



EVAR Perspective from Next Generation EVAR Devices

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Presenter Disclosure Information

Name: RICHARD R. HEUSER M.D.

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

Company Name

*QuantumCor
Spectranetics, Inc.
CSI*

Relationship

*Major Stock Holder/Medical Director
Honorarium
Stockholder*

Patents -- *RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure*





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Figure 100-7 Transabdominal aortic aneurysm exposure, vascular clamps in place, incising the aneurysm.



Aneurysms

- 1st successful open aneurysm repair was in 1951 Norman Freeman using an autogenous iliac vein graft

- Charles Dubost used an aortic homograft to replace the aneurysm

- 1st Complete Repair Occurred September 2,

1954, Richard Dwyer

**THESE THERAPIES HAVE NEVER BEEN
SUBJECTED TO LEVEL 1 EVIDENCE**



OPEN REPAIR

- Does Require Inpatient Follow Up and Surveillance
- 51% Have Endoleaks or Pseudoaneurysms
- Only 64% Fully Ambulatory Post Open Repair

WHO HAD OPEN REPAIR

18%

WOULD NOT HAVE IT AGAIN



Aneurysms

Minimally Invasive Approaches

- Embolose with electric current between needles stuck into the aneurysm 1832-1930's

- 1864's - needles into the aneurysm (up to 26 yards)

- Wrap in cellophane

AORTIC ANEURYSM





Endoluminal Stent-Graft Demonstrated Advantages

- *Minimally invasive surgery*
- *Reduced morbidity and ?mortality*
- *Less blood loss/need for transfusion*
- *Shorter hospital stay*
- *Quicker recovery time*

