

Hostile Proximal Neck: A New Conformable EVAR Device



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Currently Available Devices for EVAR in Korea, 2018



Zenith Flex,
Cook



FDA approval 2003

Endurant IIs,
Medtronic



2010

INCRAFT,
Cordis



2018

AFX2,
Endologix



2015

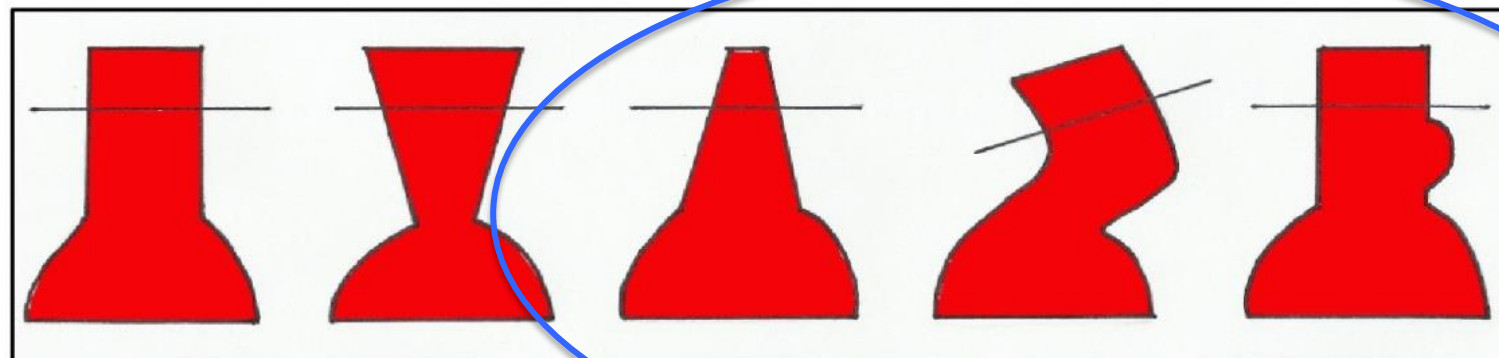
Seal,
S&G



Hostile Aortic Neck



- Aortic neck length <math>< 15\text{ mm}</math>
- Neck diameter > 28 mm
- Angulation > 60°
- Thrombus
- Calcification



Straight

Tapered

Reversed tapered

Angulated <math>< 30^\circ</math>

Bulge



Endurant

COMPLETE CONFORMABILITY OPTIMAL SEAL

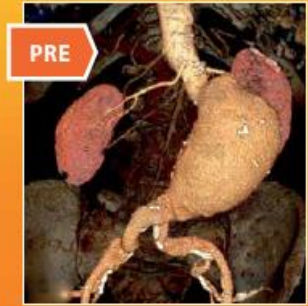
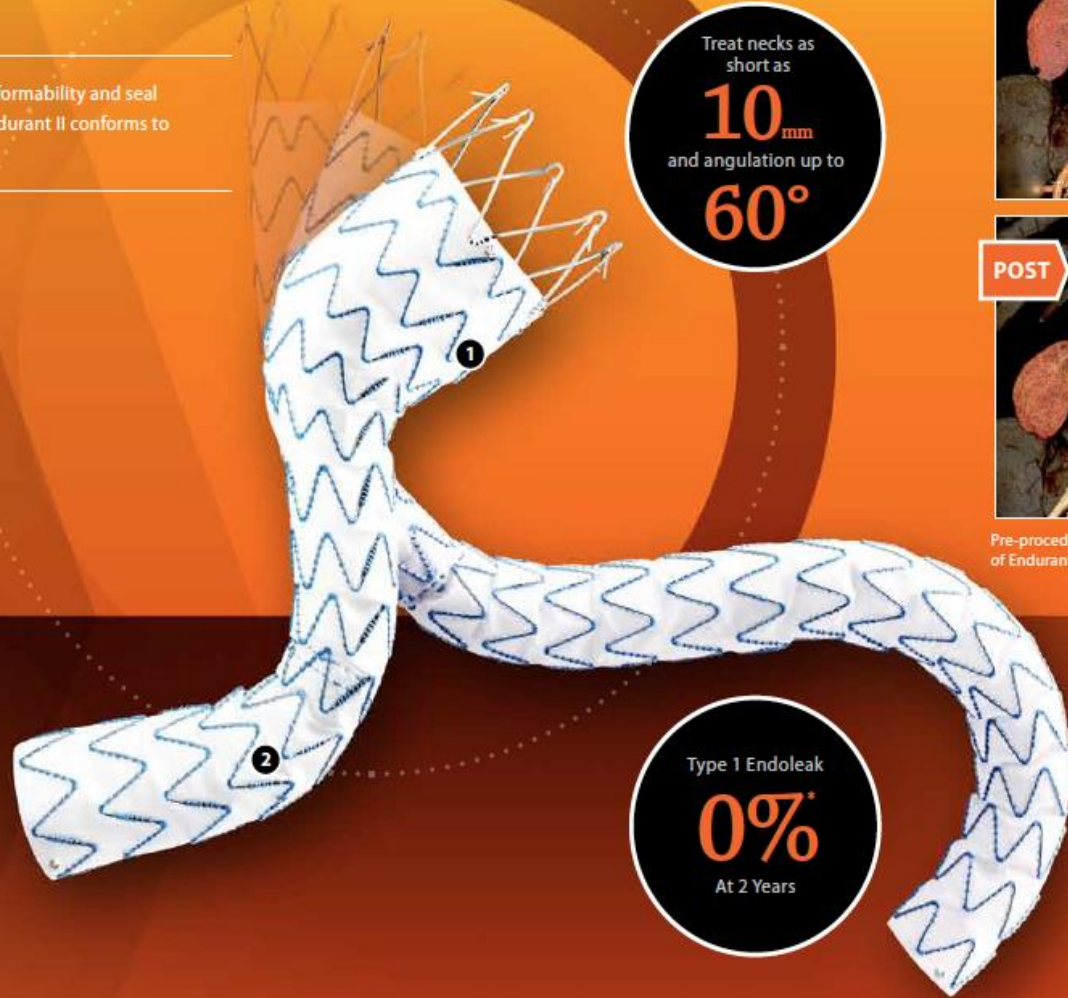
In treating anatomies both simple and daunting, conformability and seal promote success. With super-elastic nitinol stents, Endurant II conforms to tortuous iliac arteries and highly angulated necks.



1. M-shaped proximal stents provide wall apposition and minimize infolding

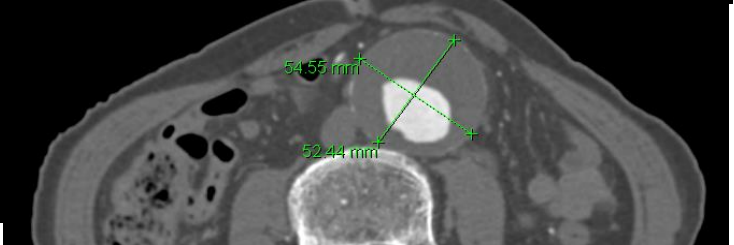
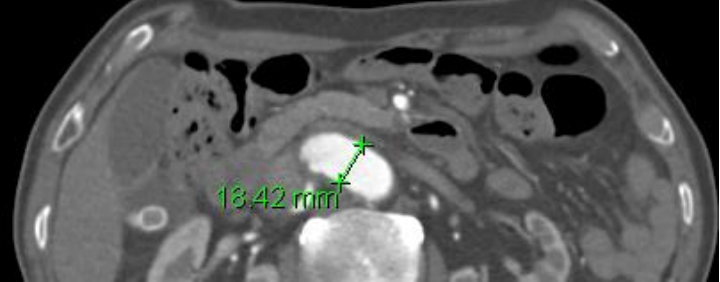
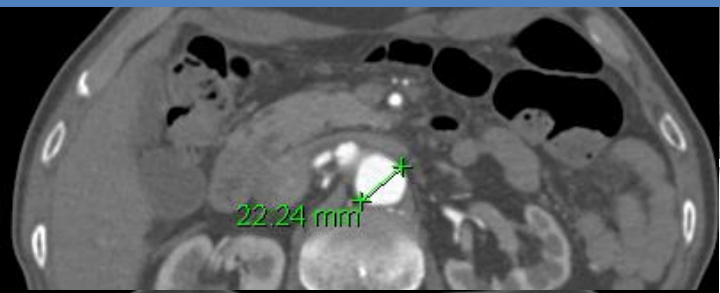


