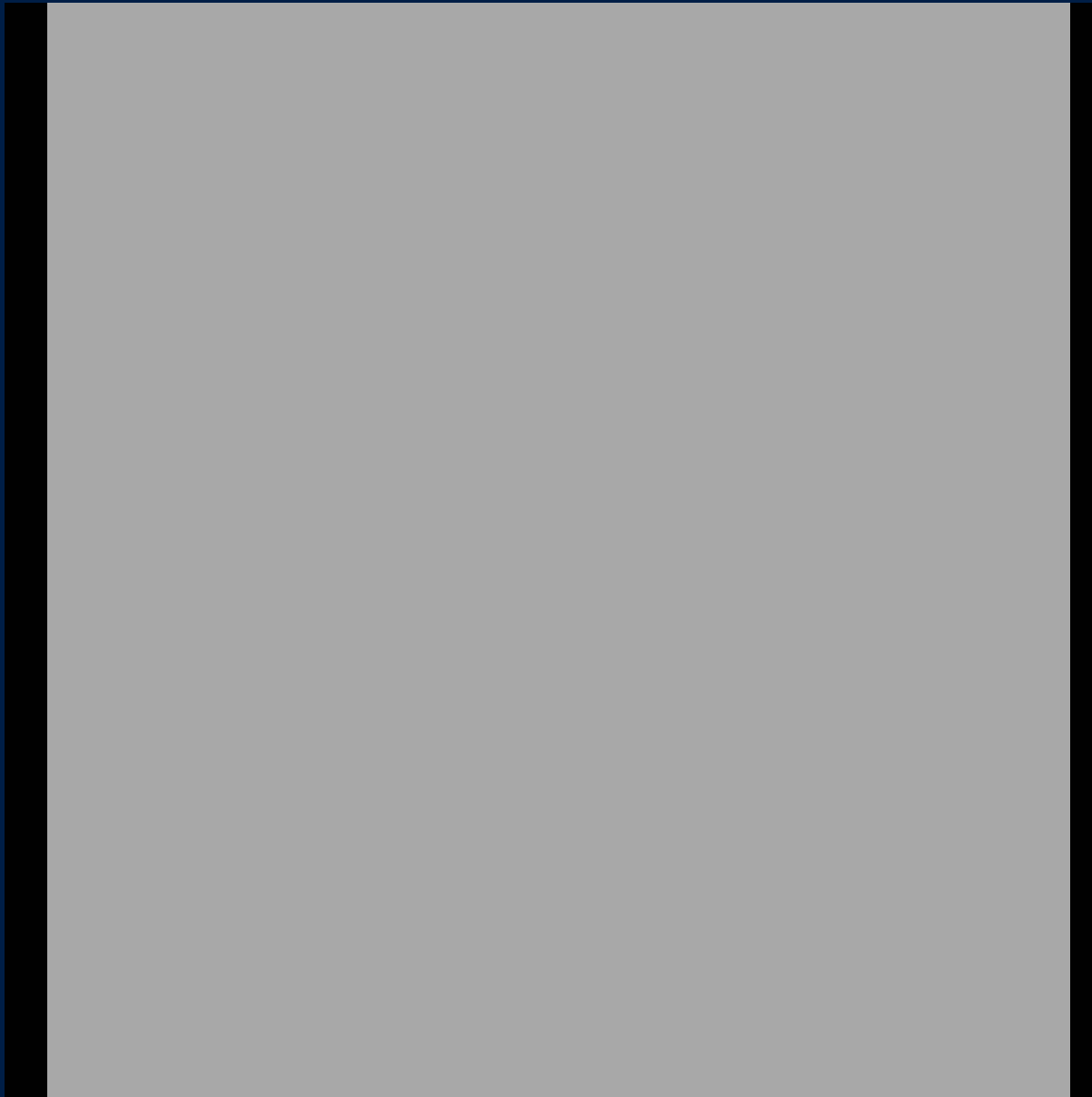
## EndoAnchor deployment





# PROPHYLACTIC ENDOANCHORS WITH INDEX EVAR

## Completion angiogram

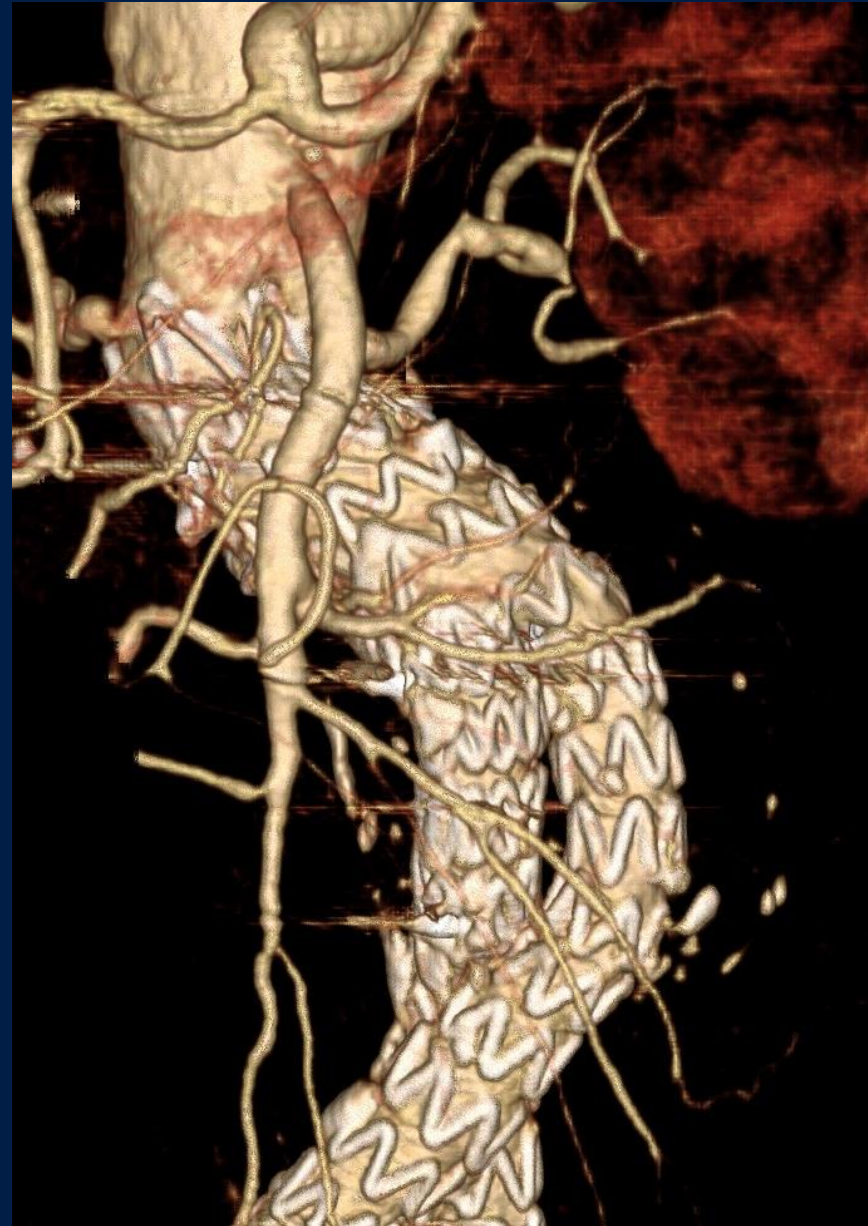
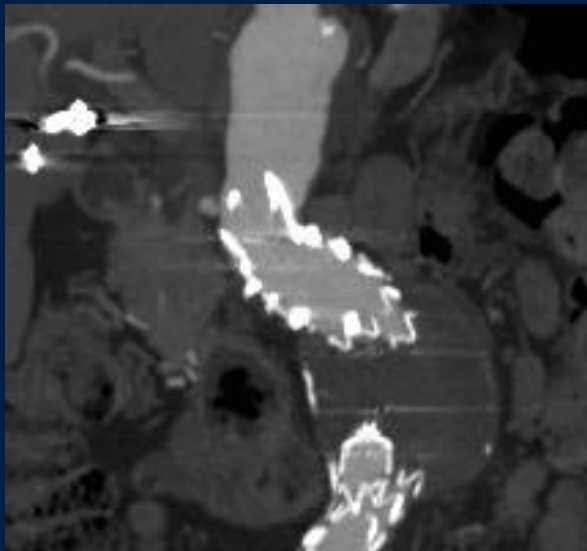
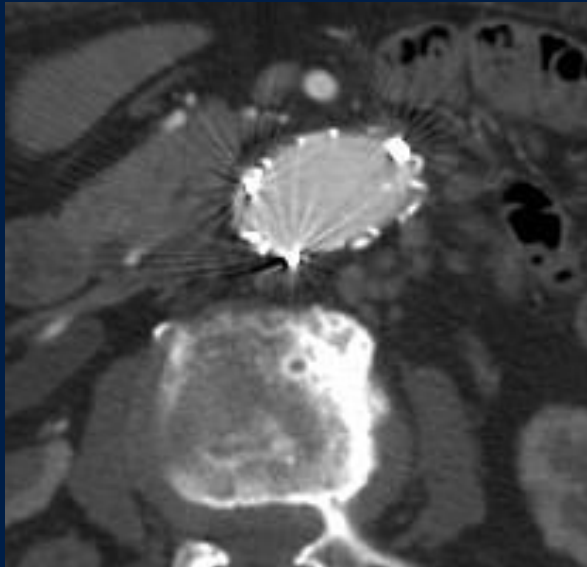
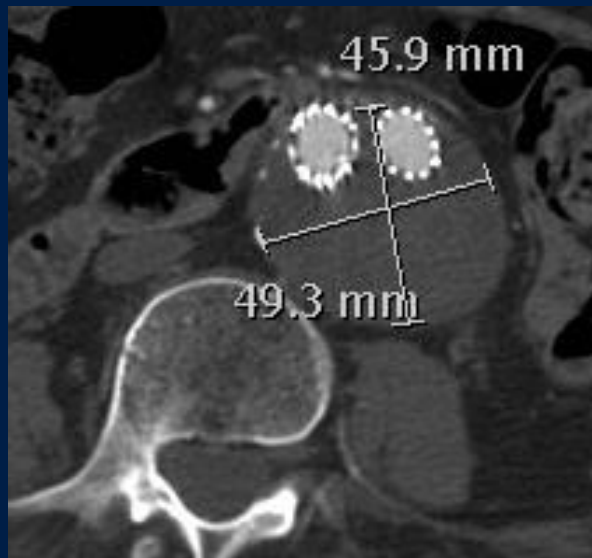




# PROPHYLACTIC ENDOANCHORS WITH INDEX EVAR

CTA @ 3 years

AAA diameter  
Down to 4.9 cm



# TOP TEN TIPS FOR ENDOANCHORS IN PRIMARY EVAR

1. Take the time for preoperative planning
2. Wishful thinking does not create a neck
3. Deliver the endograft accurately at the lowest renal artery
4. Do the aortic balloon molding first
5. Size the Aptus guide according to endograft size
6. Place the gantry at 90° angle to the applier
7. Make sure you make contact and penetrate the aortic wall
8. Anchor at the proximal fabric edge of the endograft
9. Deploy 2 rows of EndoAnchors in the neck
10. Space the EndoAnchors circumferentially

# ANCHOR REGISTRY CAPTURING REAL-WORLD USAGE

Registry Design	Prospective & Observational, International & Multi-Center, Dual-arm Registry with Core Lab Analysis
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
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

