Next-Generation of AAA EVAR Grafts: Iterative or Transformative?

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First EVAR Endograft in Human

1991 Annals of Vascular Surgery

Annals of Vascular Surgery

Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

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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 In these latter two, once the proximal neck of the aneurysm was reached, the sheath was withdrawn and the cephalic balloon inflated with a saline/contrast solution.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).

KEY WORDS: Graft-stent exclusions; grafts; abdominal aortic aneurysm; transfemoral intraluminal grafts.

Abdominal aortic aneurysm (AAA) has been recognized since antiquity as a lethal pathologic process. As a result, the last 50 years of vascular surgery have seen a variety of attempts at cure of the condition. Intraluminal wiring [1], external wrapping [2], and exclusion of the aneurysm by ligation have been tried and discarded in the past [3]. Experience with those showed that they did not offer durable protection from aneurysm rupture [4]. Neither wrapping nor thrombosis of the aneurysm protected the patient from fatal rupture [5–7].

Today, vascular surgeons are dealing with an increasingly aged population. These are persons in whom abdominal aortic aneurysms occur. Autopsy studies have placed the overall incidence of AAA disease between 1.8 and 6.6% [8–10]. Actual incidence of AAA is increasing with the aging of the population [11]. In the 30-year period of study, the incidence of AAA was seen to rise threefold. Furthermore, aneurysm screening in select populations such as first-order relatives of patients with AAA or patients in cardiovascular clinics has shown that in select populations, the incidence of aneurysms may vary from 5% to 20% [12–14].

Durable protection from aneurysm rupture began with DuBost [15] who demonstrated that aortic replacement was an effective method of treatment. Prosthetic graft replacement is the treatment of choice for aortic aneurysms today. Elective repair is regularly performed with an operative mortality of under 5% with the expectation that long-term survival is markedly extended [16, 17].

Increasingly, vascular surgeons are encountering older patients with severe co-morbid conditions. These can increase operative morbidity and may even elevate mortality of aortic surgery to a figure in excess of 60% [18]. With this in mind, new methods of aortic aneurysm exclusion deserve exploration. The following study reports on animal

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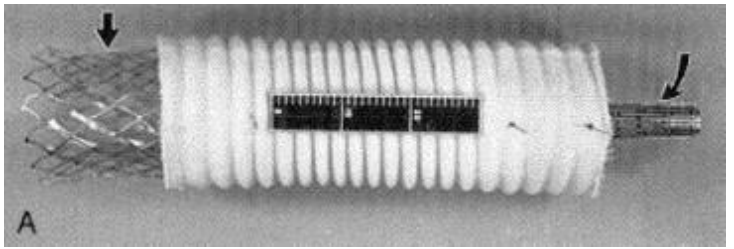
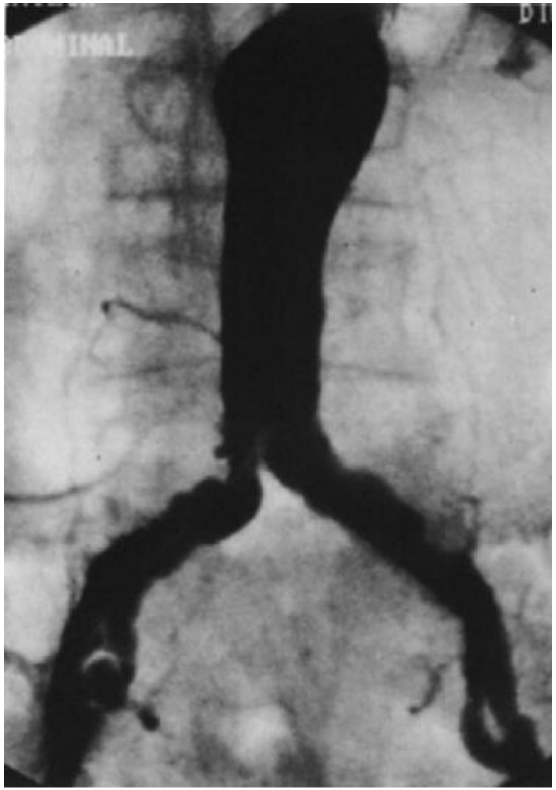
Dr. Julio Palmaz, Radiologist

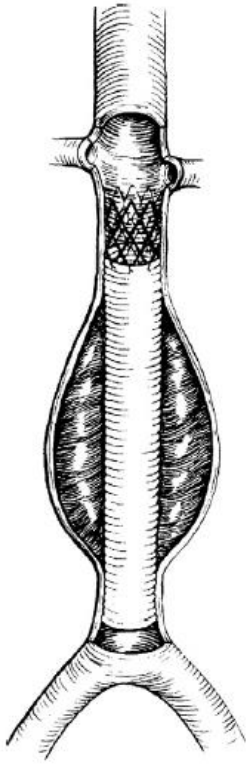


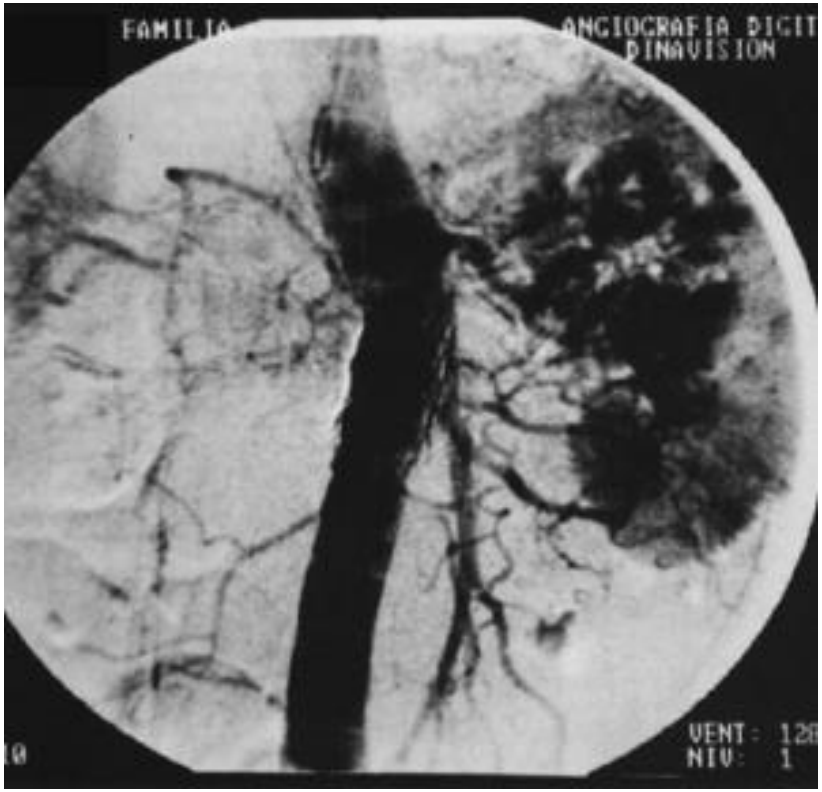
Parodi-Palmaz endograft:

Dacron + modified Palmaz stents (stainless steel, 6 x 35 mm) on a valvuloplasty balloon

The First Patient







Parodi JC, Palmaz J, Ann Vasc Surg 1991;5;491

History of EVAR Devices

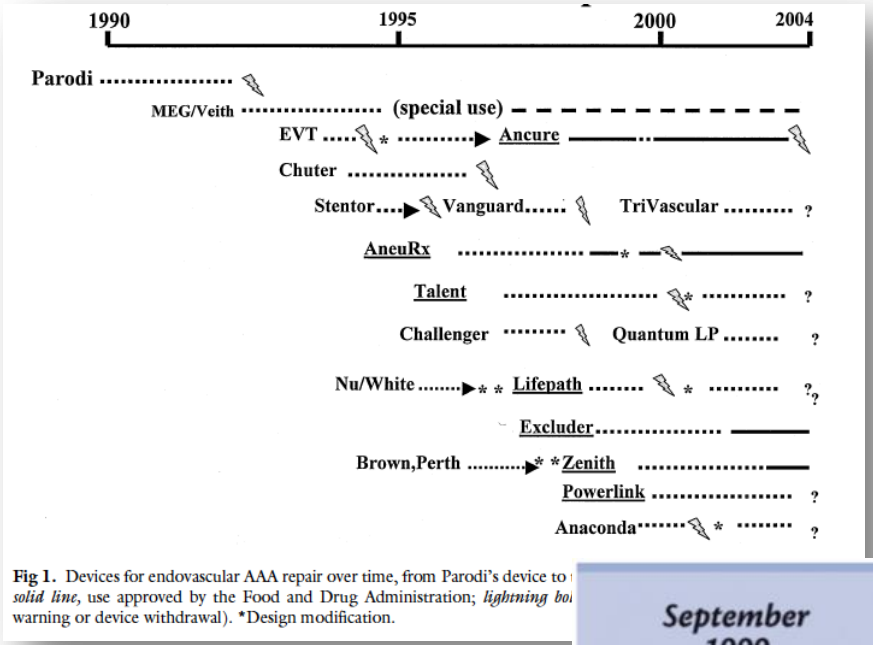
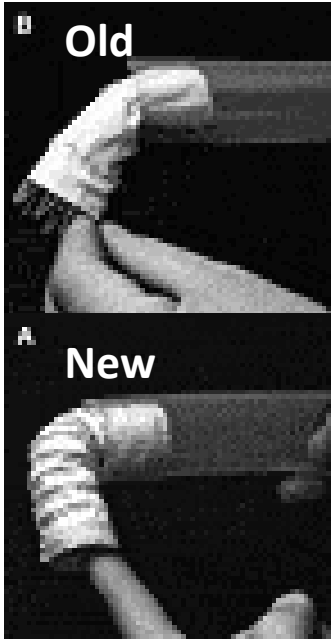


Fig 1. Devices for endovascular AAA repair over time, from Parodi's device to (*solid line*, use approved by the Food and Drug Administration; *lightning bo* warning or device withdrawal). *Design modification.

FDA Approval timeline

First Generation Endografts: Procedural Complications

- Large profile (24-28 OD)
- Surgical FA exposure& repair
- General anesthesia
- Inflexible
- Cumbersome to deploy
- Suboptimal in complex anatomy
- High incidence of procedural complications



First Generation Endografts: Complications

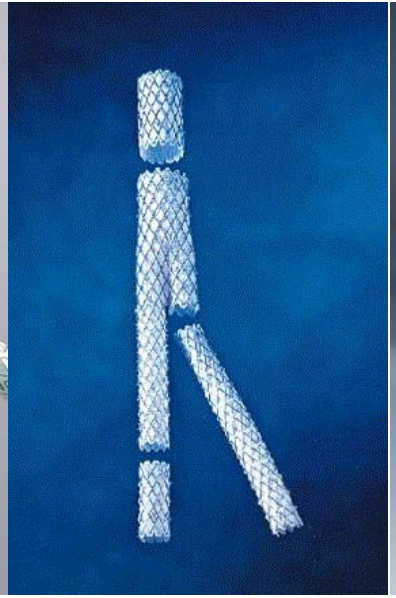
- Device Migration
- Modular component separation
- High permeability & endotension
- Endoleaks
- Loss of structural integrity

Currently Available Devices in Korea

Seal, S&G

Zenith Flex, Cook

Excluder, Gore



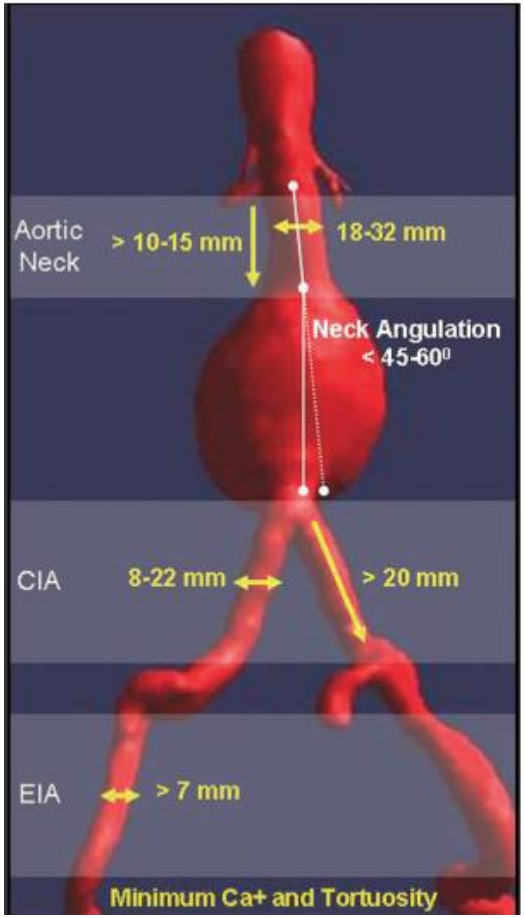
2002 Aneurex, Medtronic

2008 Talent, Medtronic

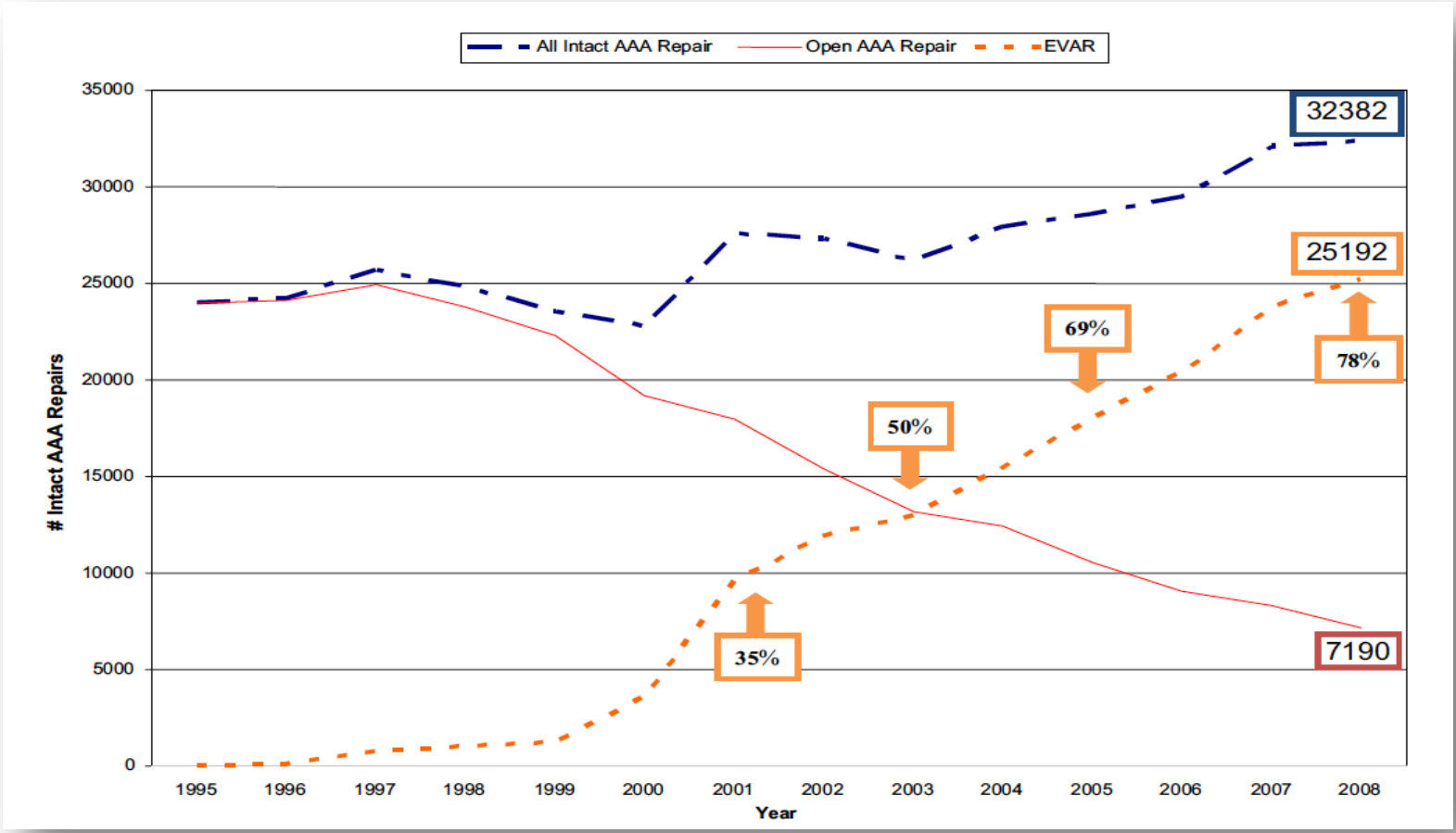
2010 Endurant, Medtronic

Suitable AAA Morphology for EVAR

- Aortic neck
  - Diameter: 18~32 mm
  - Length: >10~15 mm
  - Shape: straight, non-conical
  - Angulation <45~60°
  - Minimal thrombus or calcification
- CIA
  - Length: >20 mm
  - Diameter: 8 ~ 22 mm
- EIA
  - Diamter: > 7 mm
  - minimal Ca. & tortuosity