2. Limb stent and spacing between stents conform to anatomy to reduce kinking

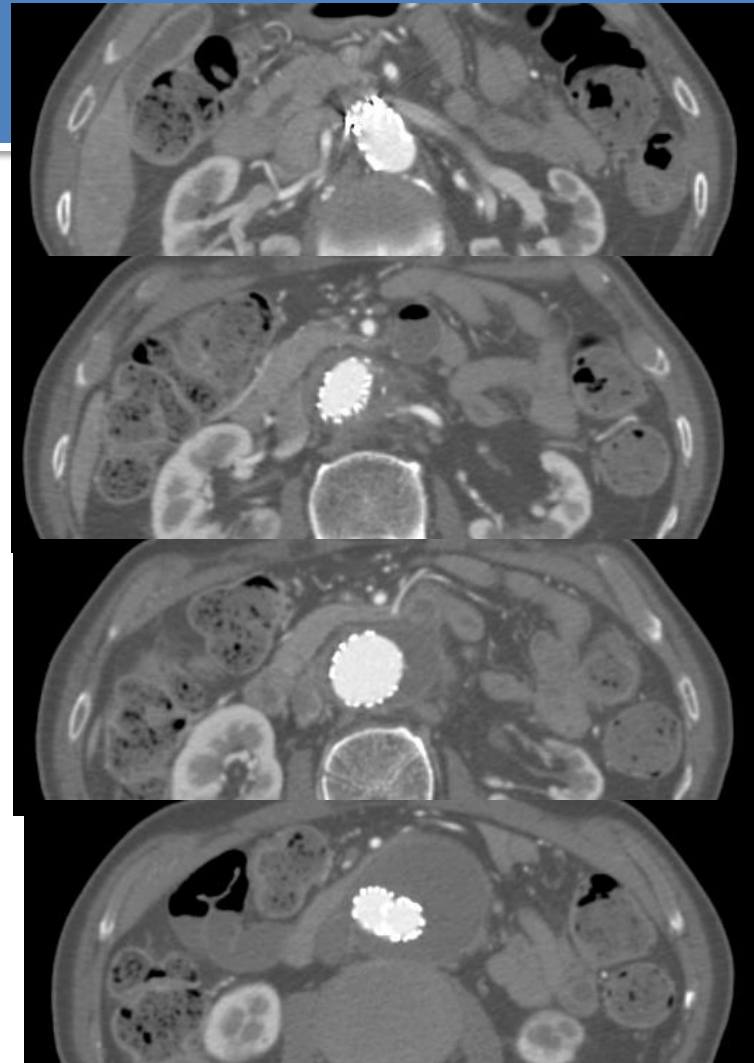
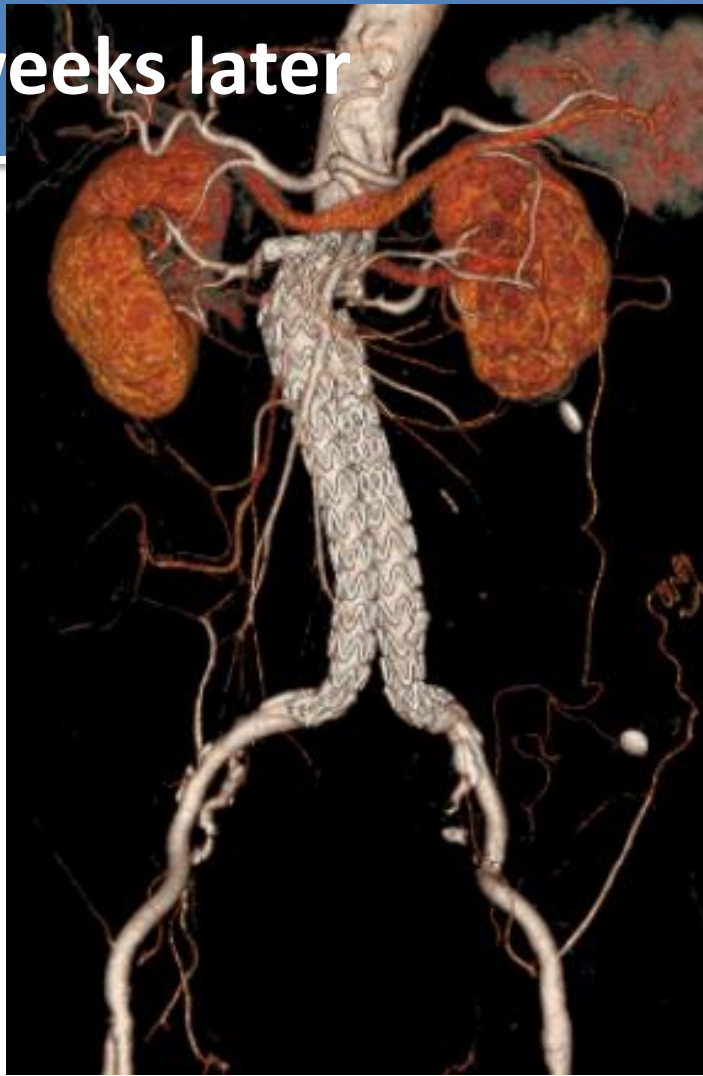


Pre-procedure and one-month follow-up of Endurant AAA stent graft.

2010-10-05



2 weeks later



AFX2 Characteristics



- **Anatomical Fixation** preserves the bifurcation enabling “up and over” procedures and eliminates gate cannulation
- **ActiveSeal™** can extend the effective seal zone beyond the neck for broader anatomical applicability
- Largest on-IFU proximal endograft **oversizing range**
- **Suprarenal and infrarenal** proximal endografts available



Stent Graft Construction



- Cobalt Chromium Alloy
- Shape Memory
- High Fatigue Resistance
- High Abrasion Resistance
- Radiopaque
- MRI compatible
- Wire size .016", .014" and .012"



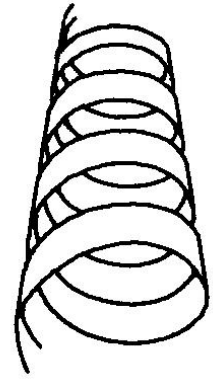
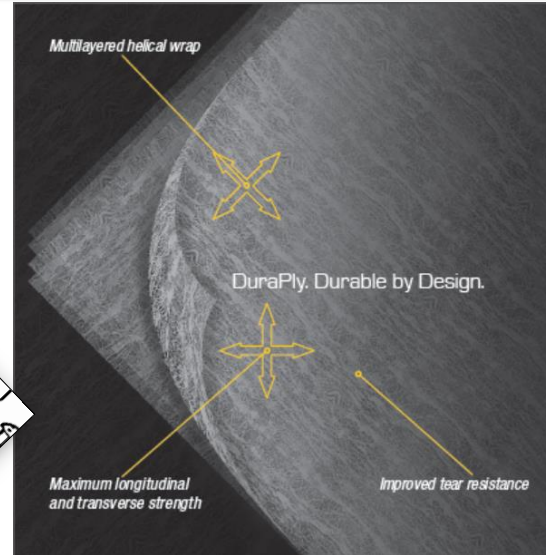
ePTFE Design



DuraPly™



Multilayer ePTFE



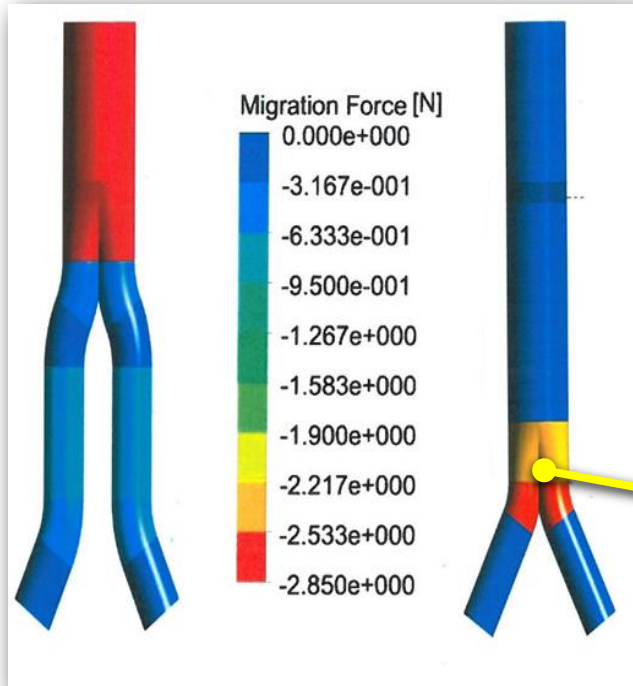
Multiple Helically Wound Layers

Developed to maximize strength in every direction while maintaining ActiveSeal™

(expanded polytetrafluoroethylene)



Anatomic Fixation Combined with High Columnar Strength Obviates Proximal Fixation



Phase I Report: Computer Simulation of Axial Forces Exerted on Idealized Stent-graft Configurations. Data on file at Endologix.

Li Z, Kleinstreuer C. Analysis of biomechanical factors affecting stent-graft migration in an abdominal aortic aneurysm model. *Journal of Biomechanics* 2006; 39: 2264-2273

Kleinstreuer C. *Biofluid Dynamics: Principles and Selected Applications*. 2006. CRC Taylor & Francis, Boca Raton/London/New York.



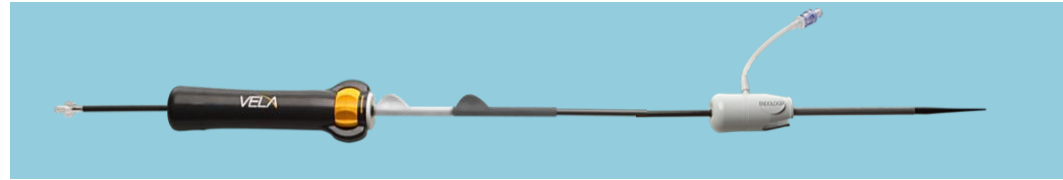
System Overview



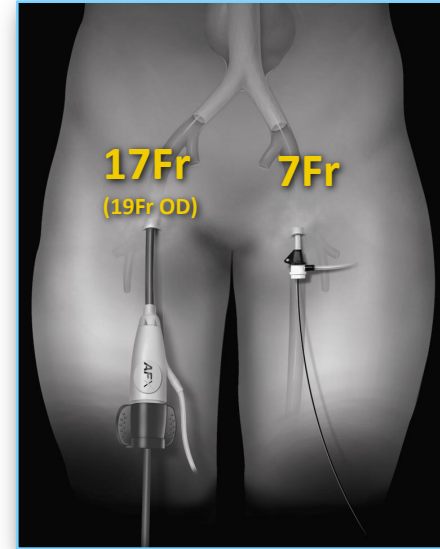
AFX 17F (19F OD) Introducer Sheath



VELA™ Proximal Delivery System



AFX®2 Bifurcated Delivery System



Insertion of Bifurcated Endograft



Intuitive, Streamlined Deployment

No time-consuming gate cannulation

- Single-step, single-motion contralateral limb deployment
- Standardized, rapid procedure steps



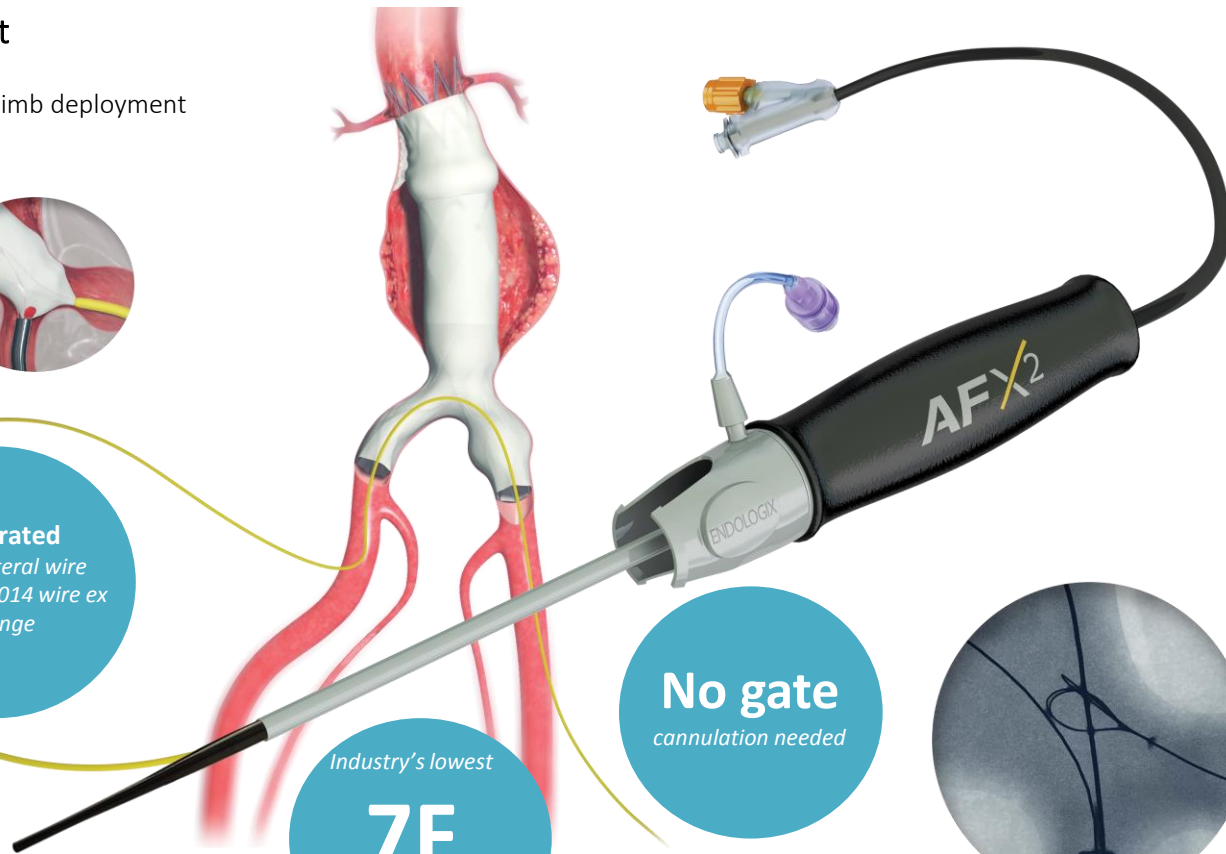
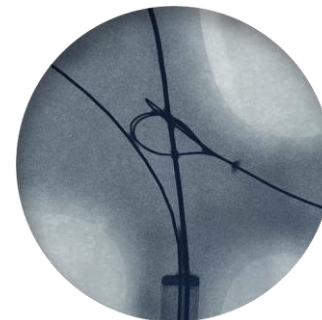
Integrated
contralateral wire
obviates 0.014 wire ex
change

