

# **Current and Next Generation AAA Endografts to Treat Simple to Complex Anatomies**

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# History of EVAR Devices

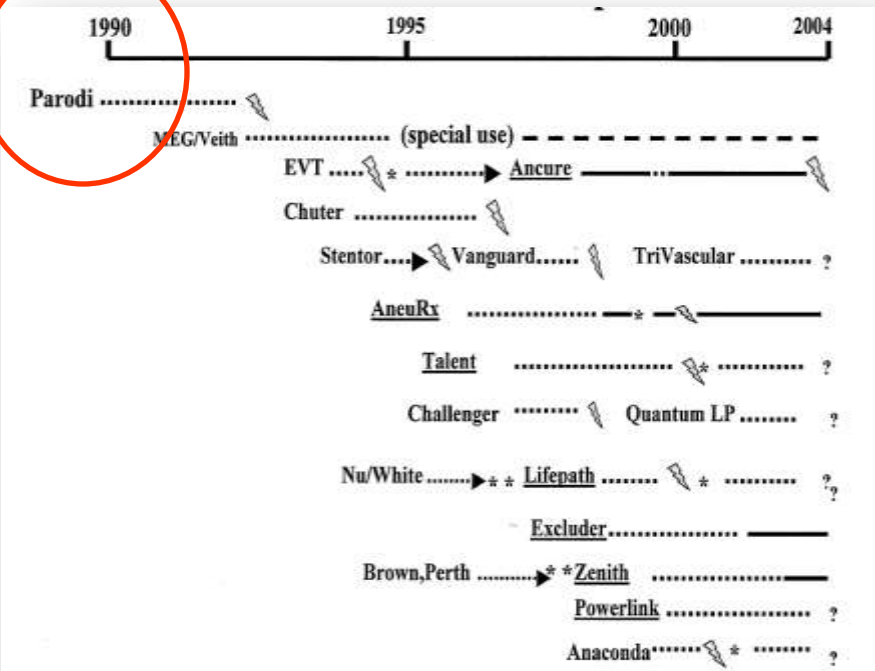


Fig 1. Devices for endovascular AAA repair over time, from Parodi's device to the present. *Dotted line*, Clinical trials; *solid line*, use approved by the Food and Drug Administration; *lightning bolt*, major pitfalls (failure modes, FDA warning or device withdrawal). \*Design modification

## FDA Approval timeline

September 1999	November 2002	May 2003	October 2004	April 2008	December 2010	June 2015	October 2015	
Ancure Guidant	AneuRx Medtronic	Excluder Gore	Zenith Cook	Powerlink Endologix	Talent Medtronic	Endurant Medtronic	Ovation Endologix	AFX Endologix
								

# Available Devices in Korea



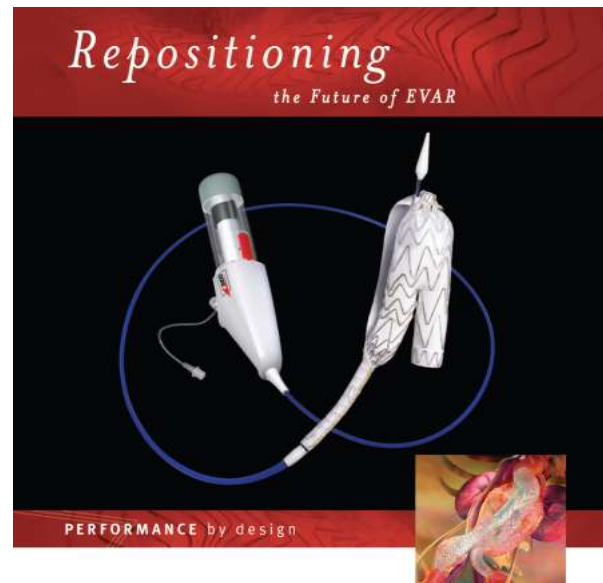
Seal  
S&G



**Zenith Flex  
Cook**



**Endurant II  
Medtronic**

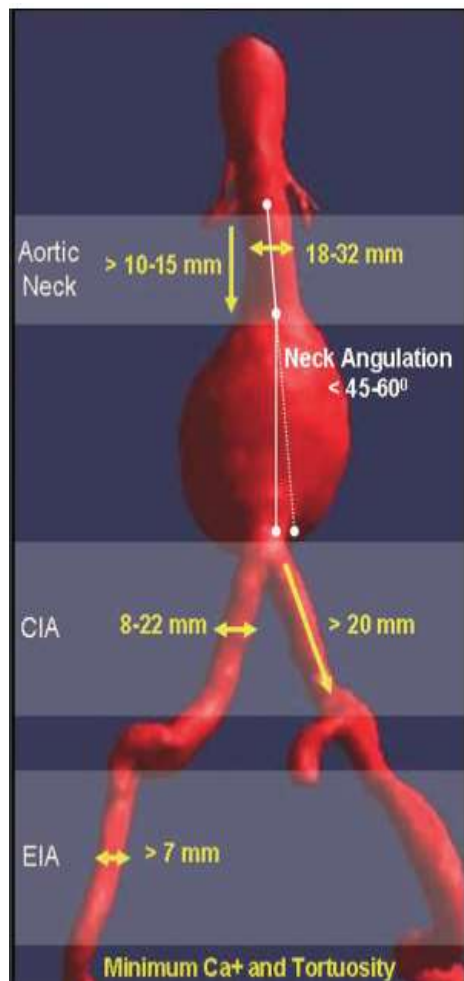


**Excluder & C3  
Gore**



**Incraft  
Cordis**

# Minimal requirement for standard EVAR



## *Proximal aortic neck*

Neck diameter  $>17$  mm,  $<32$  mm

Angle between the suprarenal aorta and the juxtarenal aorta  $<60^\circ$

Angle between the juxtarenal aorta and the long axis of the aneurysm sac  $<60-90^\circ$