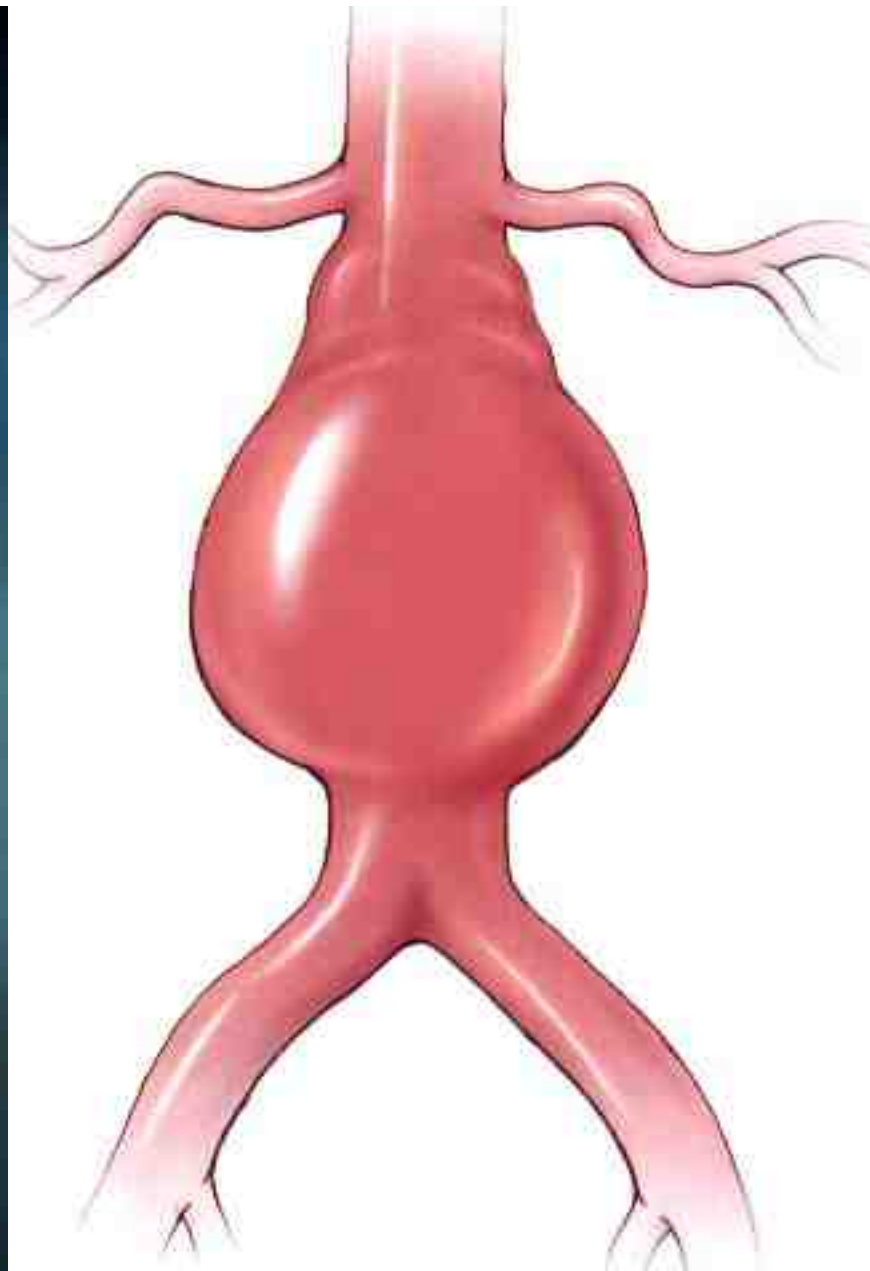
Patient Preferred Treatment

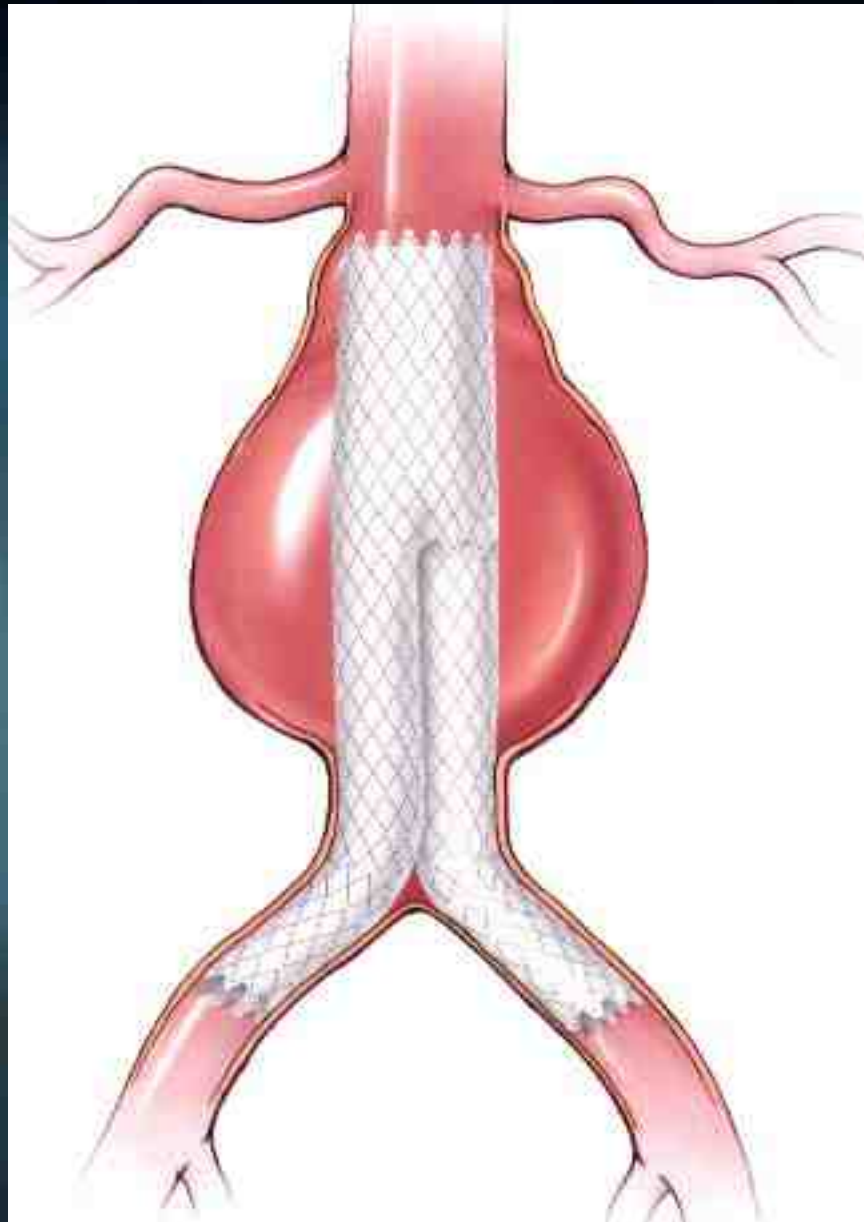


EVAR: Unmet Clinical Need

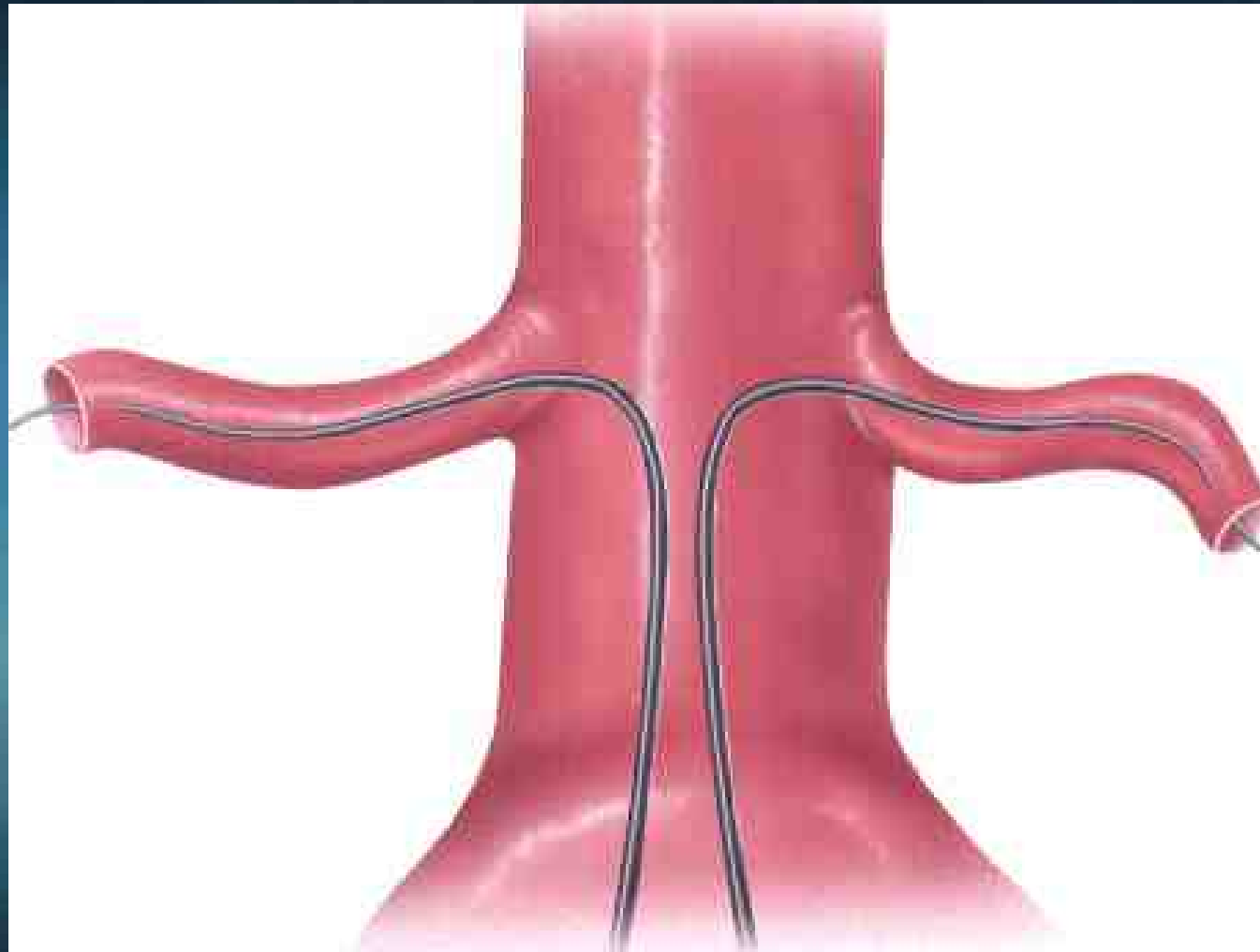
- Endoleak
 - Acute Type II, Chronic Type I, III
- Migration
 - Up/Down, Side to Side
- Stability/Durability
 - Graft Movement & Wear Over Time
- Difficult Anatomies
 - Large/Angulated Necks
- Secondary procedures
 - Endoleak Surveillance (Aneurysm Gro