## Over 680 Patients Enrolled as of November 2016



# ANCHOR REGISTRY\*

## PRIMARY ARM REPRESENTS 72.4% OF PTS

604

ANCHOR REGISTRY

437

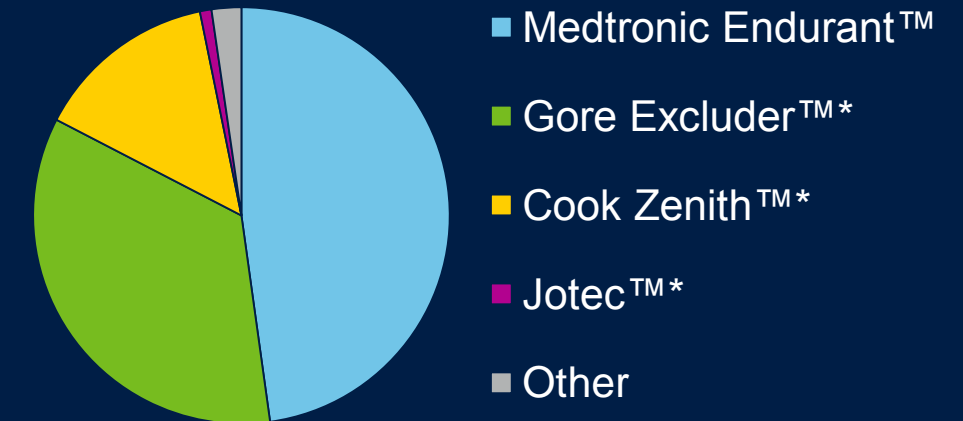
PRIMARY ARM

167

REVISION ARM<sup>1</sup>

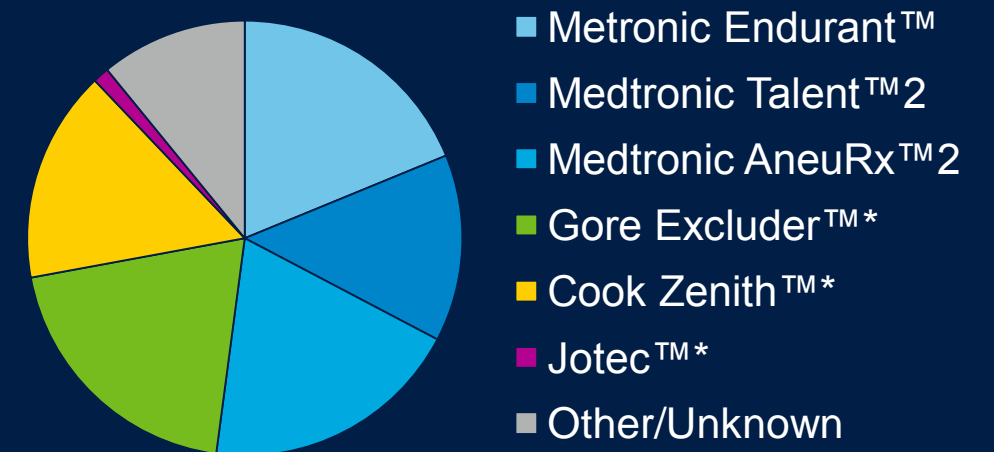
### Stent Grafts - Primary

Arm



### Stent Grafts - Revision

Arm



\*Data cut June 15, 2016

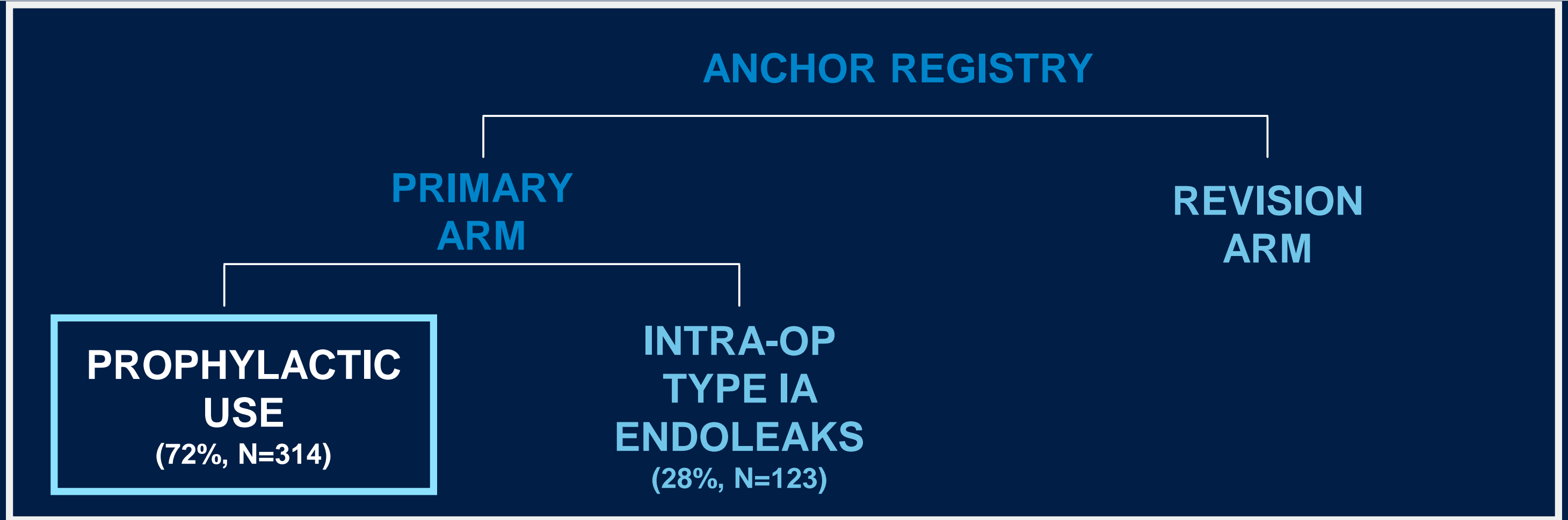
<sup>1</sup> Despite Endurant being 1 in 2 grafts in the primary arm, it is only a subset of what's being presented with complications in the revision arm

<sup>2</sup> No longer commercially available in the US



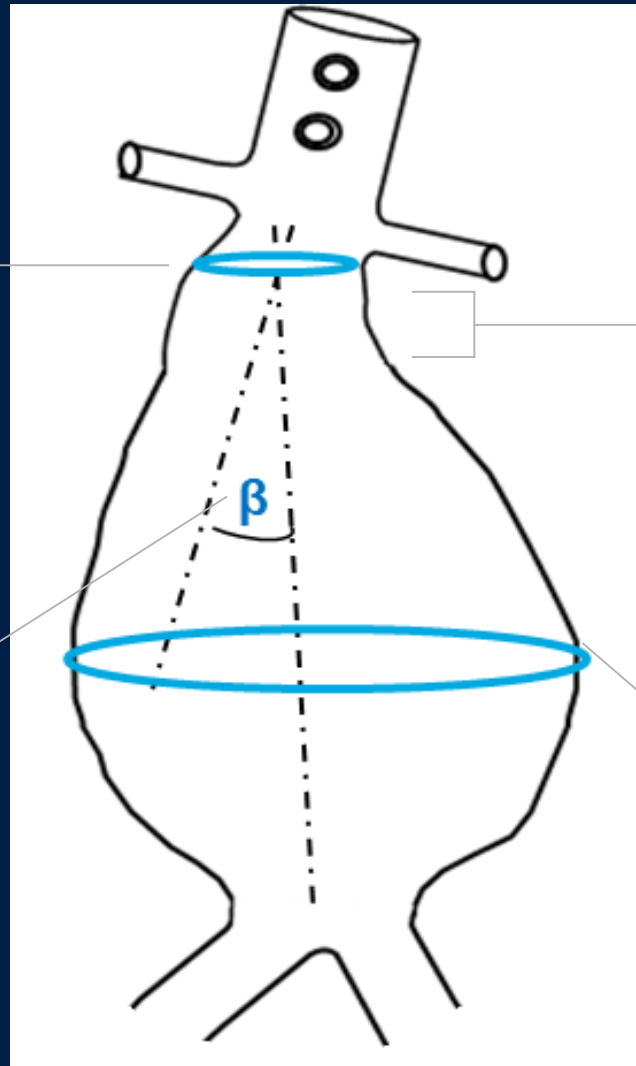
# ANCHOR REGISTRY – PRIMARY ARM (N=437)

**Prophylactic Use:** Application of EndoAnchor™ implants without evidence of type 1a endoleak, but concern for late failure and/or prevention of neck dilatation



# ANCHOR REGISTRY – PROPHYLACTIC SUBJECTS

Baseline characteristics & aneurysm measurements\*



Infrarenal Diameter:  
**25.6 mm**

Avg Neck Calcium  
Thickness: **1.2 mm**

Infrarenal  
Angulation: **24.6°**

Neck Length  
(median): **11.5 mm**

Conical Neck  
(>10%/10mm): **41.4%**

Max Aneurysm  
Diameter: **55.7 mm**



Male: 78%



Female: 22%

**Mean Age: 72.4 Years**

**HOSTILE NECKS: 91.2%**

(229/251)

- Diameter at renals >28mm
- Proximal Neck Length <15mm
- Neck Angulation >60°
- Conical (>10%/10mm)
- Thrombus/Calcium >2mm OR
- Thrombus/Calcium >1mm / 180°

\* Mean Core Lab measurements based on 251 patients with baseline CTs

# ANCHOR REGISTRY – PROPHYLACTIC SUBJECTS

## TECHNICAL SUCCESS\*

94.9%

Successful deployment of EndoAnchor™ implants with adequate penetration into aortic wall

## PROCEDURAL SUCCESS\*

94.6%

Technical success without type Ia endoleak at completion arteriography

141.1

Avg. duration  
of Procedure  
(minutes)

15.8

Avg. time to  
EndoAnchor™  
implants (minutes)

5.5

Avg. Number  
of  
EndoAnchor™  
implants

\* Site-reported data



# ANCHOR REGISTRY – PROPHYLACTIC SUBJECTS

## Proximal Endoleaks and Migration | Core Lab

	12 months	24 months
Type Ia Endoleak	0.6% (1/181)	0.0% (0/86)
Migration	0.0% (0/129)	0.0% (0/43)

Migration was assessed in comparison to the 1-month CT scan

# ANCHOR REGISTRY – PROPHYLACTIC SUBJECTS

All-Cause Mortality, Aneurysm-Related Mortality, 2<sup>nd</sup> Procedures

Kaplan-Meier Estimates	1 Year (N=301) <sup>1</sup>	2 Year (N=214) <sup>1</sup>
Freedom from ACM	94.5%	90.6%
<b>Freedom from ARM</b>	<b>98.4%</b>	<b>98.4%</b>
<b>Freedom from 2<sup>nd</sup> Procedures</b>	<b>95.9%</b>	<b>92.1%</b>