Neck length  $>10$  mm

Neck thrombus covering  $<50\%$  of the proximal neck circumference

Neck dilated  $<3$  mm within 10 mm of the most caudal renal artery

Focal neck enlargement  $<3$  mm within 15 mm from the most caudal renal artery

Neck calcification  $<50\%$  of the proximal neck circumference

## *Aortic bifurcation*

Aortic bifurcation diameter  $>20$  mm in case of a bifurcated graft

## *Iliac artery*

Iliac luminal diameter  $>7$  mm

Angle between the long axis of the aneurysm and the iliac axis  $<60^\circ$

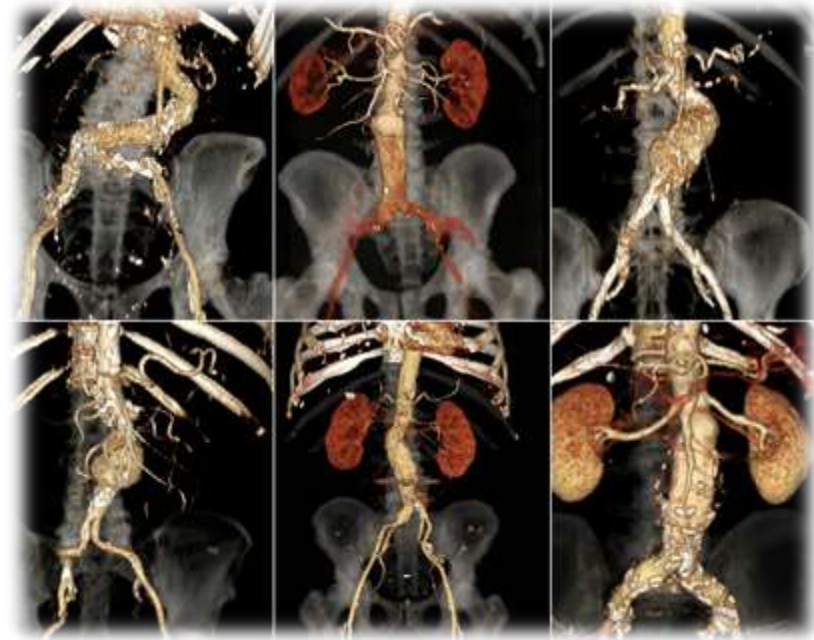
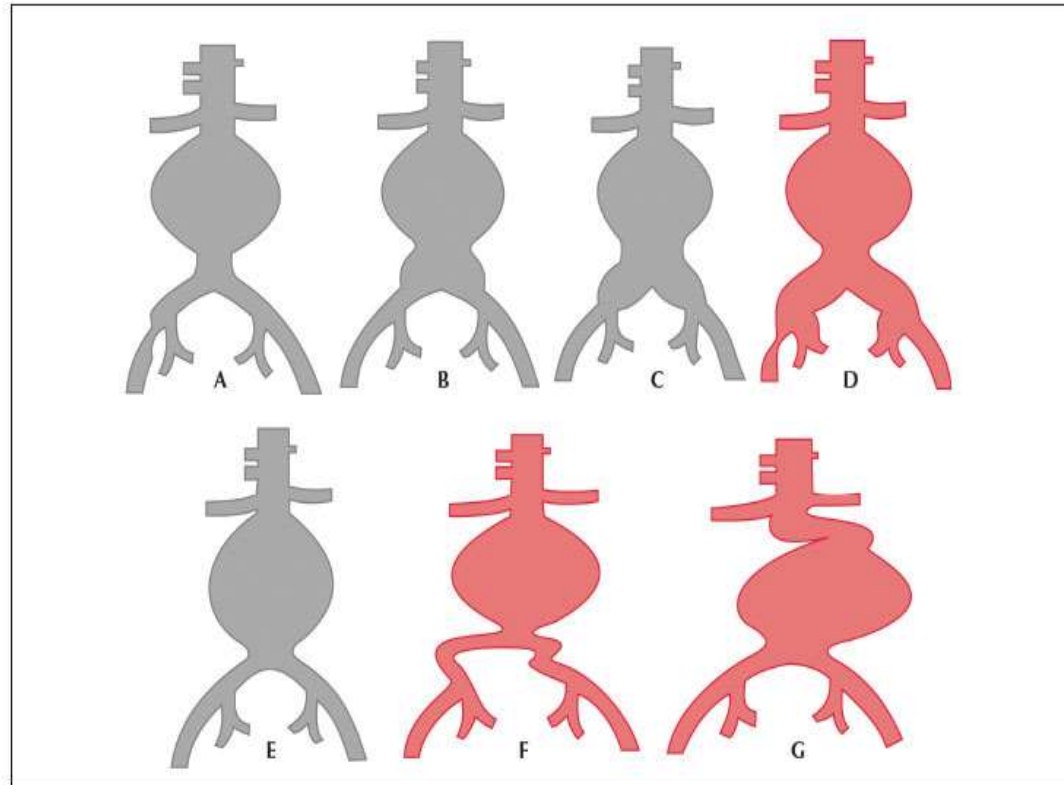
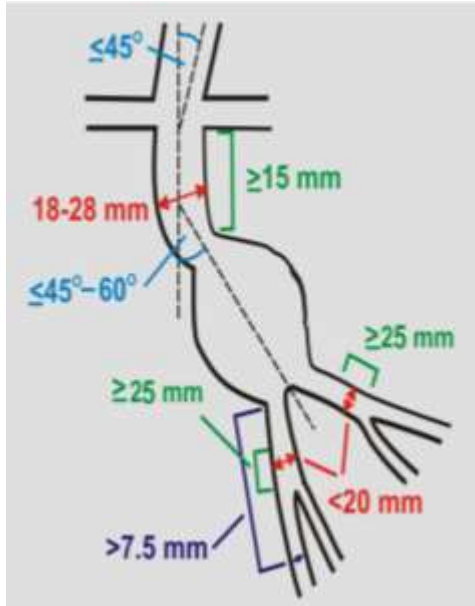
Iliac calcification: non extensively circumferential

Iliac neck diameter  $<22$  mm

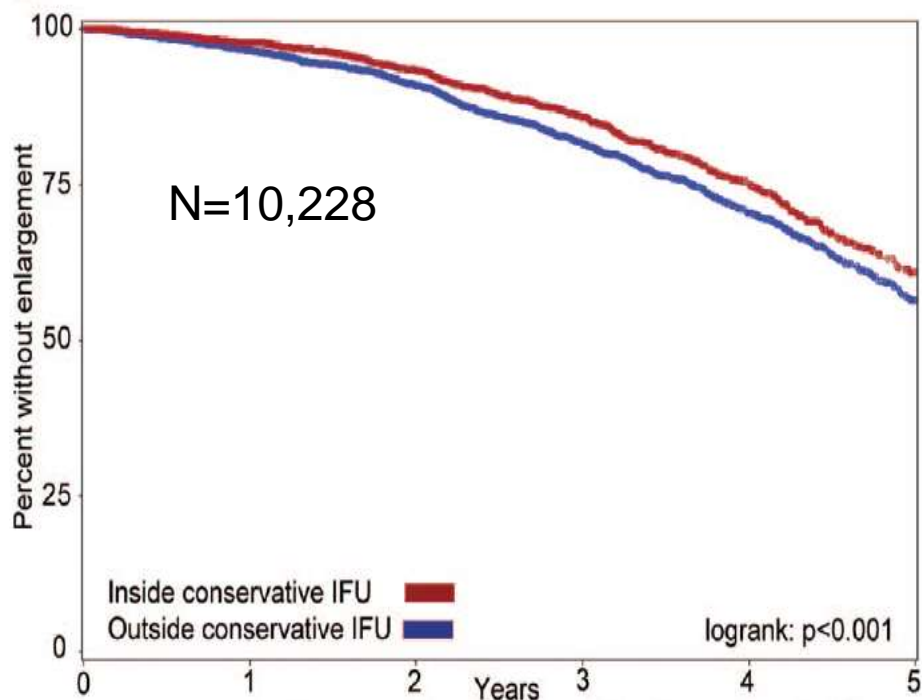
Iliac neck length  $>15$  mm



# Complex AAA



# AAA enlargement after EVAR



Year	Inside conservative IFU					Outside conservative IFU				
	1	2	3	4	5	1	2	3	4	5
Kaplan-Meier Est	97.8	93.4	85.9	75.0	61.0	96.5	90.9	81.5	70.5	56.5
Patients at Risk	2646	1572	822	407	167	3574	2139	1128	567	229
Standard Error	.26	.52	.89	1.4	2.1	.28	.51	.84	1.2	1.8

Only **40%** of patients had anatomy that met the most conservative definition of device instructions for use; **60%** met the most liberal definition of device instructions for use. **The 5-year post-EVAR rate of AAA sac enlargement was 41%**

Table 5. Determinants of Aortic Aneurysm Sac Enlargement Identified on Multivariable Cox Proportional Hazards Analysis