Industry's lowest

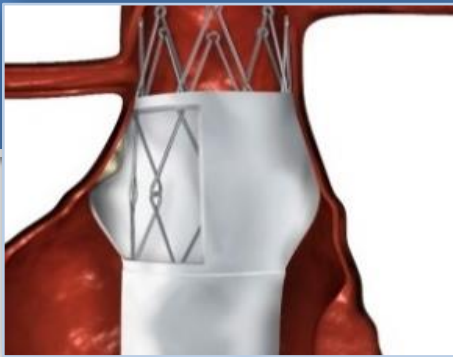
7F

contralateral
introducer

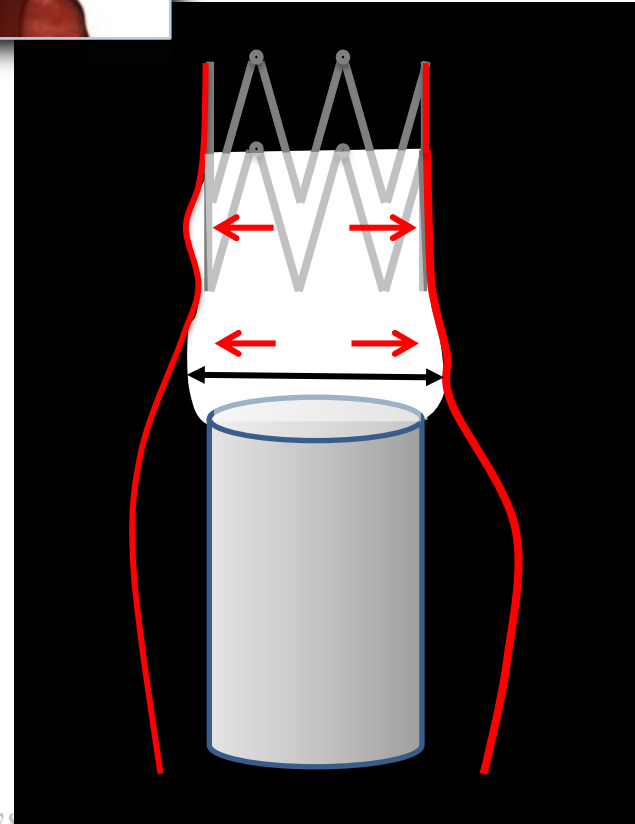
No gate
cannulation needed



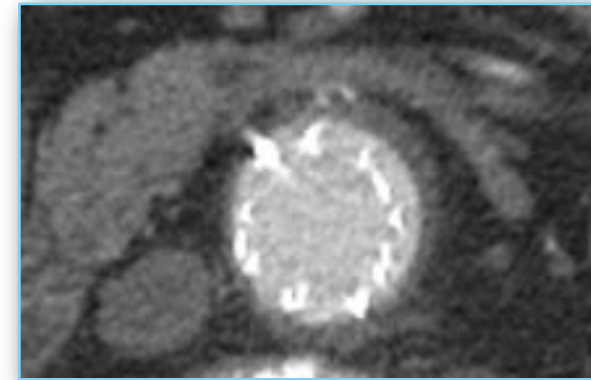
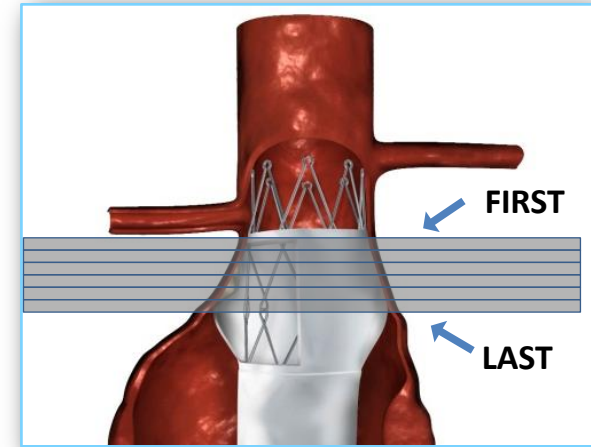
ActiveSeal



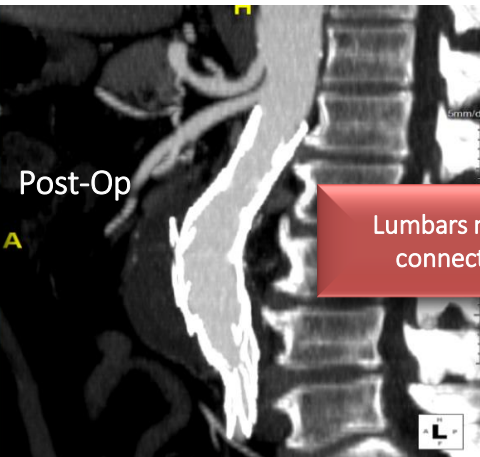
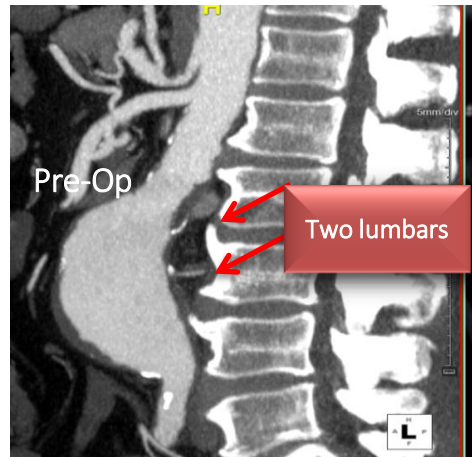
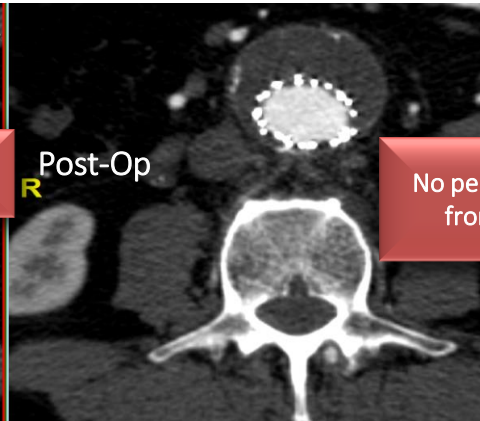
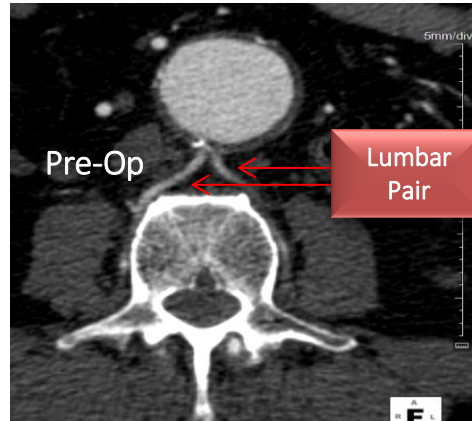
- Initial sac exclusion – radial force
- Self-expanding stent allows oversizing
- *ActiveSeal* – graft conforms to aortic wall beyond stent frame due to pressure gradient between aorta and excluded sac
- Graft material attached to stent only at ends



Active Sealing: What it looks like



Active Seal: Lumbar Obliteration



Arthurs Z. Western Vascular Surgical Society 2014

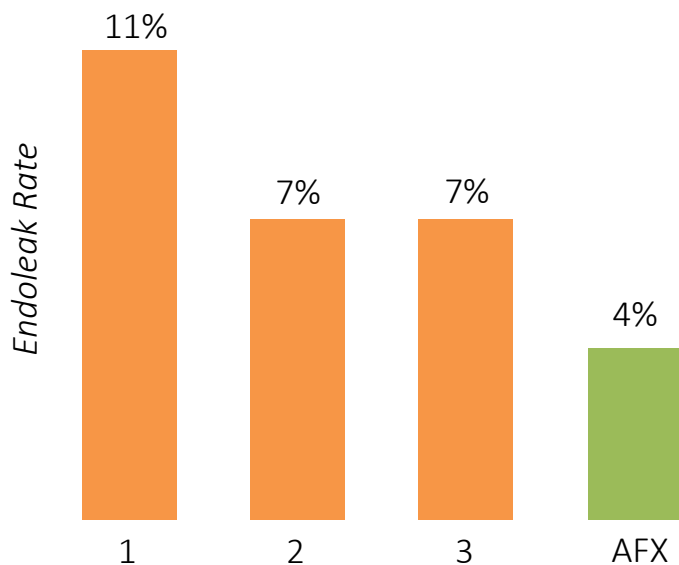
Severance Cardiovascular Hospital, Yonsei University Health System