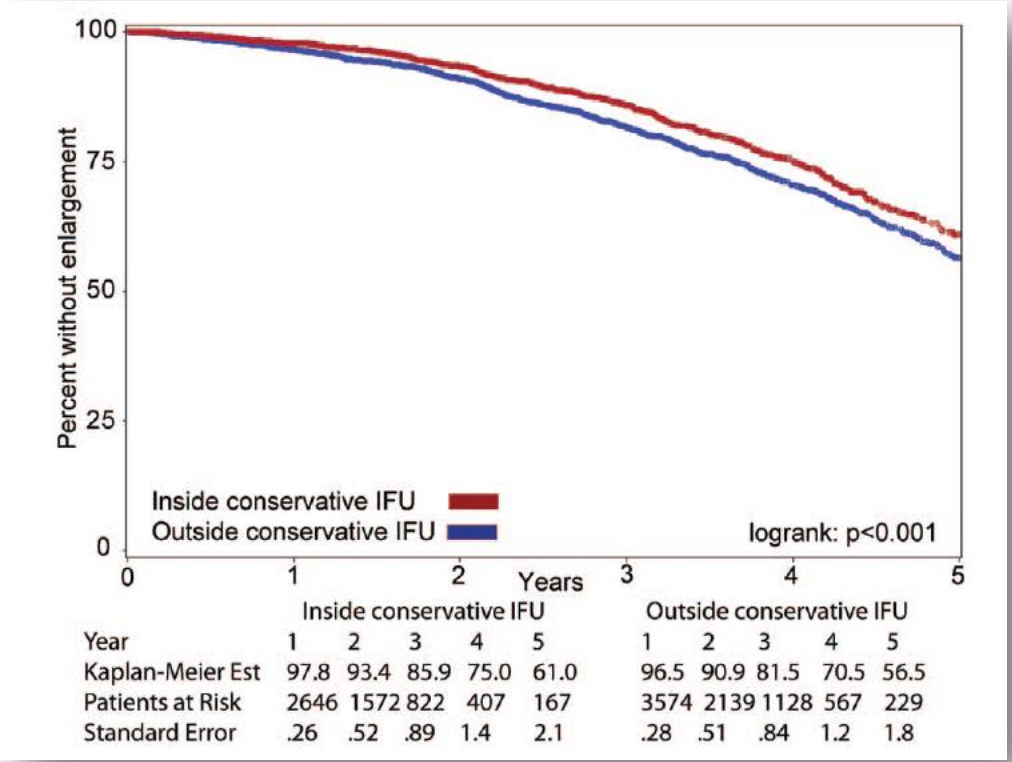


The Number of Open and Endovascular AAA Repairs in the US Medicare Population



Sachs T, J Vasc Surg 2011;54:881

AAA Enlargement after EVAR



Schanzer A, Circulation 2011;123:2848

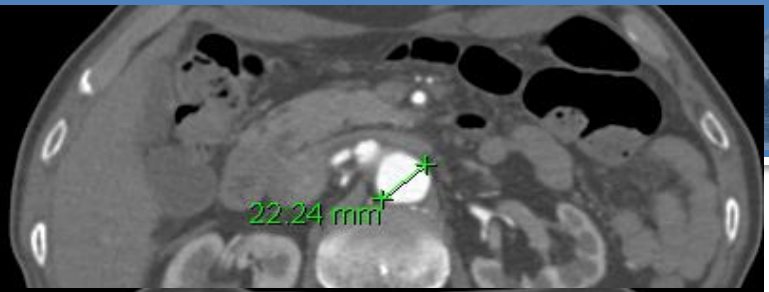
Table 5. Determinants of Aortic Aneurysm Sac Enlargement Identified on Multivariable Cox Proportional Hazards Analysis

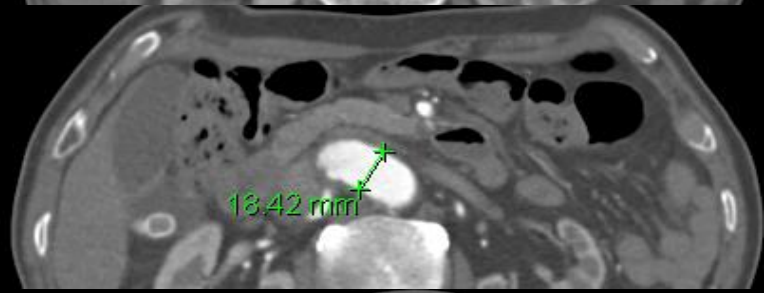
Covariates	Hazard Ratio (95% Confidence Interval)	*P*
Age, y		
<60	Reference	
60–69	0.80 (0.60–1.05)	0.11
70–79	0.87 (0.67–1.14)	0.31
≥80	1.32 (1.03–1.75)	0.05
Female	0.96 (0.82–1.13)	0.64
AAA diameter		
Maximum AAA diameter ≥55 mm	0.97 (0.86–1.10)	0.62
Aortic neck length, mm		
>15	Reference	
10–15	0.87 (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

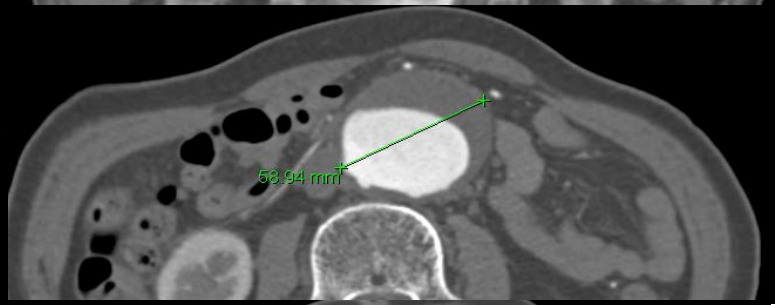
M/76 (JSS, #5809344)

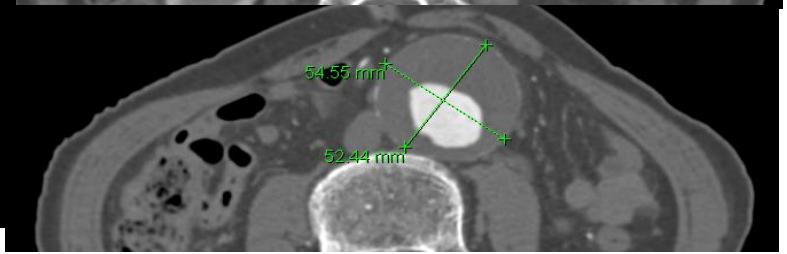
- Sx: none, Incidental AAA
- PHx:
  - Stable angina, 3-VD => CABG (July, 2010)
  - PAD => PTA (March, 2009)
  - Renal artery stenosis, bilateral
- Risk factors:
  - HTN, smoker

2010-10-05





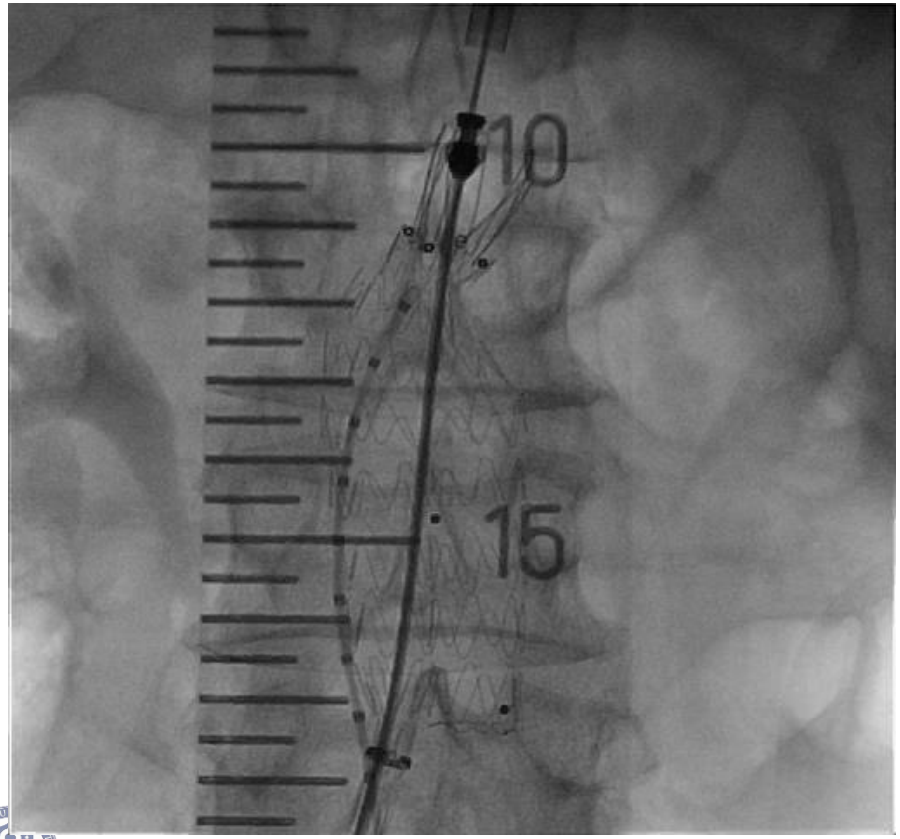


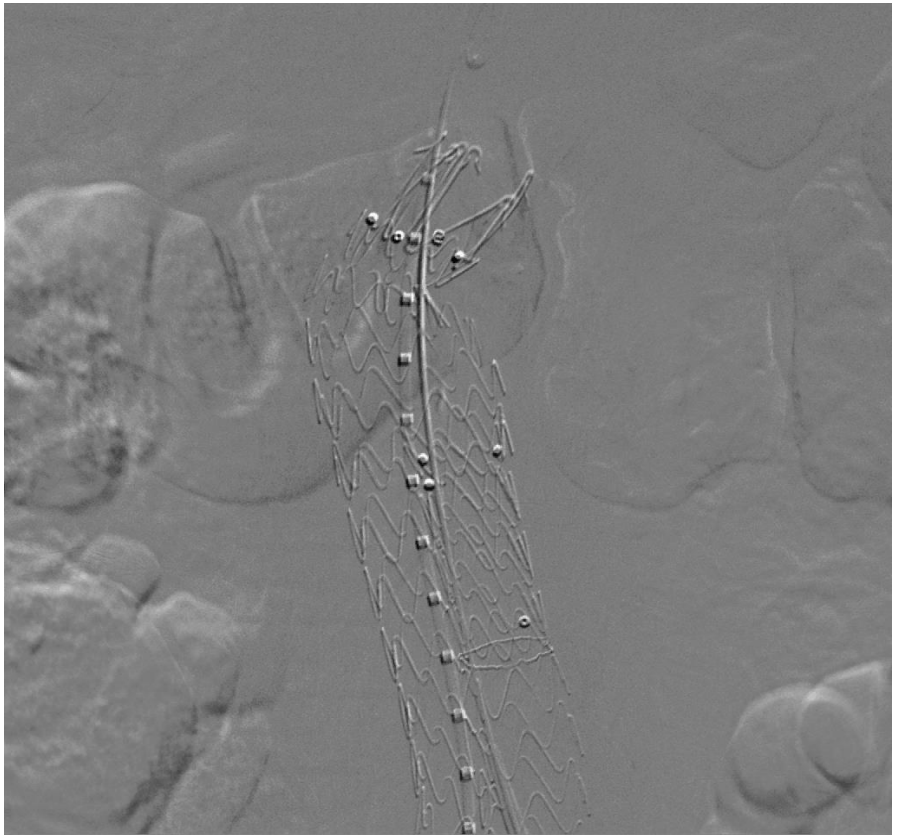


Stent-graft Implantation

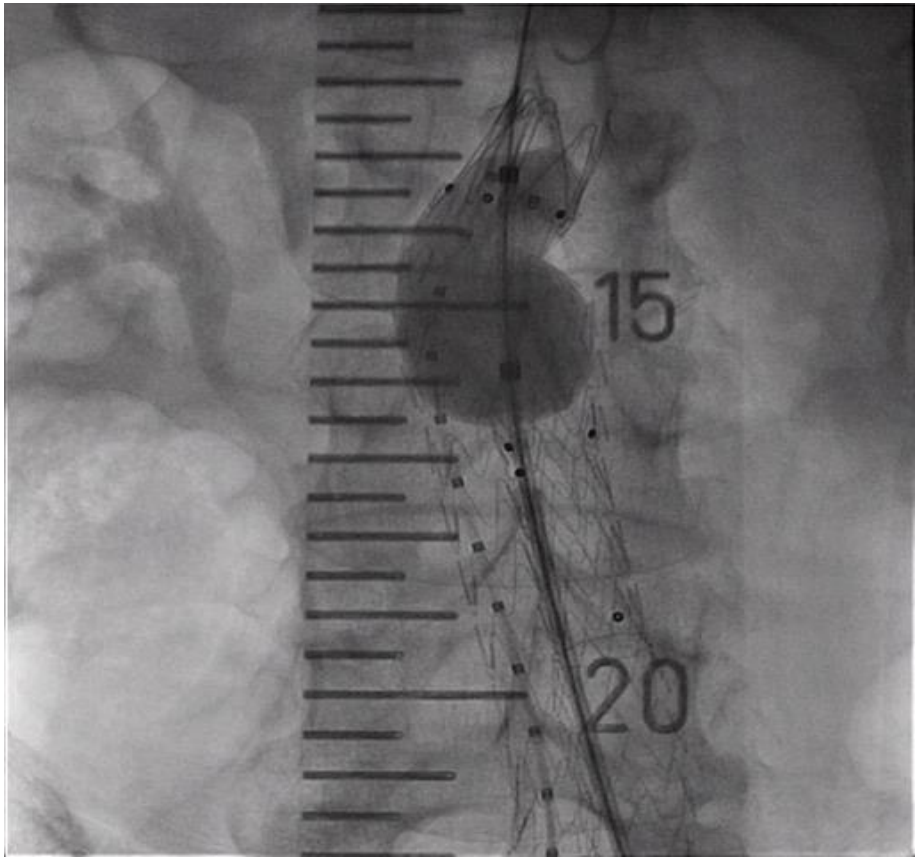
Main body: Endurant 28 x 13 x 170 mm
Lt. limb: Endurant 16 x 13 x 120mm