Covariates	Hazard Ratio (95% Confidence Interval)	P
Age, y		
<60	Reference	
60-69	0.80 (0.60-1.05)	0.11
70-79	0.87 (0.67-1.14)	0.31
$\geq 80$	1.32 (1.03-1.75)	0.05
Female	0.96 (0.82-1.13)	0.64
AAA diameter		
Maximum AAA diameter $\geq 55$ mm	0.97 (0.86-1.10)	0.62
Aortic neck length, mm		
>15	Reference	
10-15	0.87 (0.71-1.07)	0.19
<10	0.94 (0.77-1.15)	0.53
Aortic neck diameter		
Diameter at lowest renal artery <28 mm	Reference	
Diameter at lowest renal artery 28-32 mm	1.80 (1.44-2.23)	<0.0001
Diameter at lowest renal artery >32 mm	2.07 (1.46-2.92)	<0.0001
Conical neck	1.17 (0.97-1.42)	0.10
Aortic neck angle, °		
<45	Reference	
45-60	1.04 (0.90-1.21)	0.58
>60	1.96 (1.63-2.37)	<0.0001
Iliac diameter		
Both common iliac arteries $\leq 20$ mm	Reference	
Only 1 common iliac arteries >20 mm	1.46 (1.21-1.76)	<0.0001
Both common iliac arteries >20 mm	1.31 (0.99-1.74)	0.06
Endoleak during follow-up	2.70 (2.40-3.04)	<0.0001

**M/88**    **HTN, DM**



**M/75**

AAA: 56mm

Rt. CIA: 34 mm

Lt. CIA: 36 mm





**What would you do?**

# Limitations of Current Devices

## Limitations

- Hostile neck
- Inadequate sealing
- Juxta- or suprarenal AAA
- Large device profile
- AAA with Iliac involvement
- Inability of reposition



## Required Improvement

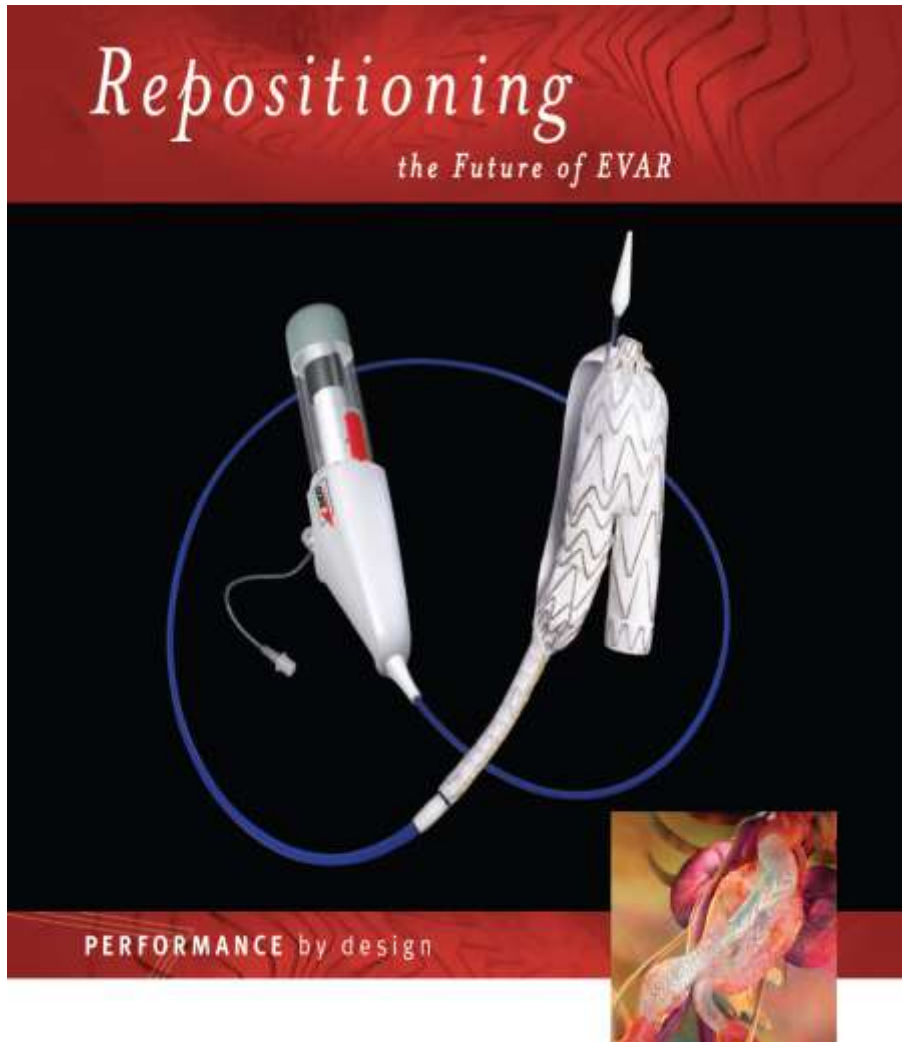
- **Flexibility** and conformability
- Controllable **deployment**
- **Migration resistance**
- Low **profile**
- **Long-term durability**
- Fenestrated/branched endograft

# Current and New generation of endograft with main features

Type of anatomic fixation and devices	Stent - main graft material	Main body delivery sheath (size)	Re-positioning mechanism	Special characteristics/features
<b>Suprarenal fixation</b>				
<i>Endurant</i> <sup>®</sup>	Nitinol-polyester	18-20F (OD) <sup>3</sup>	No	Low profile, tip capture mechanism
<i>Incraft</i> <sup>®</sup>	Nitinol-polyester	13 and 15F	Yes	Ultra-low profile, in-situ length adjustment, repositionable, active locking mechanism
<i>Ovation</i> <sup>®</sup>	Nitinol-PTFE	14-15F	No	Ultra-low profile, inflatable rings for sealing, no radial force
<i>Zenith LP</i> <sup>®</sup>	Nitinol-polyester	16-17F	No	Low profile, long main body, COOK Medical ARC technology
<b>Infrarenal fixation</b>				
<i>AFX</i> <sup>®</sup>	Cobalt chromium-STRATA <sup>1</sup>	17F	No	Anatomical fixation at the aortoiliac bifurcation, STRATA material, dual seal mechanism
<i>Anaconda One-Lok</i> <sup>®</sup>	Nitinol-polyester/tantalum	20-23F (OD)	Yes	Repositionable, preloaded wire and magnet system
<i>Aptus</i> <sup>™</sup>	Nitinol-polyester	16-18F	No	EndoStaples, polyester without stents in the main body
<i>Aorfix</i> <sup>®</sup>	Nitinol-polyester	22F	No	Coil design, closely aligned nitinol wires in the proximal part, treats neck angles $\geq 90^\circ$
<i>C3-Excluder</i> <sup>®</sup>	Nitinol-ePTFE	18-20F	Yes	Three-step deployment system, repositionable
<i>Nellix</i> <sup>®</sup>	Cobalt chromium- PEG-endobags <sup>2</sup>	17F	No	EVAS system (balloon-expandable endoframes surrounded by endobag filled with polyethylene glycol)
<b>Supra- and infrarenal fixation</b>				
<i>Treovance</i> <sup>®</sup>	Nitinol-polyester	18-19F	Yes	Both supra- and infrarenal fixation, Navitel <sup>®</sup> delivery sheath, repositionable

<sup>1</sup>multilayer ePTFE, <sup>2</sup>balloon -expandable endoframes surrounded by an endobag filled with an in-situ curing polymer, <sup>3</sup>outer diameter

# Excluder & C3 Delivery System (Gore)



- To be reconstrained the proximal end of the endograft after insertion
- Rotate or move the device up and down to reposition
- Facilitate contralateral gate cannulation and placement of the endograft closer to the lowest renal artery
- Decrease the risk of inadequate sealing and consequent graft migration and endoleaks.



