AAA Graft: Current Status and Future Perspectives

Woong Chol Kang M.D.

Cardiology, Gachon University Gil Medical Center
Incheon, Korea

History of EVAR Devices

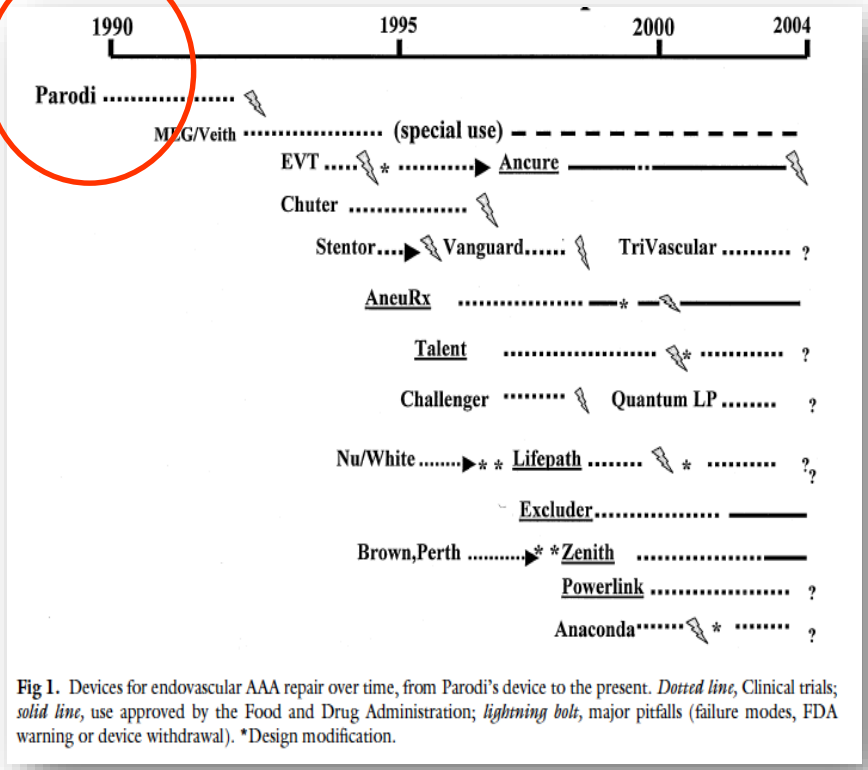


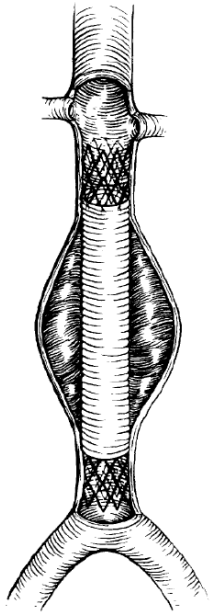
Fig 1. Devices for endovascular AAA repair over time, from Parodi's device to the present. *Dotted line*, Clinical trials; *solid line*, use approved by the Food and Drug Administration; *lightning bolt*, major pitfalls (failure modes, FDA warning or device withdrawal). *Design modification.

1990 → Paradigm Shift in Aortic Aneurysm Treatment: EVAR

Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

J.C. Parodi, MD*, J.C. Palmaz, MD†, H.D. Barone, PhD, *Buenos Aires, Argentina, and San Antonio, Texas*

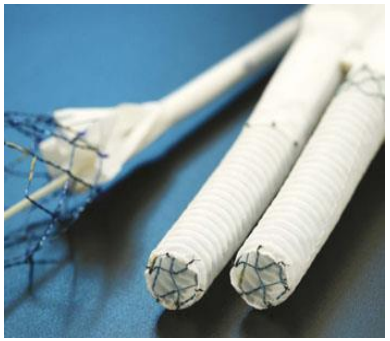
This study reports on animal experimentation and initial clinical trials exploring the feasibility of exclusion of an abdominal aortic aneurysm by placement of an intraluminal, stent-anchored, Dacron prosthetic graft using retrograde cannulation of the common femoral artery under local or regional anesthesia. Experiments showed that when a balloon-expandable stent was sutured to the partially overlapping ends of a tubular, knitted Dacron graft, friction seals were created which fixed the ends of the graft to the vessel wall. This excludes the aneurysm from circulation and allows normal flow through the graft lumen. Initial treatment in five patients with serious co-morbidities is described. Each patient had an individually tailored balloon diameter and diameter and length of their Dacron graft. Standard stents were used and the diameter of the stent-graft was determined by sonography, computed tomography, and arteriography. In three of them a cephalic stent was used without a distal stent. In two other patients both ends of the Dacron tubular stent were attached to stents using a one-third stent overlap. In these latter two, once the proximal neck of the aneurysm was reached, the sheath was withdrawn and the cephalic balloon inflated with a saline/contrast solution. The catheter was gently removed caudally towards the arterial entry site in the groin to keep tension on the graft, and the second balloon inflated so as to deploy the second stent. Four of the five patients had heparin reversal at the end of the procedure. We are encouraged by this early experience, but believe that further developments and more clinical trials are needed before this technique becomes widely used. (*Ann Vasc Surg* 1991;5:491–499).



FDA approved EVAR Devices

September 1999		November 2002	May 2003	October 2004	April 2008	December 2010	May 2013	June 2015	October 2015
Ancure Guidant	AneuRx Medtronic	Excluder Gore	Zenith Cook	Powerlink Endologix	Talent Medtronic	Endurant Medtronic	Aorfix Lombard	Ovation Endologix	AFX Endologix
									

Available Devices in Korea



Seal
S&G

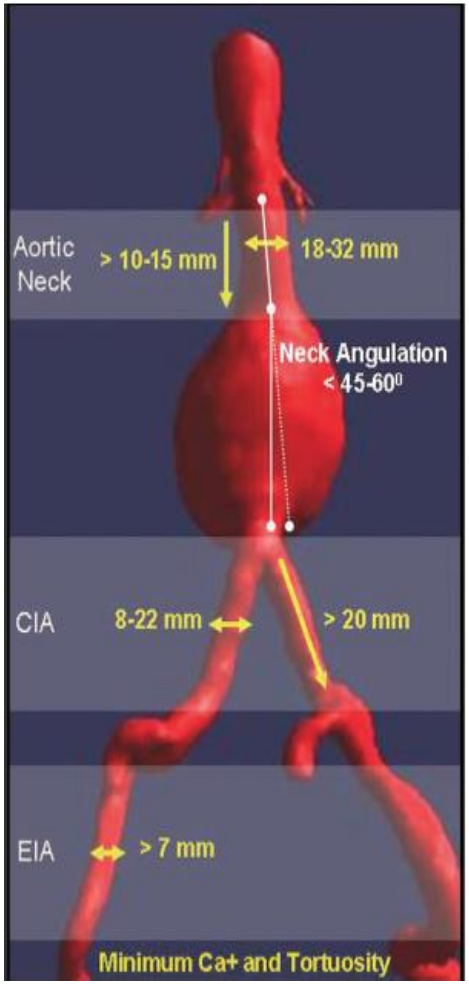
Zenith Flex
Cook

Endurant IIs
Medtronic

Incraft
Cordis

AFX2
Endologix

Minimal requirement for standard EVAR



Proximal aortic neck

- Neck diameter >17 mm, <32 mm
- Angle between the suprarenal aorta and the juxtarenal aorta <60°
- Angle between the juxtarenal aorta and the long axis of the aneurysm sac <60-90°
- 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