<sup>1</sup> Number of subjects at risk at the beginning of interval

# USE ENDOANCHOR™ IMPLANTS PROPHYLACTICALLY TO...

Prevent/Mitigate Risk for Type Ia Endoleaks

Improve the Durability of EVAR for “Hostile” AAA Necks

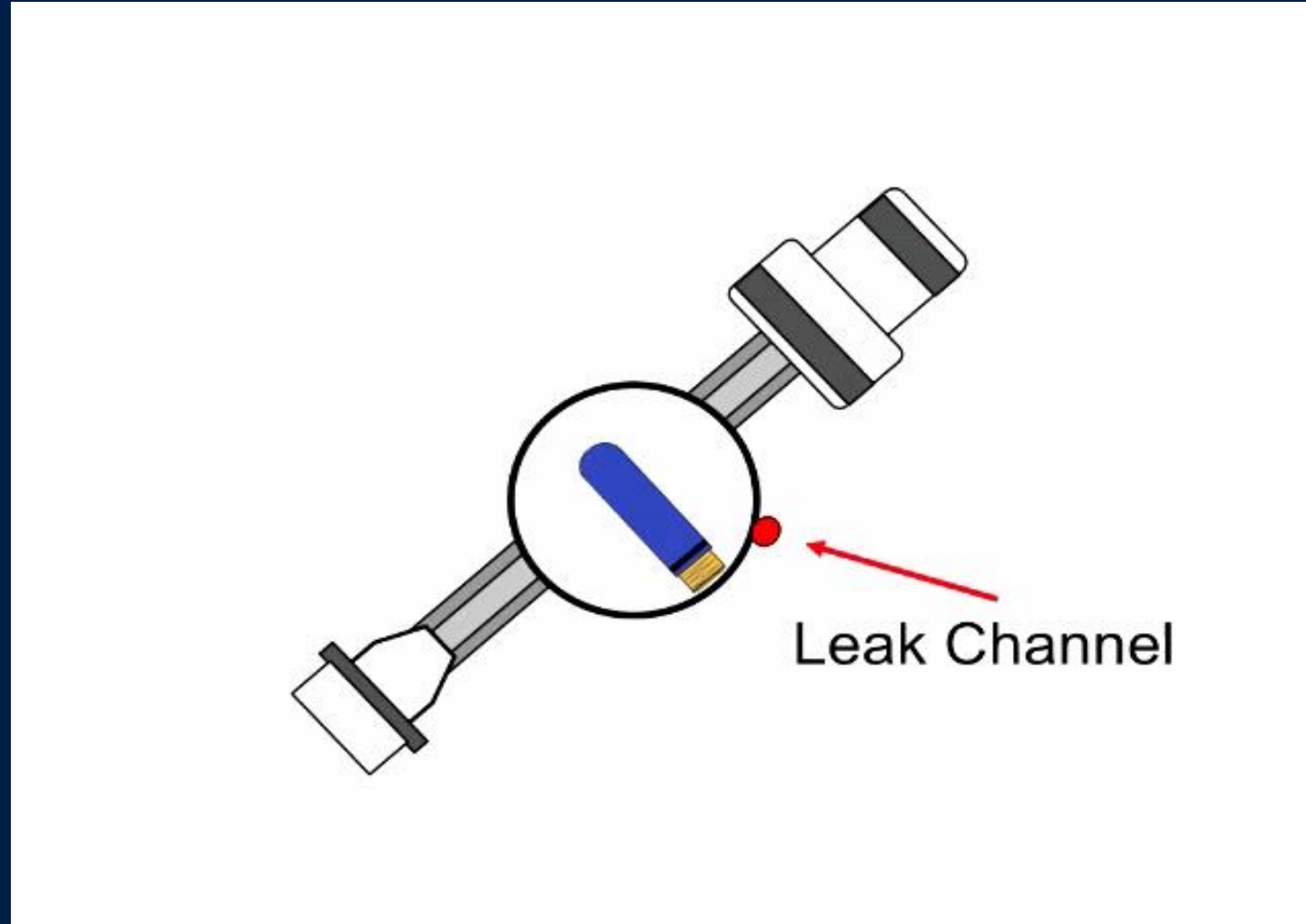
Short, Wide,  
Angled, Conical

Thrombus and Calcium



# Technique: C-Arm Positioning for Type 1 EL Treatment

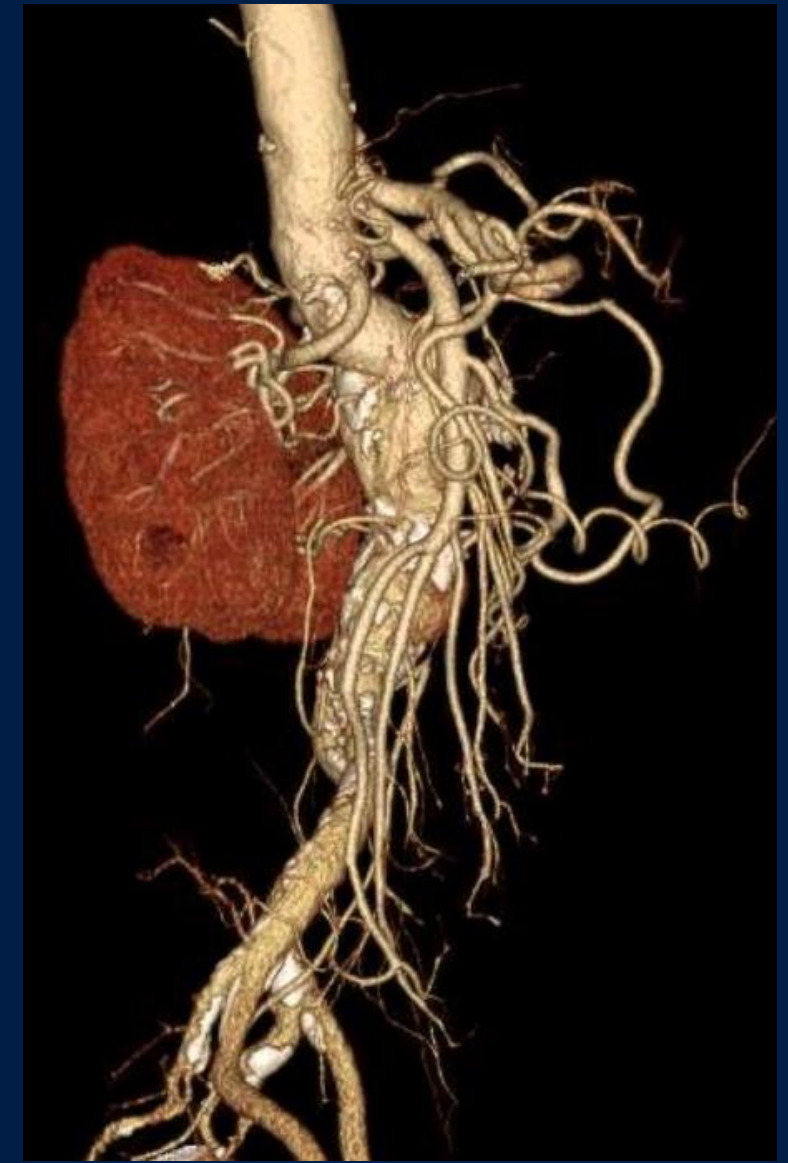
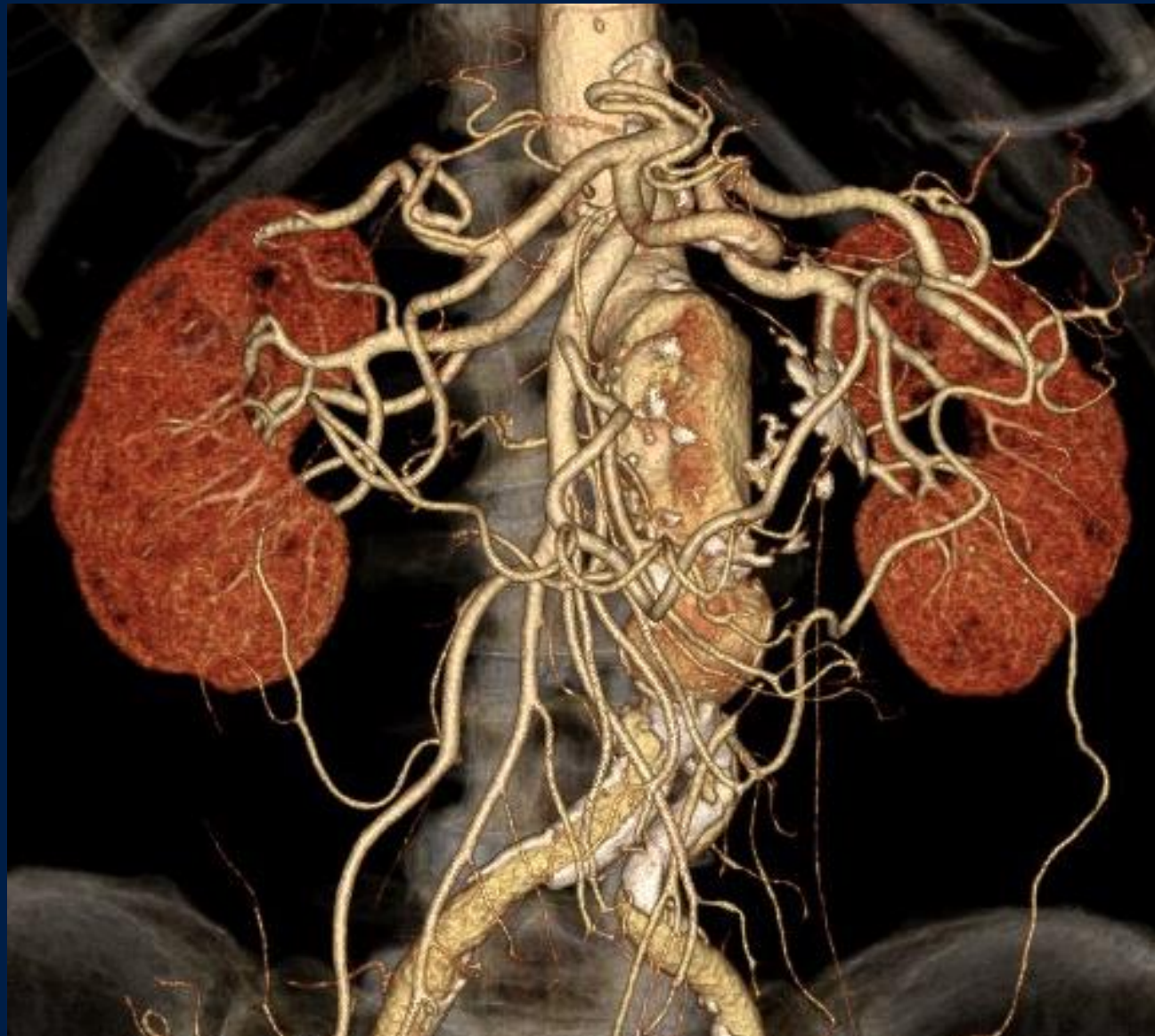
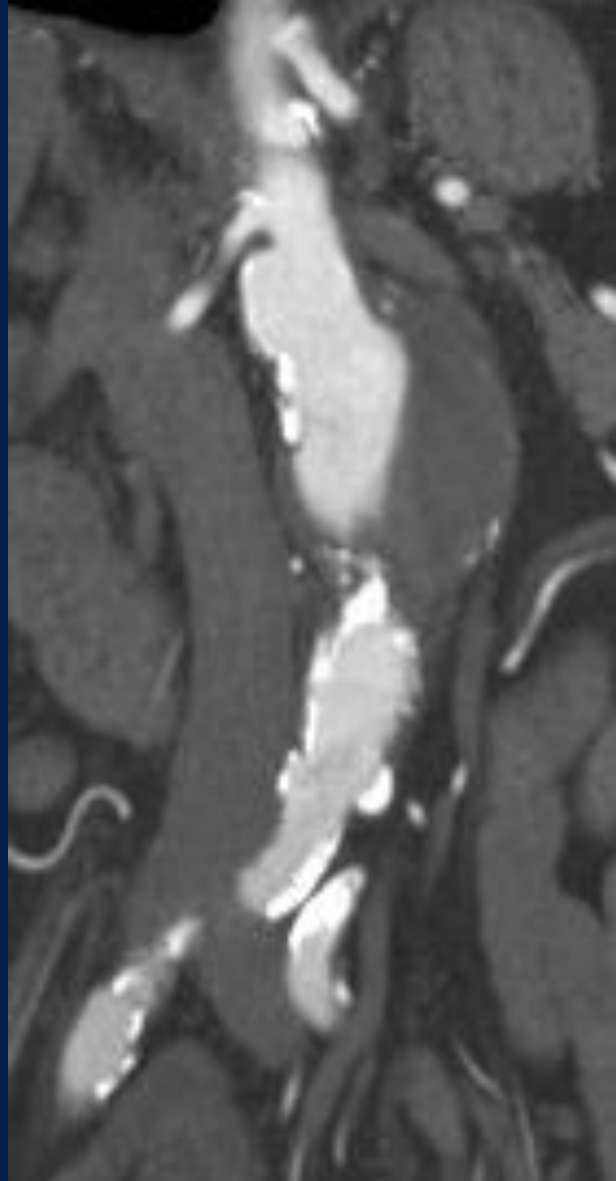
Move C-Arm in 15-20 degree increments



- Identify leak channel and then create a “suture line” along wall.
- Circumferential anchoring before/after T1 EL treatment is recommended: address concerns of long-term neck morphology changes

# THERAPEUTIC ENDOANCHORS WITH INDEX EVAR

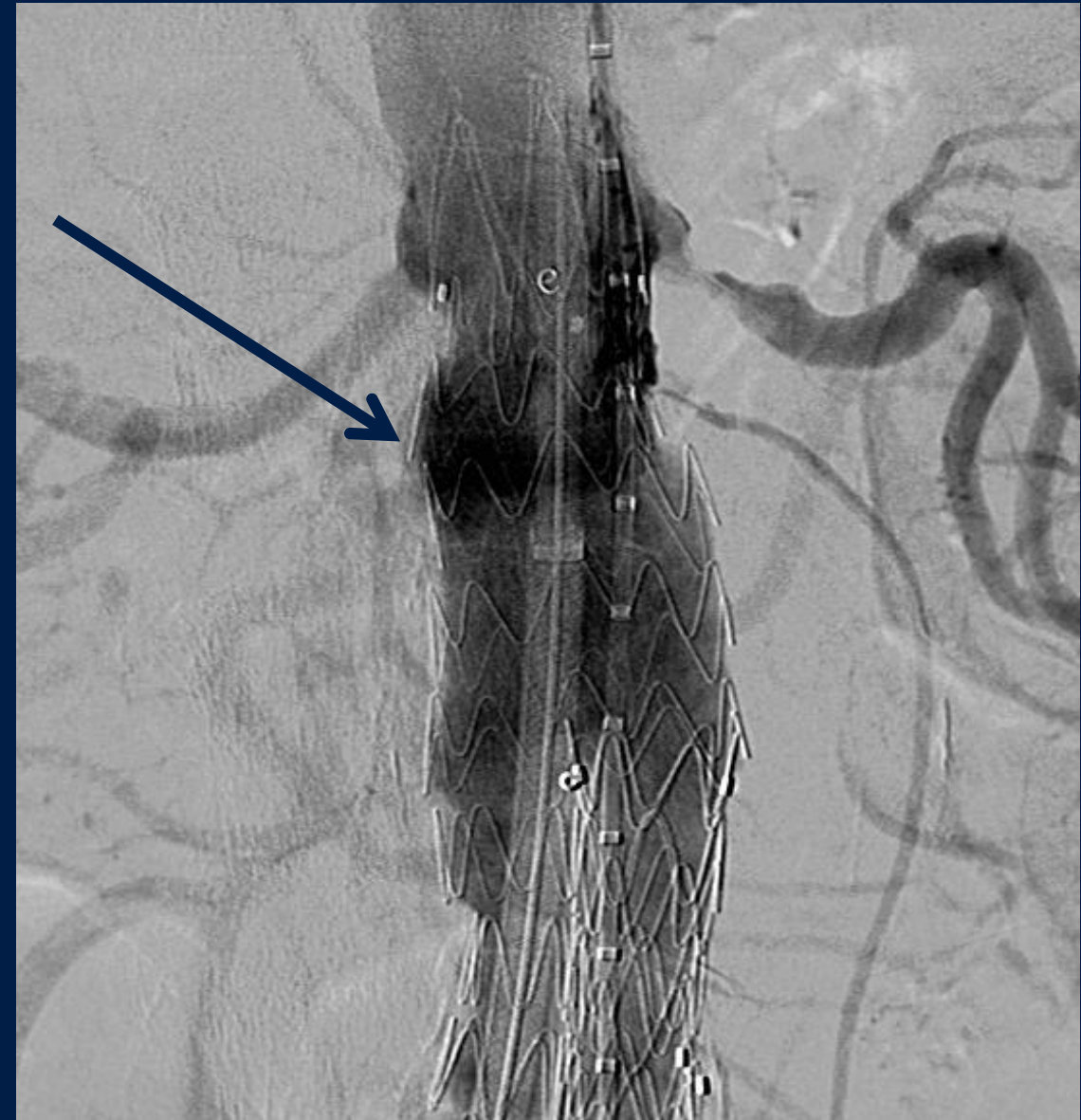
82 y.o male patient; CTA: short, conical angulated neck