# Incraft (Cordis)

## 3-PIECE MODULAR SYSTEM:

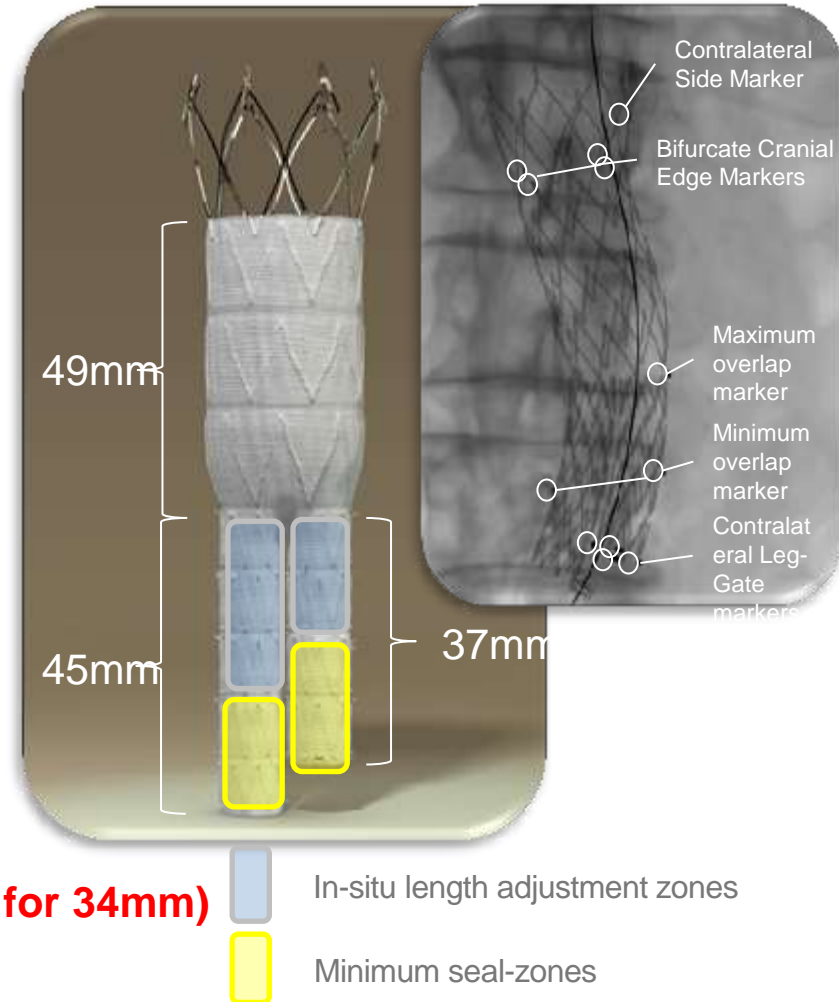
- Low porosity polyester graft
- Segmented nitinol stents
- **Supra-renal fixation**

## CUSTOMIZATION:

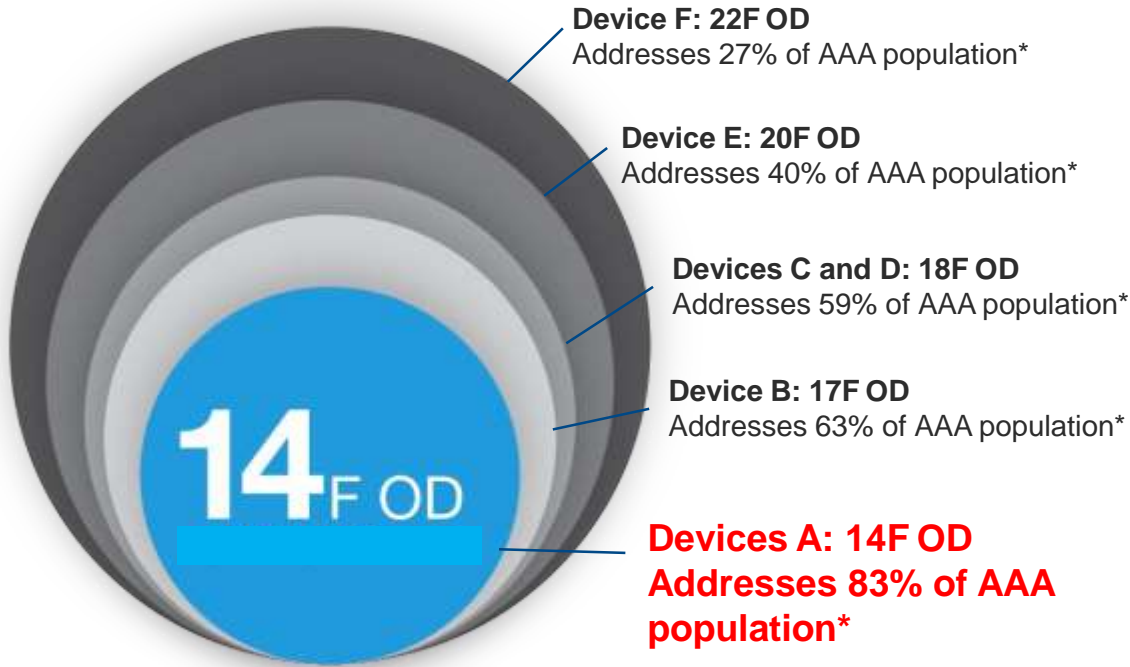
- Bilateral in-situ length adjustment up to 3cm\*
- Partial proximal re-positioning
- Few units to fit broad anatomical coverage

## ULTRA-LOW PROFILE:

- **Delivery System-14Fr O.D (22,26,30mm) (16F for 34mm)**
- Catheter-like shaft flexibility



# Low Profile, Expanded Options



\* Patient's Access Vessel Size Distribution  
(Derived from M2S Measurement Database of 43,000 CT Scans)

Narrow Access



Tortuous Anatomy



# EVAR devices (Endologix)

EVAR

EVAS



## AFX® Platform

- Anatomical Fixation
- Preserve bifurcation
- Infra/suprarenal fixation options



## OVATION® Platform

- Proximal fixation
- Ultra-low profile
- Polymer sealing ring
- Highly flexible



## NELLIX® Platform

- AAA fixation
- Complete aneurysm polymer sealing
- Lowest endoleaks

# AFX (Endologix)

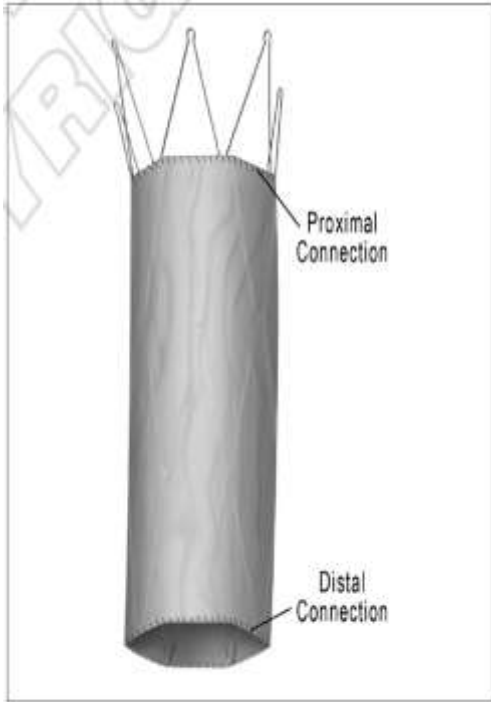


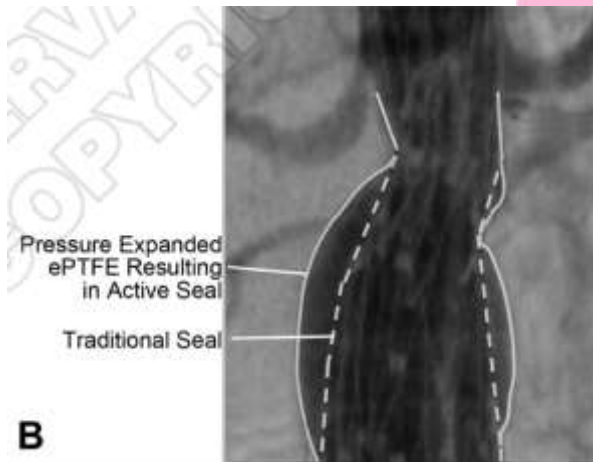
Figure 2.—The graft material is connected to the metal frame of the cuff only at the proximal and distal ends.