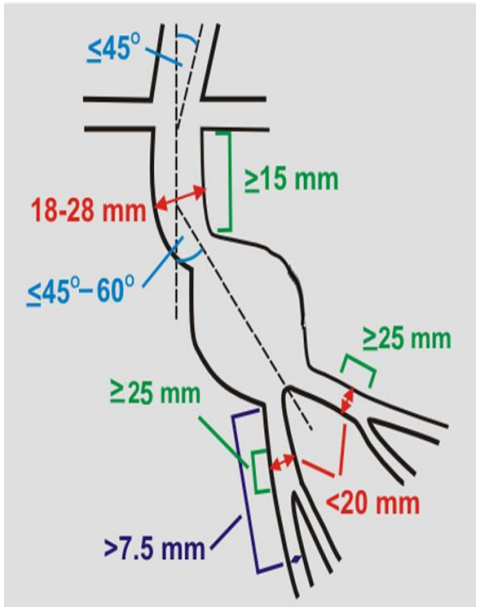
Aortic bifurcation

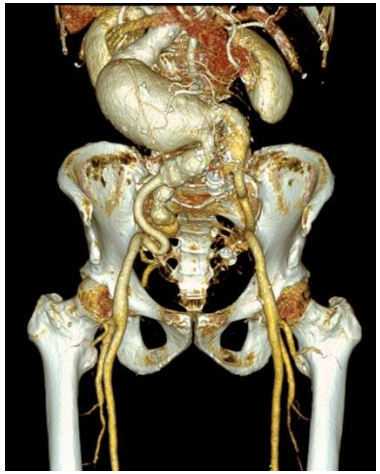
- Aortic bifurcation diameter >20 mm in case of a bifurcated graft

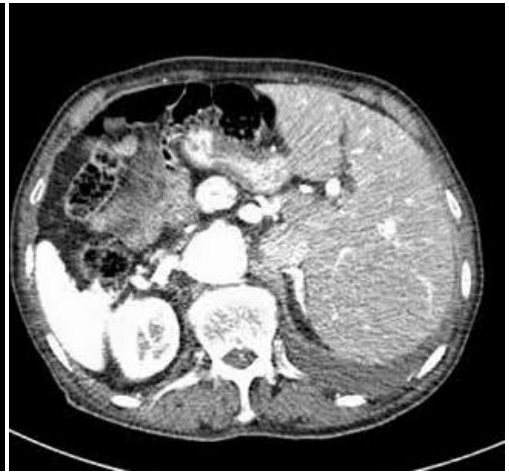
Iliac artery

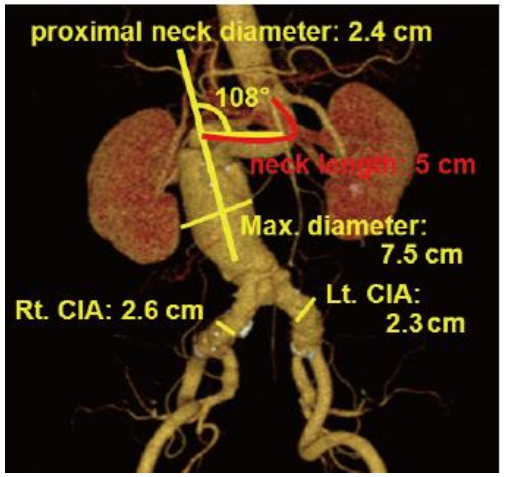
- Iliac luminal diameter >7 mm
- Angle between the long axis of the aneurysm and the iliac axis <60°
- Iliac calcification: non extensively circumferential
- Iliac neck diameter <22 mm
- Iliac neck length >15 mm