Active Seal: Effect on Endoleak

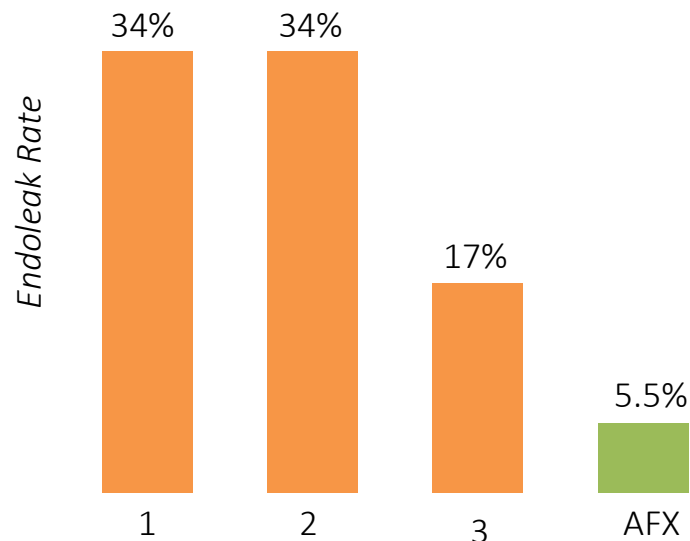


Type IA Endoleak – Hostile Necks



1. AbuRhama et al, J Vasc Surg 2011; 54: 13-21. 149 patients @ 1 year
2. Stather et al. Endovascular Aortic Aneurysm Repair in Patients with Hostile Neck Anatomy. J EVT 2013;20:623-637. 2454 patients @ >30 days
3. Torsello et al, J Vasc Surg 2011; 54: 300-6. 56 patients @ 1-year

Type II Endoleak



1. G. Torsello et al, J Vasc Surg epub 2014 – Cordis Incraft™ Innovation Trial, 1-y results
2. Ovation Prime® IFU
3. E. Cieri et al, J Vasc Surg 2014; 59: 930-7. 1063 pts @ 1-year



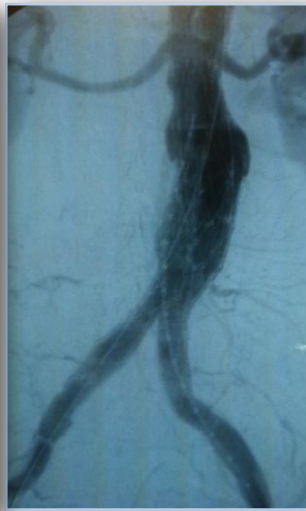
Advantages of Anatomical Fixation

Unibody Design in Tight Distal Anatomies

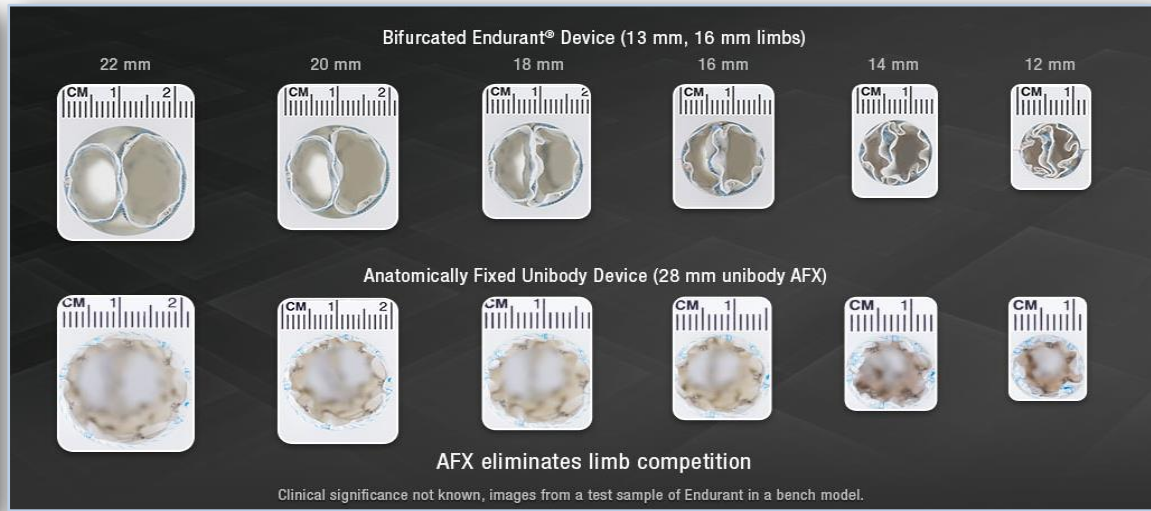
Pre



Post



Limb Competition in Tight Distal Aorta



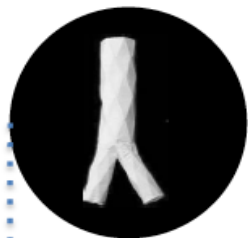
- Obviates gate cannulation
- Eliminates limb competition
- Mitigates limb occlusion



Product Timeline

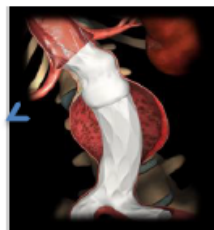


POWERLINK US APPROVAL



2005

AFX



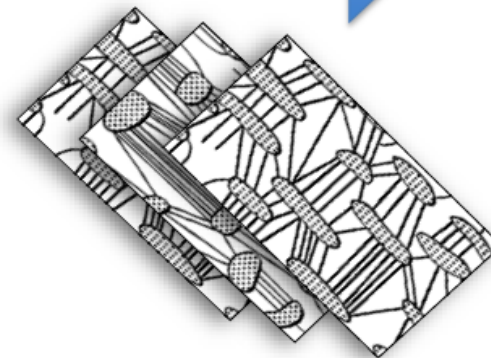
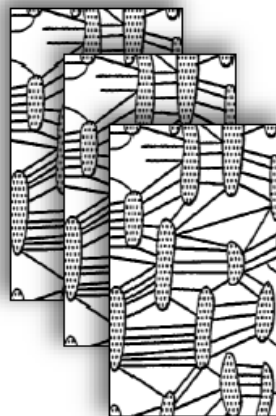
Strata

2011



2014

2015



Strata Graft Devices Recalled Due to Risk of Type III Endoleak



Endologix Recalls More Than 61,000 AAA Systems Due to Endoleak Risk

By MedTech Intelligence Staff

No Comments



There have been reports of Type IIIa and IIIb endoleaks related to the company's AFX Endovascular AAA Systems.



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Email

Endologix's AFX Endovascular AAA System has been recalled due to reports of certain endoleaks—Type IIIa and IIIb endoleaks, which can lead to an abdominal aortic aneurysm rupture or death. The Class I recall affects 61,300 devices that were manufactured between March 2011 and present time. As noted on FDA's website, [most of the endoleaks have occurred](#) with the AFX with Strata graft material. However: "Endologix has not manufactured the AFX with Strata graft material since July 2014 and health care providers were advised to remove any remaining inventory from shelves in December 2016. However, the AFX with Duraply graft material and AFX2 devices have been distributed for a shorter time and it is unclear if these devices have fewer endoleaks or if they have not been implanted long enough for endoleaks to occur," states FDA.

Severance Cardiovascular Hospital, Yonsei University Health System

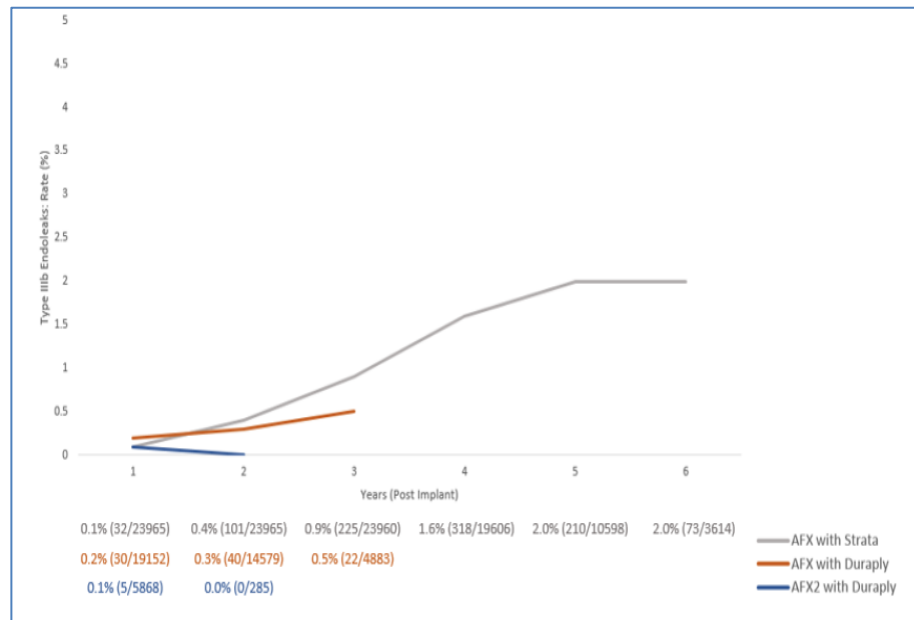
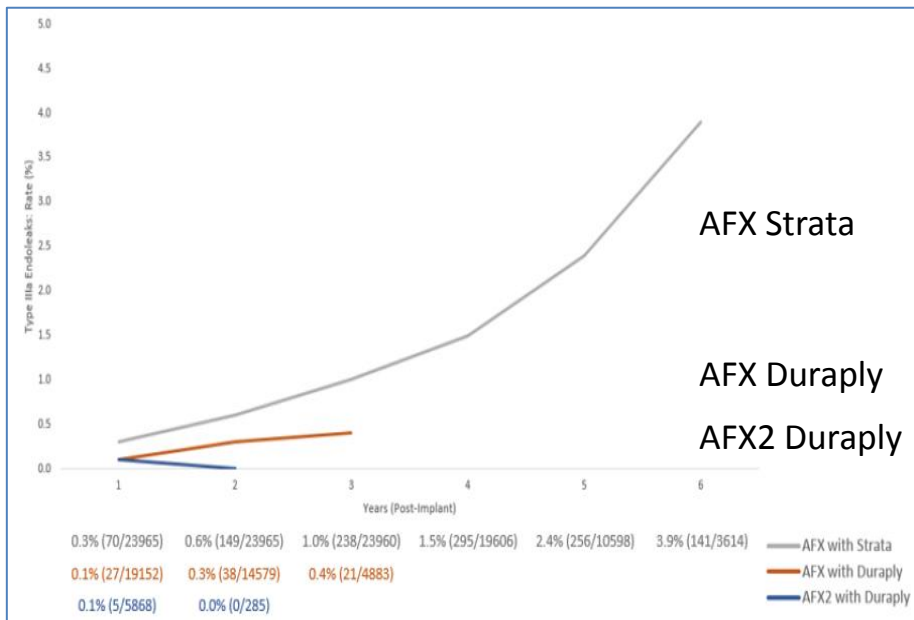


Type III Endoleak Complaints



Type IIIa:
Midgraft hole

Type IIIb:
Junctional leak



Indication for Use



- Adequate iliac/femoral access: diameter ≥ 6.5 mm
- Non-aneurysmal aortic neck
 - length of ≥ 15 mm
 - diameter of ≥ 18 mm and ≤ 32 mm
 - neck angle of $\leq 60^\circ$
- Aortic length ≥ 1.0 cm longer than the body portion of the bifurcated graft.
- Common iliac artery distal fixation site:
 - length of ≥ 15 mm
 - diameter of ≥ 10 mm and ≤ 23 mm
 - iliac angle of $\leq 90^\circ$ to the aortic bifurcation
 - ability to preserve at least one hypogastric artery
- Extension stent grafts must have the ability to overlap the bifurcated stent graft by **at least 30 to 40mm proximally and at least 15 to 20 mm distally.**



Device Sizing

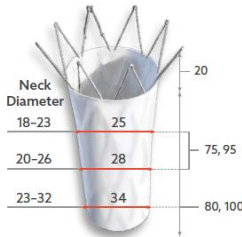


STEP 1

Choose Proximal Endograft

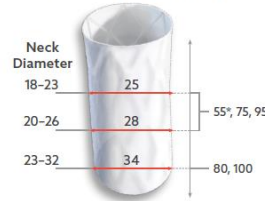
Measure aortic neck diameter and renal to bifurcation distance to select aortic extension.