**ActiveSeal™**  
extends the seal  
zones



**Anatomical fixation**  
preserves the  
distal aortic  
bifurcation  
enabling "up  
and over"  
procedures





# Ovation (Trivascular, Endologix)

Ovation iX™  
Abdominal Stent Graft System

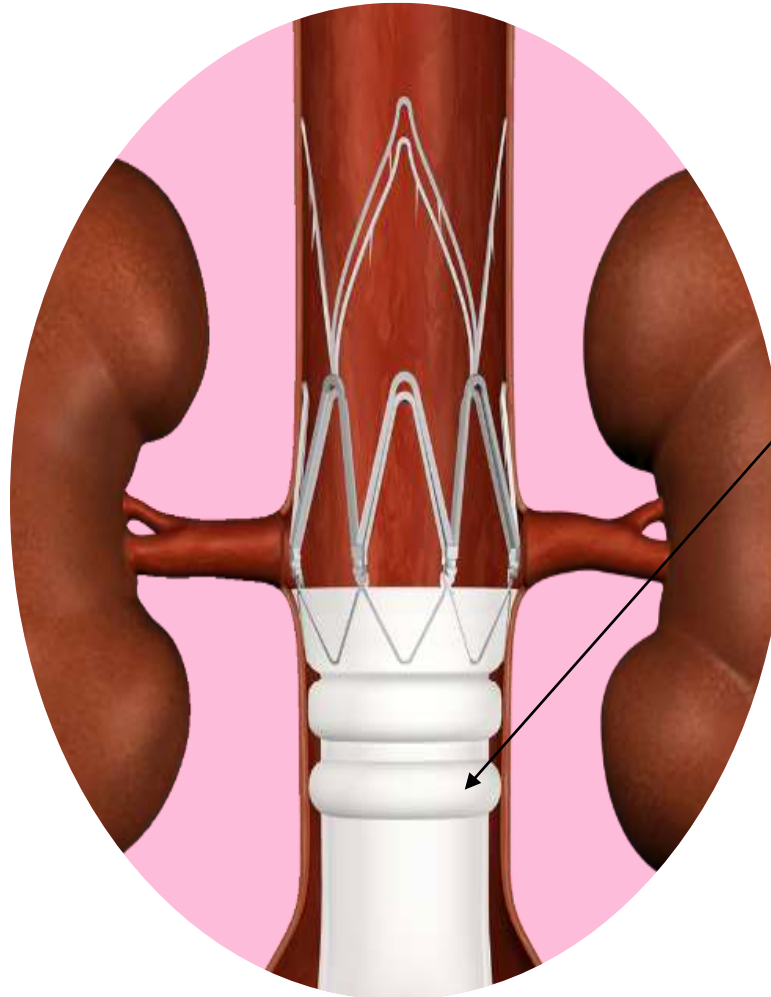


## Lowest profile

of any FDA approved  
EVAR device (14F)

## Highly flexible

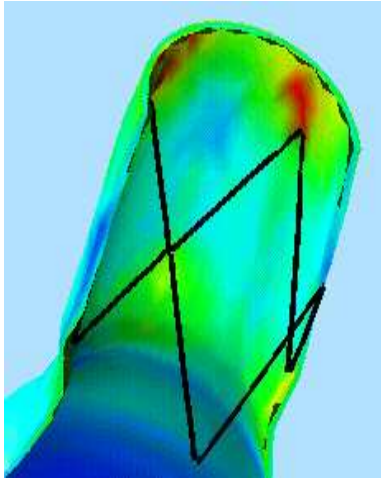
limbs & delivery  
system



**Polymer sealing ring**- inflated with a low-viscosity radiopaque polymer during stent-graft deployment, provides effective sealing

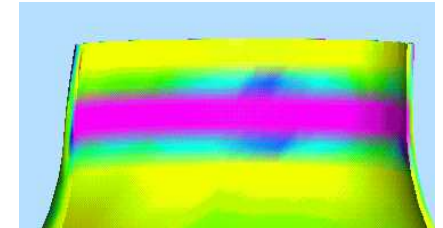
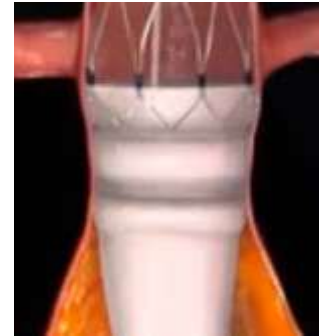
# Sealing Ring Technology Creates Continuous Wall Apposition

## Self Expanding Stent Graft



Wire and fabric grafts create *discontinuous* points of apposition in irregular and/or tapered anatomy

## Ovation Stent Graft



**Ovation sealing ring** creates uniform *continuous* wall apposition, even in irregular and/or tapered anatomy

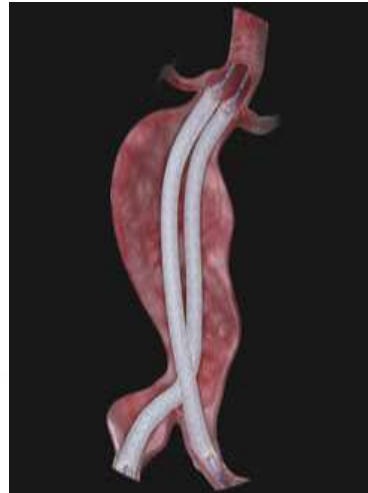
# Nellix (Endologix)

## THE NEW PARADIGM IN AAA THERAPY

**Simplified** procedure  
& planning

**Complete** aneurysm  
sealing to  
confidently treat  
more patients

**Lowest** overall  
endoleak rate and  
reduced secondary  
interventions



Nellix<sup>®</sup>  
EndoVascular Aneurysm  
Sealing System



**EndoBags are filled  
with Polymer** to seal  
the entire aneurysm



# EndoStaples (Aptus, Medtronic)

## Aptus™ Heli-FX™ EndoAnchor™ System

Helical screw (3 mm diameter, 4 mm depth)



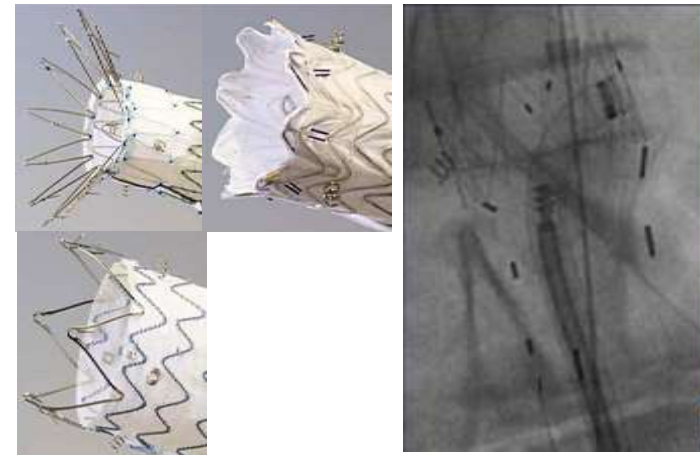
electronically controlled  
Aptus Applier