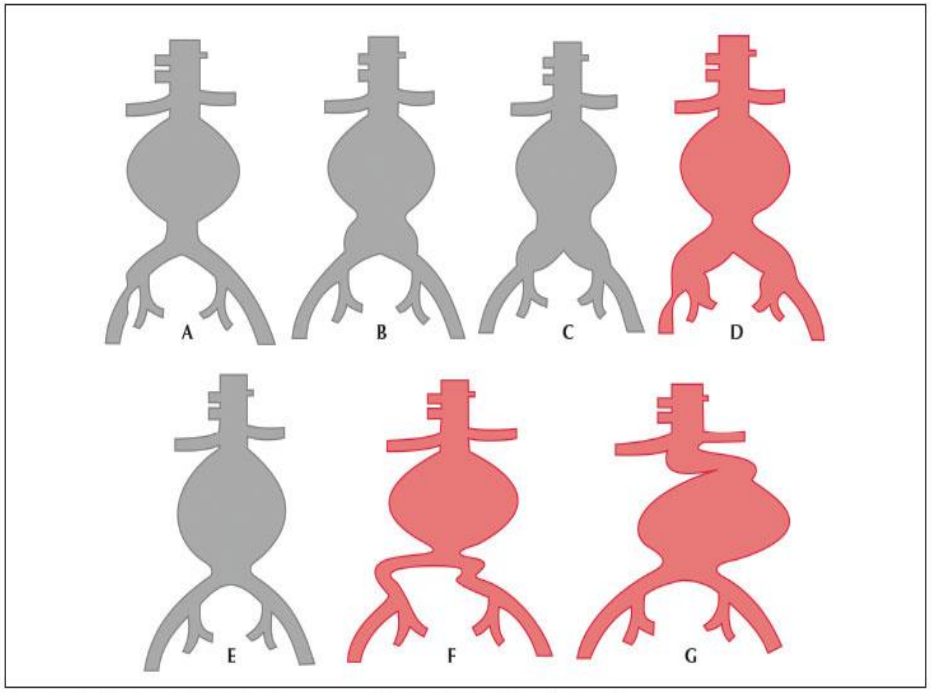
Complex AAA

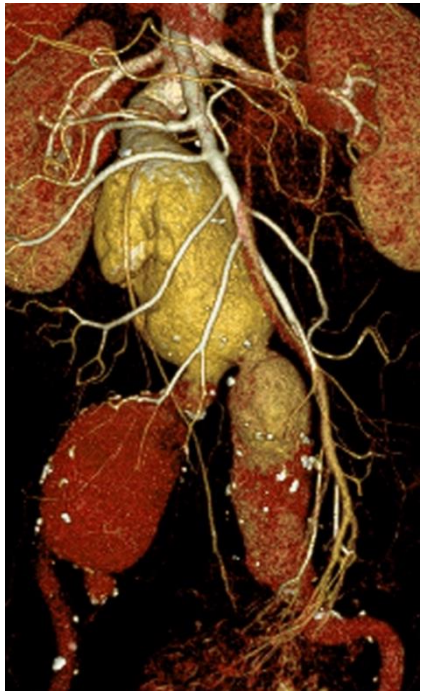

≤45°
≥15 mm
18-28 mm
≤45°–60°
≥25 mm
≥25 mm
<20 mm
>7.5 mm

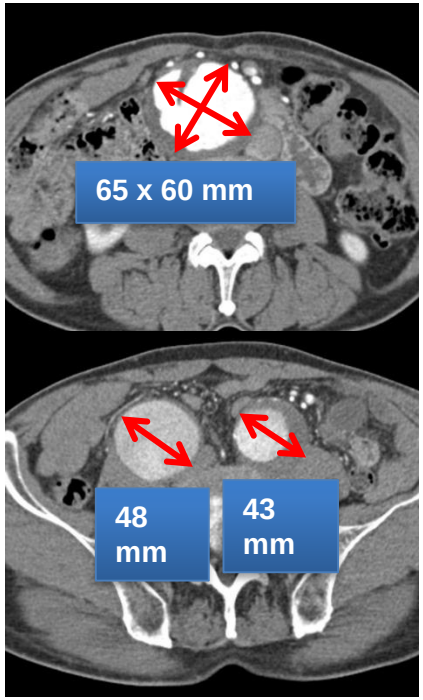




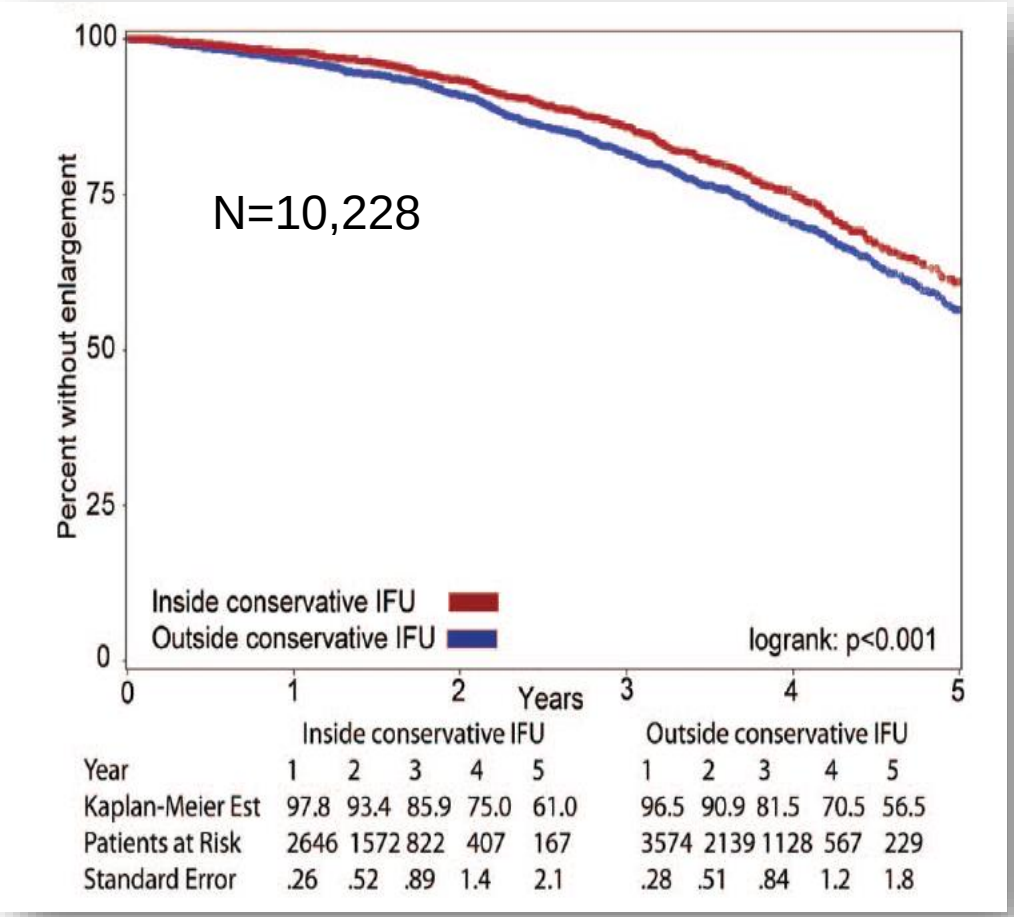

proximal neck diameter: 2.4 cm
108°
neck length: 5 cm
Max. diameter:
7.5 cm
Rt. CIA: 2.6 cm
Lt. CIA:
2.3 cm


A
B
C
D
E
F
G




65 x 60 mm
48 mm
43 mm

AAA enlargement after EVAR



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

Circulation 2011;123:2848

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
≥80	1.32 (1.03–1.75)	0.05
Female	0.96 (0.82–1.13)	0.64
AAA diameter		
Maximum AAA diameter ≥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 ≤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

Current AAA graft with main features

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

[1]mulitlayer ePTFE, [2]balloon –expandable endoframes surrounded by an endobag filled with an in-situ curing polymer, [3]outer diameter