2010-10-15

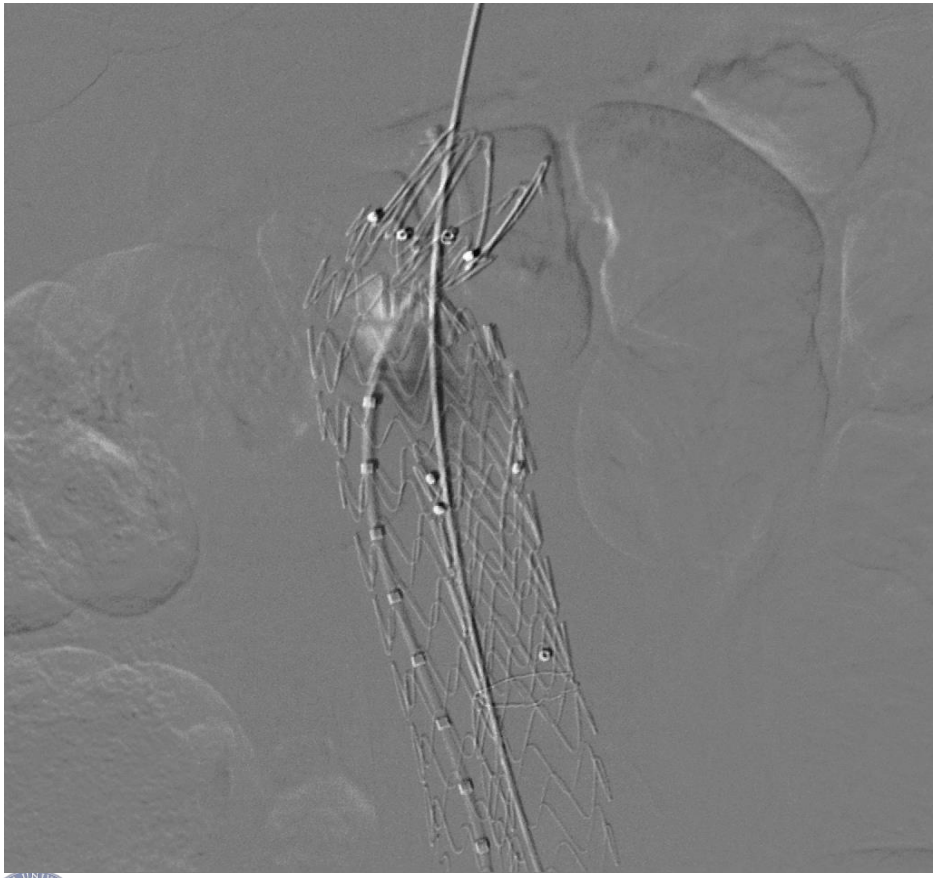


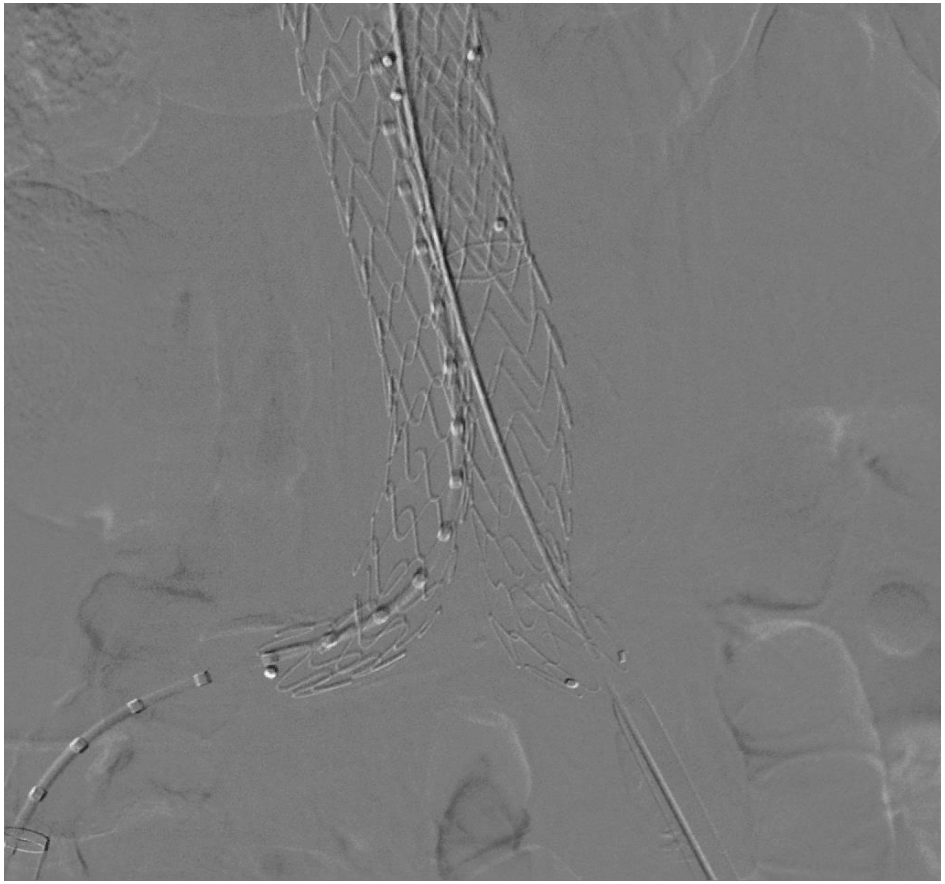


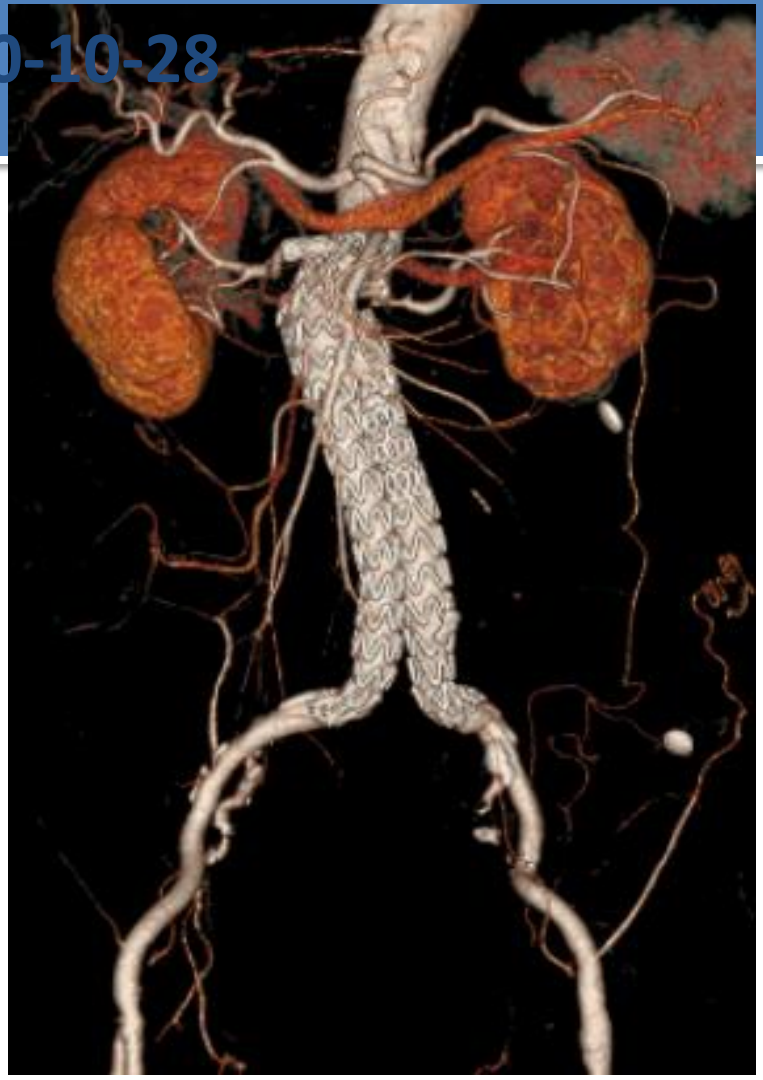
Ballooning

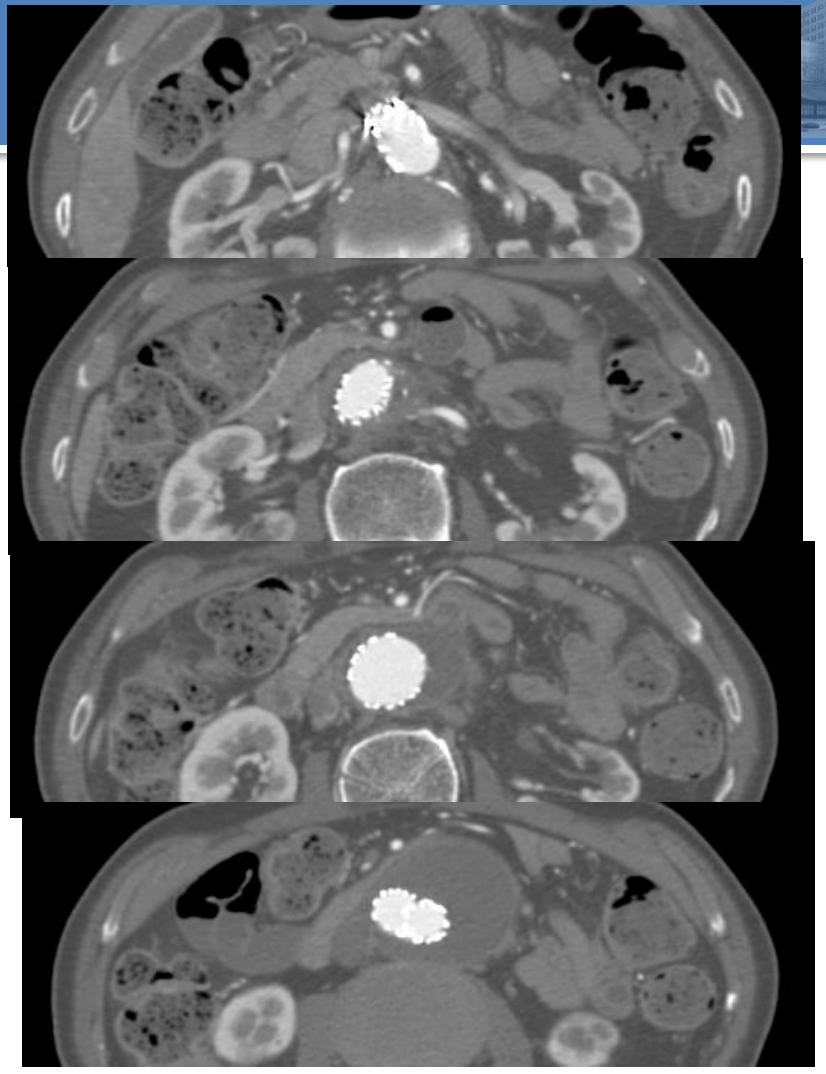


After Balloonning







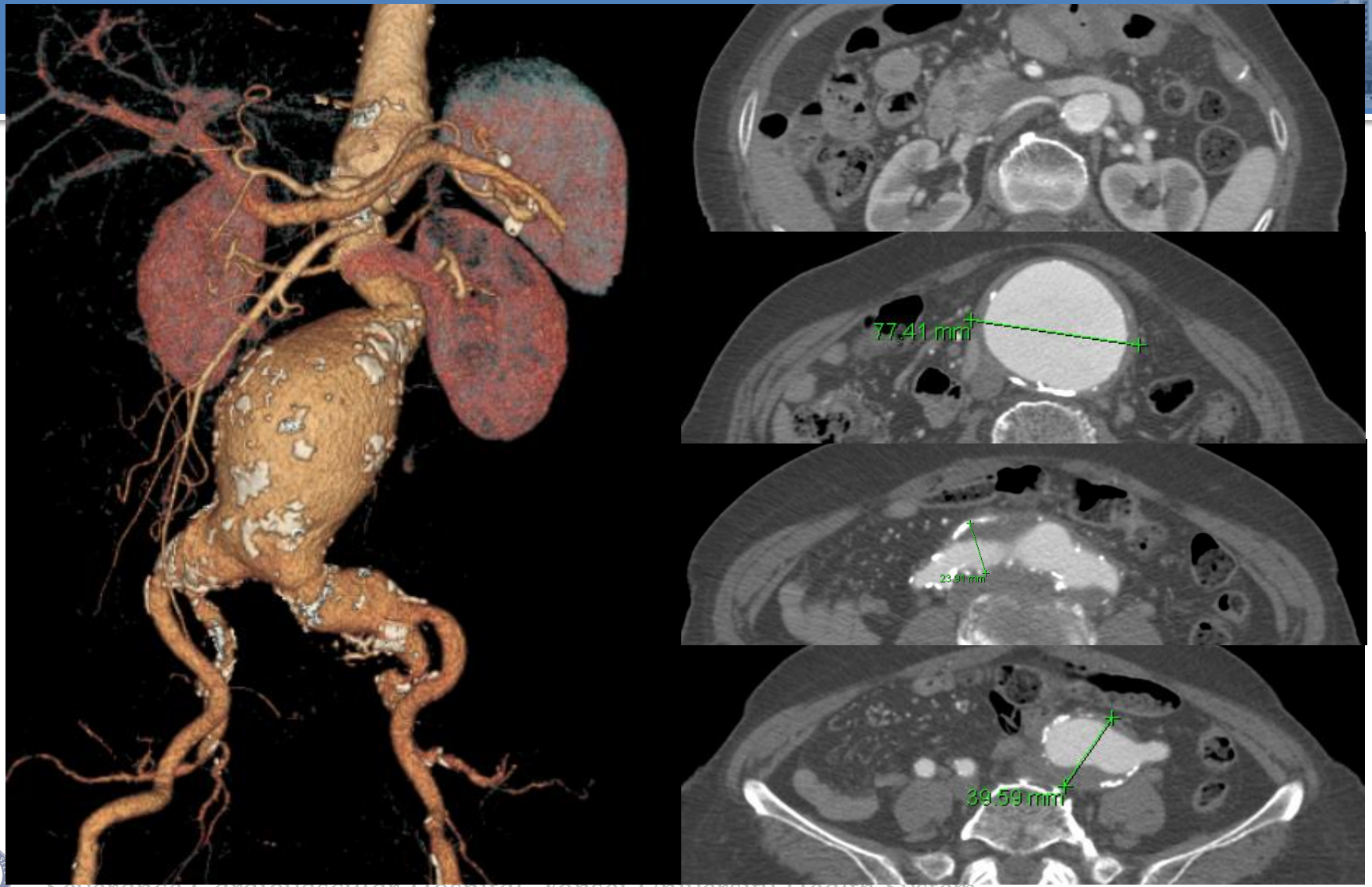


F/81 (HYJ, #5612086)

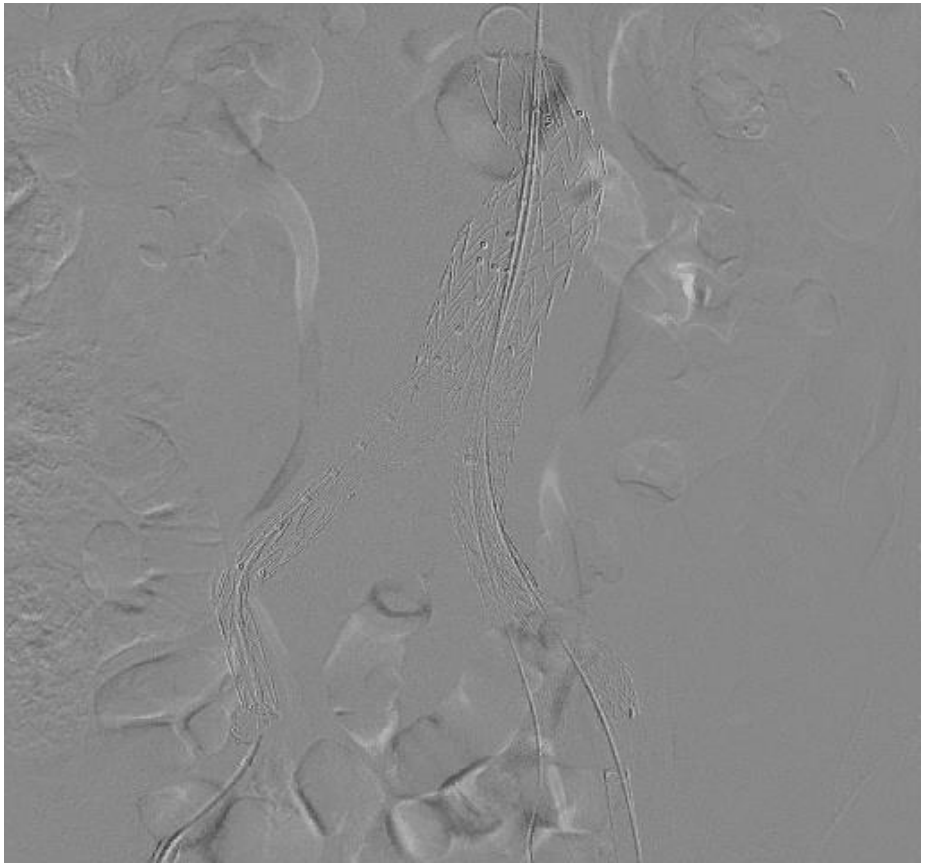
- CC: palpable abdominal mass
- Risk factors: HTN
- Ht 158 cm, Wt 57 kg
- Echo: EF = 70%, no RWMA
- Lab: Cr 0.99mg/dL