- Prevents migration and limits proximal neck dilation
- Augments proximal seal in challenging anatomy
- Compatible with leading endografts

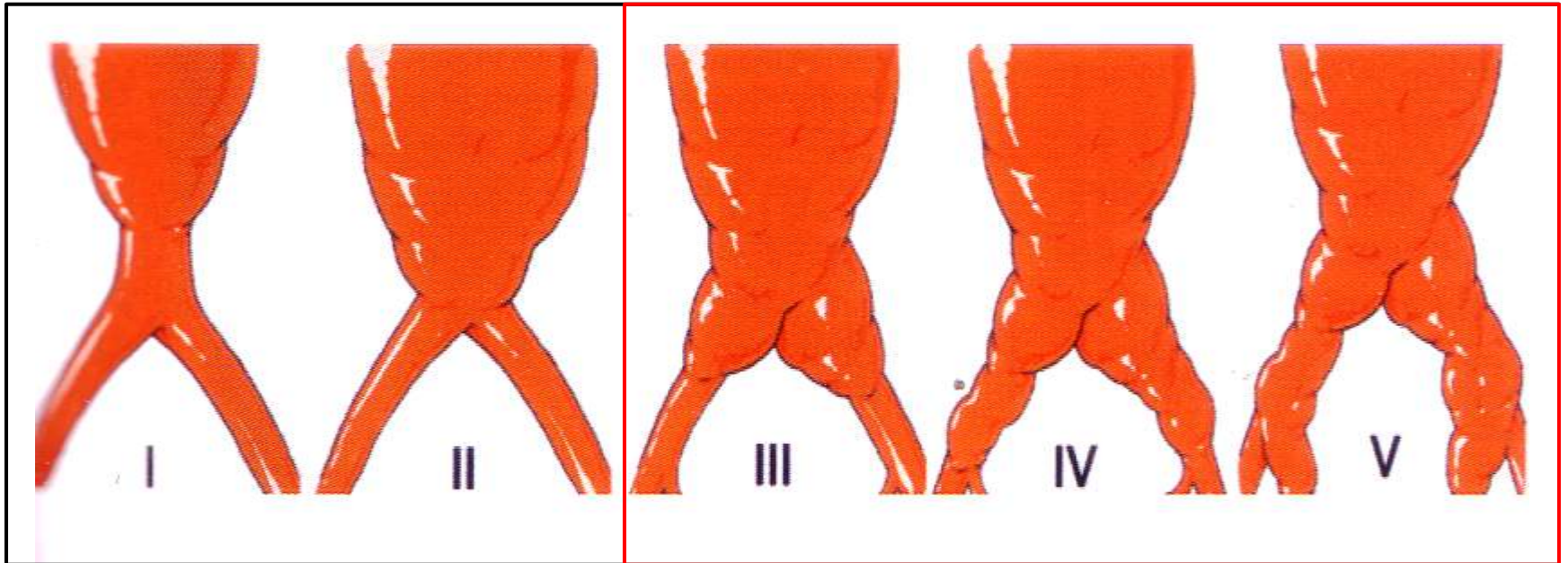


Deflexible 16Fr OD,  
62cm working length



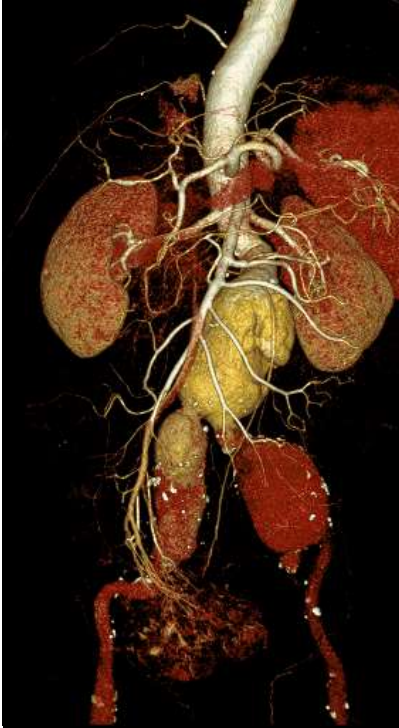
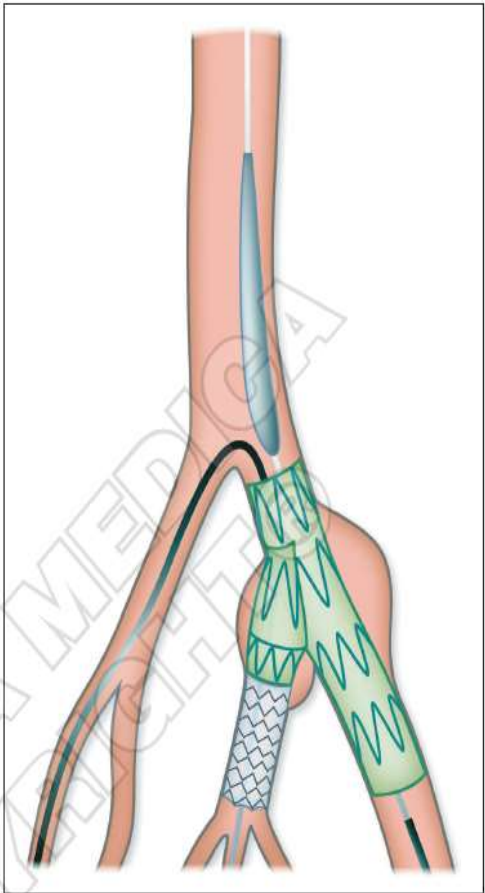