Limitations of Current Devices

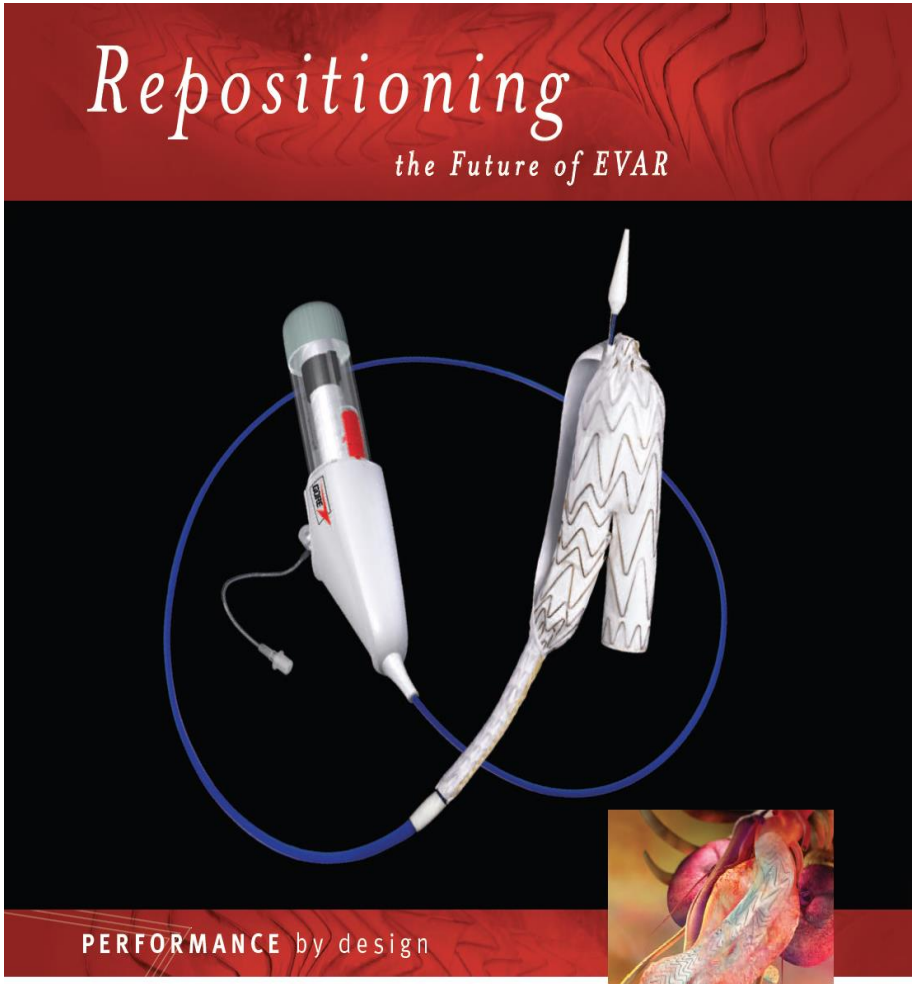
Limitations

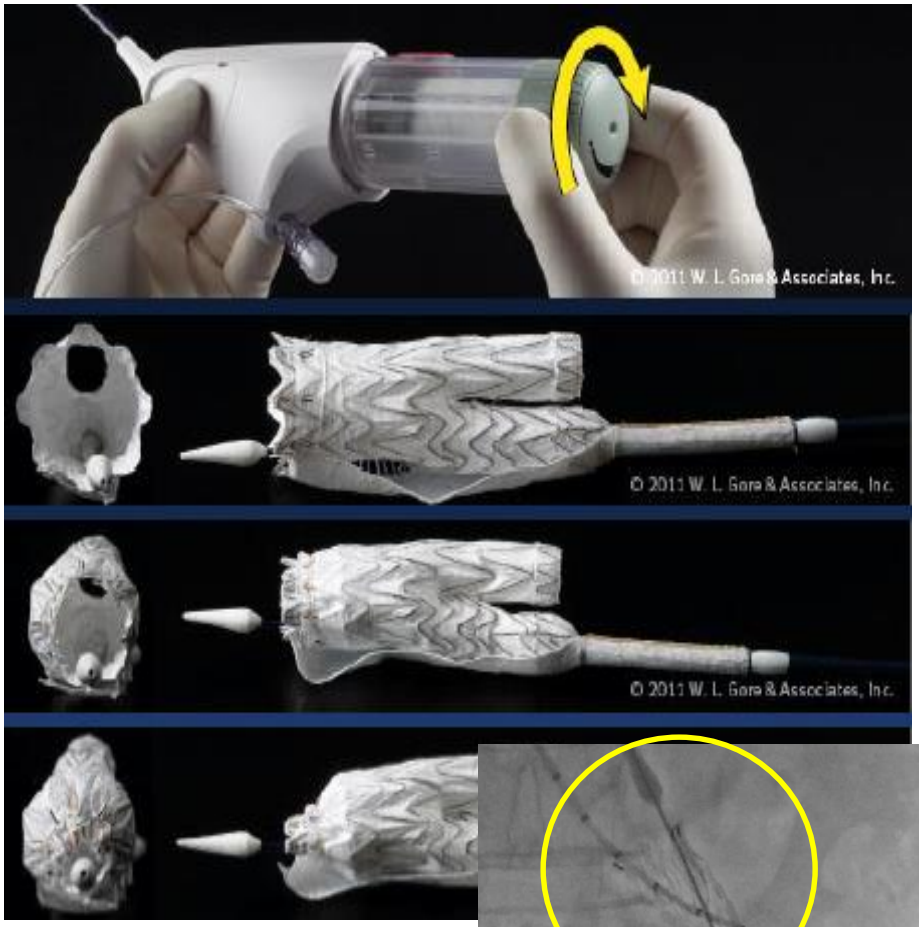
- Hostile neck
- Inadequate sealing
- Juxta- or suprarenal AAA
- Large device profile
- AAA with Iliac involvement
- Inability of reposition

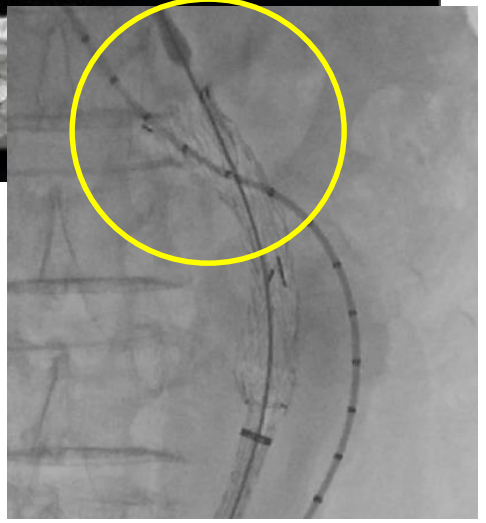
Required Improvement

- **Flexibility / Conformability**
- **Controlled deployment**
- **Migration resistance**
- **Low profile**
- **Long-term durability**

Excluder & C3 Delivery System (Gore)







- **Reconstrain the proximal end of the endograft.**
- **Repositioning of endogrft**
  risk of graft migration and endoleaks.

Incraft (Cordis)

3-PIECE MODULAR SYSTEM:

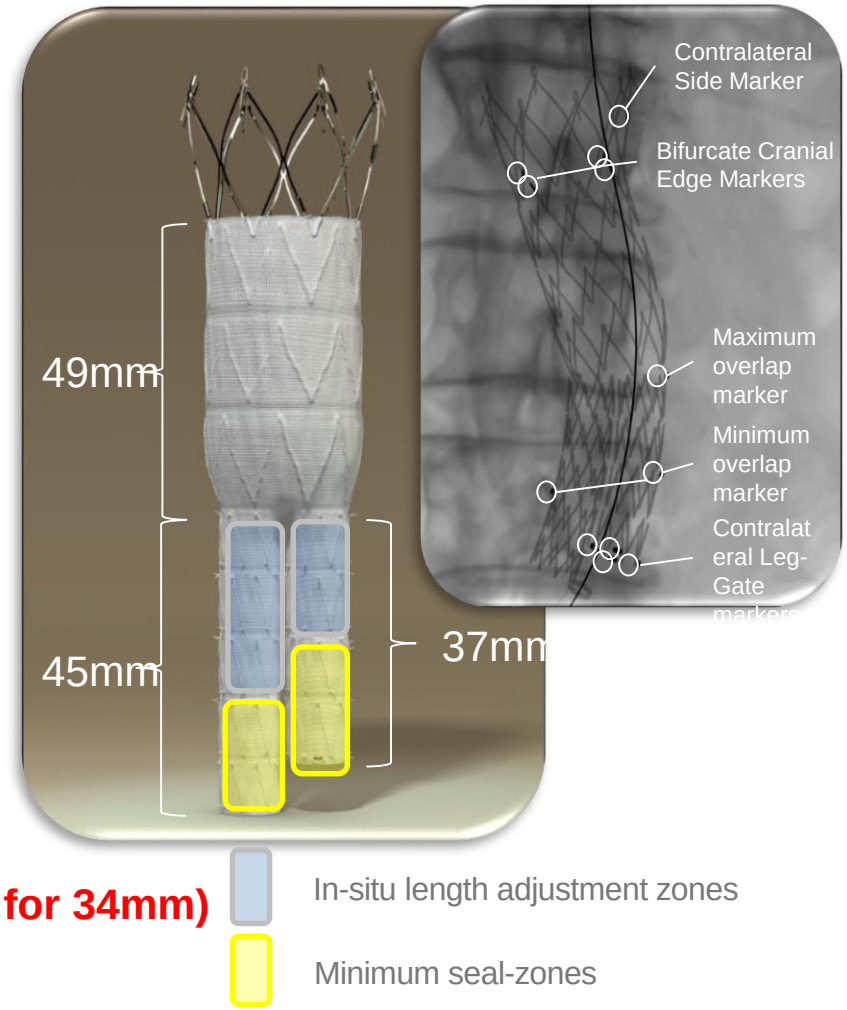
- Low porosity polyester graft
- Segmented nitinol stents
- **Supra-renal fixation**

CUSTOMIZATION:

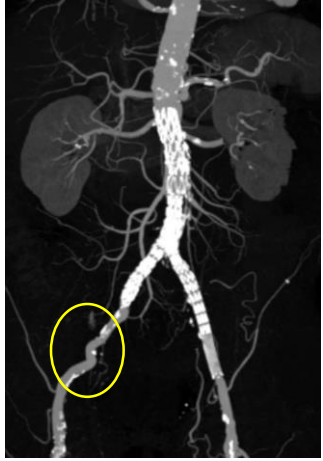
- Bilateral in-situ length adjustment up to 3cm*
- Partial proximal re-positioning
- Few units to fit broad anatomical coverage