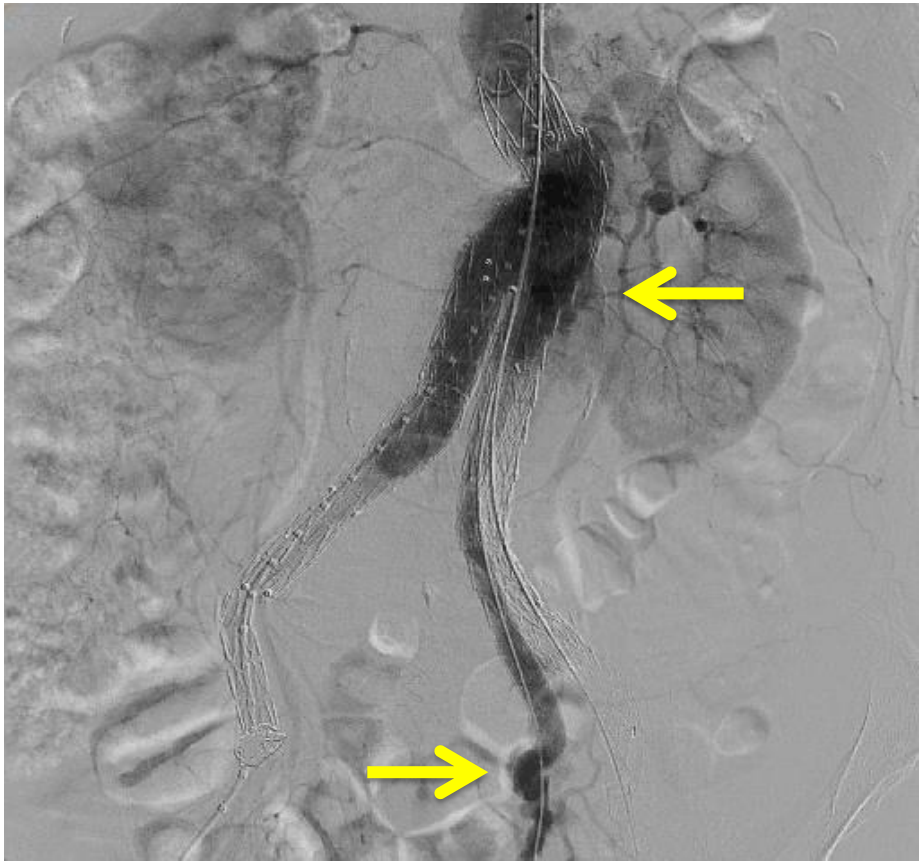
  hsCRP 8.0 mg/L

  T.chol/LDL/hdl/TG 179/119/29/89mg/dL


77.41 mm
23.91 mm
39.59 mm

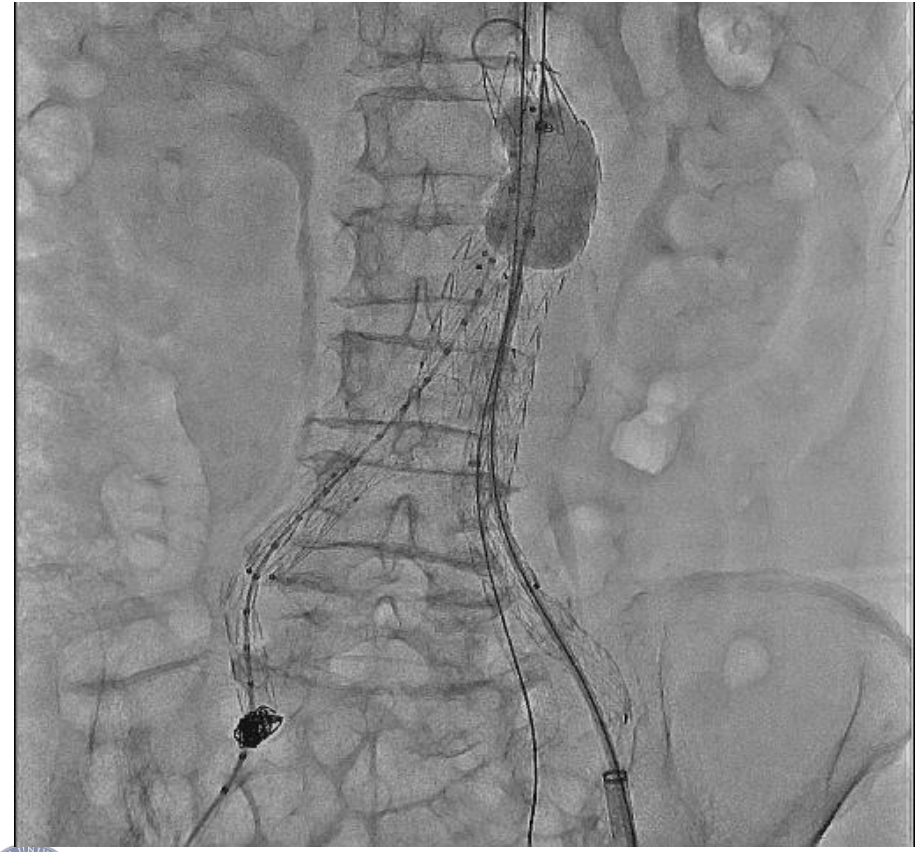
Post stent-graft aortography

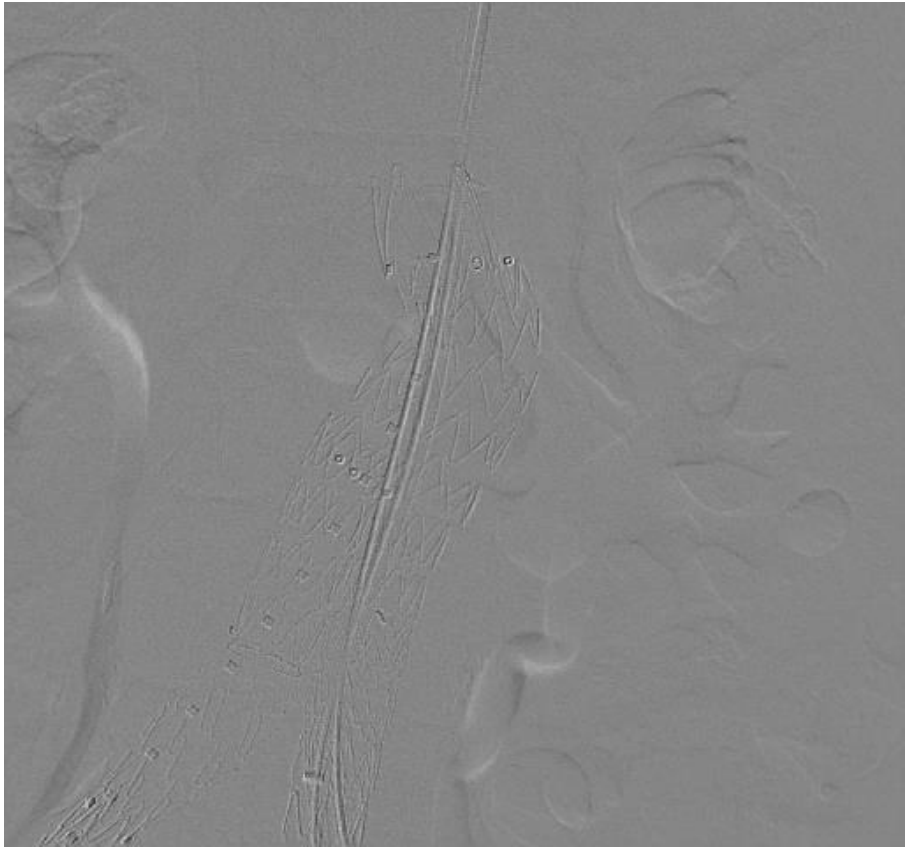




Ballooning

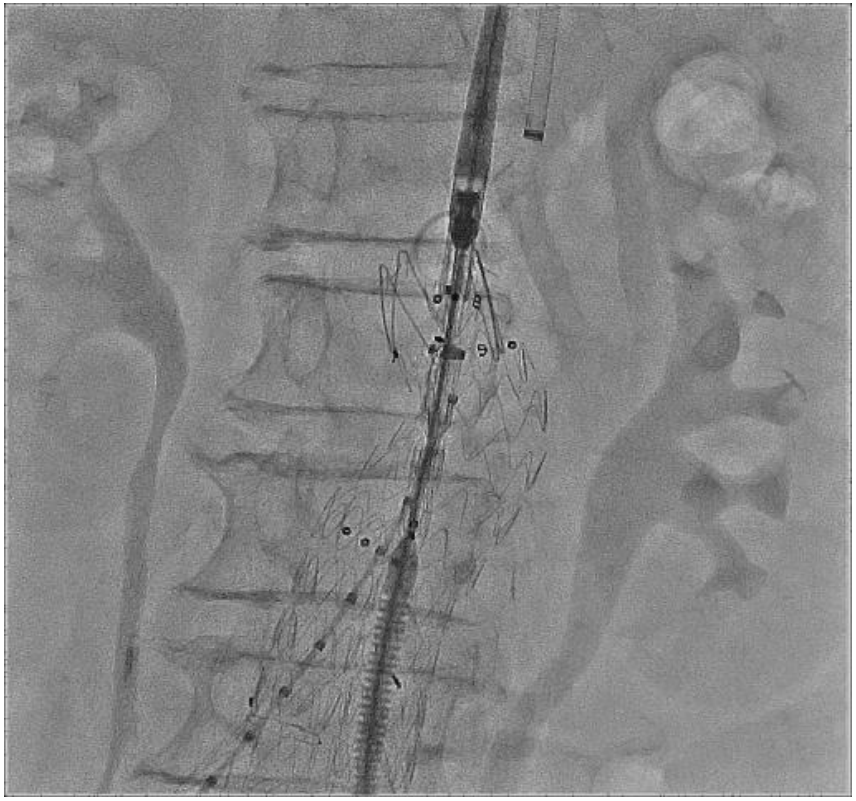
Reliant balloon

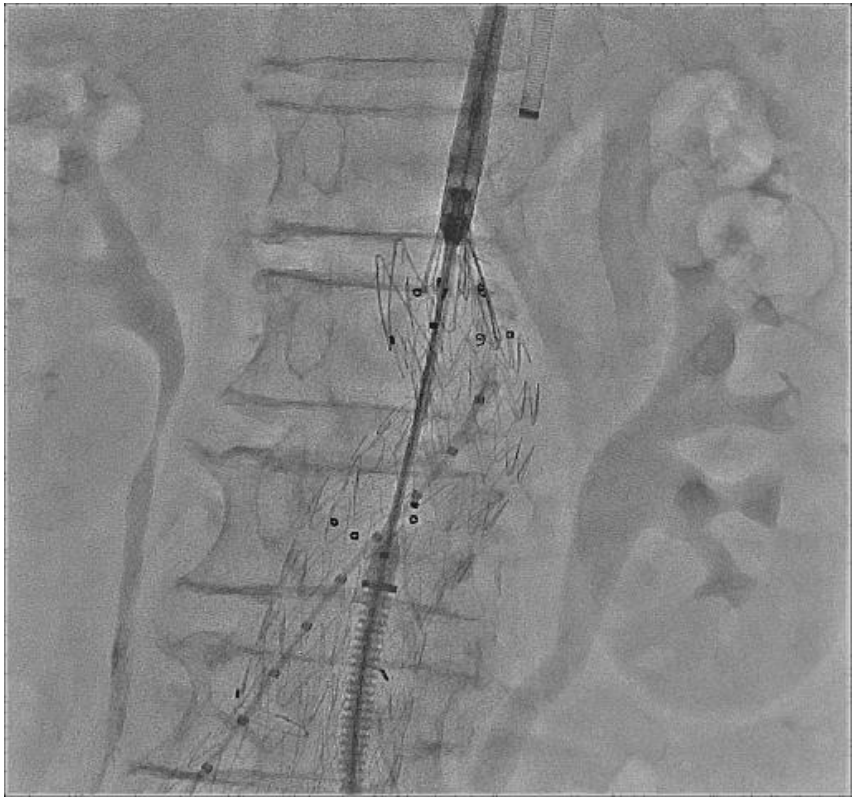




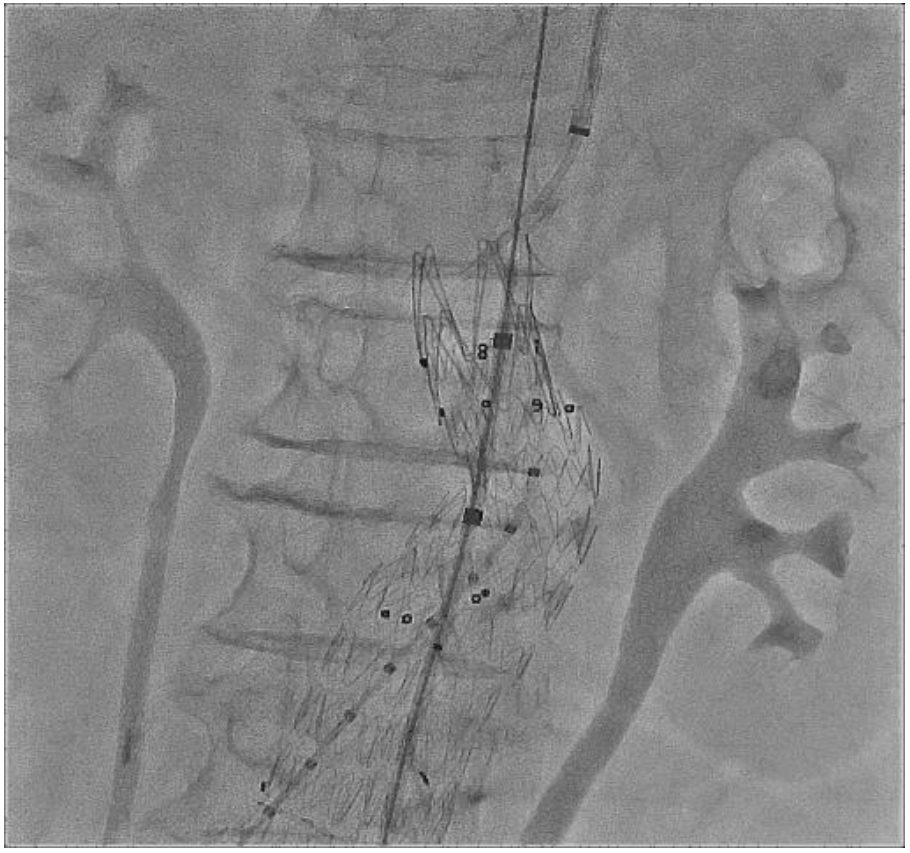
Aortic extension

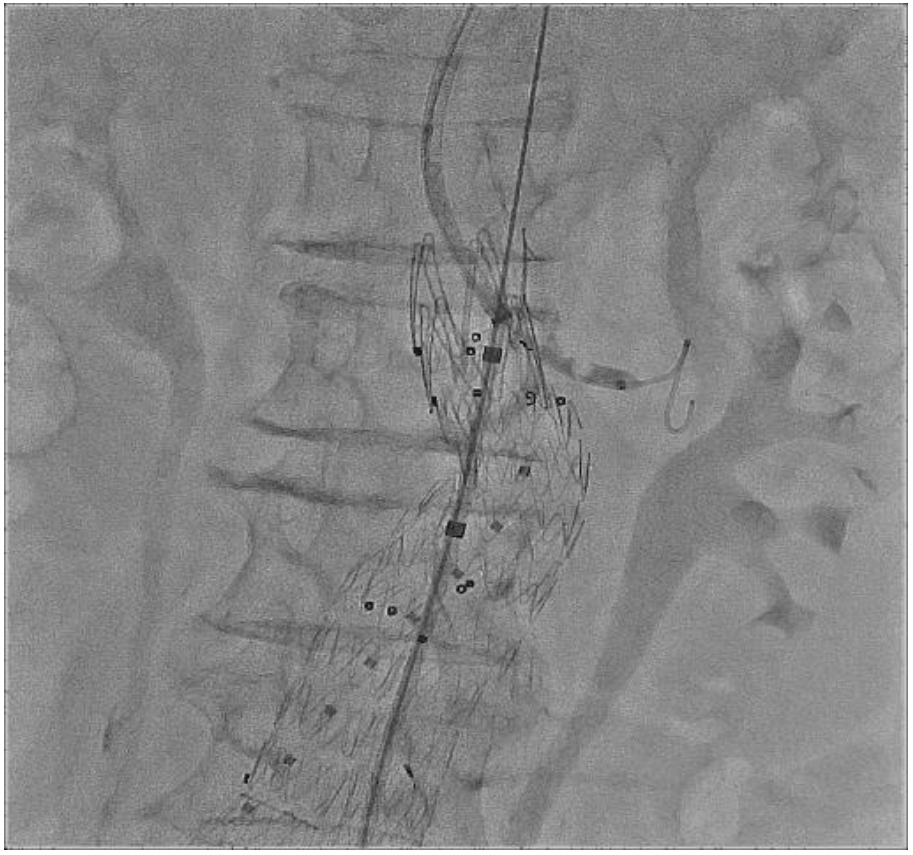
Endurant aorta cuff (25-45)



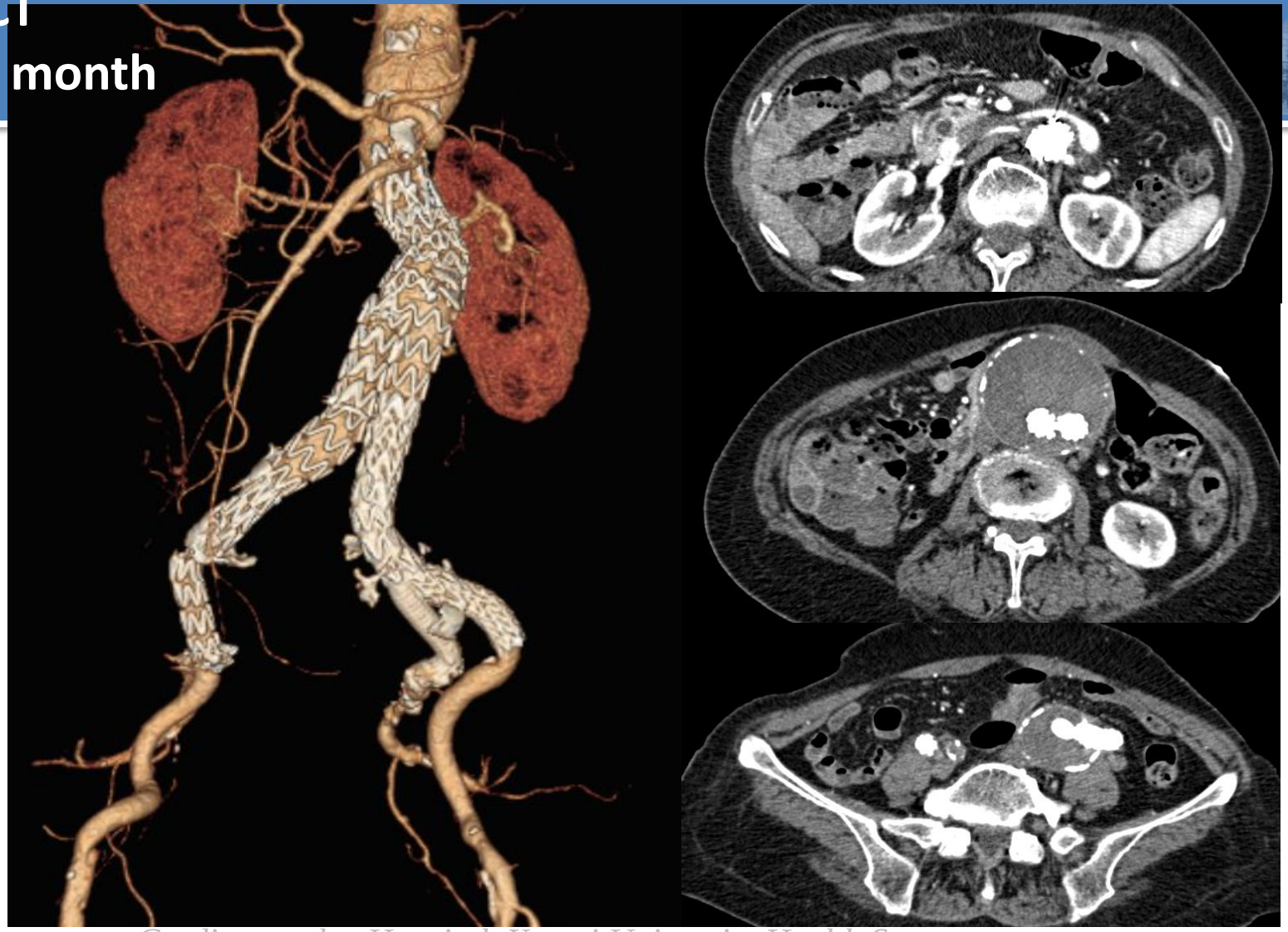


Jailed left renal artery





FU CT
At 1 month



Limitations of Current Devices

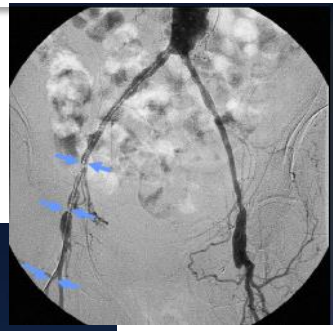
Limitations

- Hostile neck