# THERAPEUTIC ENDOANCHORS WITH INDEX EVAR

Post deployment angiogram: Type Ia endoleak





# THERAPEUTIC ENDOANCHORS WITH INDEX EVAR

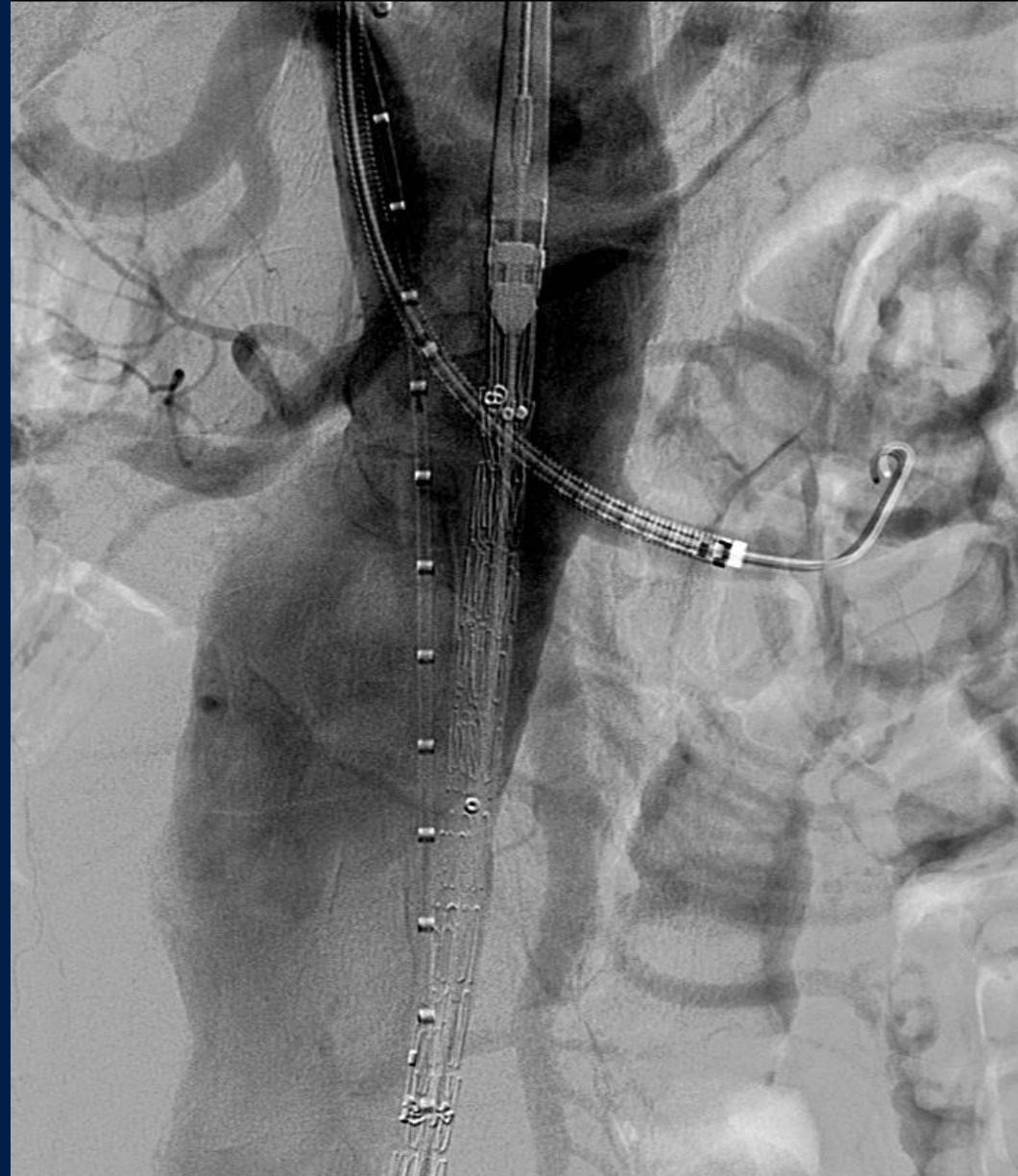
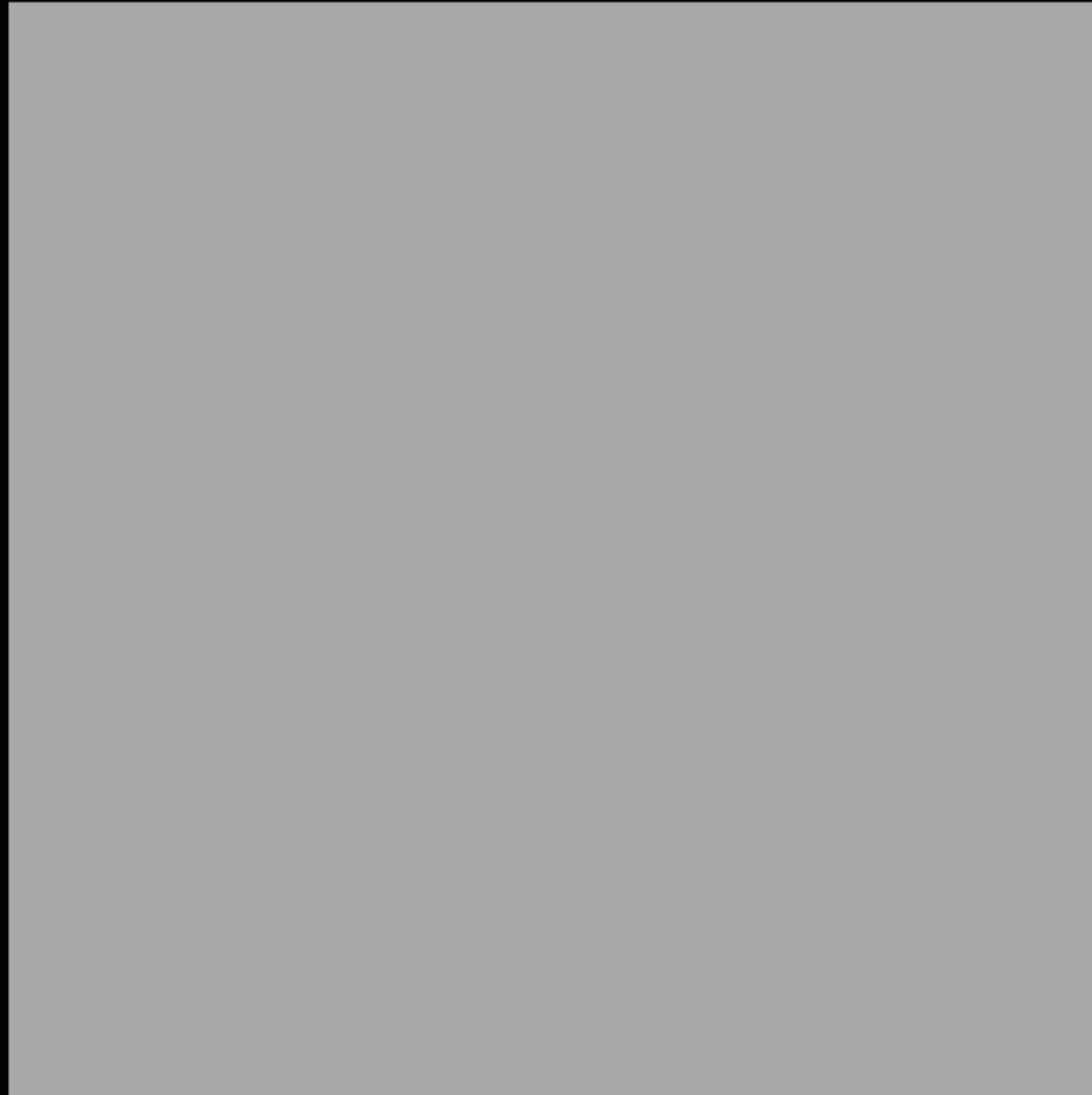
Post EndoAnchors completion angiogram: resolved endoleak