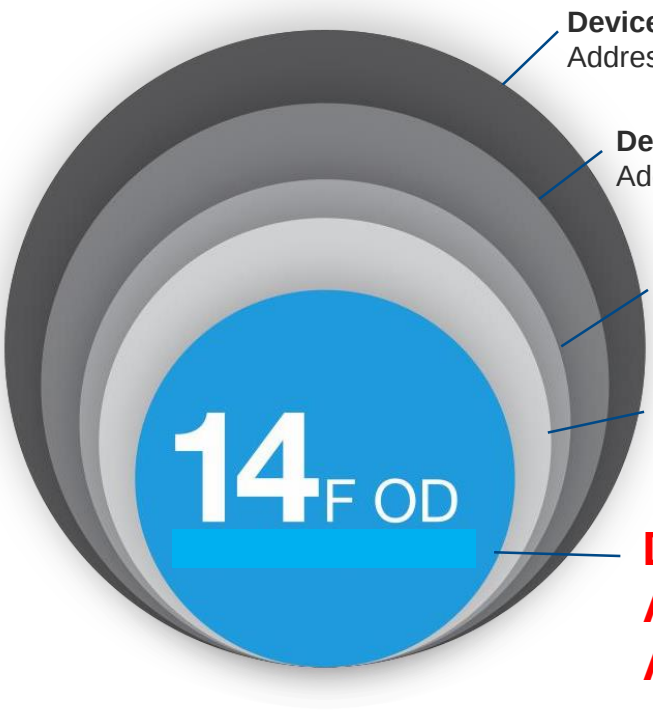
ULTRA-LOW PROFILE:

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



Low Profile, Expanded Options





Device F: 22F OD
Addresses 27% of AAA population*

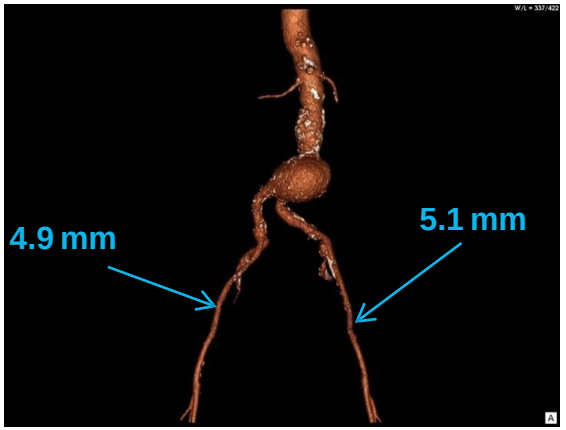
Device E: 20F OD
Addresses 40% of AAA population*

Devices C and D: 18F OD
Addresses 59% of AAA population*

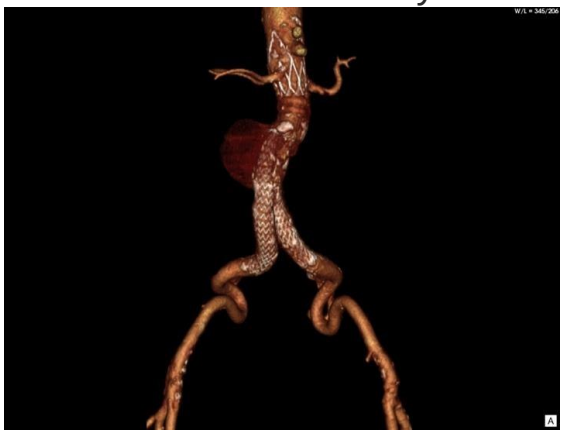
Device B: 17F OD
Addresses 63% of AAA population*

Devices A: 14F OD
Addresses 83% of AAA population*

Narrow Access



Tortuous Anatomy



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

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)

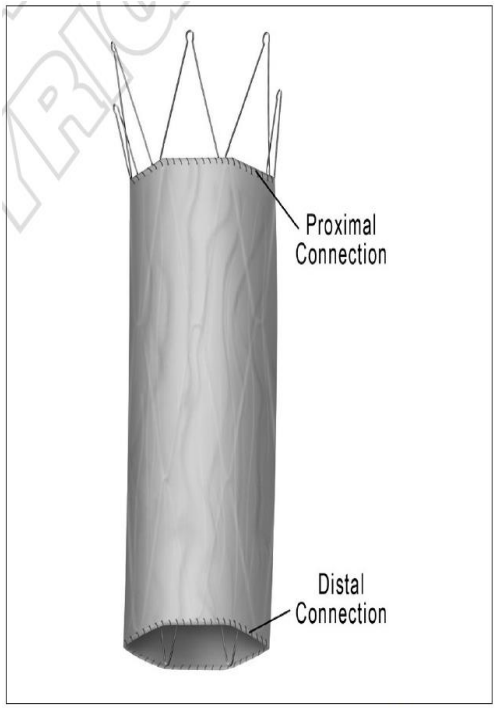
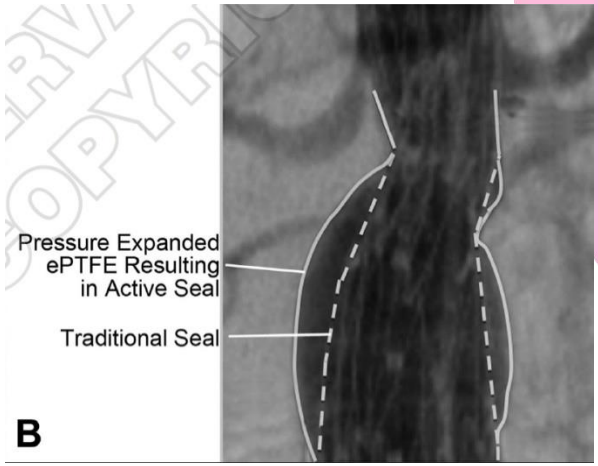
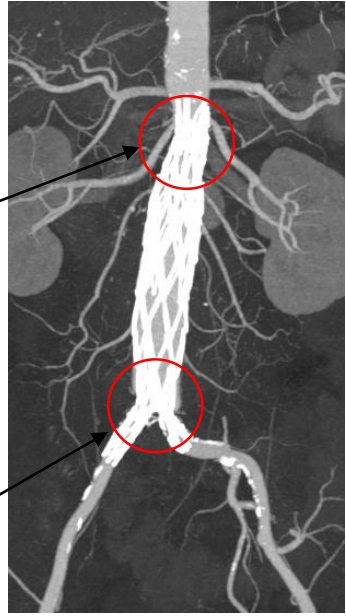
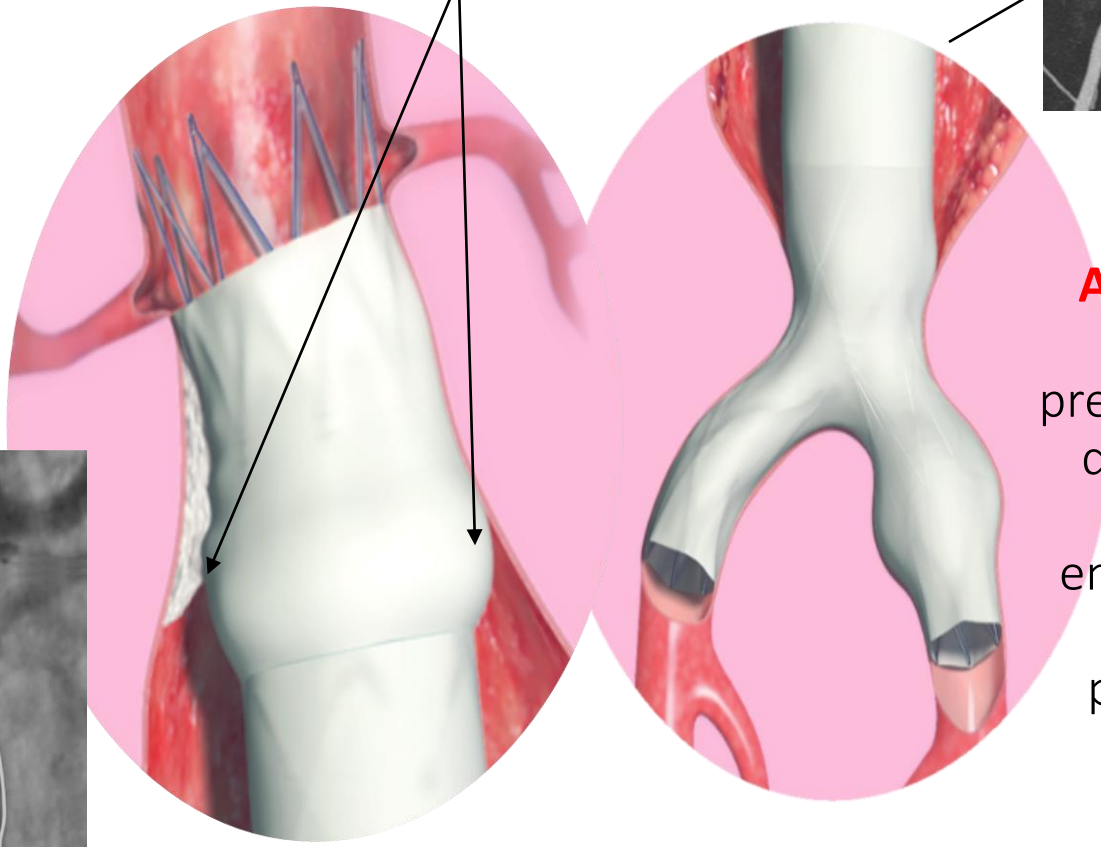