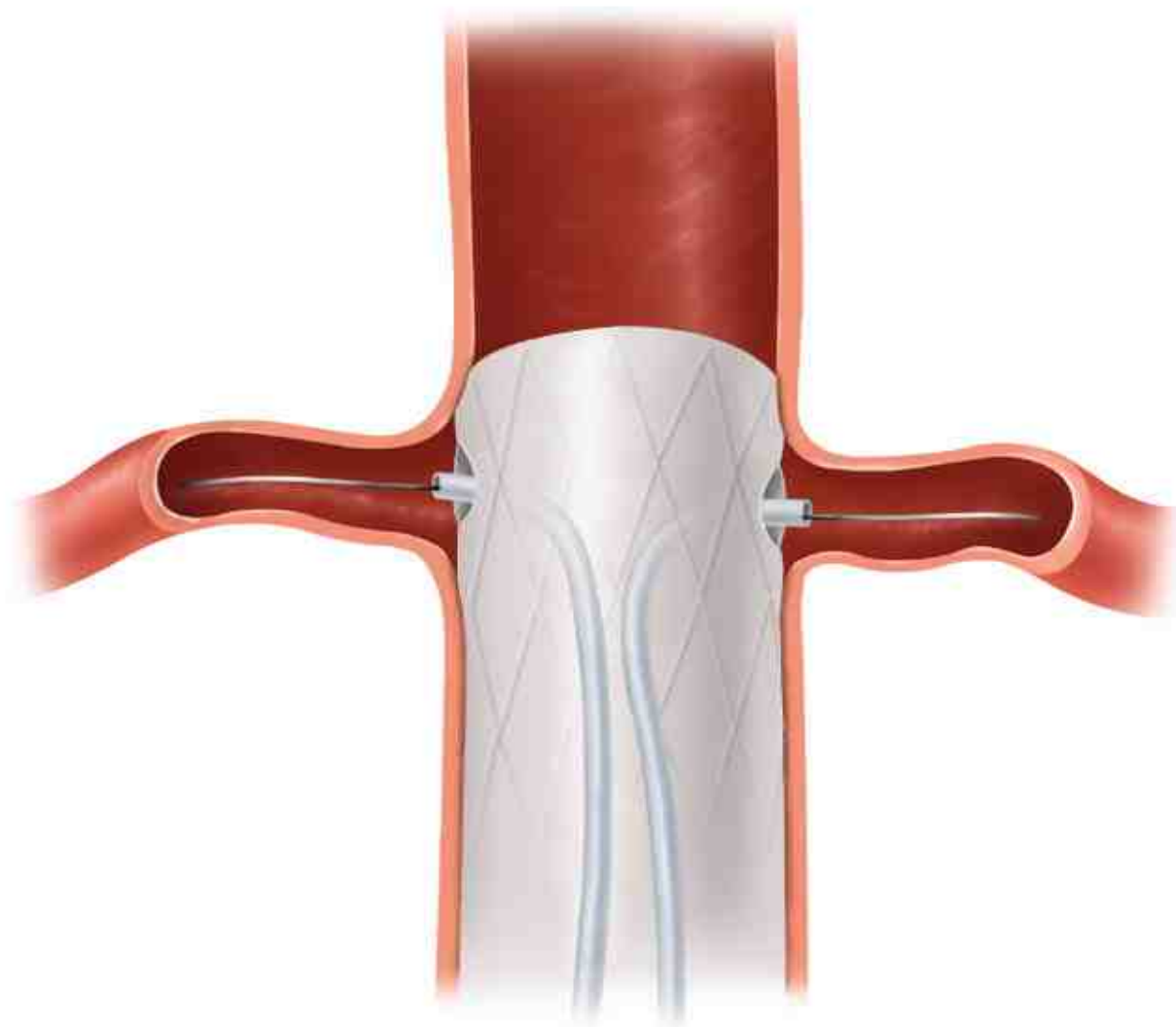


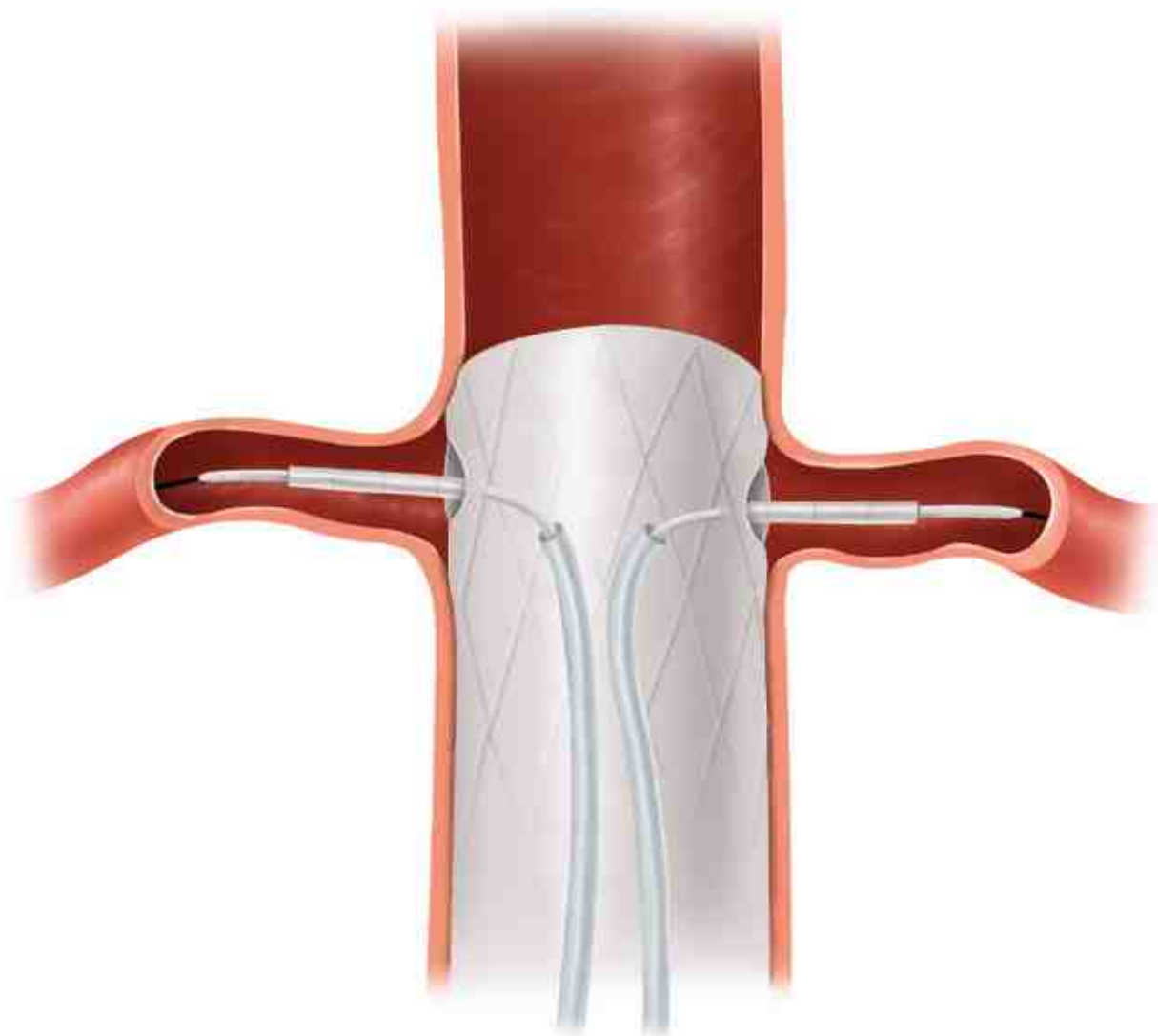


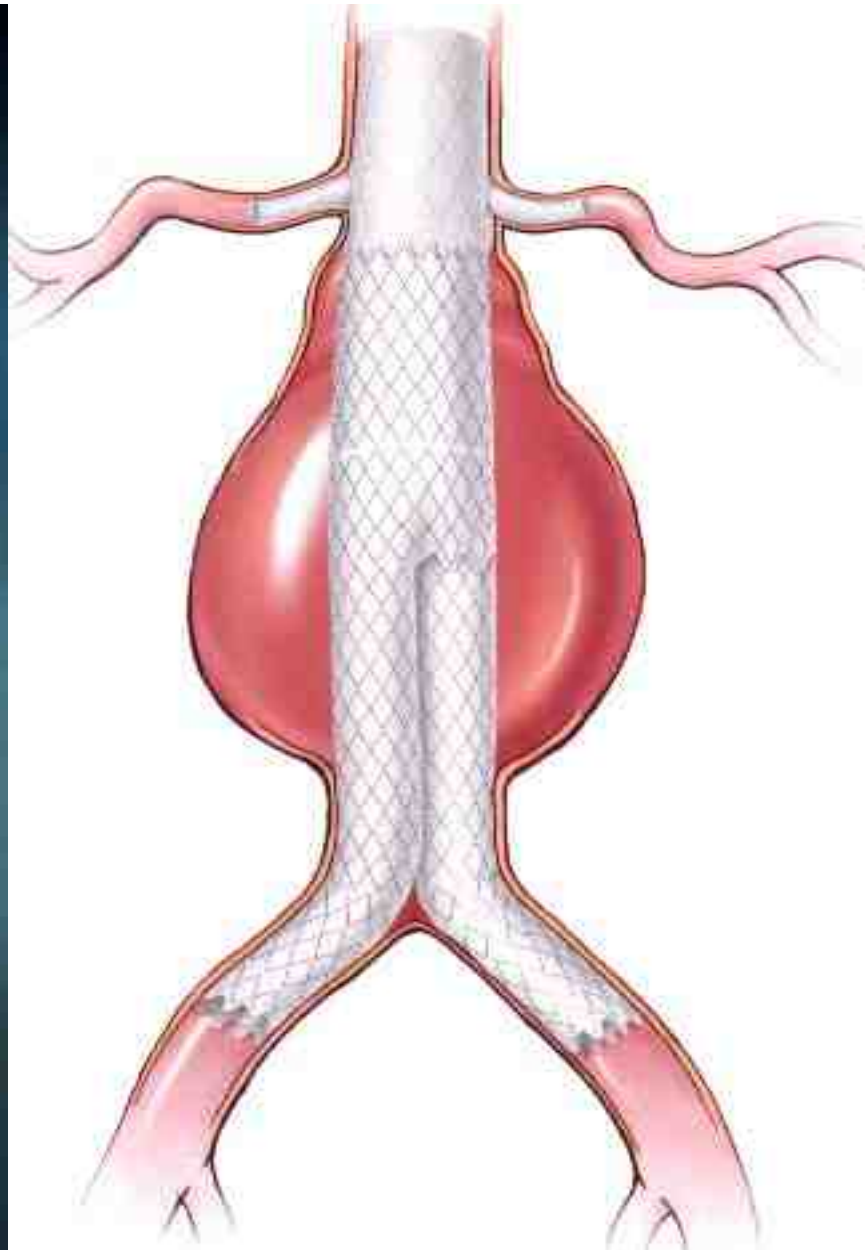


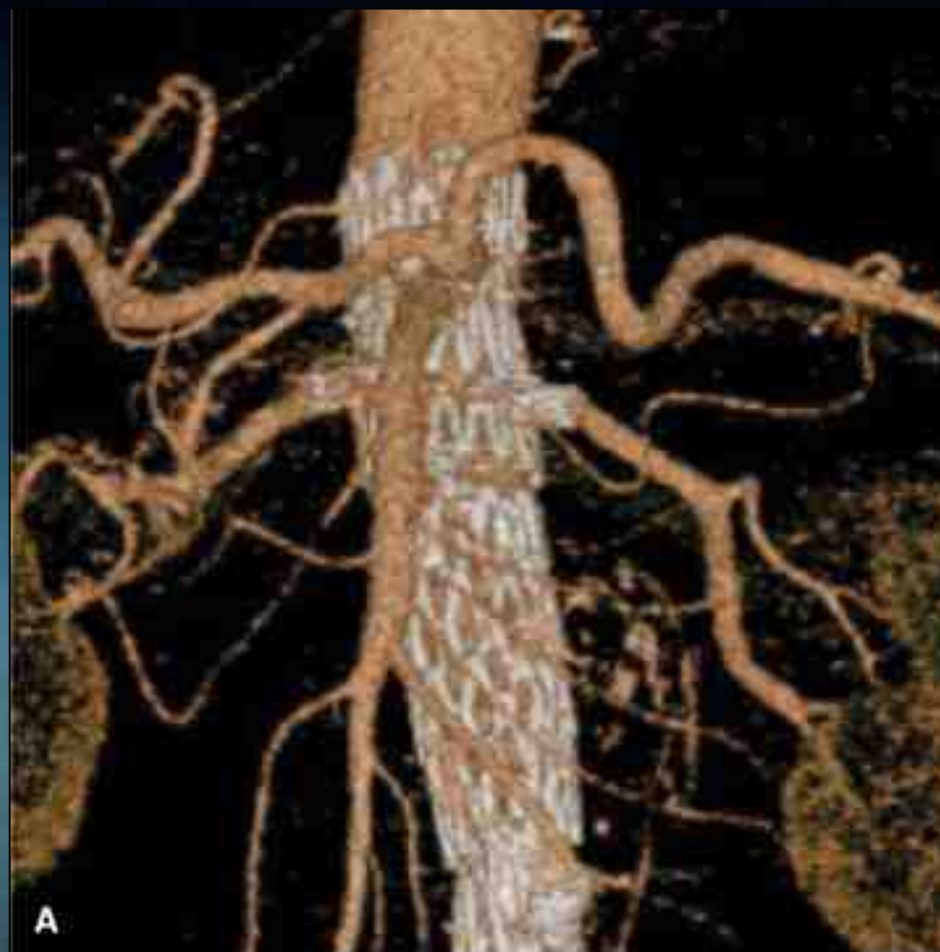