- Inability of reposition
- Large device profile
- Endoleak
- Juxta- or suprarenal AAA

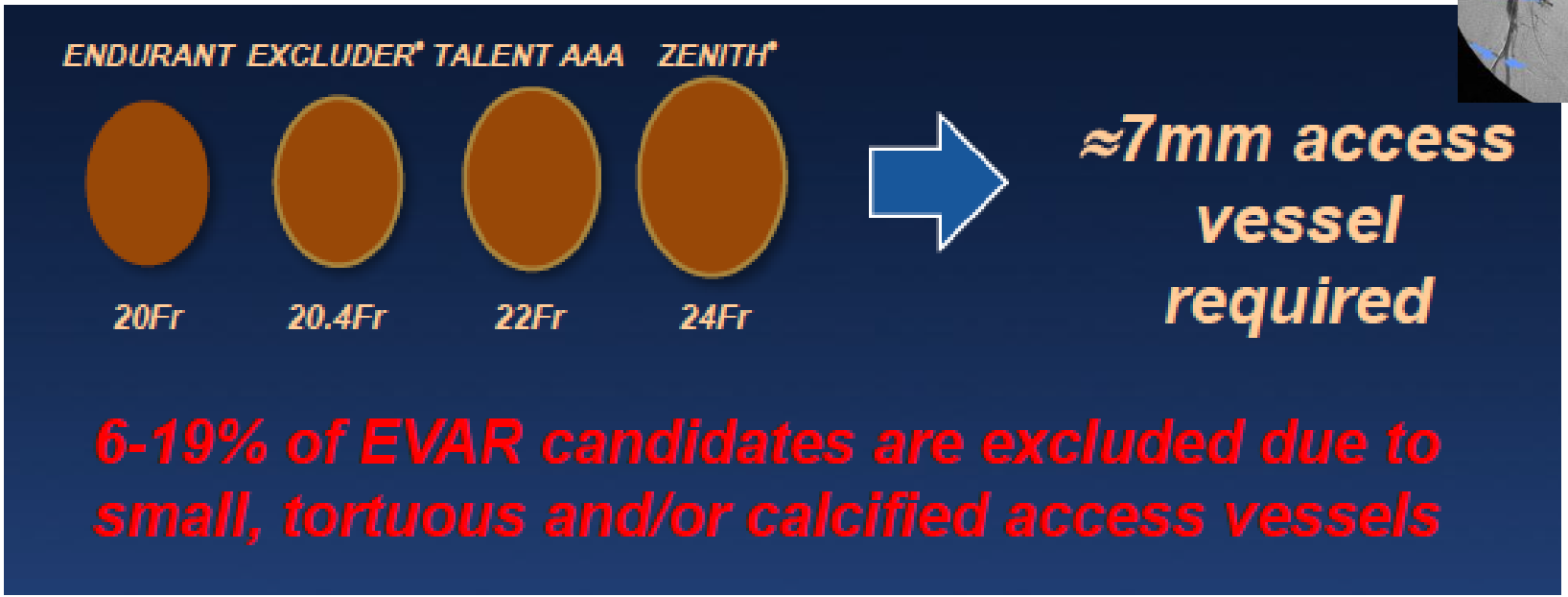
Required Improvement

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

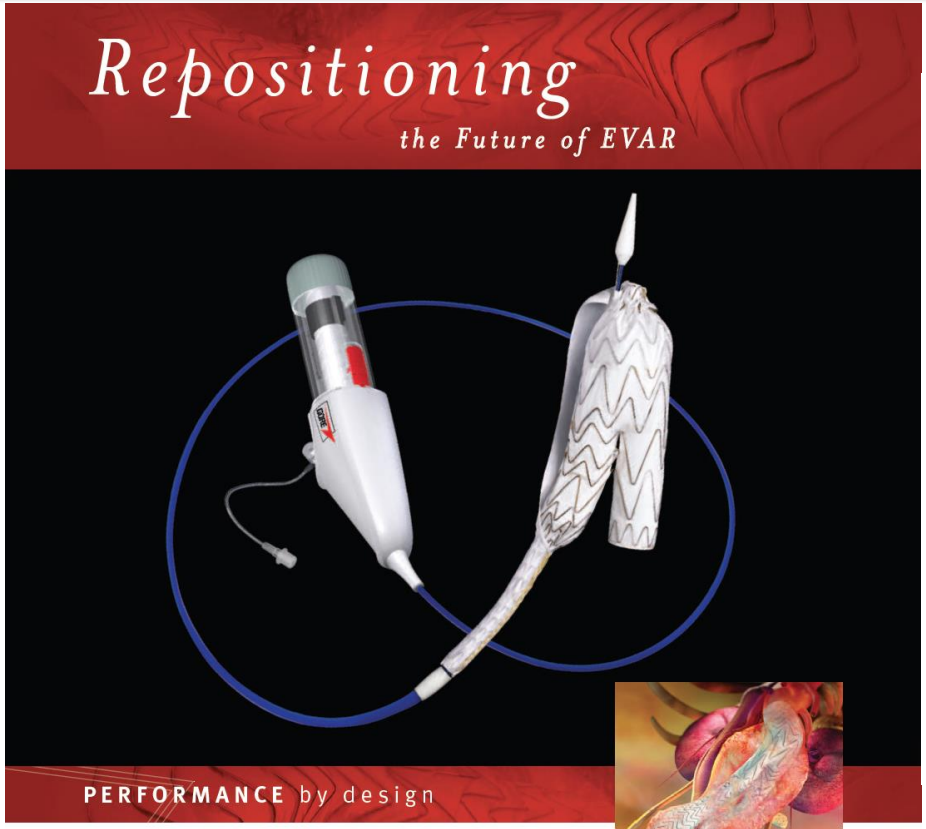
Current Delivery System Profiles



Outer diameters



Excluder & C3 Delivery System (Gore)



35 mm Trunk-Ipsilateral Legs

- Expands aortic neck diameter treatment range to 19–32 mm*
- 18 Fr low profile design
- 36 mm Aortic Extender also available

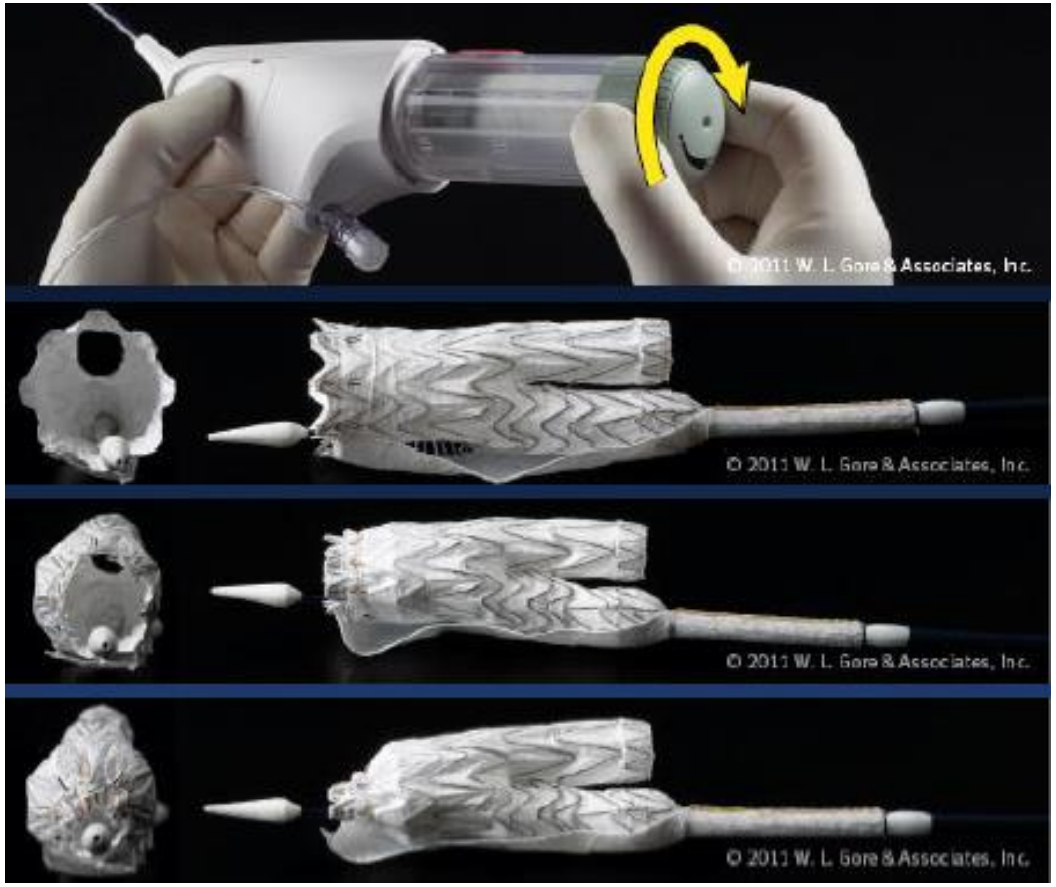
23 and 27 mm Contralateral Legs

- Expands iliac diameter treatment range to 8–25 mm
- 14–15 Fr introducer sheath compatible
- Available in 10, 12 and 14 cm lengths