Figure 2.—The graft material is connected to the metal frame of the cuff only at the proximal and distal ends.



ActiveSeal™ extends the seal zones





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

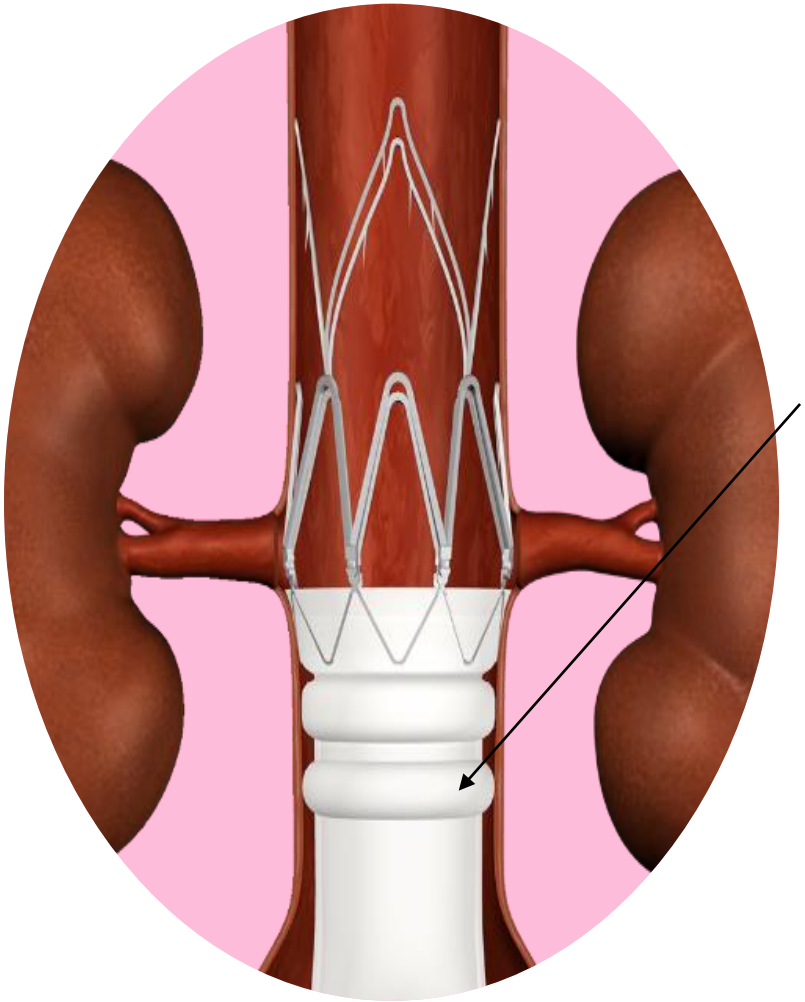
Ovation (Trivascular, Endologix)

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

Nellix (Endologix)

THE NEW PARADIGM IN AAA THERAPY

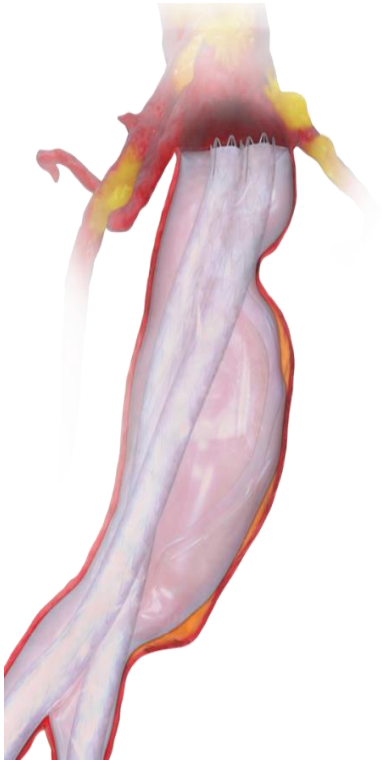
Nellix®
EndoVascular Aneurysm Sealing System

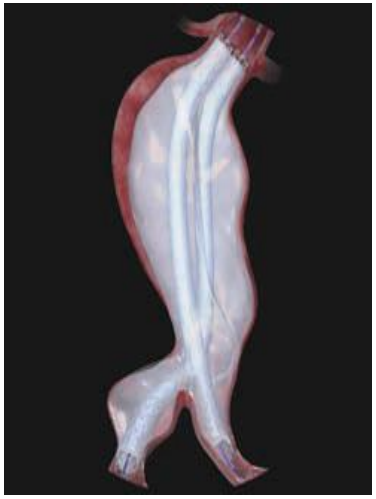
Simplified procedure & planning

Complete aneurysm sealing to

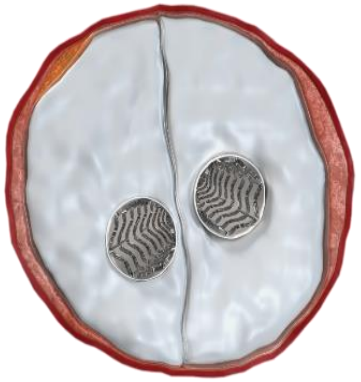
confidently treat more patients

Lowest overall endoleak rate and reduced secondary interventions





EndoBags are filled with Polymer to seal the entire aneurysm



vascularnews

Unrestricted sales of the Nellix System to cease as use is limited to current indications

7th January 2019 862

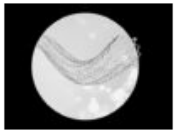
Unrestricted sales and use of the Nellix System (Endologix) will cease immediately, in order to ensure optimal outcomes for patients, according to Endologix. The product will only be available for use under clinical protocol with pre-screened patients that adhere to the current indications.