VELA™ Suprarenal Endograft



Common Iliac Artery Length

VELA™ Infrarenal Endograft

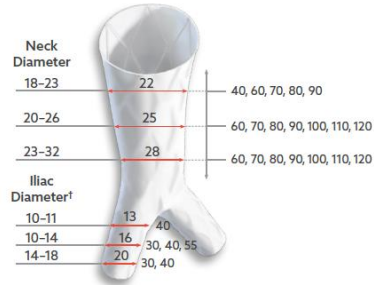


STEP 2

Select Iliac Limb Dimensions

Measure common iliac artery diameters and lengths to select iliac limb dimensions.† Consider iliac extensions, if applicable (Step 4).

AFX®2 Bifurcated Stent Graft



STEP 3

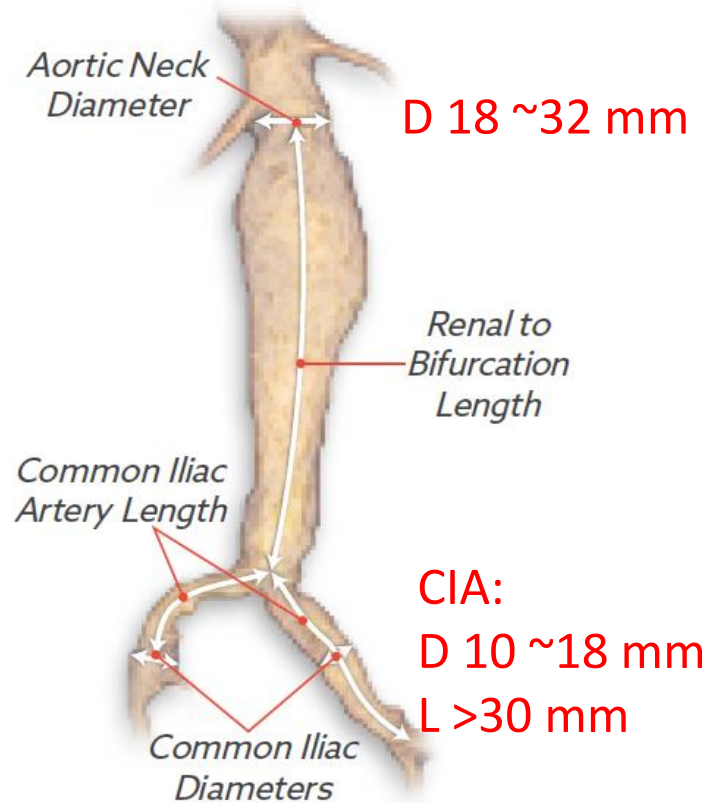
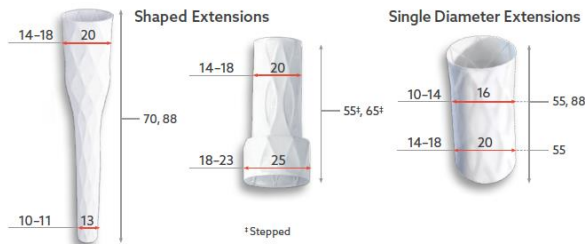
Select Bifurcated Stent Graft

Use the renal to bifurcation length to choose the length of the main body. Ensure appropriate overlap with aortic extension. For main body diameter, select the appropriate size device based on the IFU.

STEP 4

Choose Iliac Extensions, If Applicable

Ensure appropriate overlap with iliac limbs of the bifurcated stent graft.

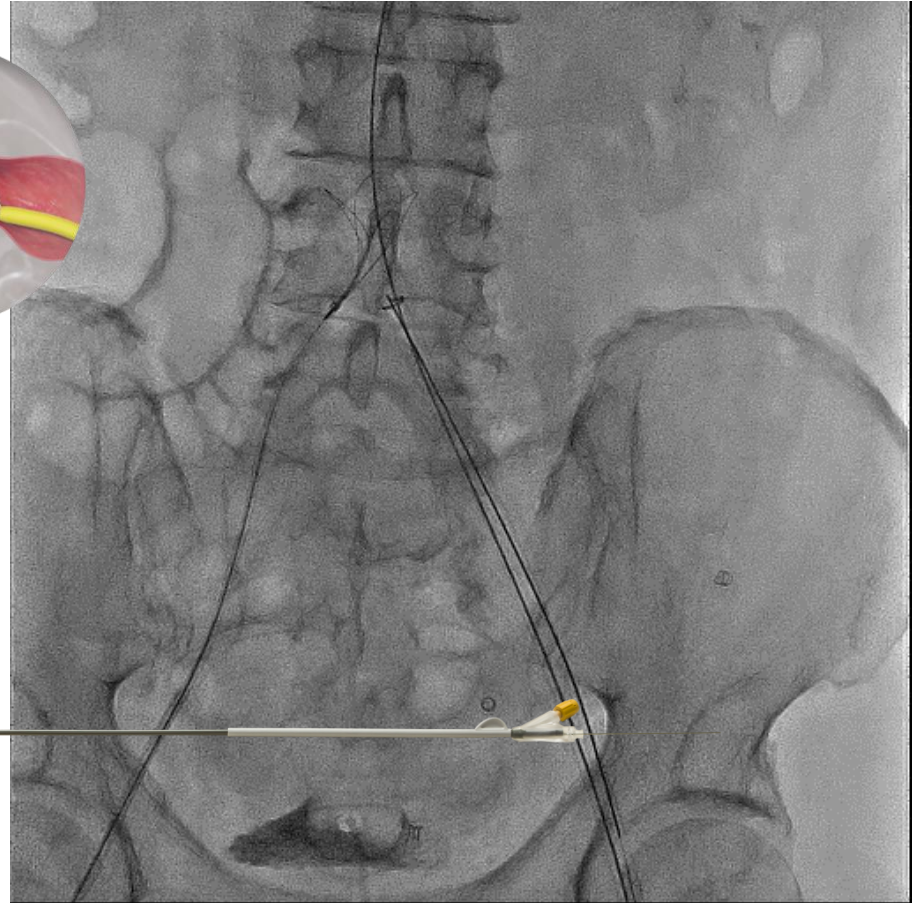




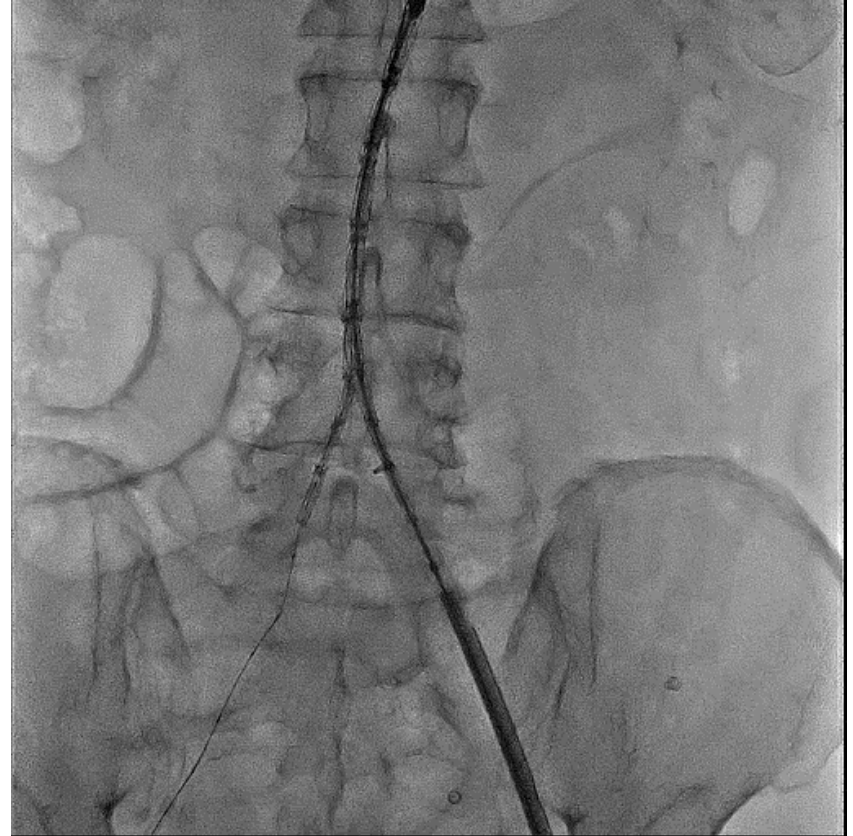
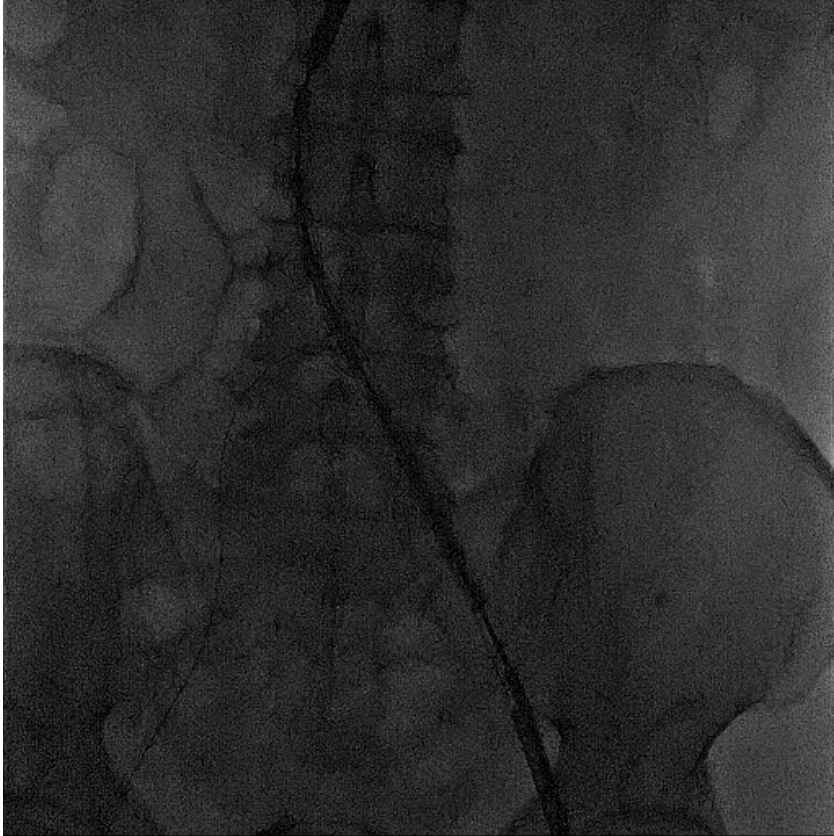
- Incidental AAA
- PHx: HTN, stroke, dyslipidemia