Reposition Endograft

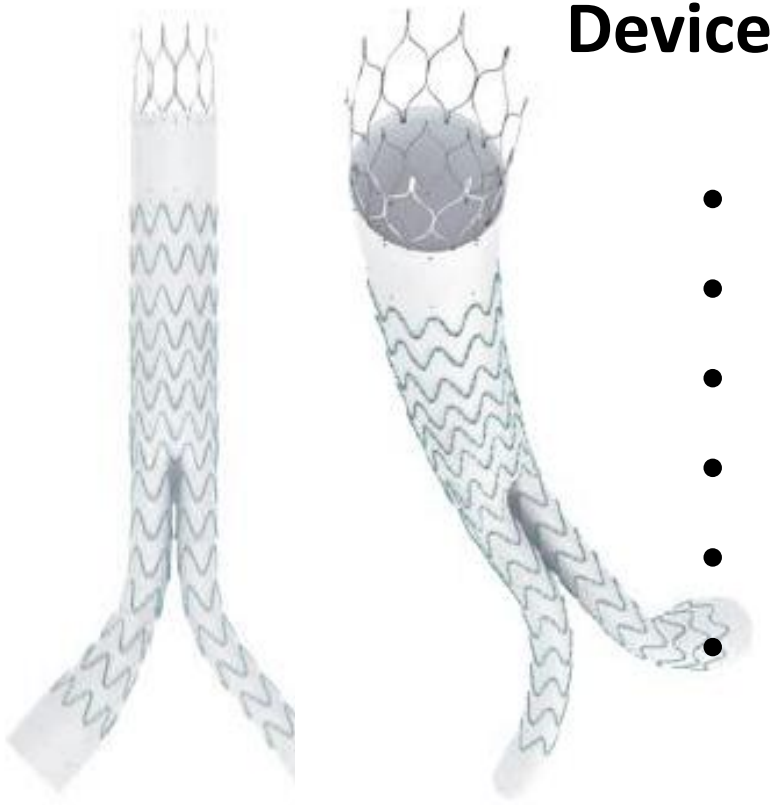
Constrain to Enable Repositioning

- slowly constrain the proximal end / anchors
- reposition the trunk
- slowly re-open to engage the proximal anchors



C3 Delivery System

Zenith Low Profile (Cook)



Device profile: 18-22 Fr ID => 16Fr ID

- *Nitinol instead of Stainless*
- *New suprarenal stent design*
- *New capless constraint*
- *New Stent configuration*
- *Woven polyester fabric*
- *New Dilator tip and Cannula*

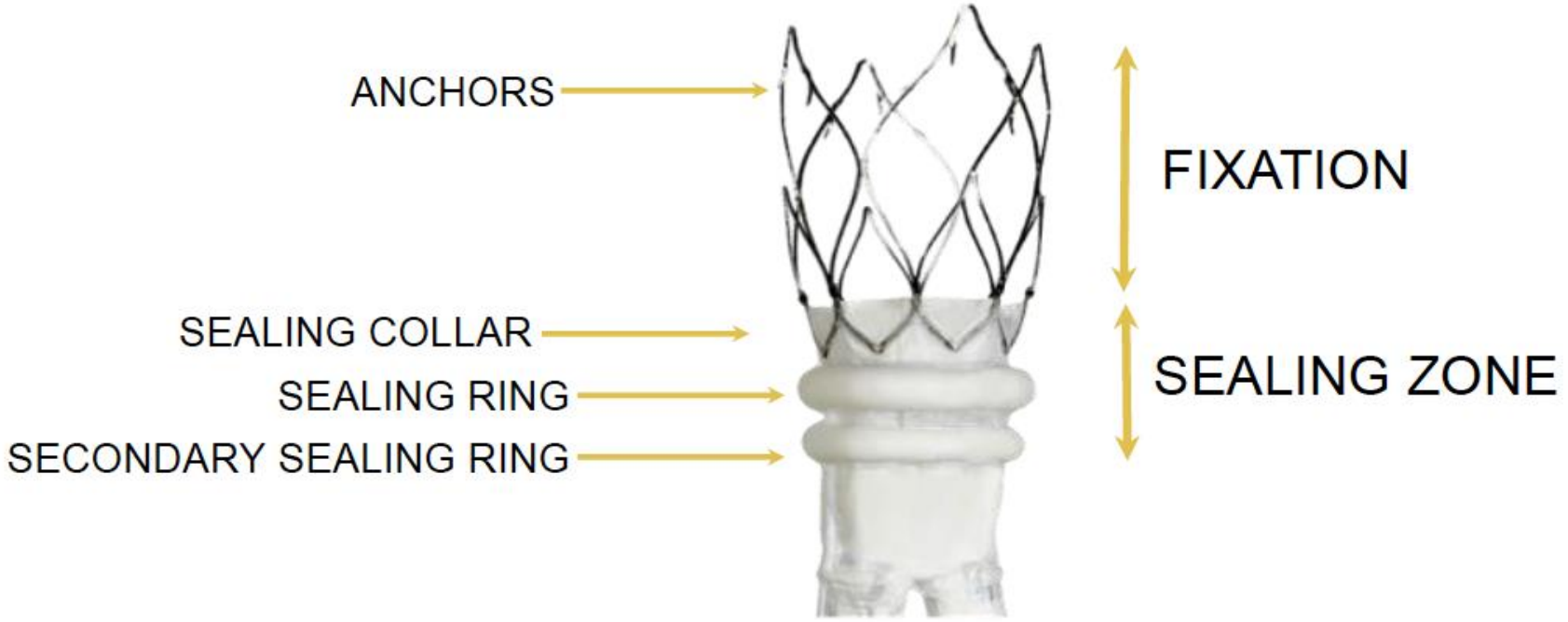
Ovation (Trivascular)

CE Mark Approved
August 2010

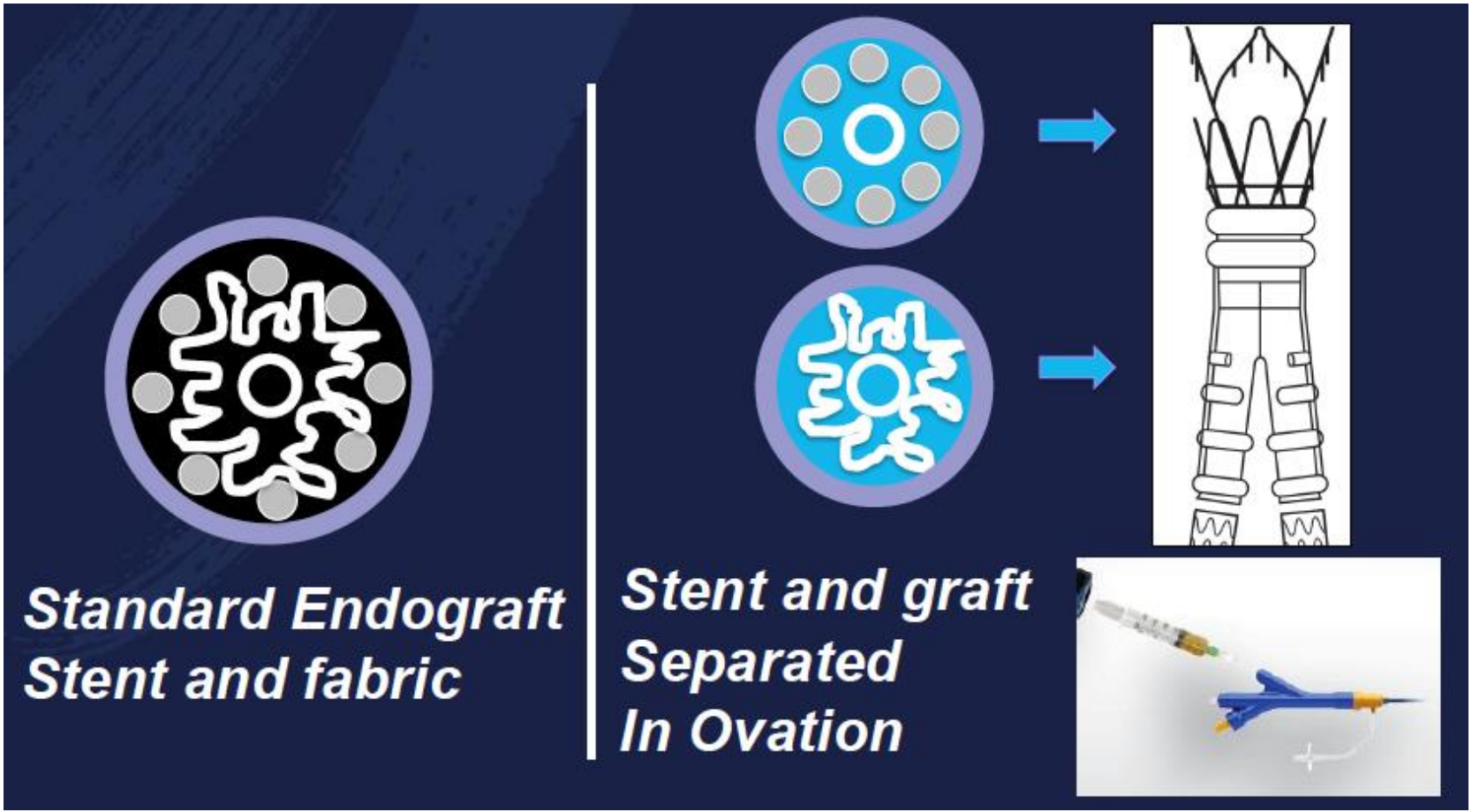
14F OD Aortic Body
13F OD Iliac Limbs

- Tri-modular design
- Suprarenal stent with integral anchors
- Inflatable sealing rings
- Low viscosity, radiopaque biocompatible fill polymer
- Kink resistant iliac limbs
- Hydrophilic catheter coating

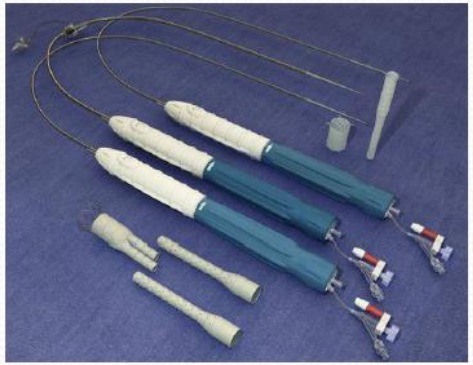
Ovation (Trivascular)



Ovation (Trivascular)



InCraft (Cordis)



3-piece modular system:

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

Customization:

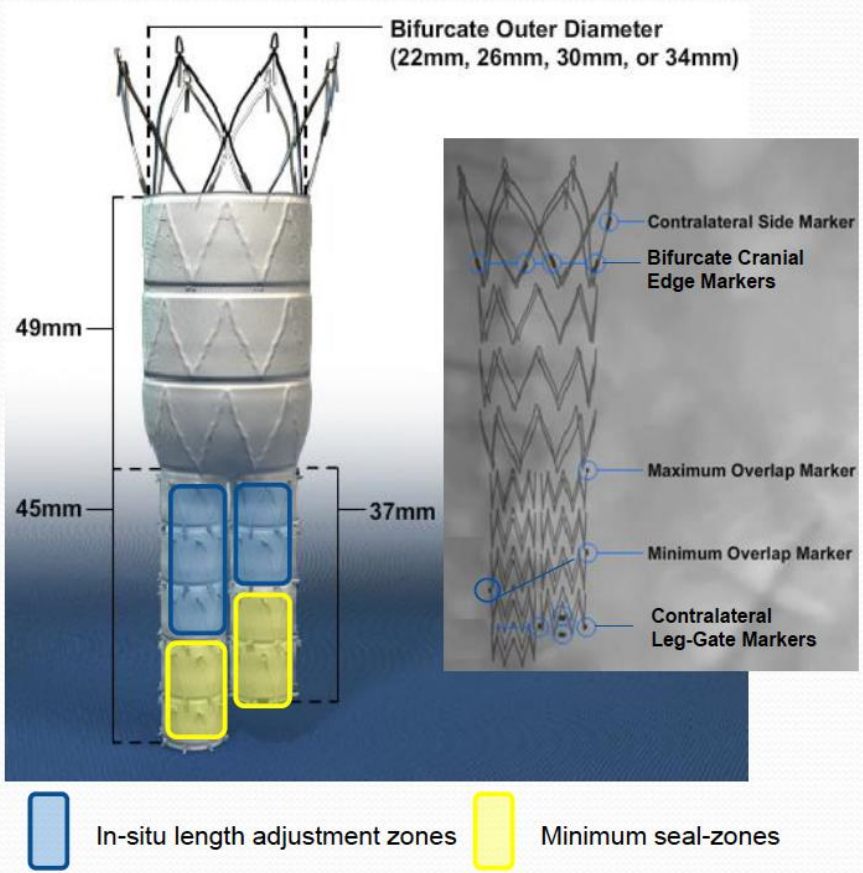
- ✓Bilateral in-situ length adjustment up to 3cm
- ✓Partial proximal re-positioning
- ✓"Few-fits-most" surgical graft concept

Ultra-low Profile:

- ✓13F Integrated Delivery System -14F O.D.
- ✓Catheter-like shaft flexibility

InCraft (Cordis): Aorta Body

- Flared bare trans-renal stent with 8 laser-cut barbs (10 for 34 mm AB).
- **4 diameter** sizes (22, 26, 30 and 34mm) allowing treatment of proximal aortic **neck diameters from 17-31mm**.
- Delivery system with a built-in sheath introducer with an outer diameter of **14F** (16F for 34 mm AB).

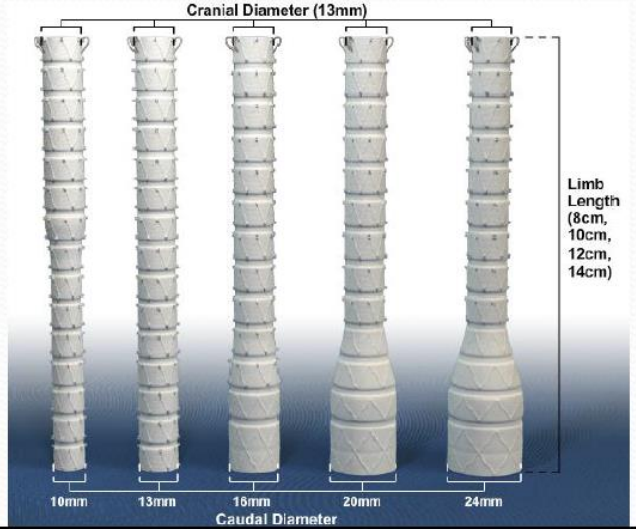


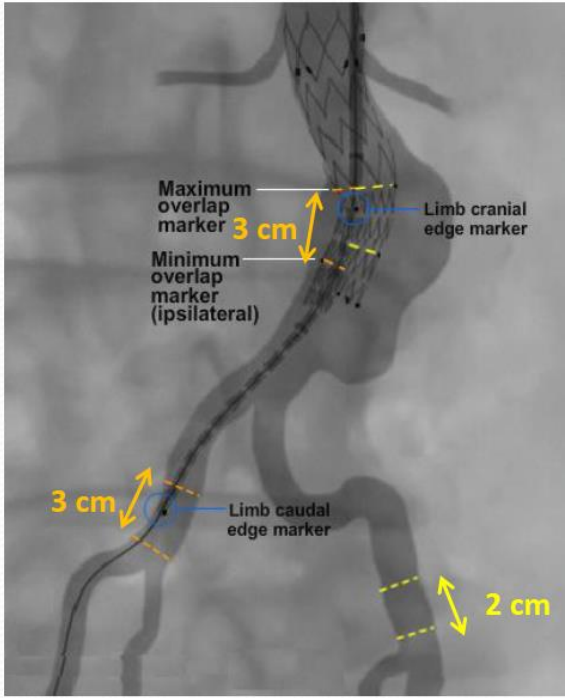
InCraft (Cordis): Iliac Limbs

- Iliac Limb Prostheses available in **5 diameters distally** (10, 13, 16, 20 and 24mm) accommodating iliac arteries ranging from **7-22mm**.