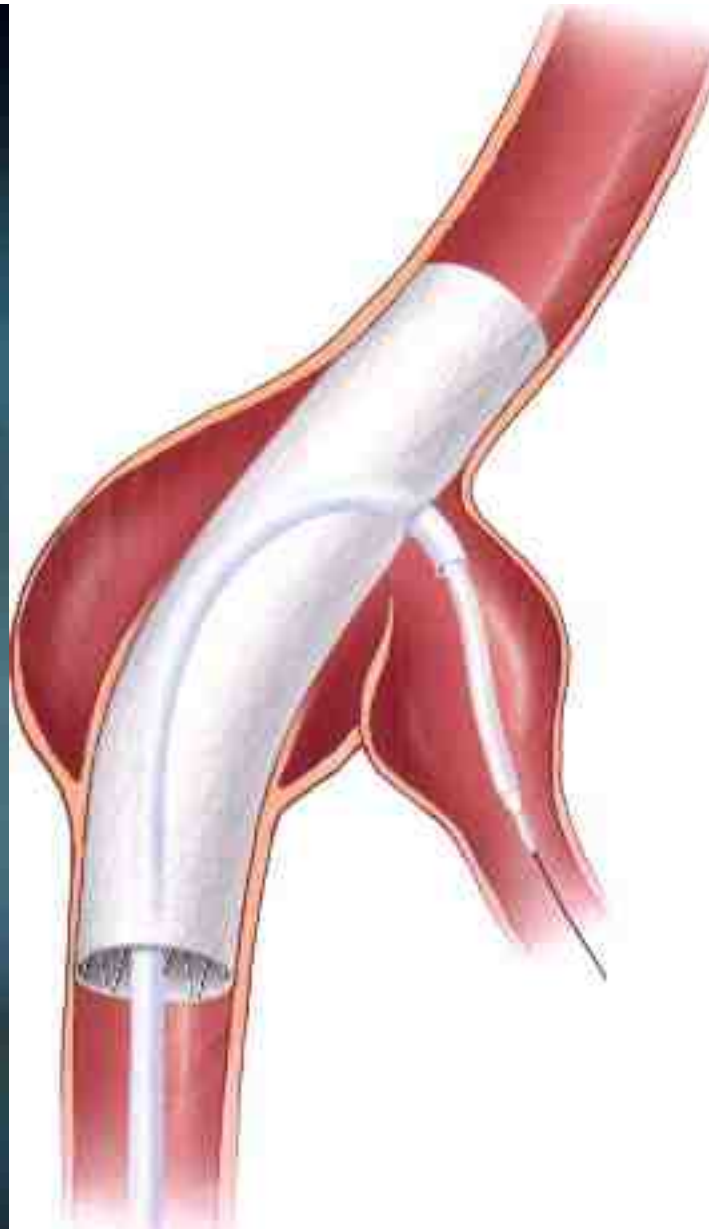


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Figure 101-3 A, Three-dimensional reconstruction after fenestrated stent-graft with bare stents in the renal arteries. (Courtesy Dr. E. L. Verhoeven.) B, Artist's impression of branched endograft currently validated in experiment. (Courtesy Dr. W. Wisselink.)