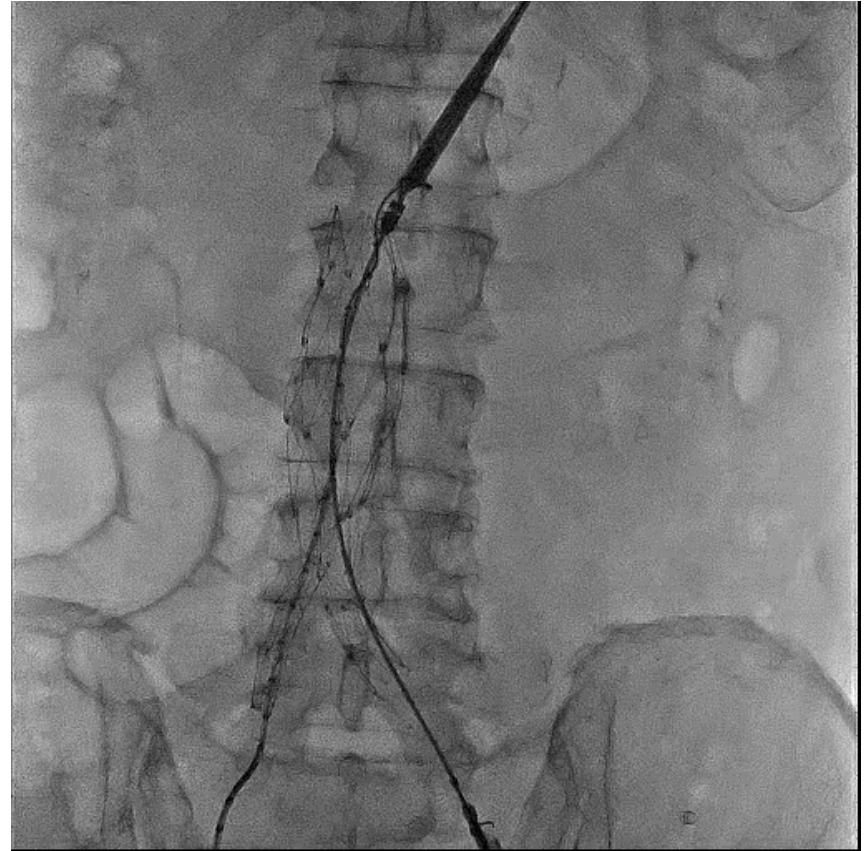
Snaring Contralateral Wire



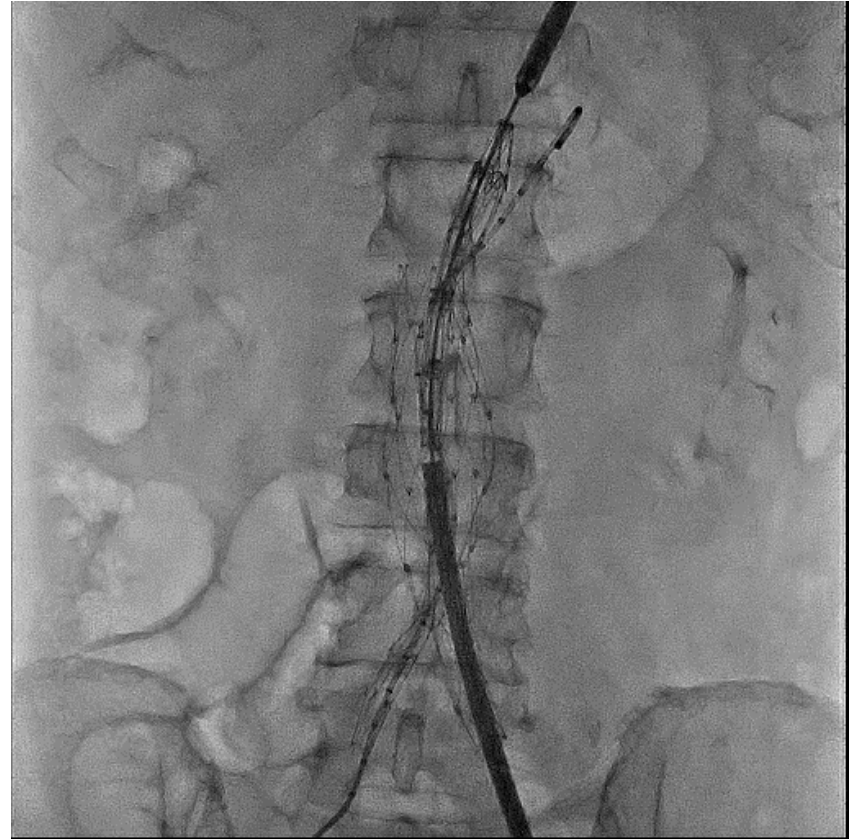
Positioning of Bifucated SG



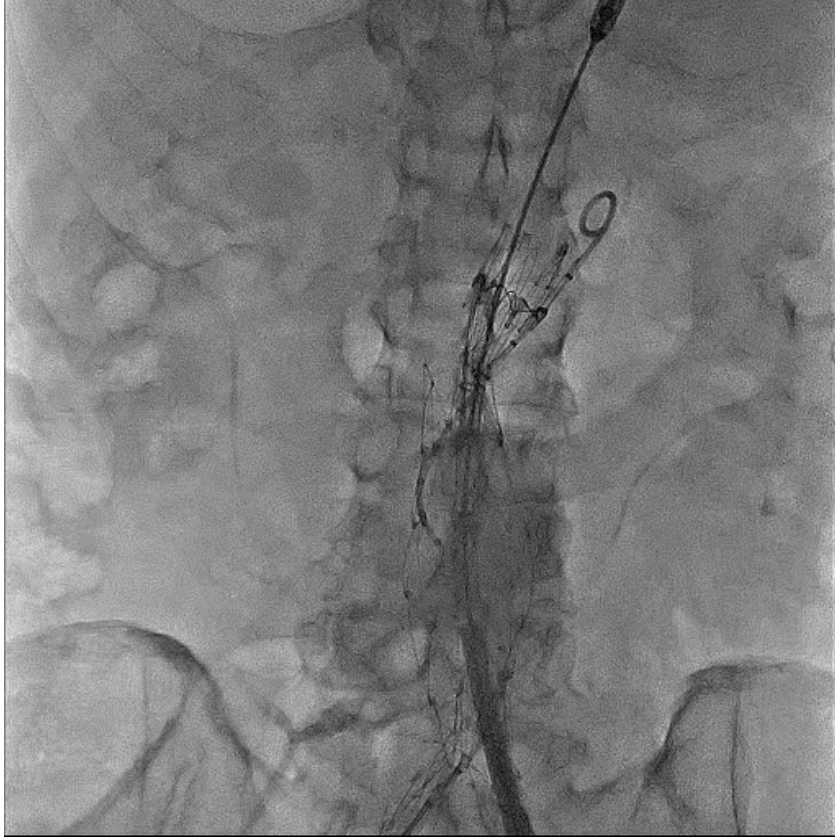
Deployment of Bifurcated SG



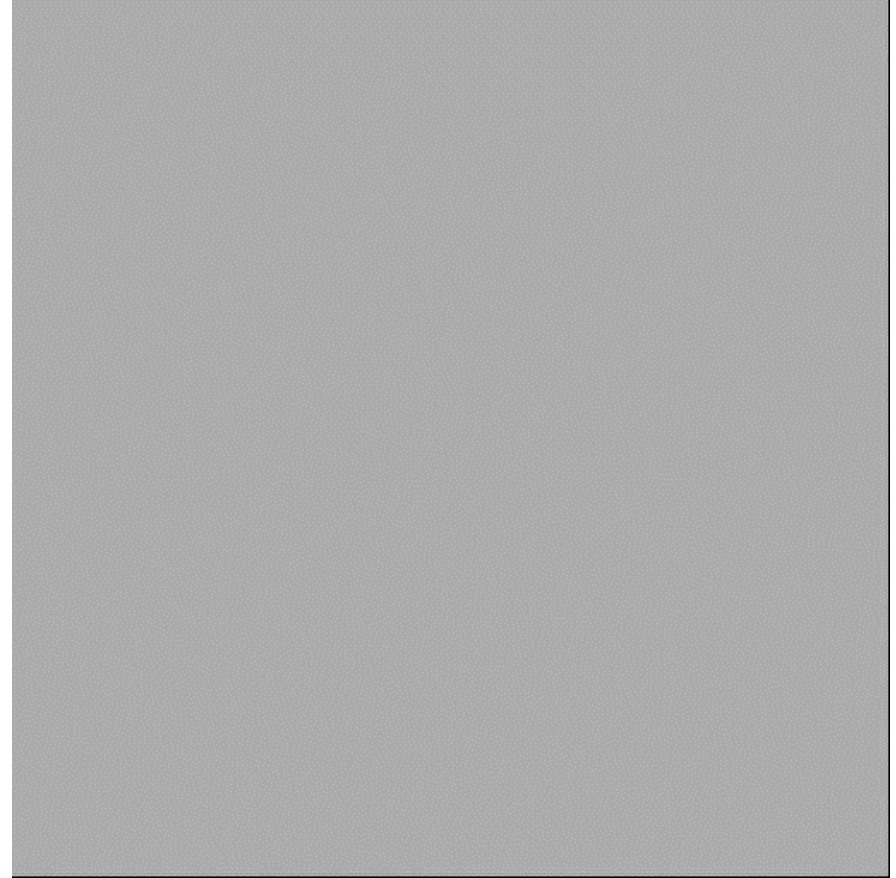
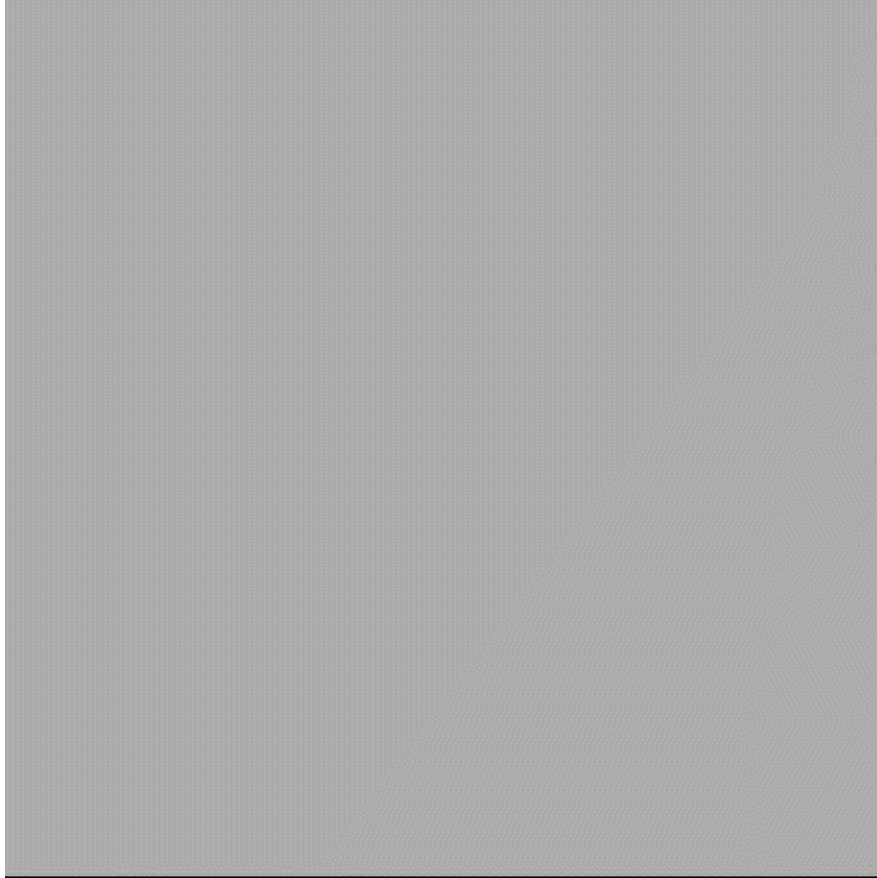
Positioning Vela Proximal SG