- **4 limb lengths** (8, 10, 12, and 14mm) to treat a overall treatment length range of **12-21 cm**.

- Profile of delivery system for the Iliac Limbs is 12F O.D. (12.5 F for 24 mm IL) .



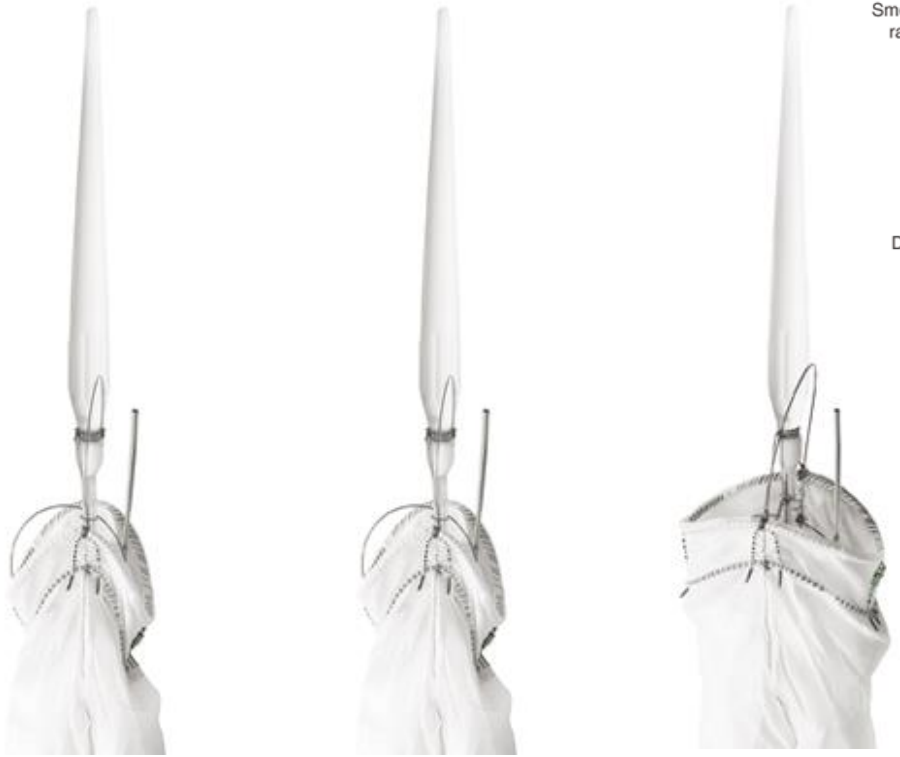


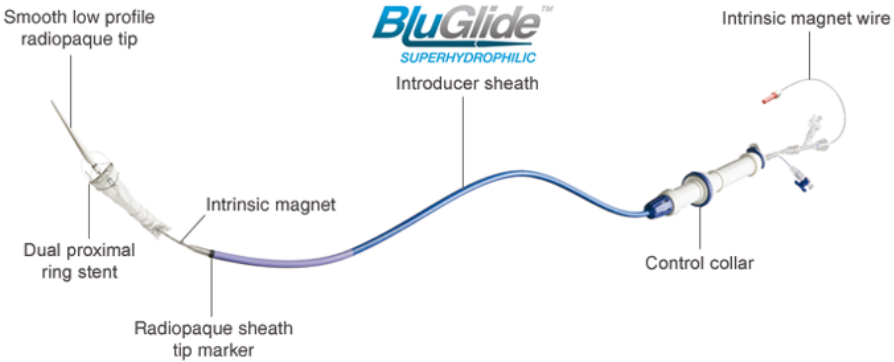
Anaconda (Vascutek, Terumo)

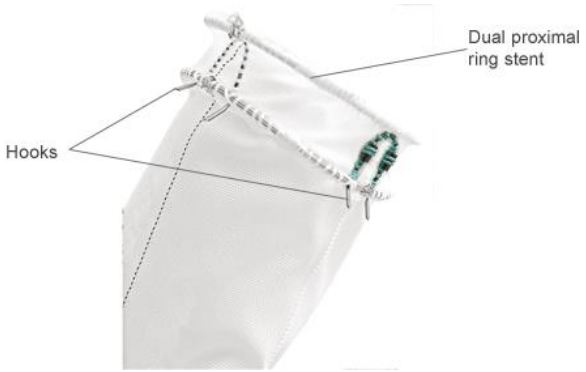
- Modular type:
  - Avoid mechanical coupling of perirenal aorta to iliacs
  - Avoid longitudinal rigidity
  - Enhance radial support
- Transmural Hooks
- Advanced deployment methodology:
  - Repositionalbe
  - Contralateral limb: magnet assisted cannulation

Reposition**able**

Deployed Collapsed Re-deployed

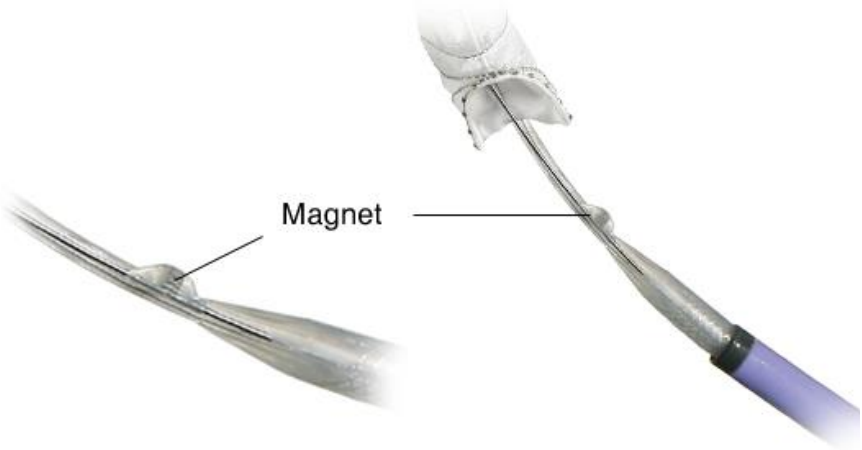


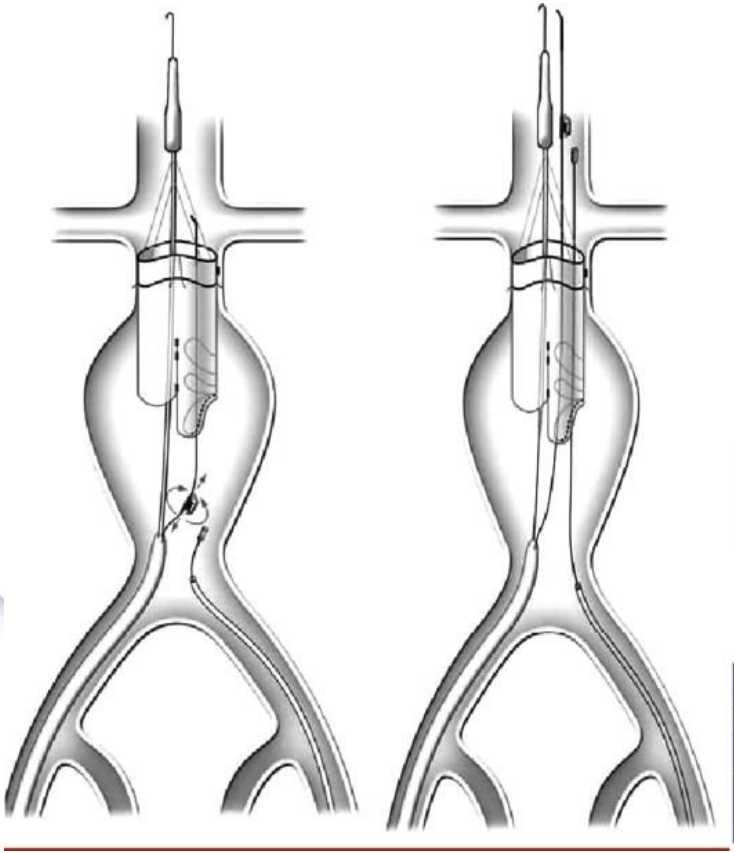




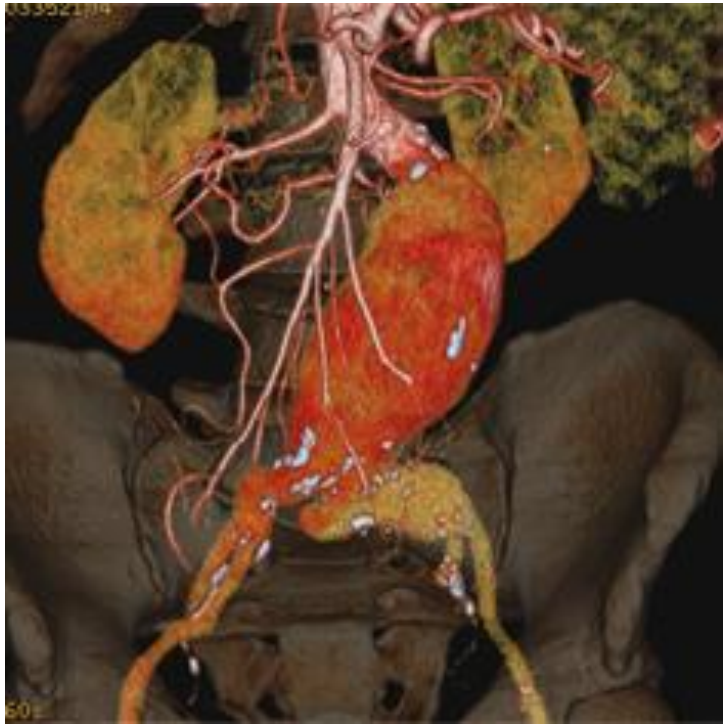
Contralateral Limb

Magnet assisted cannulation

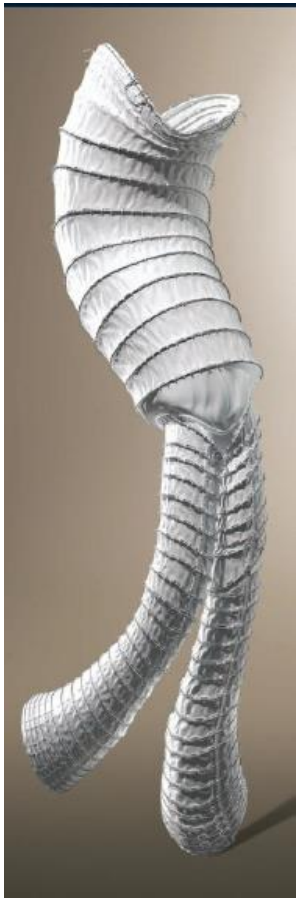




Anaconda (Terumo)

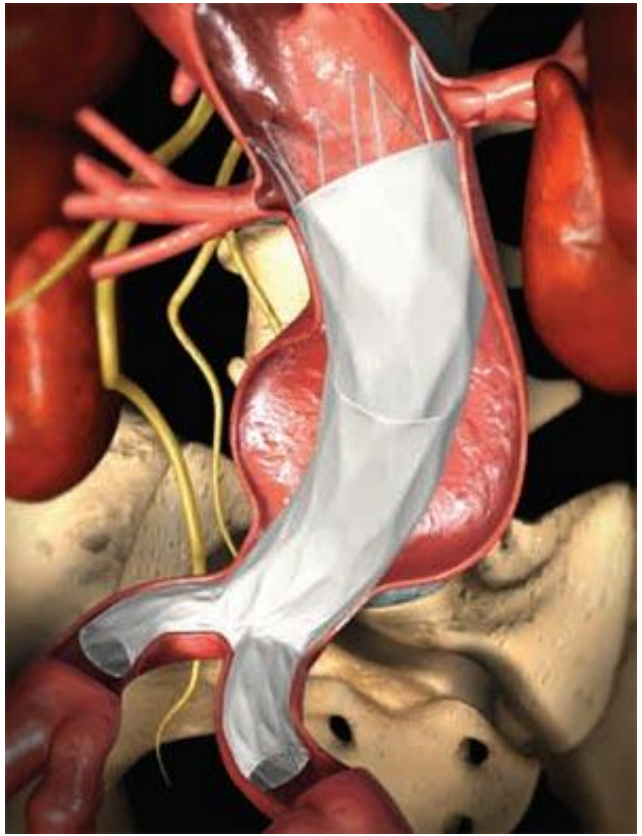


Aorfix (Lombard Medical)



- Infra-renal Graft
- Circumferential rings give high flexibility
- 4 pairs of hooks proximally
- 8 mm long primary seal zone
- Can be placed trans-renally
- Soft and highly conformable

Powerlink (Endologix)



Newer Divices Profiles

Company	Device	Profile	Neck Length	Neck Diameter	Iliac Diameter
Endologix	AFX	19F	15mm	32mm	23mm
Medtronic	Endurant	18F - 20F	10mm	32mm	23mm
Cook	Zenith LP	16F - 18F	15mm	32mm	23mm
Gore	C3	18F - 20F	15mm	29mm	23mm
Trivascular	Ovation	14F - 15F	7mm	32mm	23mm
Endologix	Nellix*	17F - 18F	5mm	34mm	35mm
JNJ	Incraft	14F	15mm	32mm	23mm
Terumo	Anaconda	21F - 23F	15mm	32mm	23mm

Nellix (Endologix)

- Dual balloon expandable endoframes
- Polymer filled endobags
- => obliterate aneurysm sac, provide support and eliminate endoleak space
- Fixation is not dependent on proximal neck and iliac arteries
- Common iliac aneuryms are treated with preservation of internal iliac

Endovascular Aneurysm Sealing

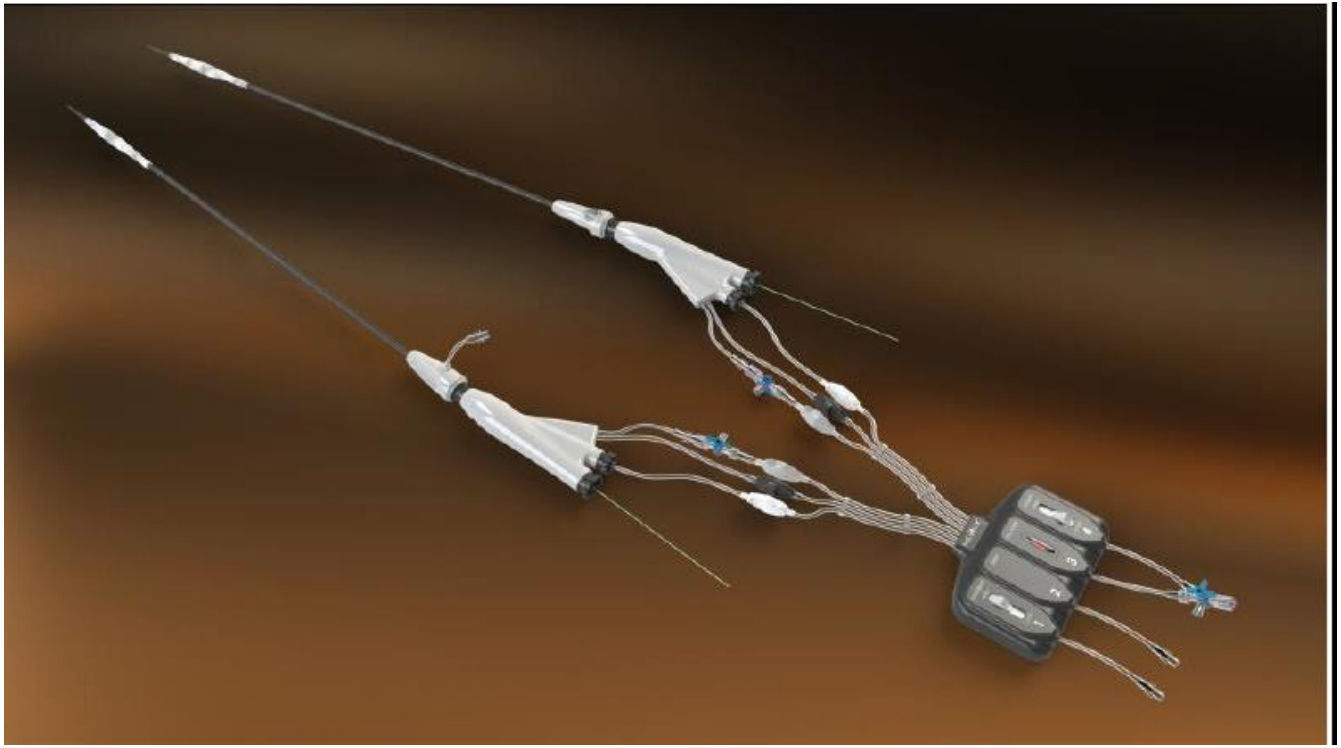
1. Two Delivery Catheters access the Aneurysm