AAA sac regression  
of 11 mm at 1 year  
Thrombosed sac  
No endoleak

# THERAPEUTIC ENDOANCHORS WITH INDEX ChEVAR

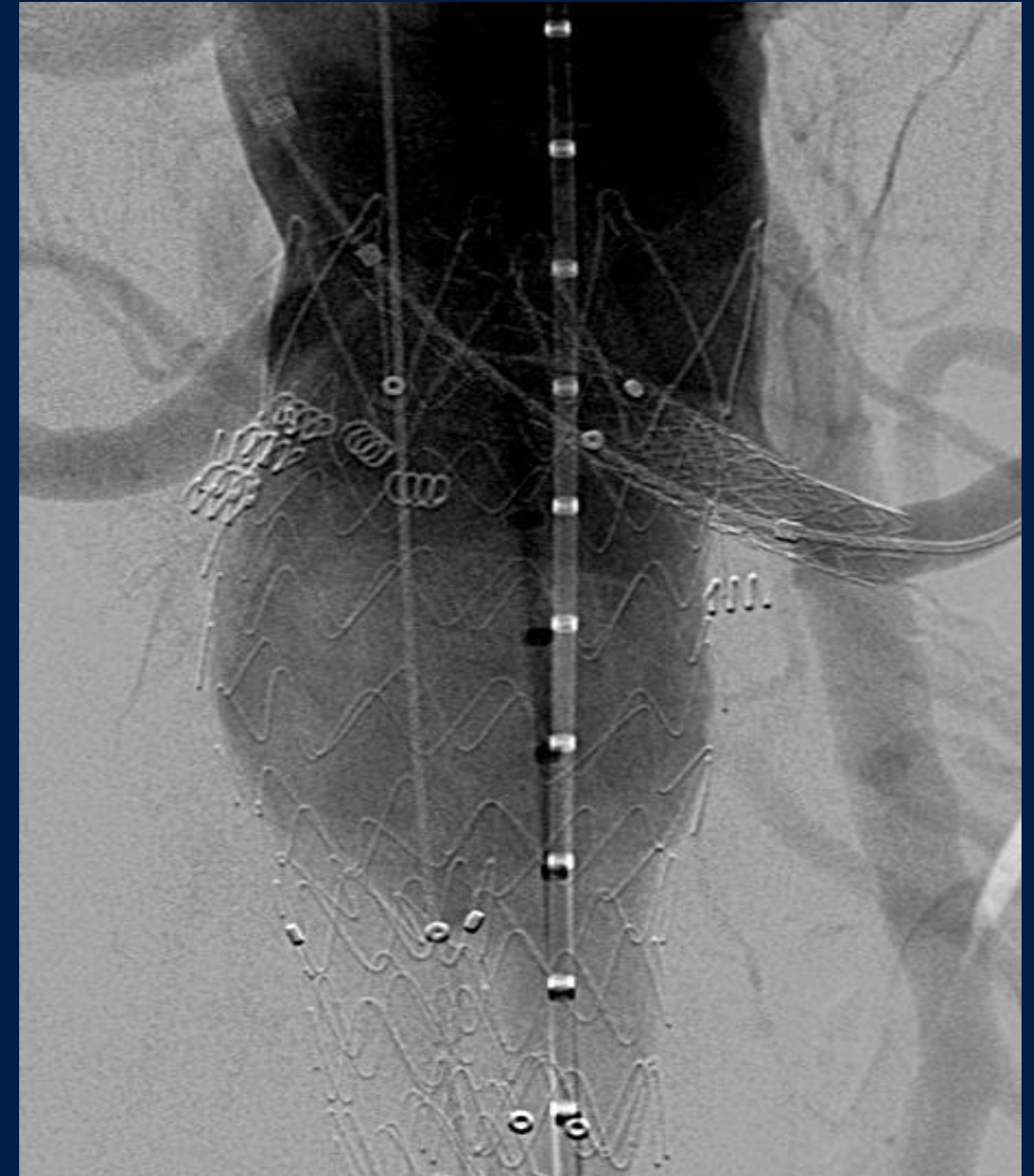
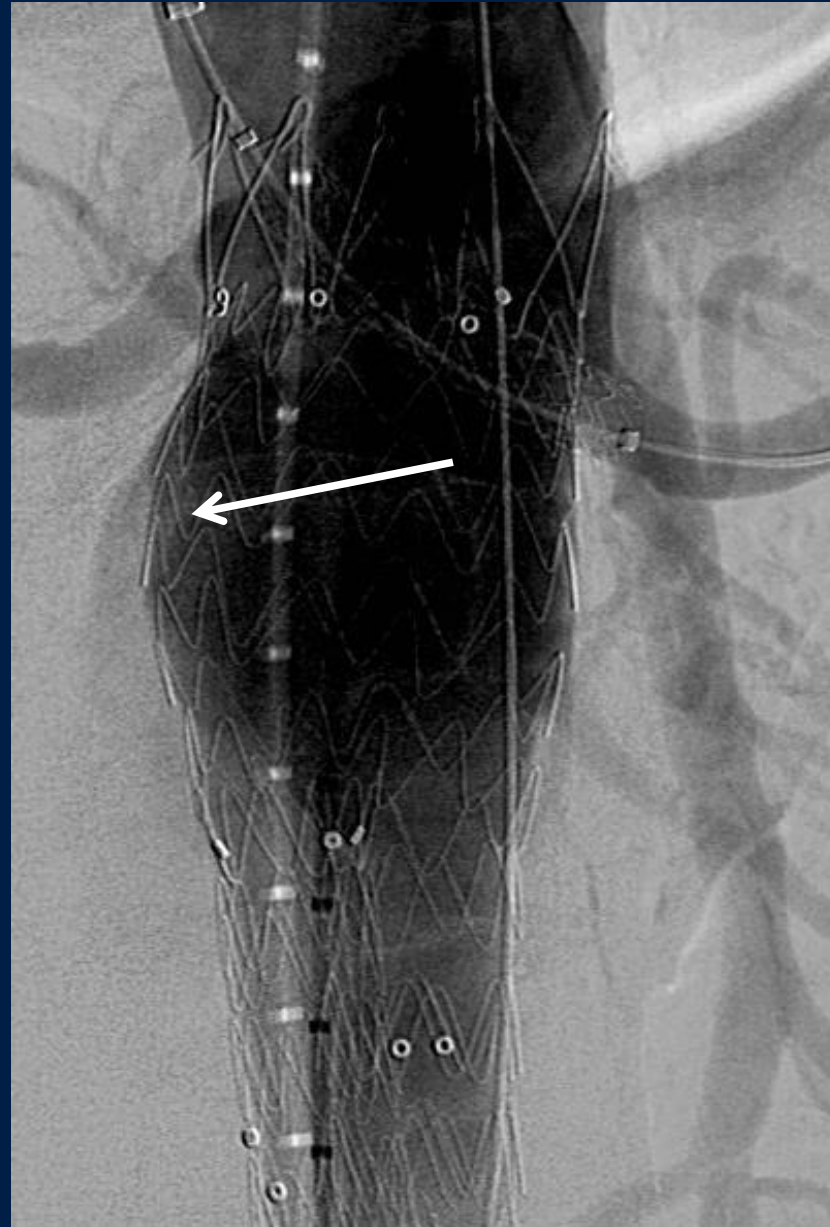
85 y.o. male patient with ruptured juxtarenal AAA



# THERAPEUTIC ENDOANCHORS WITH INDEX CHEVAR

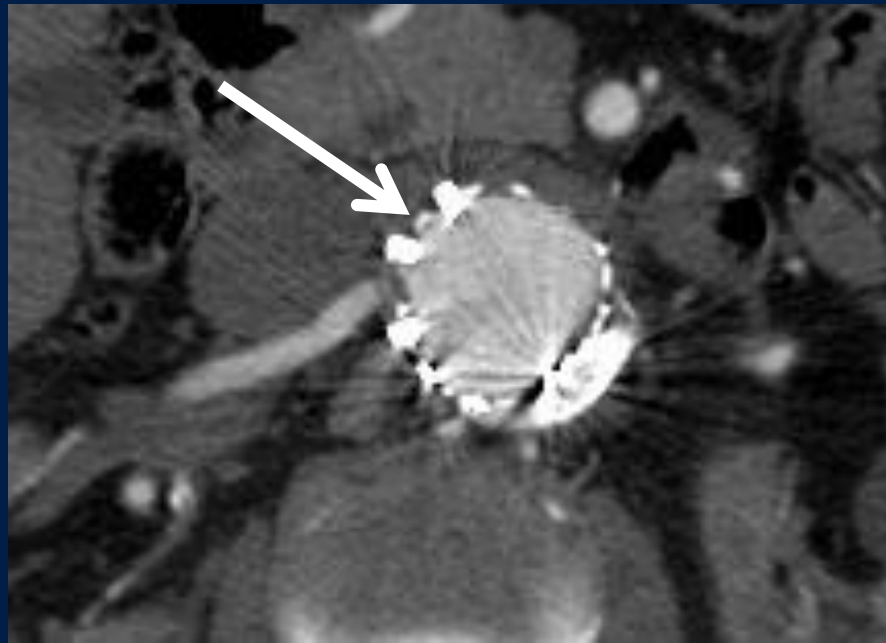
Intraop angio: Type Ia endoleak

Corrected by EndoAnchors

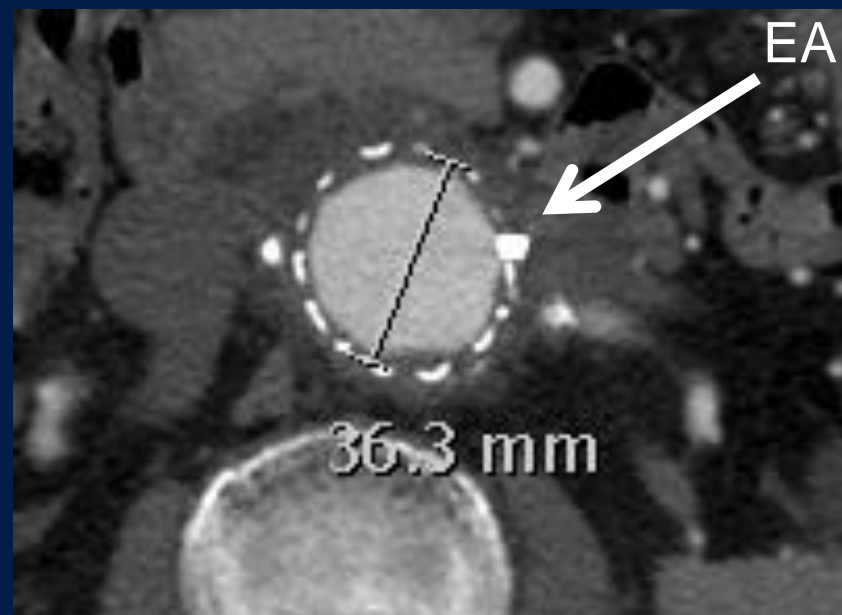




# THERAPEUTIC ENDOANCHORS WITH INDEX CHEVAR



EndoAnchor below the left renal chimney



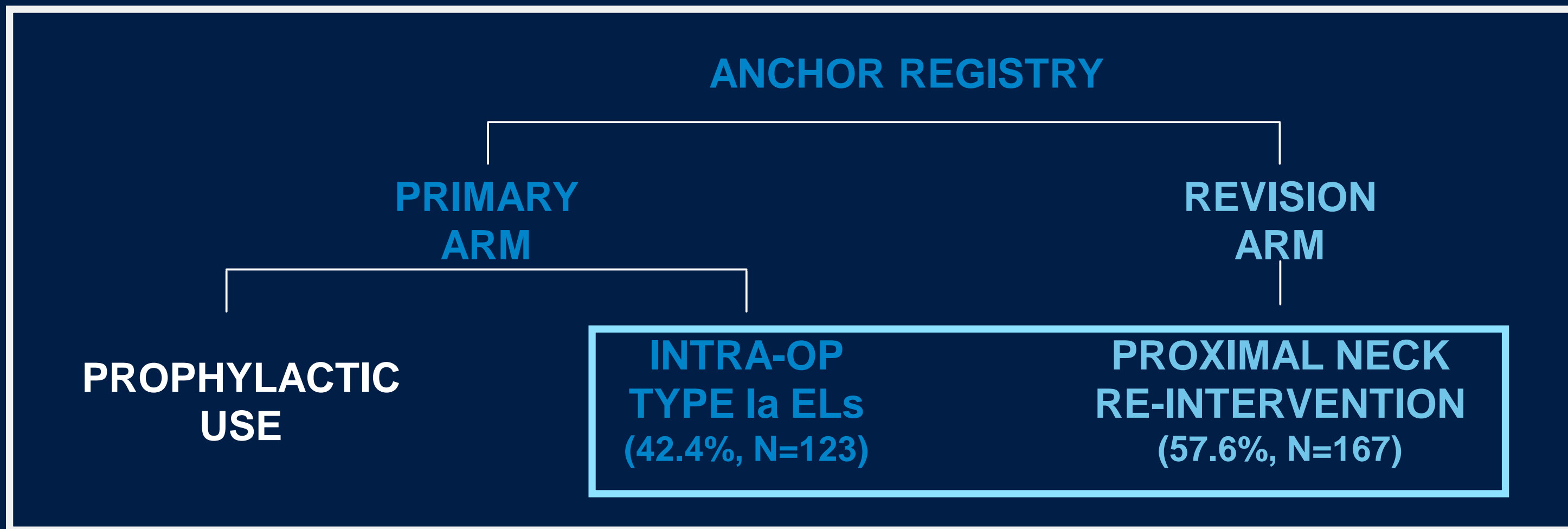
EA



EA

# ANCHOR REGISTRY – THERAPEUTIC USE (N=290)

Therapeutic Use cohort consists of patients receiving EndoAnchor™ implants to treat complications (type 1a EL, migration, neck dilatation) in the Primary and Revision Arms.



# ANCHOR REGISTRY – THERAPEUTIC USE

## Indications for EndoAnchor™ Implants

Intra-Op T1 EL Pts – within  
index procedure  
N=123

- 16.3% Urgent Cases
- 100% Type 1a Endoleak



Male: 73%



Female: 27%

Mean Age: 74.5 Years

Revision Pts – post-EVAR follow-up  
N=166

- 22.7% Urgent Cases
- 12% Migration
- 59% Type 1a Endoleak
- 18% Migration and Type 1a Endoleak



Male: 81%



Female: 19%

Mean Age: 77.6 Years

# ANCHOR REGISTRY – THERAPEUTIC USE IN INTRA-OP T1 EL

Baseline characteristics & aneurysm measurements\*



Male: 73%



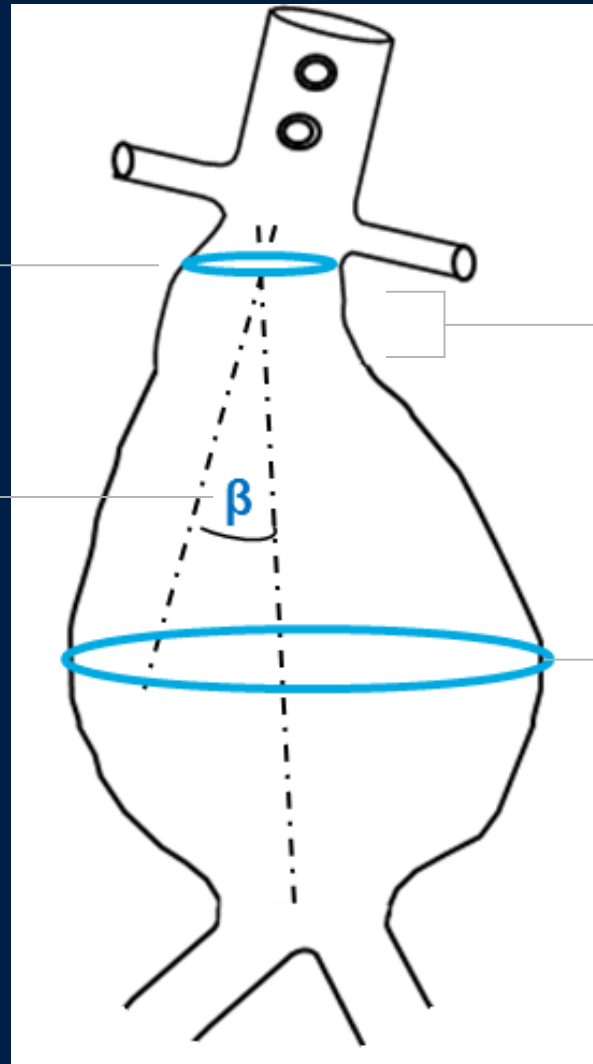
Female: 27%

Mean Age: 74.5 Years

Infrarenal Diameter:  
**26.2 mm**

Infrarenal  
Angulation: **26.6°**

Conical Neck  
(>10%/10mm): **40.2%**



Neck Length  
(median): **12.1 mm**

Aneurysm Diameter:  
**57.0 mm**

Avg Neck Calcium  
Thickness: **1.2 mm**

## HOSTILE NECKS: 82.2%

(88/107)