# AAA Extend to Iliac Arteries

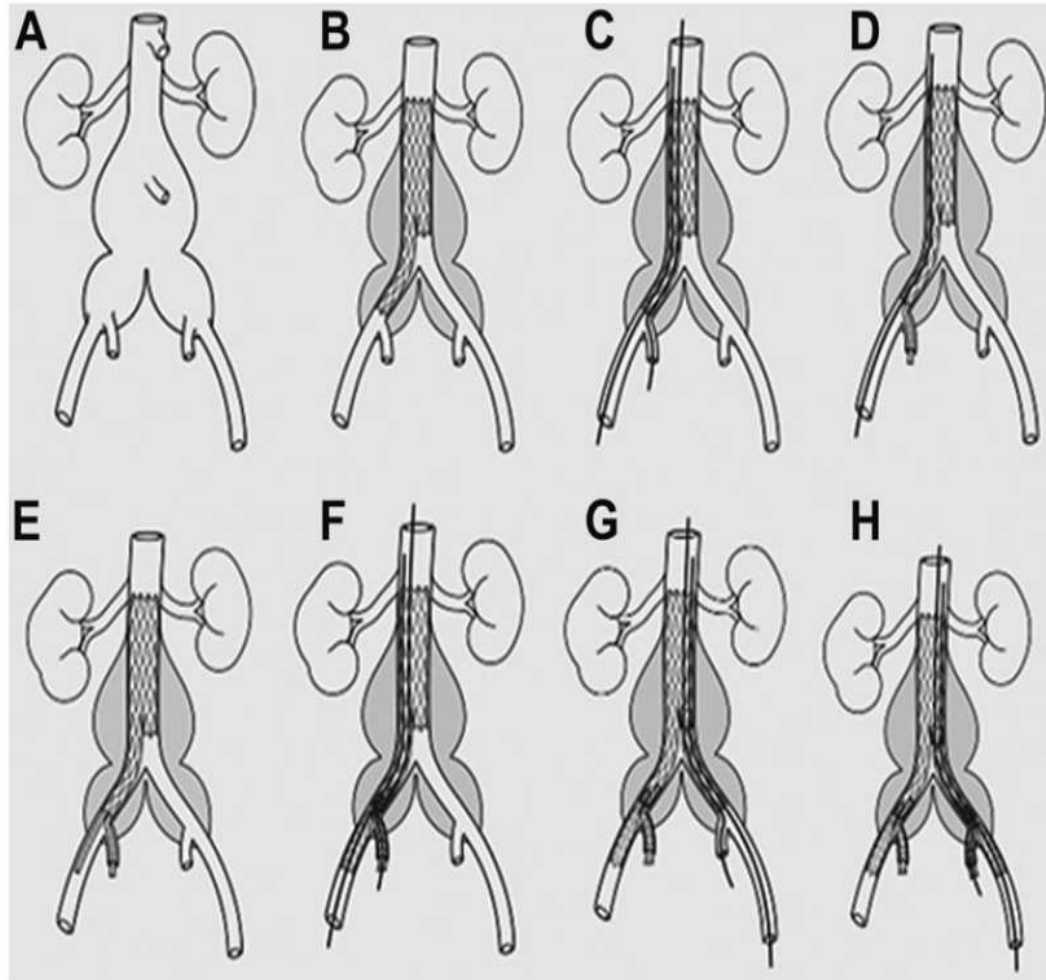


**20-30%**

M/73

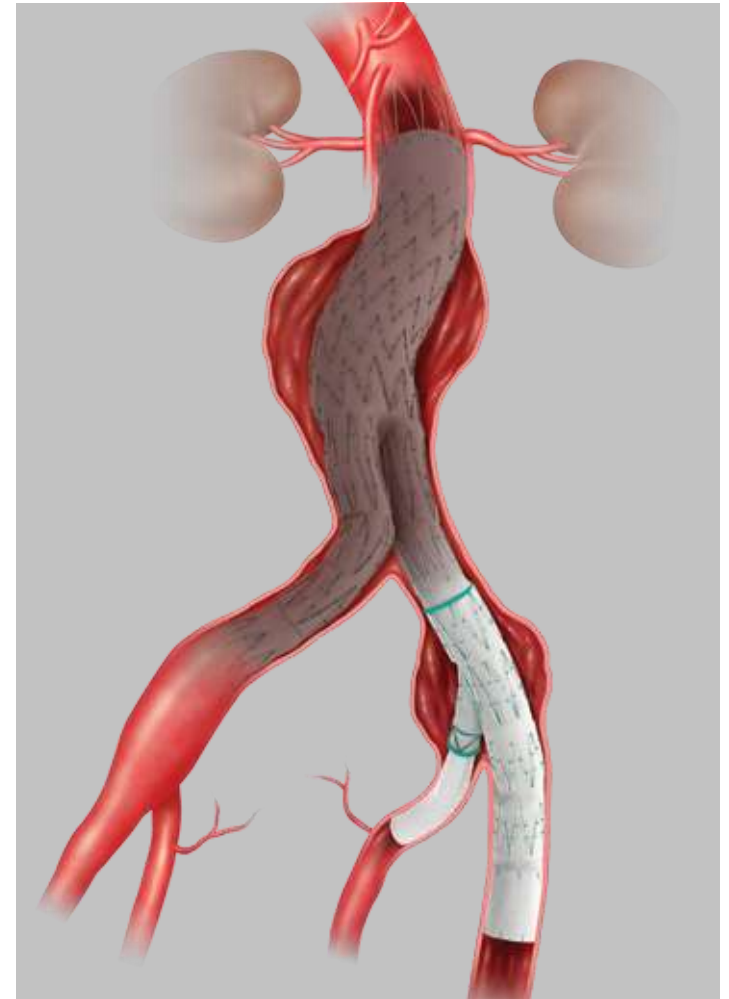
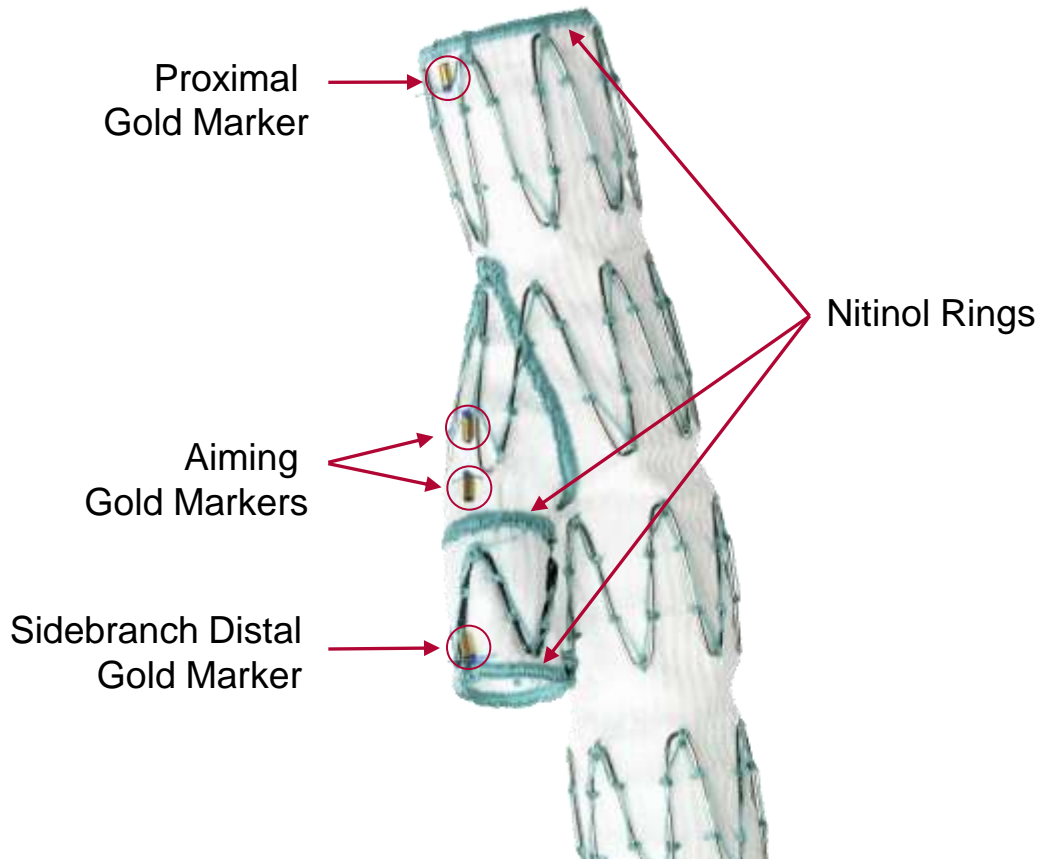