2. Sheaths are retracted to expose Endografts and Endoframes mounted on Balloons

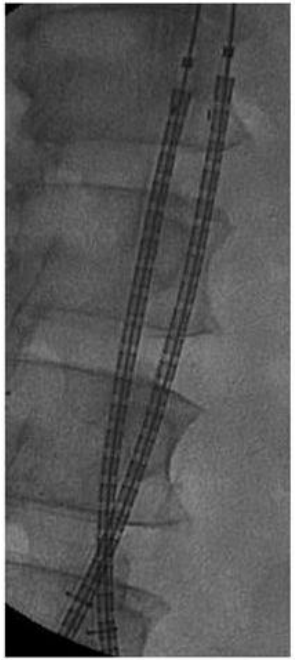
3. Balloons are inflated to expand Endoframes. Endografts are then filled with Polymer

4. Balloons are removed and Endoprosthesis is delivered. Extension cuffs are used per patient's anatomical needs.

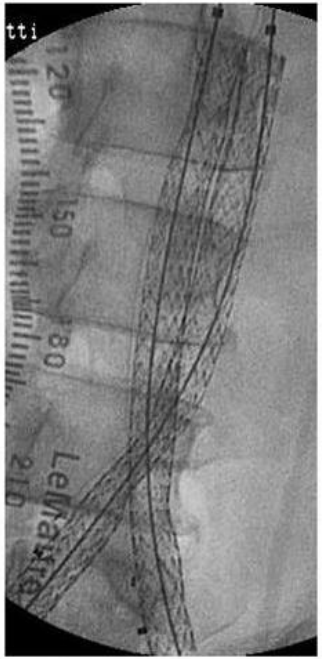
Nellix Endovascular System Operator Console



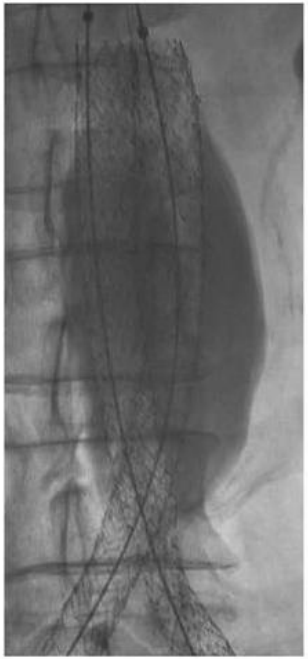
Nellix (Endologix)



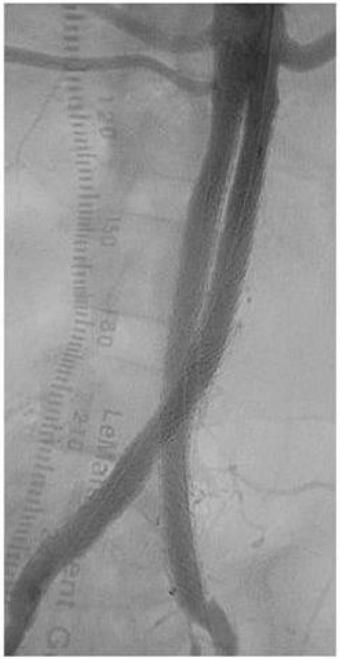
Unexpanded Endoframes



Expanding Endoframes

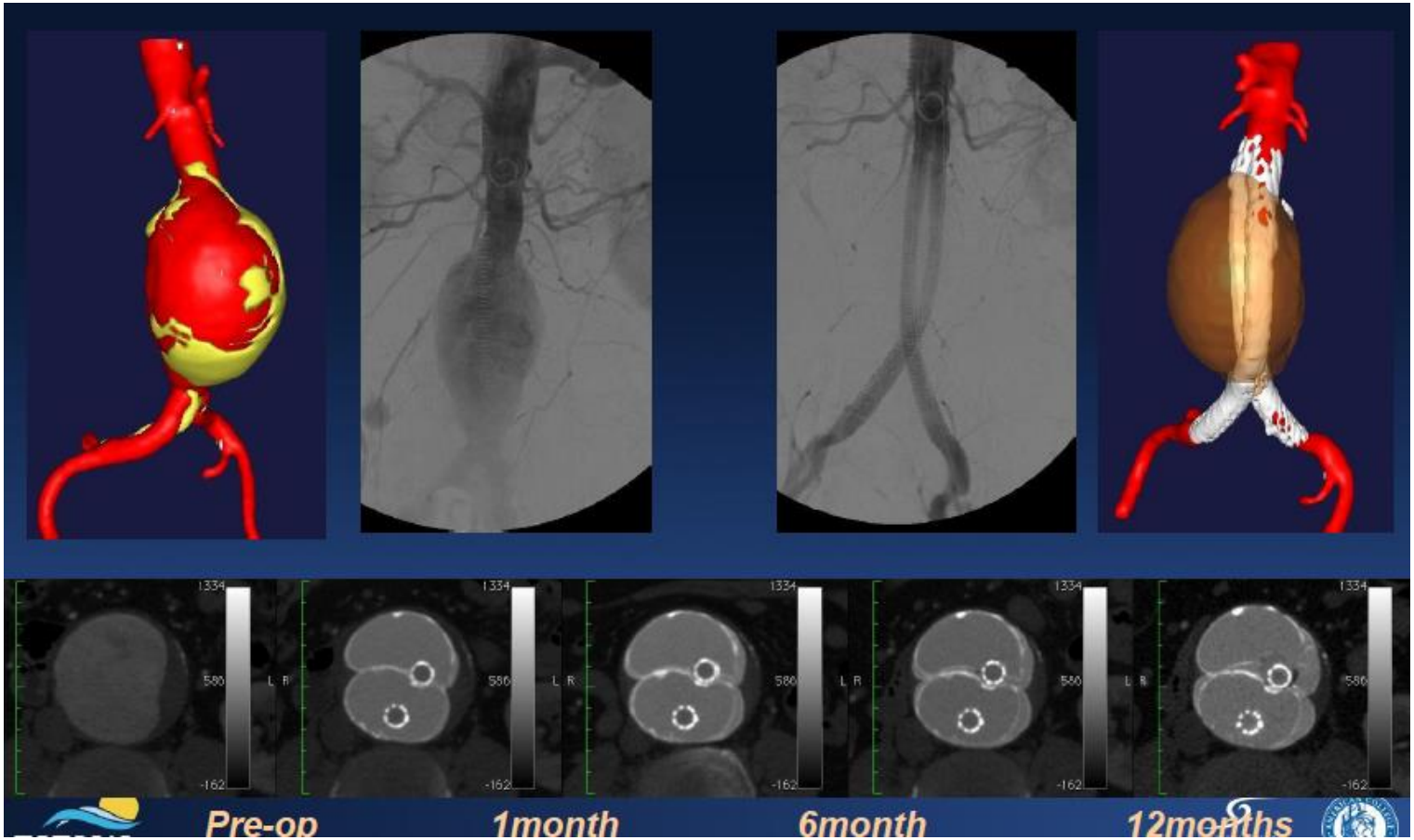


Polymer Filled Endobag



Completion Angiogram

Results of EVAS

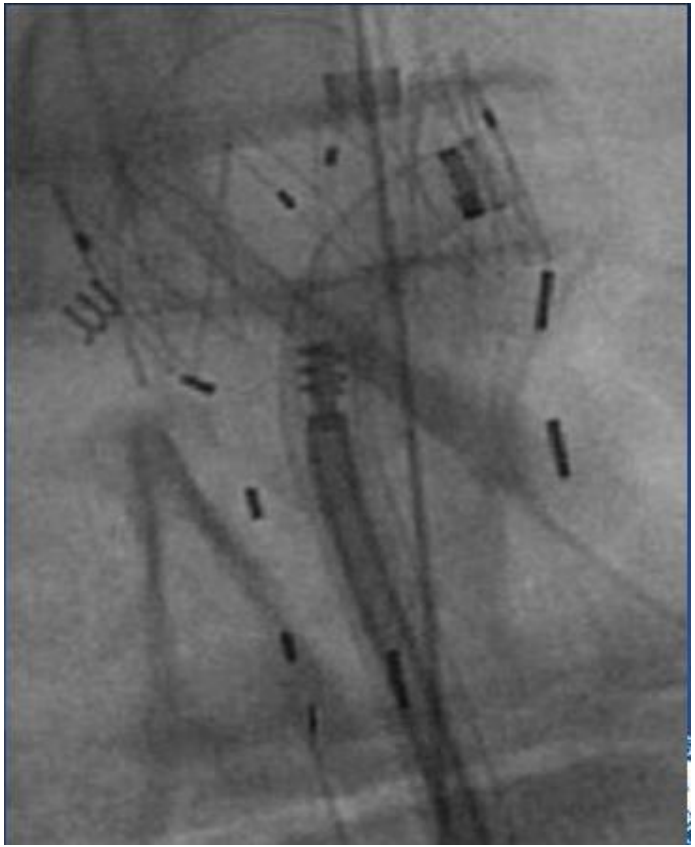


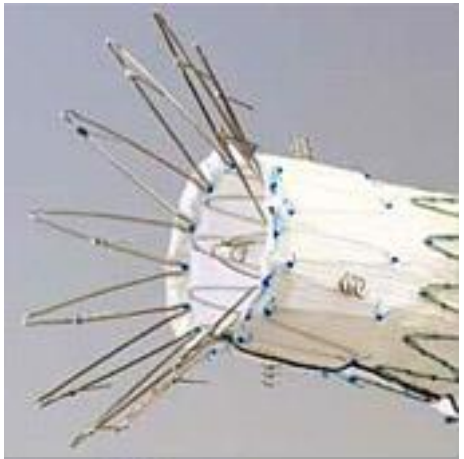
EndoStaples (Aptus)

Helical screw (4 mm depth)

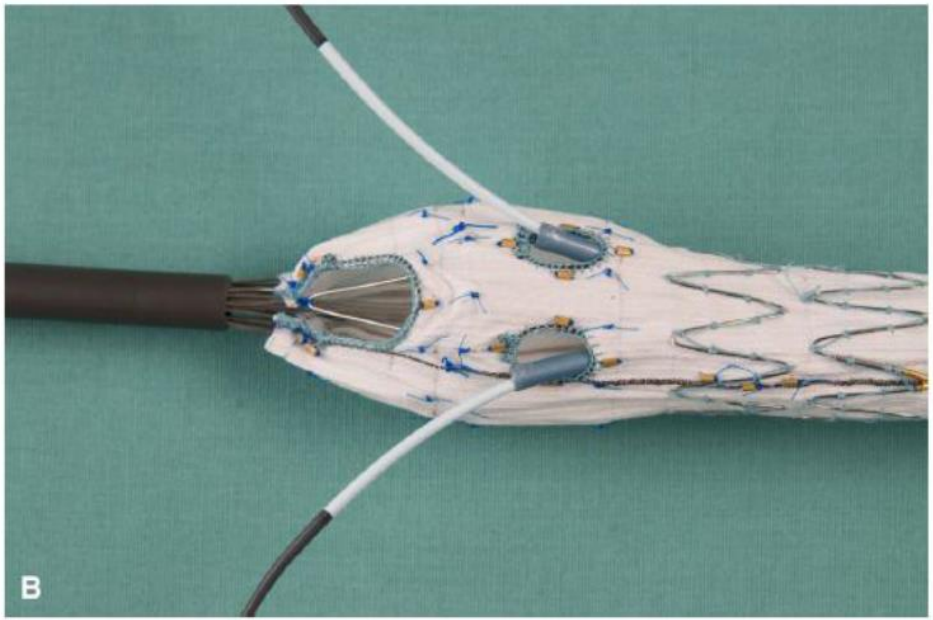
- Prevents migration and limits proximal neck dilation
- Augments proximal seal in challenging anatomy
- Compatible with leading endografts

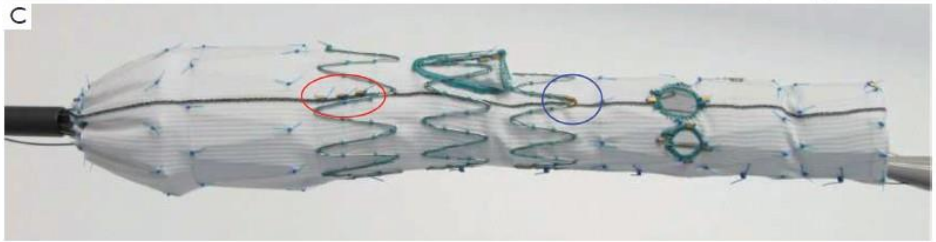
EndoStples (Aptus)

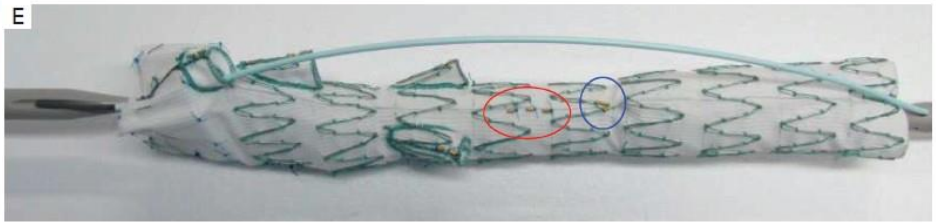




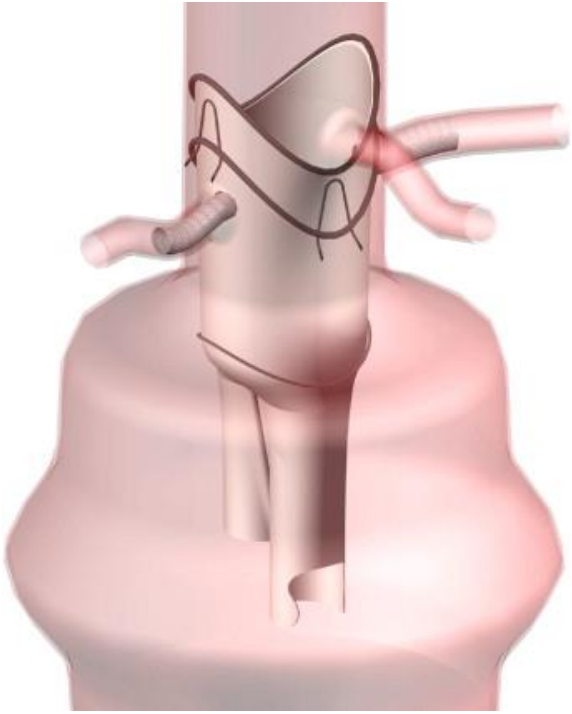
Fenestrated/Branched Stent Grafts (Cook)







Fenestrated Anaconda



Ventana Fenestrated (Endologix)

Conclusions

- Next generation devices are transforming to solve unmet clinical need and.
- More flexible devices with lower profile are available.
- New devices may eliminate endoleaks by aneurysm sealing
- Endostaples may achieve better fixation.
- Branched or fenestrated endografts may enable EVAR in juxta- and suprarenal AAA.
- However, efficacy and safety of newer devices needed to be validated in larger clinical trials.


Thank you
for your attention!