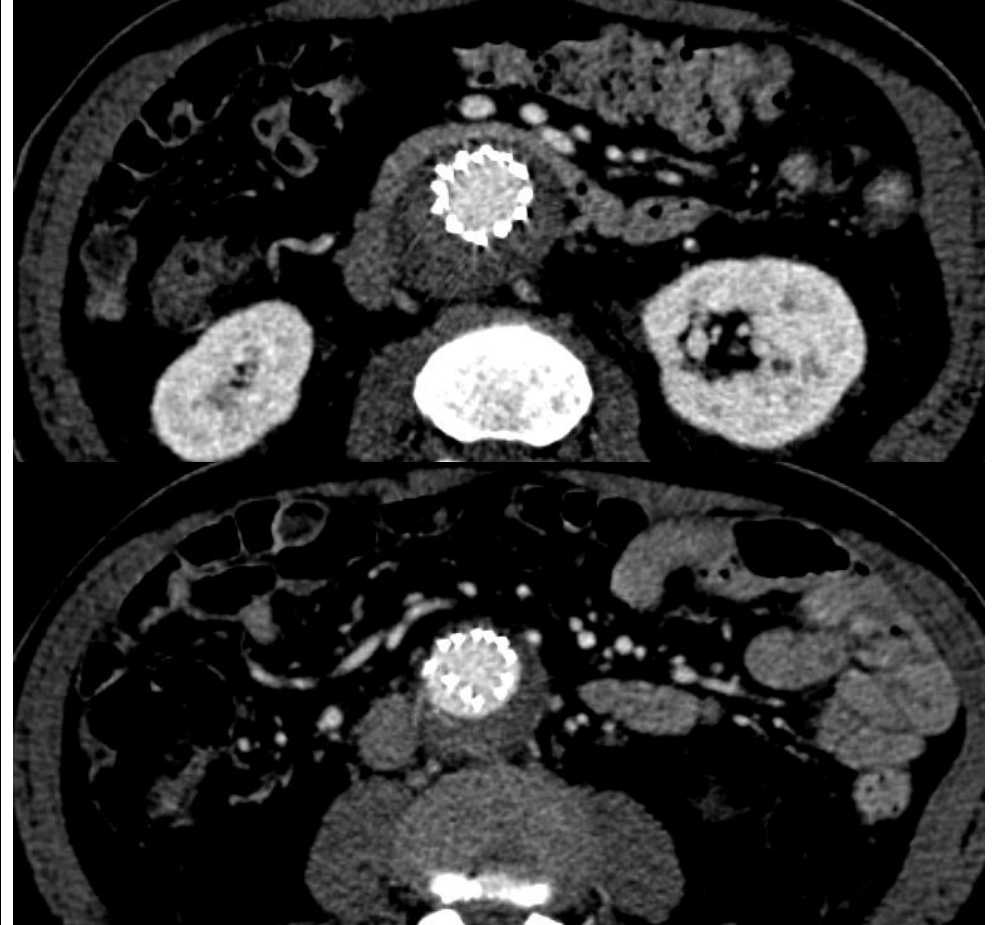
Deployment of Vela Proximal SG



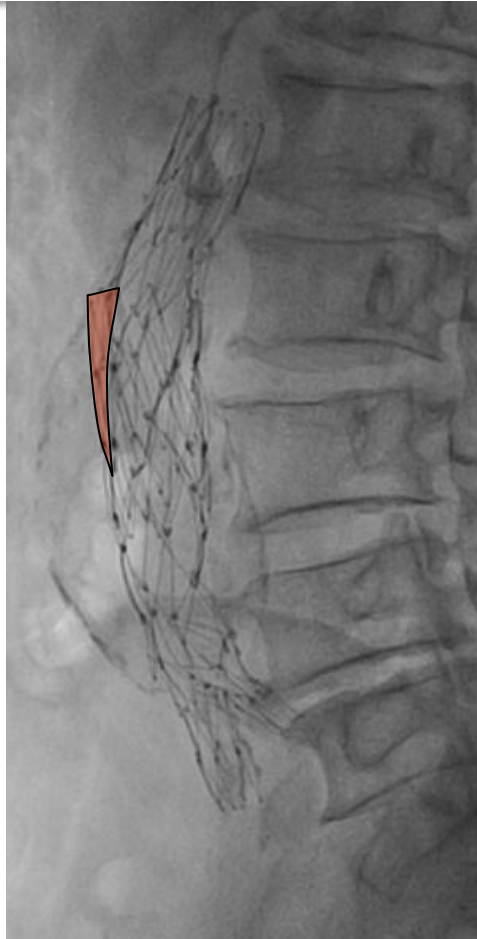
Final Angiogram



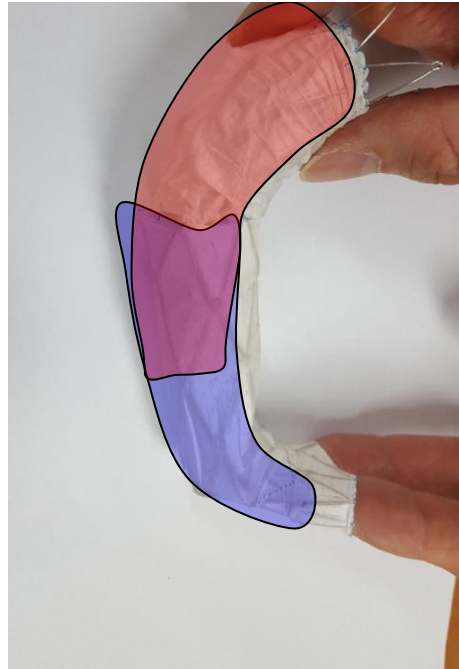
Follow-up CT at 2 Days Later



Persistent Type III Endoleak, Mechanism 2?



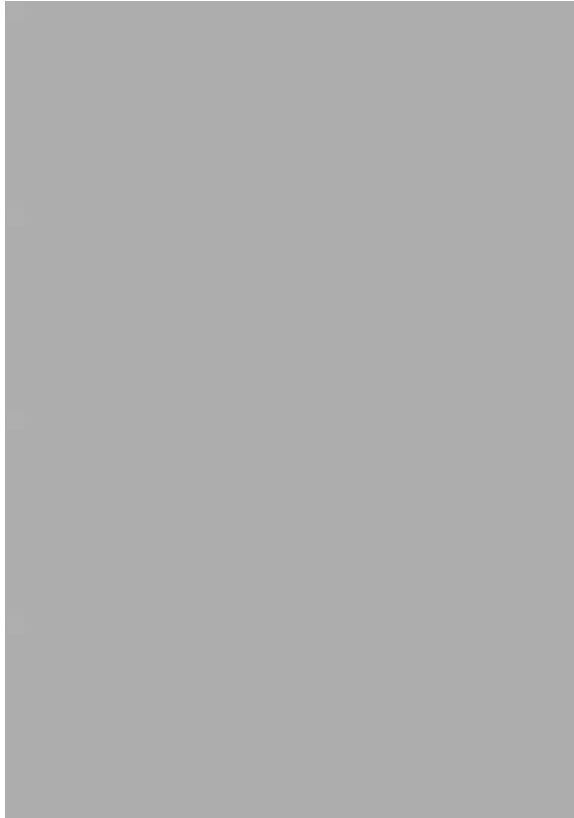
Minimal overlapping 30~40 mm !



Slide by Dr. Jae-Hwan Lee



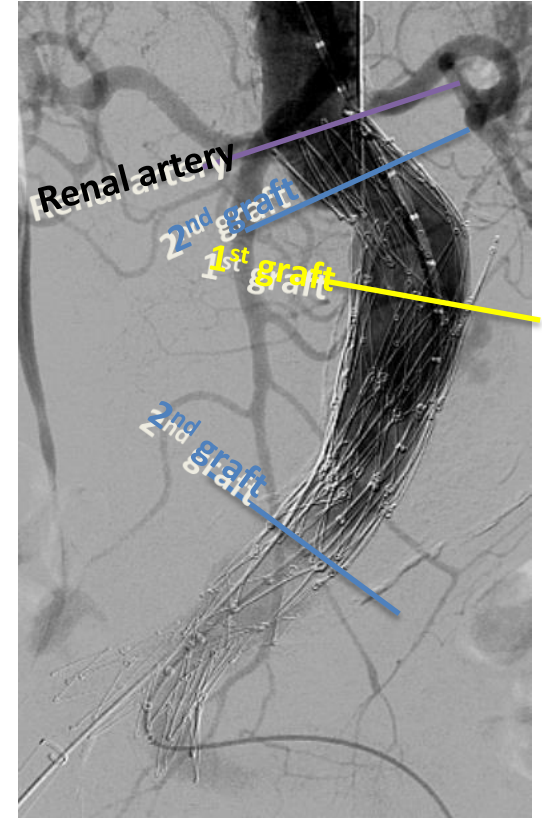
How To Solve Angulation With AFX?