# Sandwich technique for involving CIA aneurysm





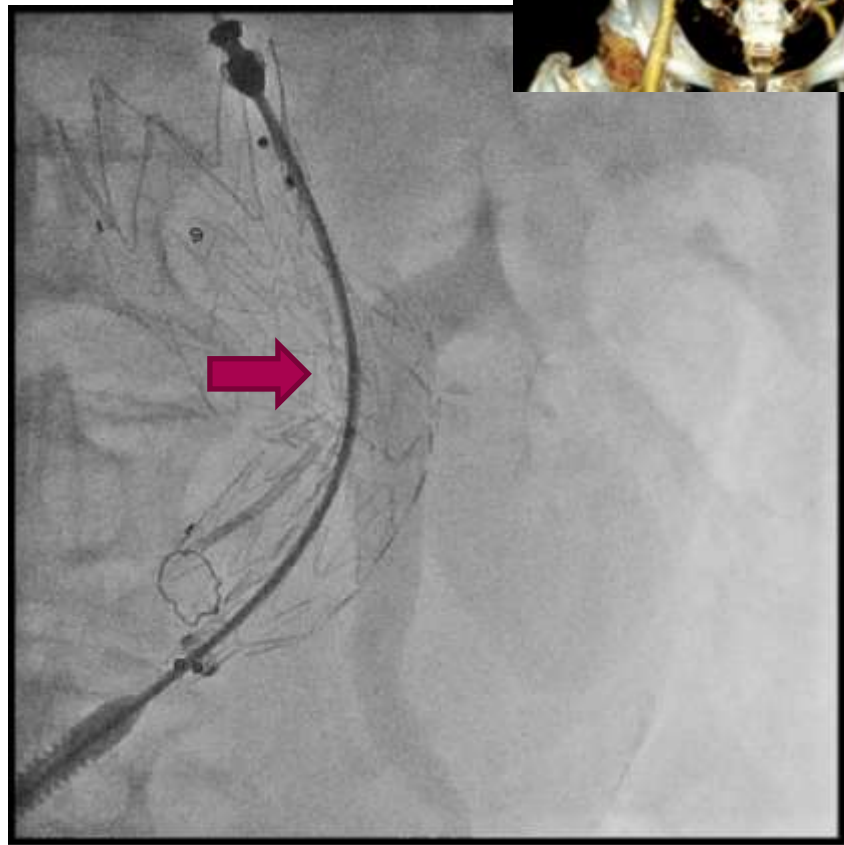
# Endovascular repair of aortoiliac aneurysm with IBD (COOK)





**What did I do ?**

# Stent-graft



0.035 terumo stiffwire, Lunderquist wire

Mustang 8 x 40 mm PTA balloon

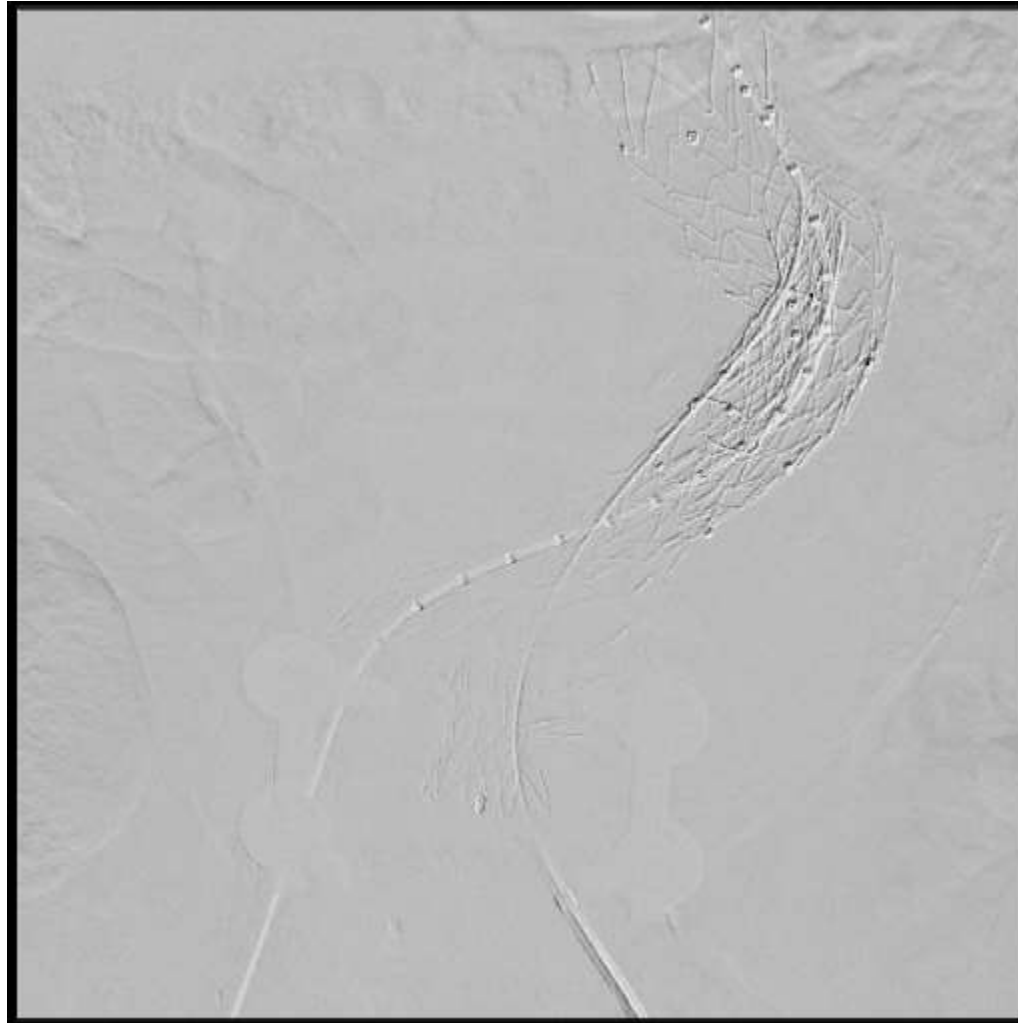
Palmatz stent (P4014) & Mustang 12 x 60 mm PTA balloon by hand mounting

# Palmatz stent



0.035 terumo stiffwire, Lunderquist wire  
Mustang 8 x 40 mm PTA balloon  
Palmatz stent (P4014) & Mustang 12 x 60 mm PTA balloon by hand mounting

# FU angiography



# EVAR with Sandwich technique

Endurant SG: 23 x 124 mm

Endurant SG: 16 x 82 mm

Viabhan SG: 8 x 10 mm

Endurant SG: 16 x 9.3 mm

Endurant SG: 16 x 124 mm

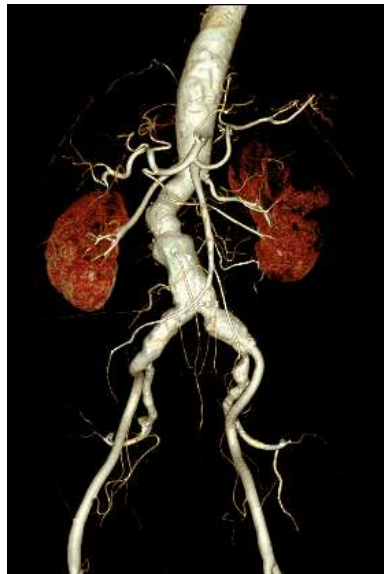
Endurant SG: 10 x 82 mm



postop



3months later





# Conclusions

- Next generation devices are transforming to solve unmet clinical need of current devices.
- **More flexible** devices with **lower profile** are available.
- New devices may **eliminate endoleaks** (aneurysm sealing)
- **Branched** or fenestrated endografts may enable EVAR in juxta- and suprarenal AAA or **involving iliac artery**.
- However, efficacy and safety of newer devices needed to be validated in larger clinical trials.

***Thank you for your attention!***