- Diameter at renals >28mm
- Proximal Neck Length <15mm
- Neck Angulation >60°
- Conical (>10%/10mm)
- Thrombus/Calcium >2mm OR
- Thrombus/Calcium >1mm / 180°

\* Mean Core Lab measurements based on 107 patients with baseline CTs



# ANCHOR REGISTRY – THERAPEUTIC USE IN REVISION SETTING

Baseline characteristics & aneurysm measurements\*

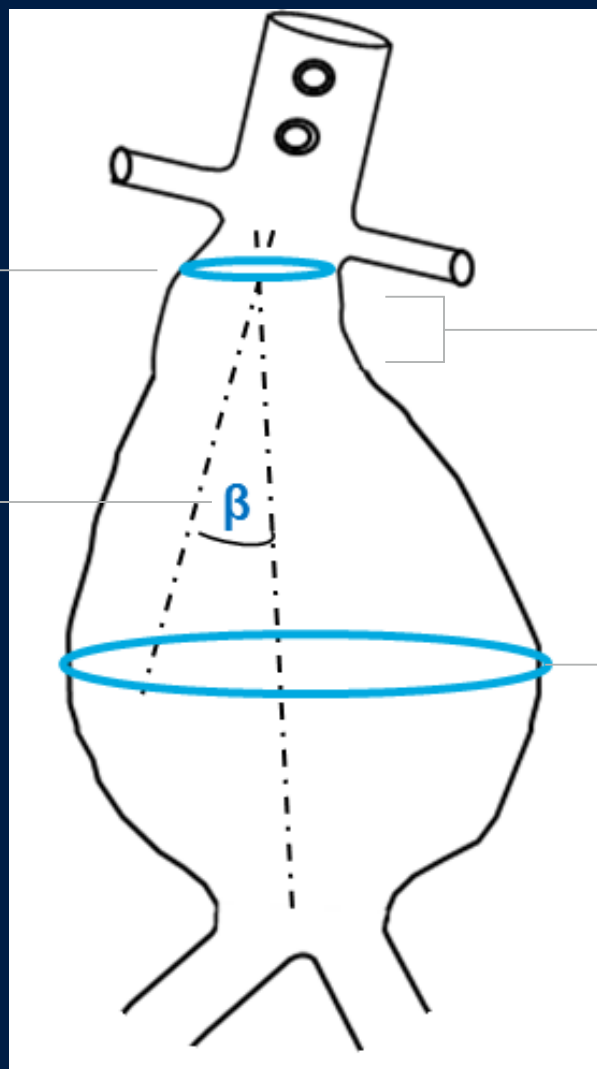


Male: 81%



Female: 19%

Mean Age: 77.6 Years



Neck Length  
(median): **10.2 mm**

Aneurysm Diameter:  
**69.6 mm**

Avg Neck Calcium  
Thickness: **0.27 mm**

## HOSTILE NECKS: 88.4%

(129/146)

- Diameter at renals >28mm
- Proximal Neck Length <15mm
- Neck Angulation >60°
- Conical (>10%/10mm)
- Thrombus/Calcium >2mm OR
- Thrombus/Calcium >1mm / 180°

\* Mean Core Lab measurements based on 146 patients with baseline CTs

# ANCHOR REGISTRY – THERAPEUTIC USE

## TECHNICAL SUCCESS

Successful deployment of EndoAnchor™ implants with adequate penetration into aortic wall



## PROCEDURAL SUCCESS

Technical success without type Ia endoleak at completion arteriography



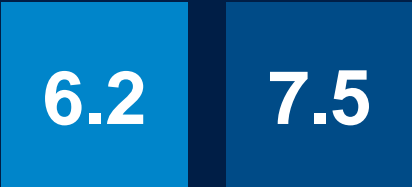
Avg. duration of Procedure (min)



Avg. time to EndoAnchor™ implants (min)



Avg. number of EndoAnchor™ implants



\* Site-reported data

# ANCHOR REGISTRY – THERAPEUTIC USE

## Proximal Endoleaks and Migration | Core Lab

Intra-Op Type 1 EL	12 months	24 months
Type 1a Endoleak	1.4% (1/70)	2.9% (1/35)
Migration	0.0% (0/44)	0.0% (0/17)

Revision Setting	12 months	24 months
Type 1a Endoleak	19.2% (15/78)	11.1% (3/27)
Migration	0.0% (0/55)	0.0% (0/16)

# ANCHOR REGISTRY – THERAPEUTIC USE

## All-Cause Mortality, Aneurysm-Related Mortality, 2<sup>nd</sup> Procedures

Intra-Op Type 1 EL	1 Year	2 Year
Freedom from ACM	95.5% (117) <sup>1</sup>	89.9% (79) <sup>1</sup>
<b>Freedom from ARM</b>	<b>98.4% (117)<sup>1</sup></b>	<b>98.4% (79)<sup>1</sup></b>
<b>Freedom from 2<sup>nd</sup> Procedures</b>	<b>97.9% (117)<sup>1</sup></b>	<b>92.9% (78)<sup>1</sup></b>

Revision Setting	1 Year	2 Year
Freedom from ACM	88.2% (158) <sup>1</sup>	75.6% (94) <sup>1</sup>
<b>Freedom from ARM</b>	<b>96.5% (158)<sup>1</sup></b>	<b>92.9% (94)<sup>1</sup></b>
Freedom from 2 <sup>nd</sup> Procedures	84.8% (156) <sup>1</sup>	79.9% (81) <sup>1</sup>



# THERAPEUTIC USE SUMMARY

EndoAnchor™ implants to treat index procedure Type Ia endoleaks associated with excellent results through 2-Year follow-up

**97.1  
%**

97.1% of patients treated for Intra-op T1 EL had decreasing or stable AAA sacs at 2-years

**92.9  
%**

92.9% of patients treated for Intra-op T1 EL were free from 2<sup>nd</sup> procedures through 2-years

EndoAnchor™ implants used in a revision setting are successful in majority of cases

**89.7%**

89.7% of patients treated in the Revision Arm had decreasing or stable AAA sacs at 2-years

**79.9%**

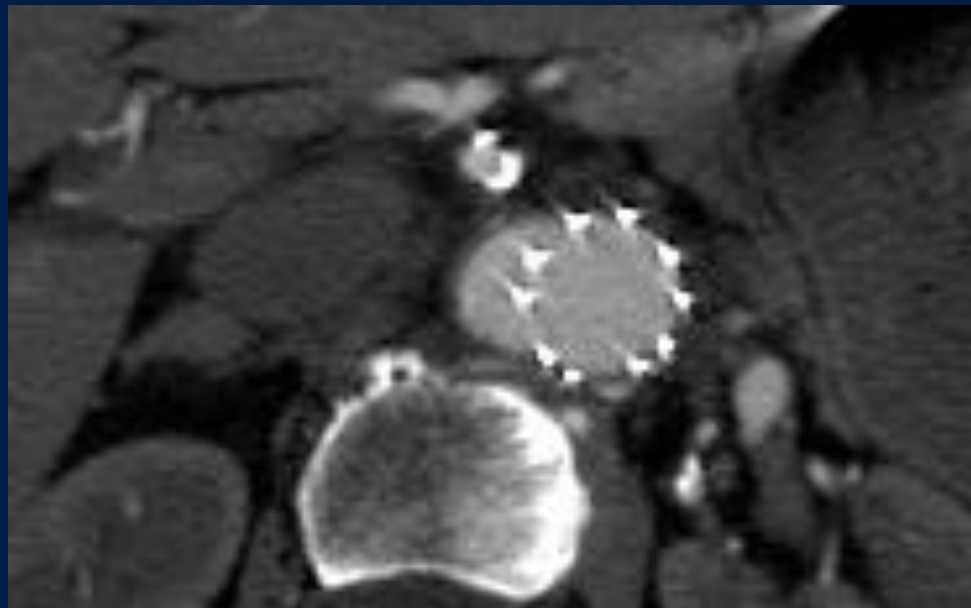
79.9% of patients treated in the Revision Arm were free from 2<sup>nd</sup> procedures through 2-years

# THERAPEUTIC ENDOANCHORS WITH ChEVAR

EL

- 87 y.o. female patient
- PMHx: HTN, CAD, CKD II
- PSHx: PCI x 3, EVAR
- Presenting with acute back pain