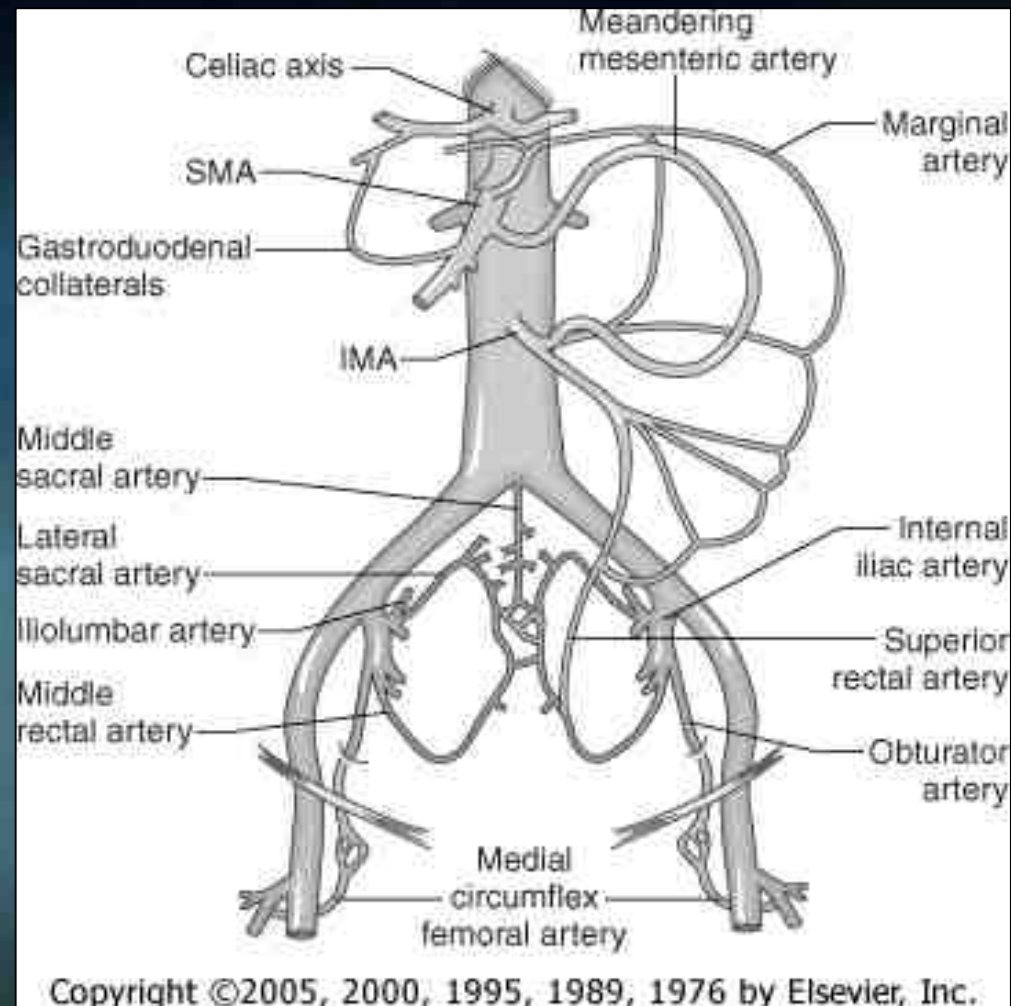
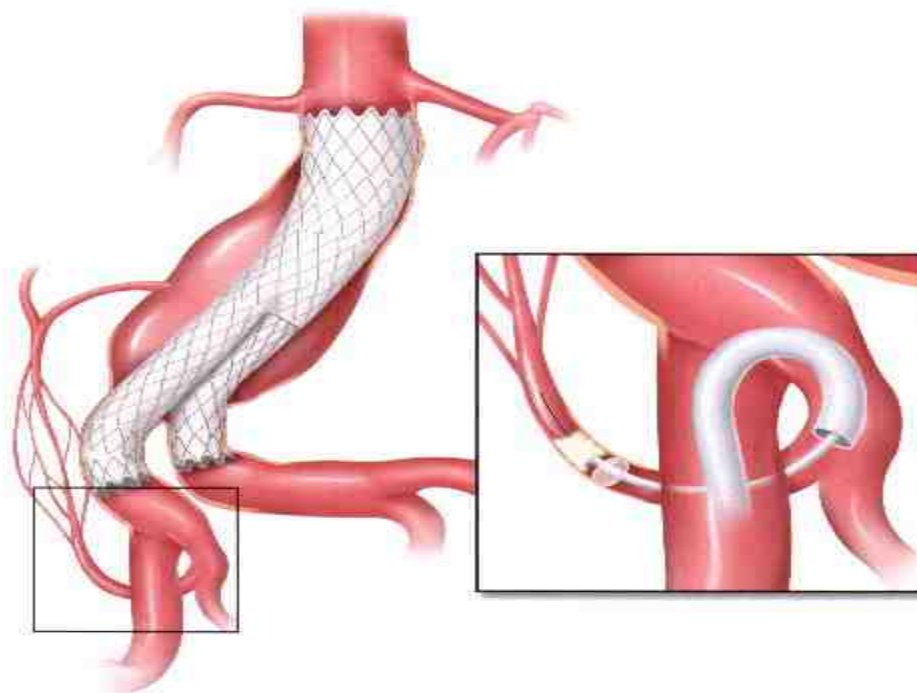
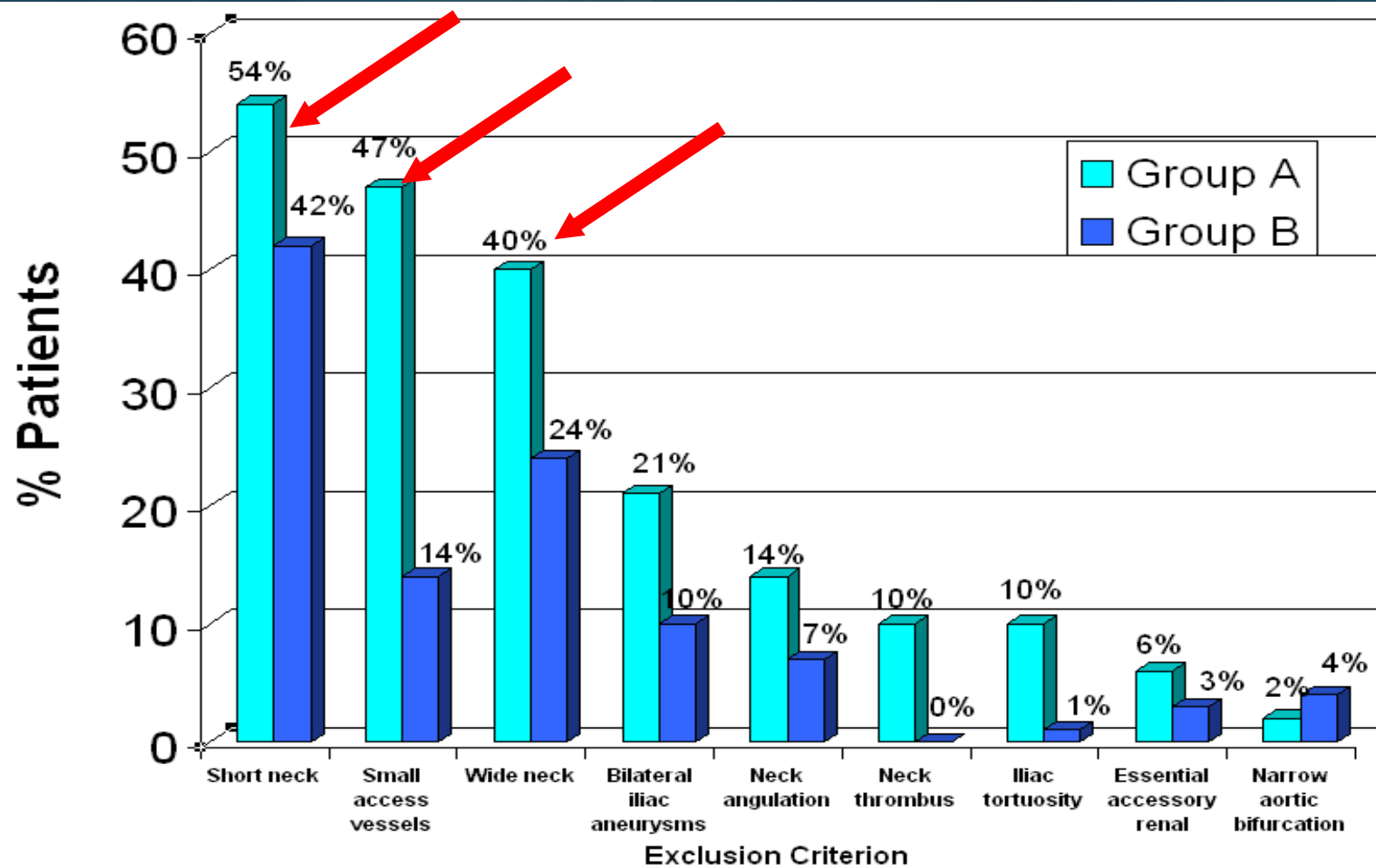