"We monitor the performance of the Nellix System through clinical trials, our complaint monitoring system, physician interaction and available publications," says Matt Thompson, Chief Medical Officer of Endologix. "Our independently adjudicated data from the EVAS1 IDE [Investigational Device Exemption] clinical trial indicates that the Nellix System has performed well when used consistently with the current indications. However, data from recent Nellix publications leave us concerned that outcomes are suboptimal when the system is used outside current instructions for use."

Most read in past 7 days

Meta-analysis finds a higher risk of death in the long term...

6th December 2018



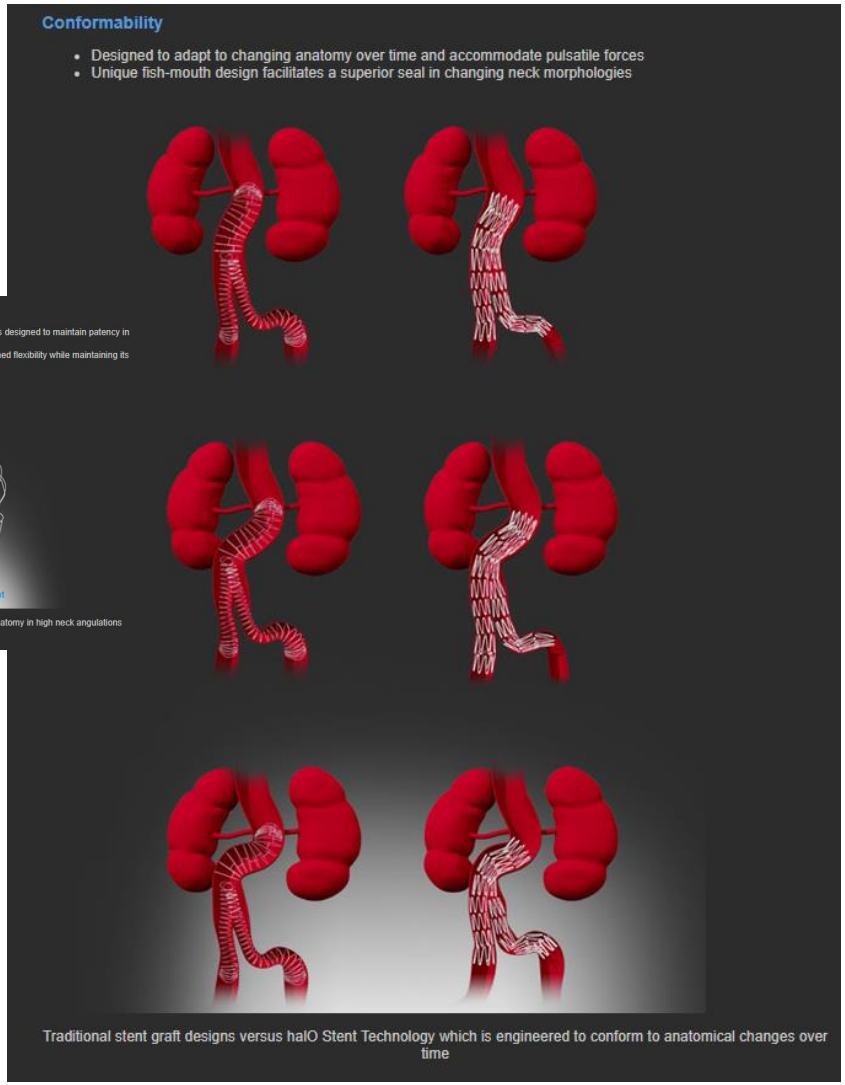
Cook Medical releases patient-level data from Zilver PTX paclitaxel-eluting stent study

24th April 2019

Tomographic 3D ultrasound imaging "the way forward" for vascular surgeons

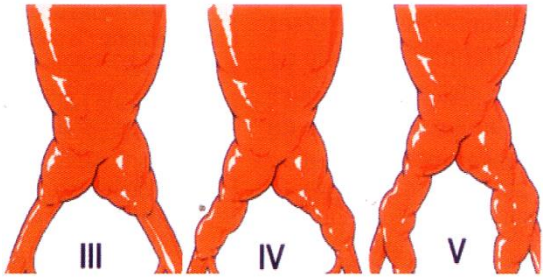
24th April 2019

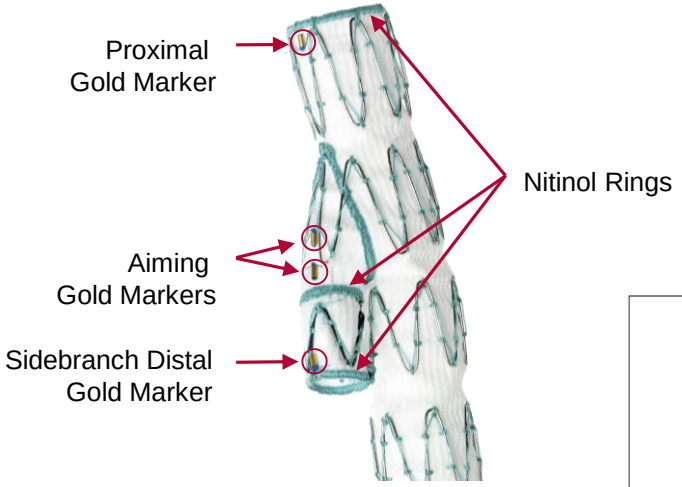
Lombard Aorfix

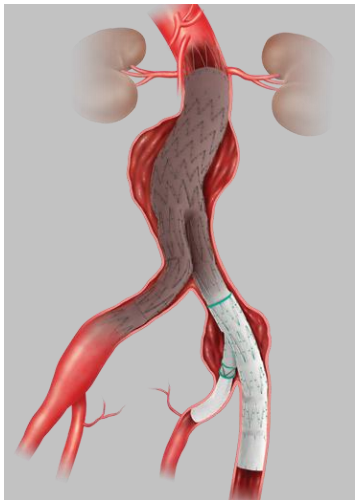


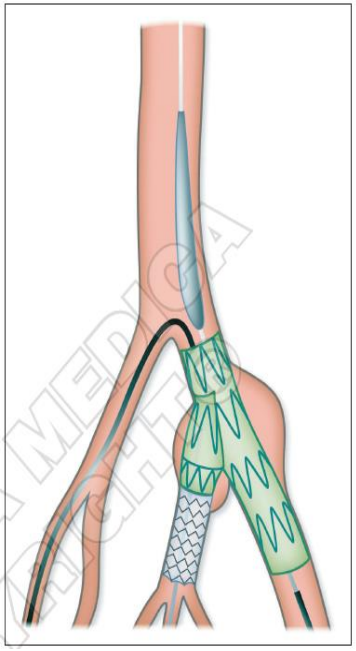
- Ring body and helical limb structure provide better flexibility in angulated neck and tortuous anatomy