Bifurcated graft



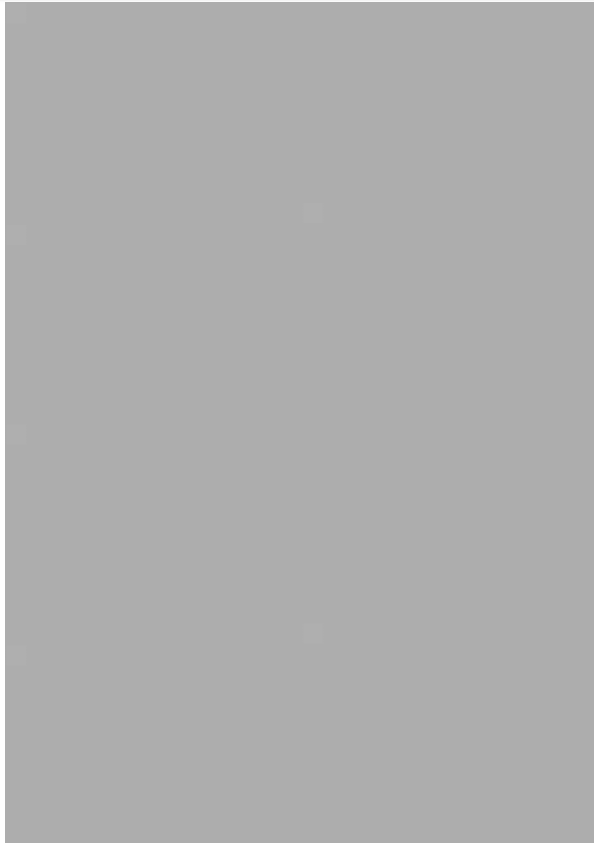
The 2nd graft



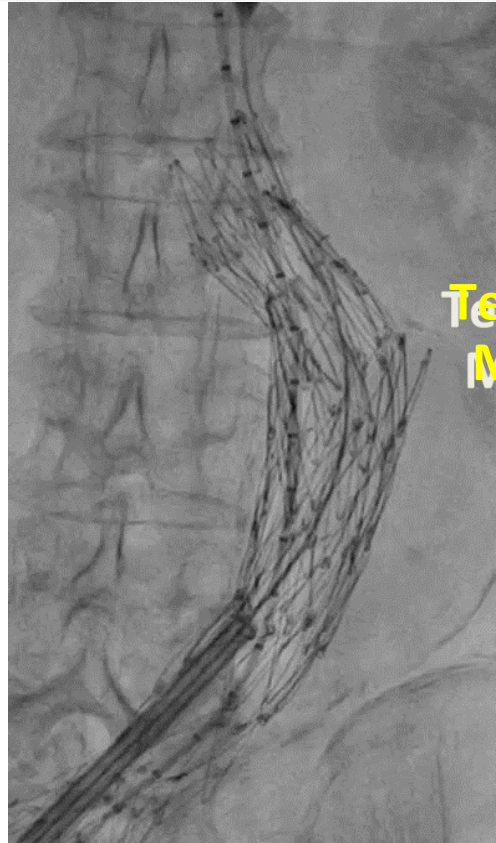
Slide by Dr. Jae-Hwan Lee



How To Solve Angulation With AFX?

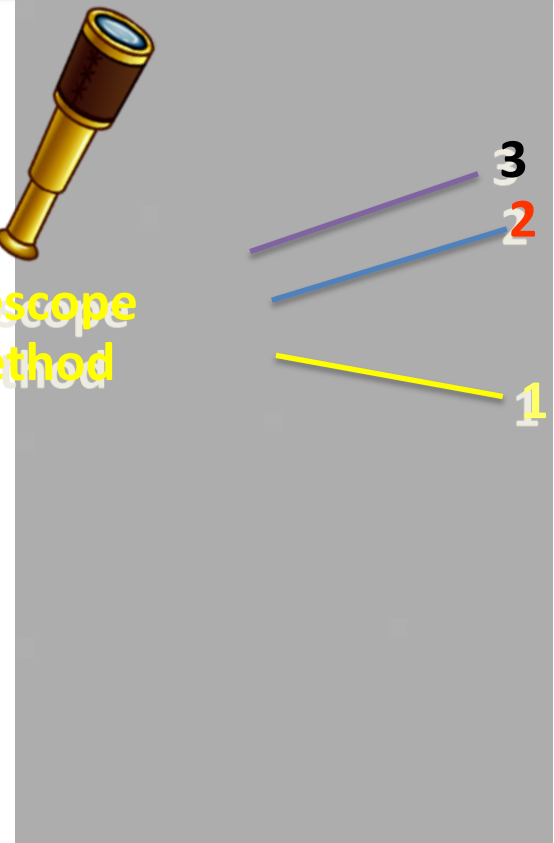


After 2nd graft



The 3rd graft

Telescope
Method



Final

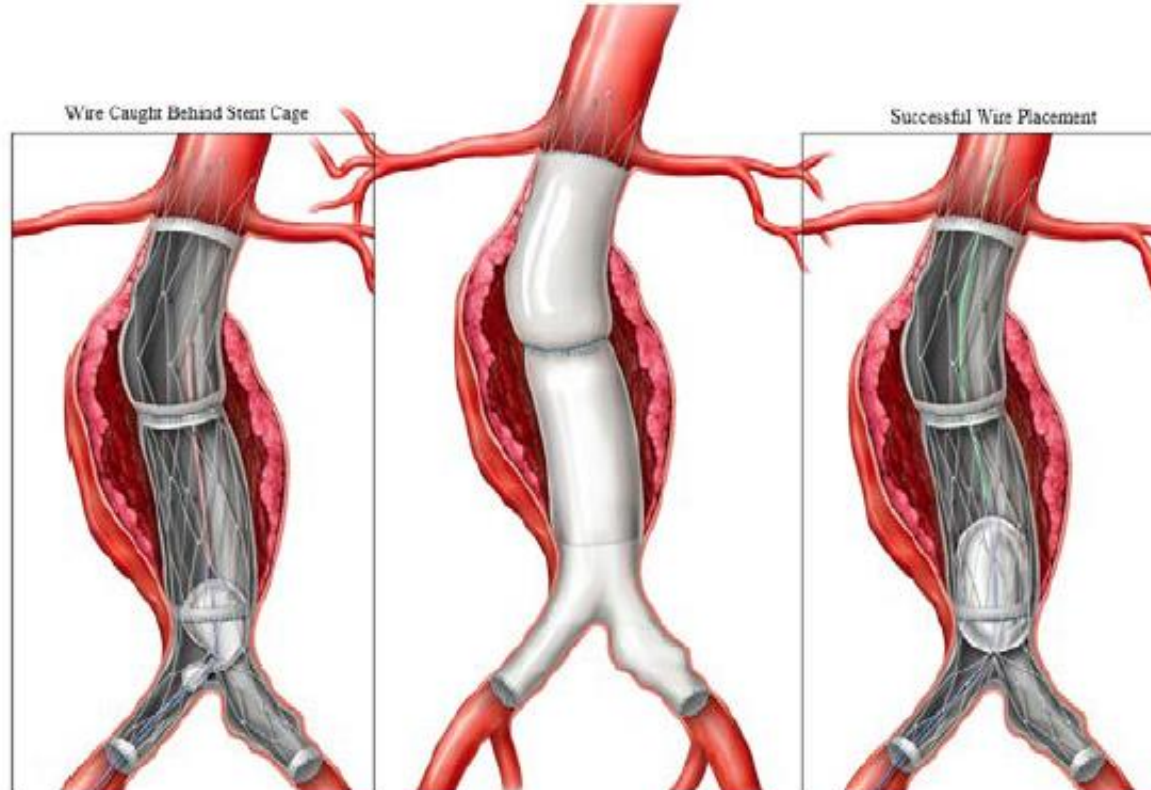
Slide by Dr. Jae-Hwan Lee



Recommendations for intervening through an AFX device



Use of a Balloon to Confirm Correct Placement of Guidewire

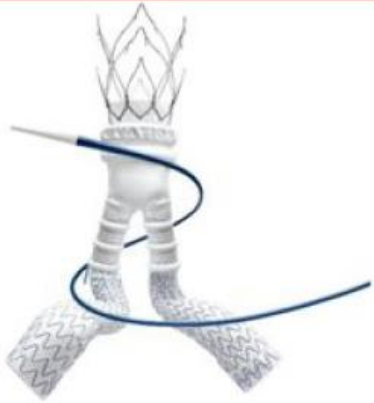


New Devices for Hostile Neck



Combined portfolio enables physicians to treat the most patients within IFU

EVAR



TriVascular Ovation

- Proximal fixation
- Ultra-low profile
- Polymer sealing ring
- Highly flexible
- 4-Year f/u



Endologix AFX

- Anatomical Fixation
- Preserve bifurcation
- Infra/suprarenal
- 7+ year f/u

EVAS



Endologix Nellix

- AAA fixation
- Complete polymer sealing
- Infrarenal + ChEVAS
- Lowest endoleaks
- 1-Year f/u



Company Recommendations



*Clinical references on file at Endologix.
Prevalence totals are >100% because many patients have more than one anatomical feature.
Ruptures are off-label.*

AAA Anatomy and Prevalence		Nellix	AFX	Ovation
STANDARD ANATOMY	40%	■	■	■
CHALLENGING NECKS				
Short Necks	36%	■		
Reverse Taper Necks	33%	■	■	■
Necks w/Thrombus	14%		■	■
Angled Necks (>60°)	9%			
CHALLENGING ACCESS				
Ectatic Iliacs	36%	■		
Narrow Distal Aorta (<16mm)	28%		■	■
Small & Calcified Arteries	27%			■
Tortuous Iliacs	19%			■
OTHER				
Small Flow Lumen	15%		■	■
Ruptures	8%		■	



Summary



- AFX2 has unique designs of anatomic fixation and active sealing with theoretical advantages.
- However, especially in AAA with angulated aortic neck, caution needs to be paid to obtain sufficient overlap between SGs in order to prevent Type III endoleaks.
- Long-term clinical data are needed to prove the effectiveness and safety of AFX2 in the treatment of AAA.



Thank You for Your Attention!