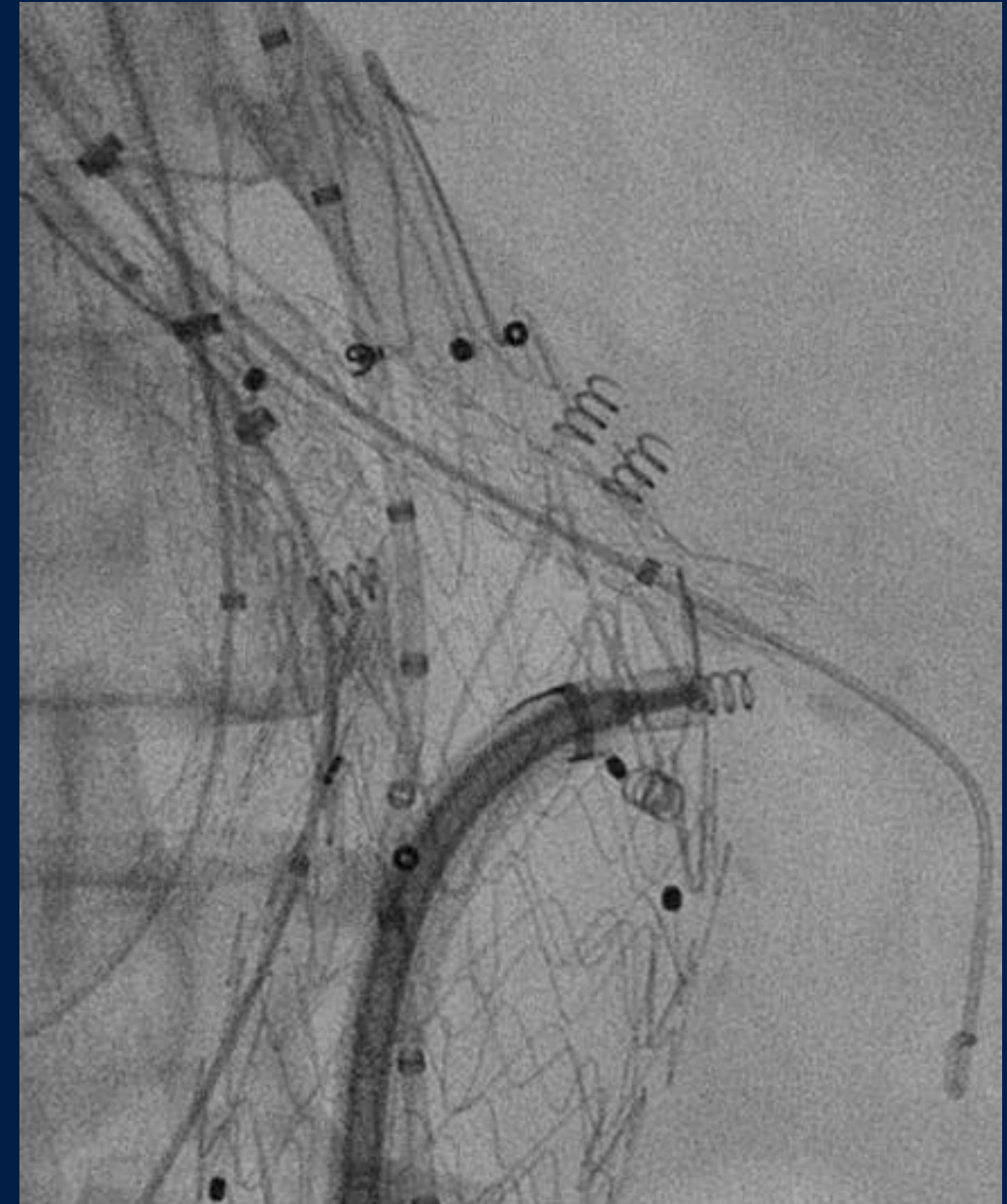
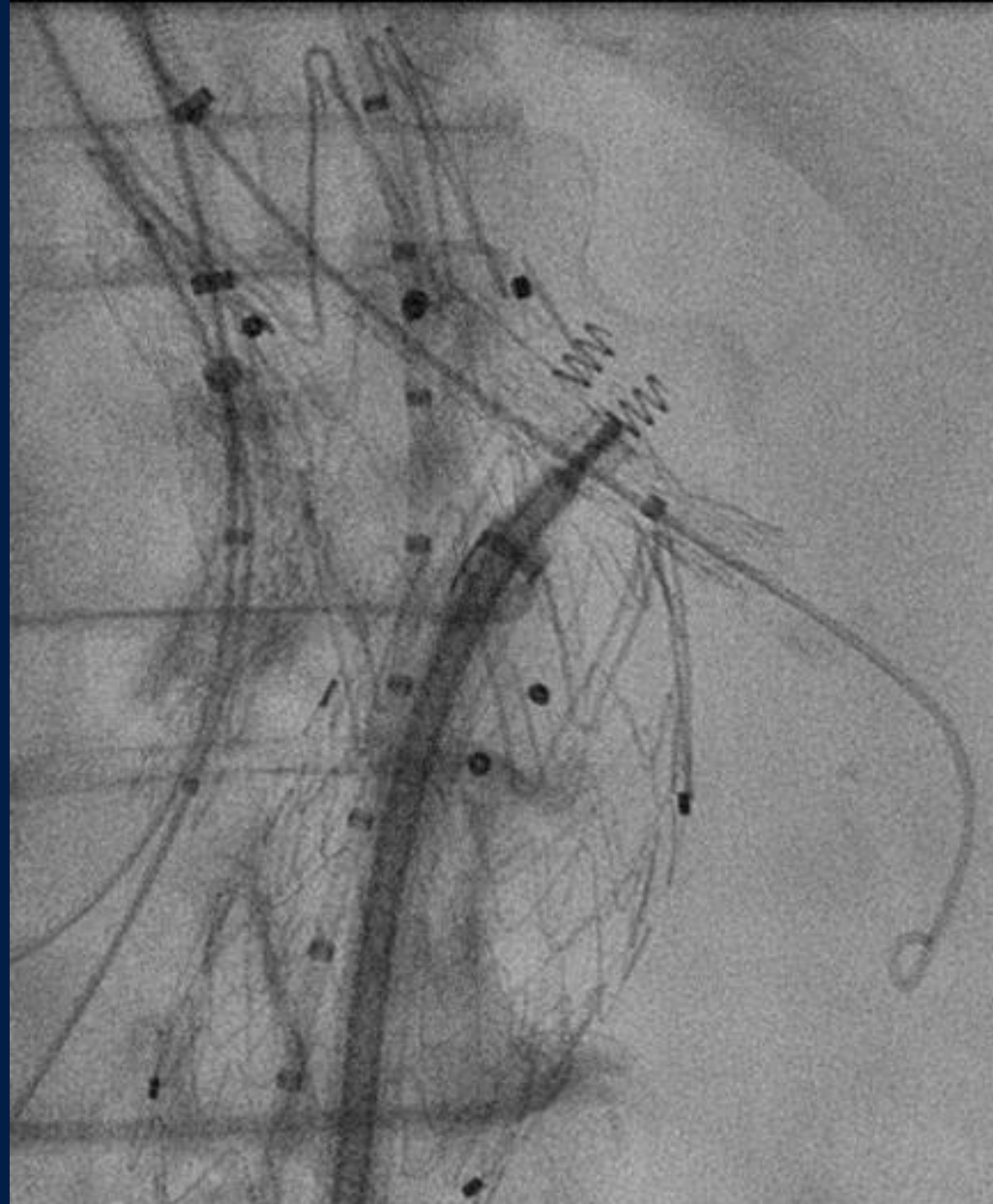
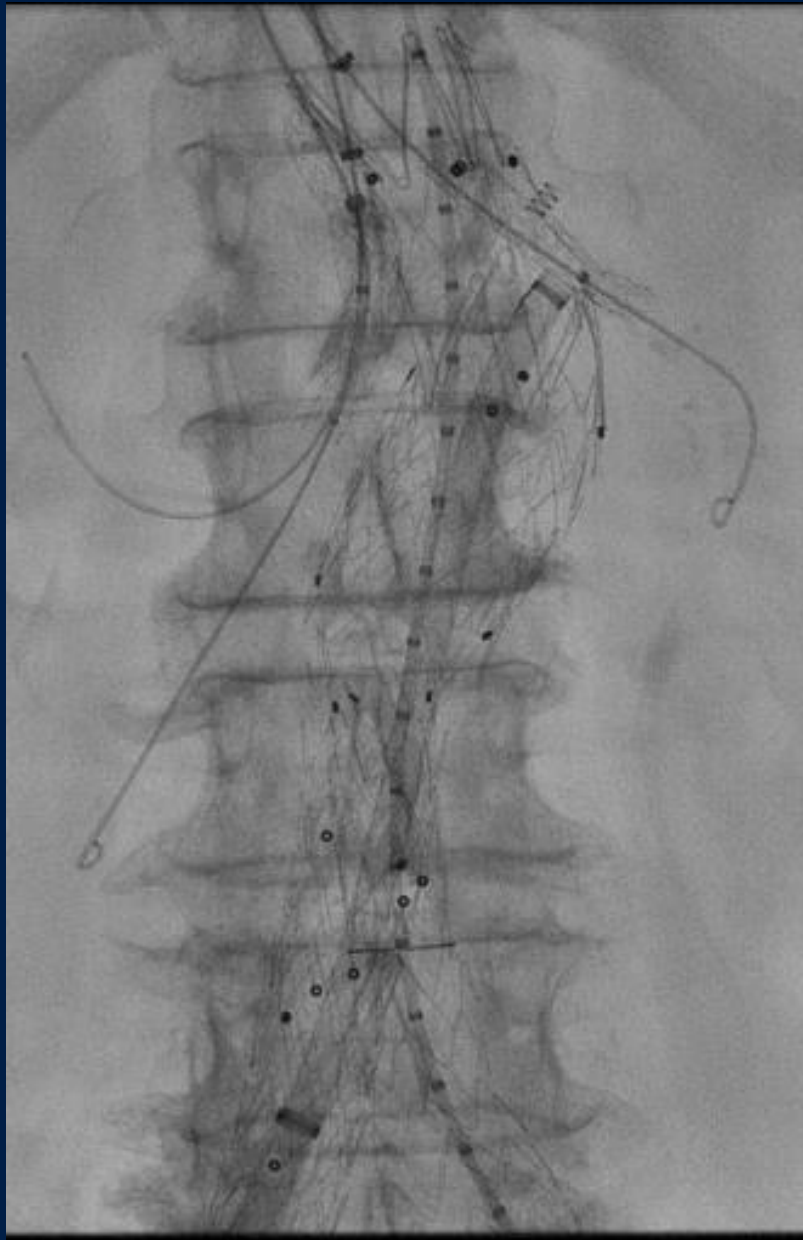
Contained ruptured AAA with a type Ia & right Ib endoleaks



Redo EVAR with Endurant cuff  
& triple chimneys  
Right hypogastric embolization  
and iliac extension

# THERAPEUTIC ENDOANCHORS WITH ChEVAR

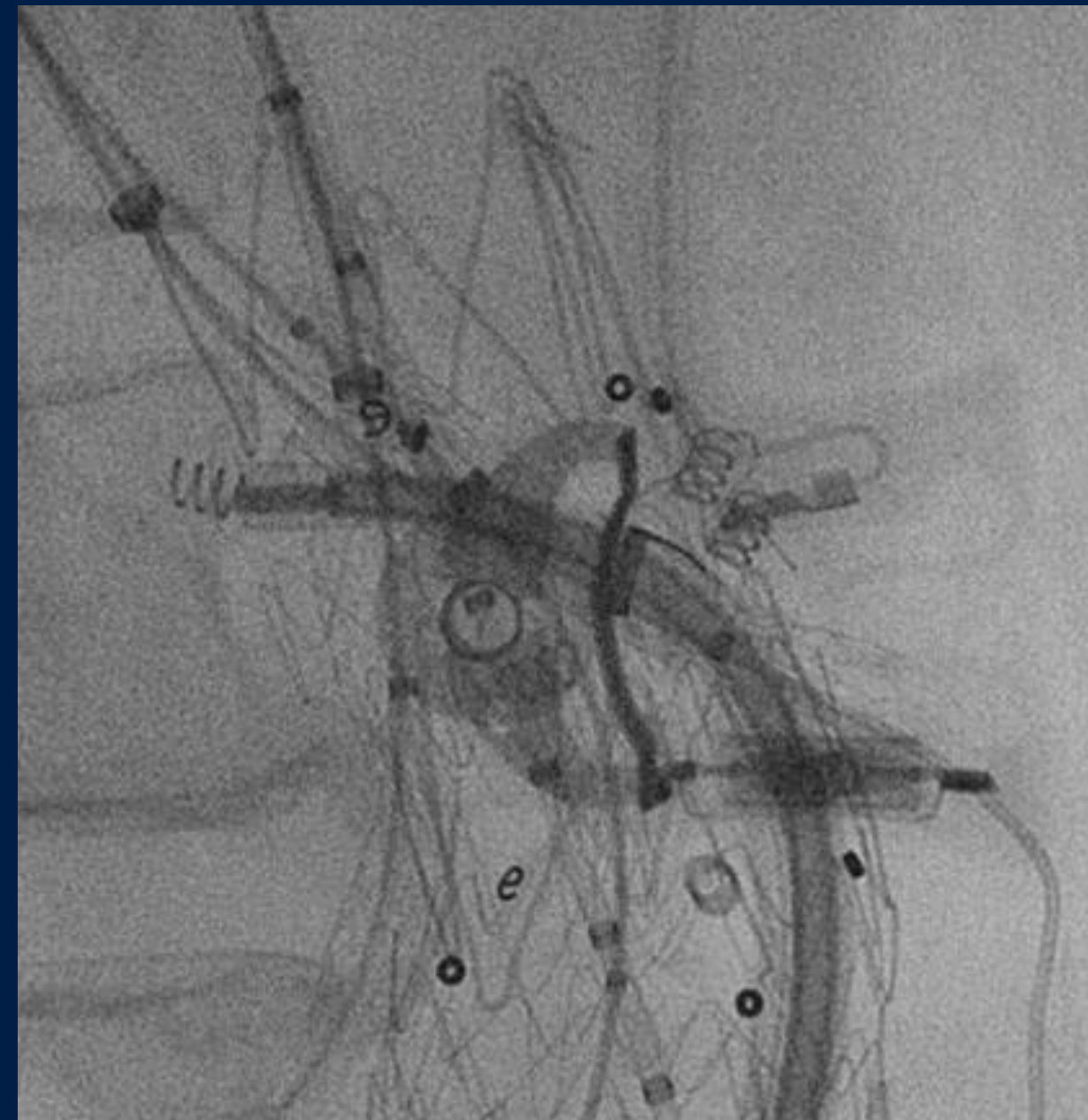
Placement of EndoAnchors above and below the left renal chimney