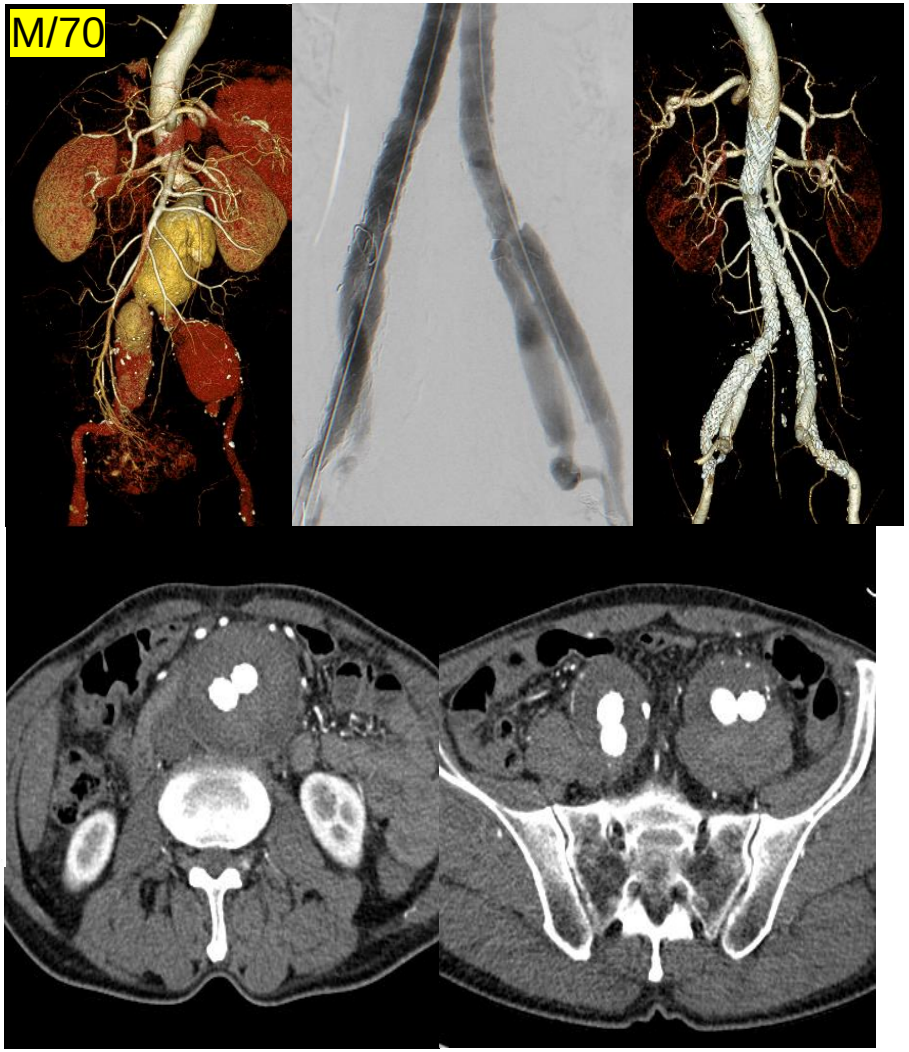
Endovascular repair of aortoiliac aneurysm with IBD





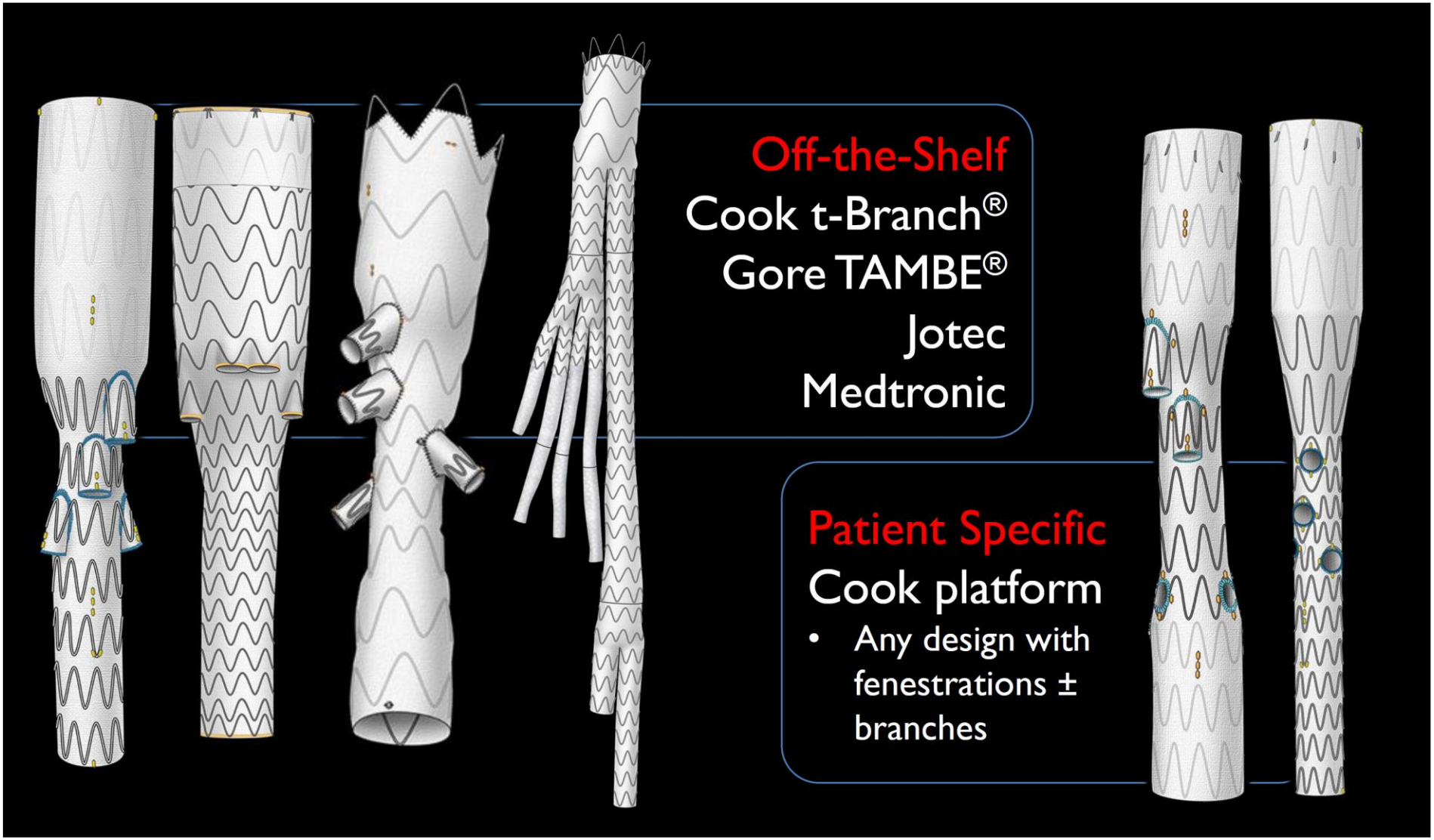






- Mid-term results showed high patency and low reintervention rates.

Branched and Fenestrated Stent-Grafts



Conclusions

- **Current AAA grafts have many limitations to manage AAA with complex anatomy.**
- **Next generation devices are transforming to solve unmet clinical need of current devices.**
- **New devices should fit unfavorable AAA anatomy (more flexible, lower profile, IBD, branched SG etc) and have long-term durability which is validated in large clinical trials.**

Michael Lawrence-Brown *David Hartley*

"It has become clear that not only the technology but also disease progression plays an important role in the durability of endovascular aortic therapy."