# THERAPEUTIC ENDOANCHORS WITH ChEVAR

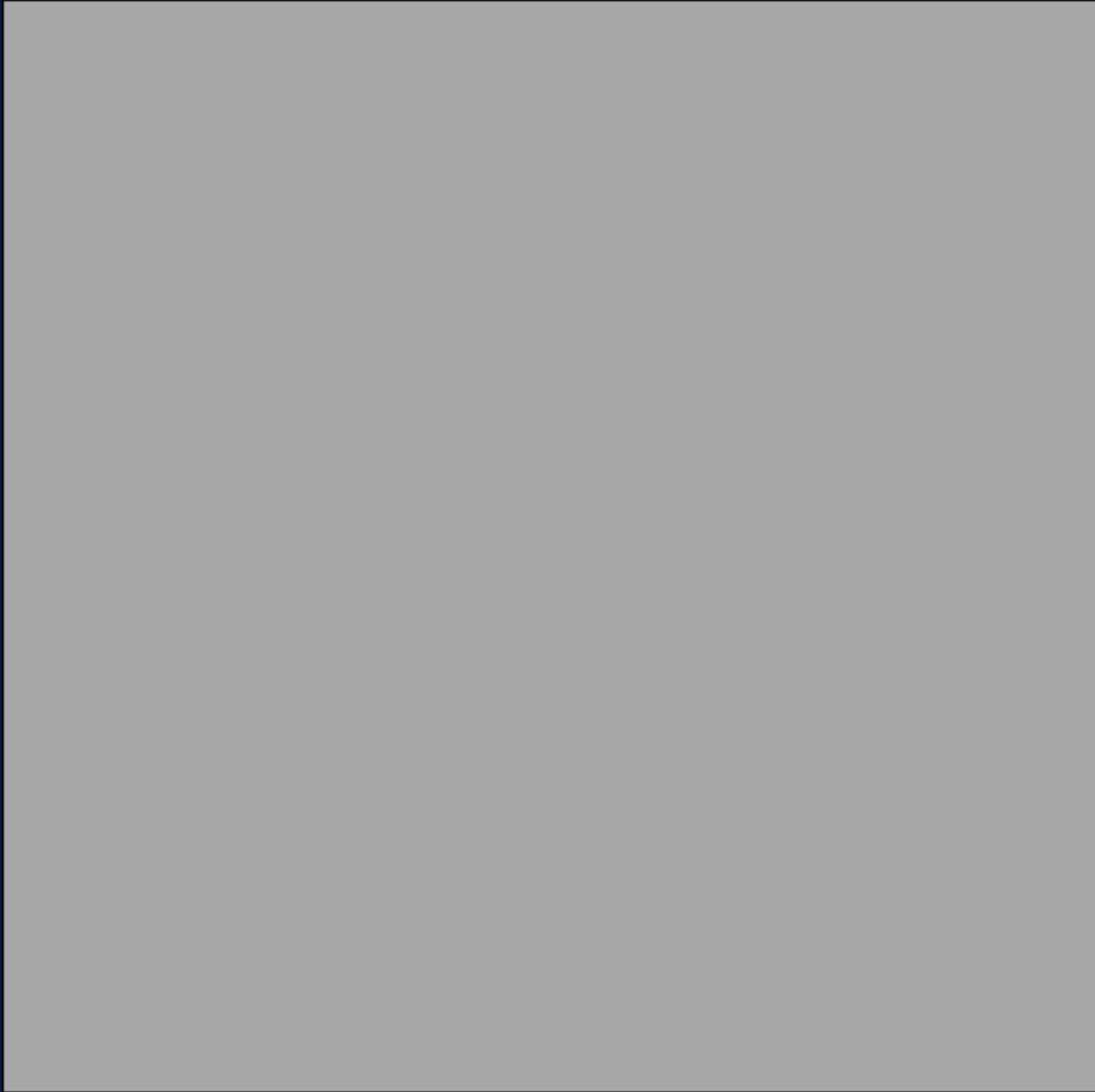
## Posterior Placement of EndoAnchors





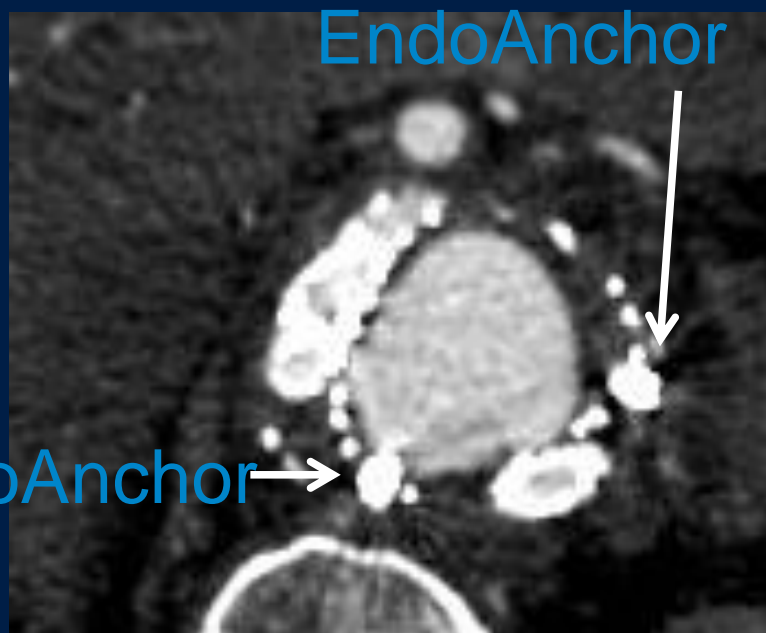
# THERAPEUTIC ENDOANCHORS WITH ChEVAR

Completion angiogram in RAO

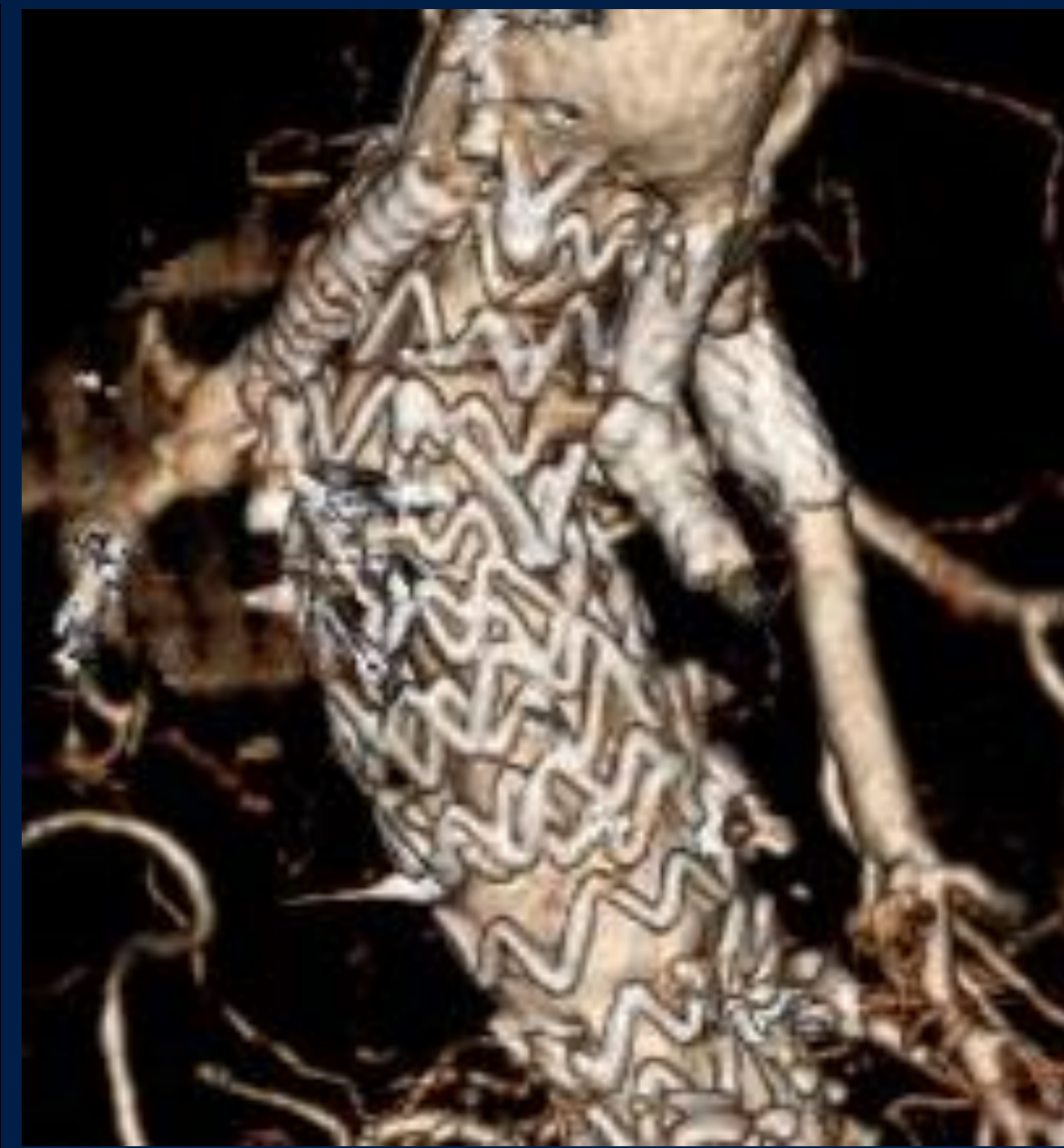


# THERAPEUTIC ENDOANCHORS WITH CHEVAR

POST OP CTA  
All 3 chimneys



CTA at 3 years: no endoleak





# CONCLUSIONS

EVAR in difficult aortic necks leads to poorer outcome and open repair should be considered in properly selected patients and in experienced hands

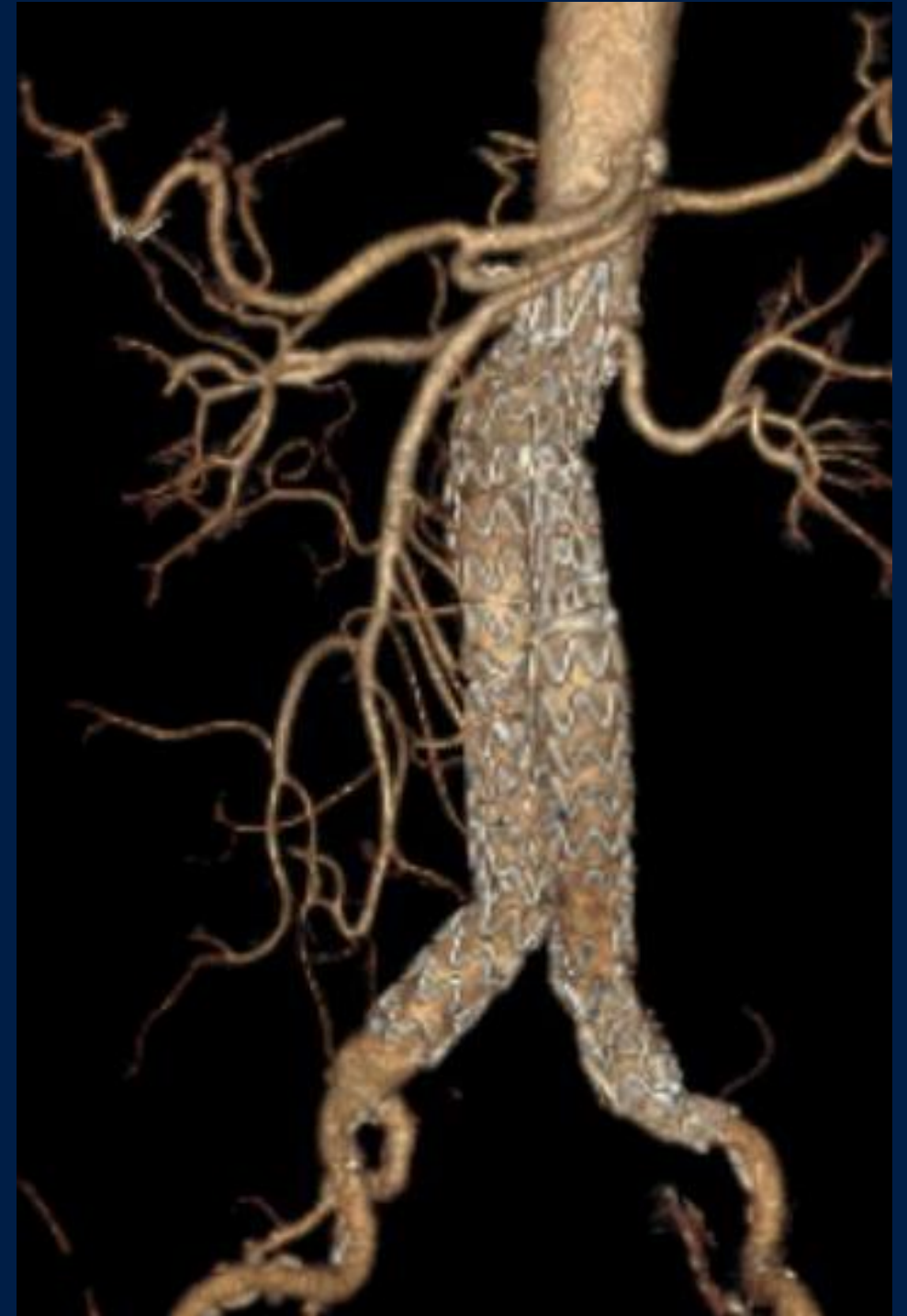
The deployment of EndoAnchors during EVAR is simple, intuitive, safe and effective.

The learning curve is relatively short and experience allows deployment in more challenging anatomy



# CONCLUSIONS

Data from the ANCHOR Registry suggest that with careful patient selection and case planning, some patients with hostile necks can be treated both safely and effectively with standard EVAR combined with EndoAnchors and without more advanced endograft technology







# Academia

Medical Education

***THANK YOU***