Figure 100-13 Important collateral pathways for the sigmoid colon and pelvis. IMA, inferior mesenteric artery; SMA, superior mesenteric artery. (From Bergman RT, Gloviczki P, Welch TJ, et al: The role of intravenous fluorescein in the **detection of colon ischemia during aortic reconstruction**. *Ann Vasc Surg* 6:74, 1992.)





Exclusion Criteria for EVAR



GORE EXCLUDER® New Product Development Efforts



31mm GORE EXCLUDER® AAA Endoprosthesis

- Recent US launch in May 2009
- Treat aortic necks with inner diameters 27-29 mm
- Features
 - No scallops
 - Longer (8cm) Trunk body
 - 20 Fr profile
 - Same flexibility and deliverability as previous design



Larger diameter Contralateral Leg Devices

- Device diameters up to 27 mm
- Treat iliac inner diameters up to 25 mm
- Flexible
- Conformable
- High patency
- Low kinking



GORE EXCLUDER[®] featuring C3 Delivery

- No changes to the EXCLUDER[®] Device
- Maintain all attributes of current device
 - Small delivery profile, starting as small as 12Fr
 - Highly flexible
 - Durable device construction
- C3 Delivery system is highly precise
 - Optional: Simple way to reposition Trunk-Ipsilateral Leg component
 - Optional: Able to move Trunk proximally, distally, and/or rotate
 - Potentially reduced cannulation time
- Maintain a simple mechanism
 - Minimal deployment steps
 - Same deployment mechanics

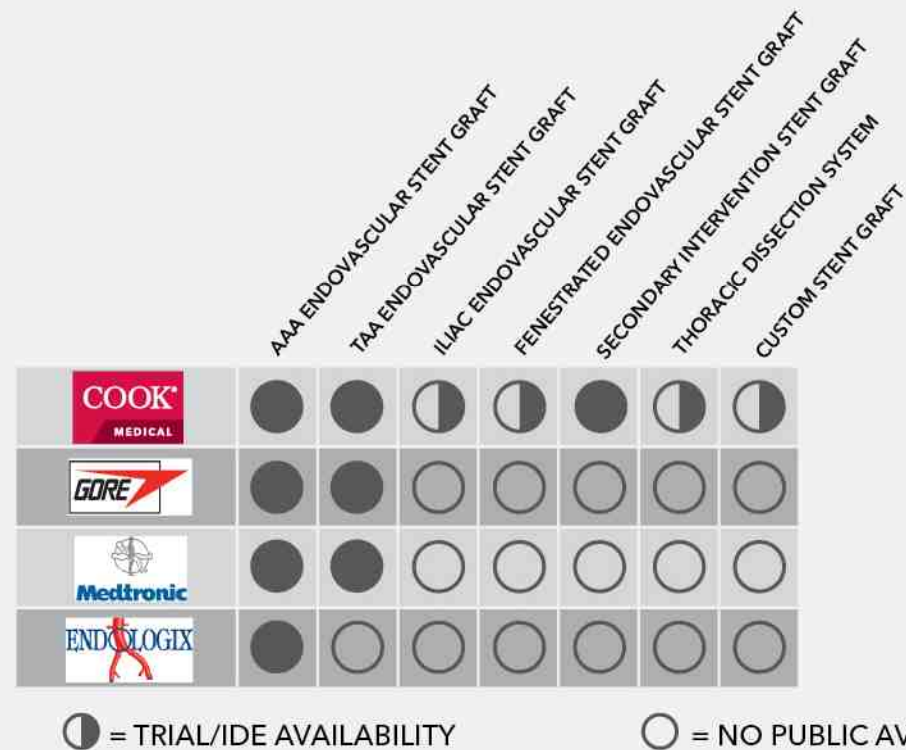


Next Generation GORE EXCLUDER® AAA Endoprosthesis

- Currently in early testing phase



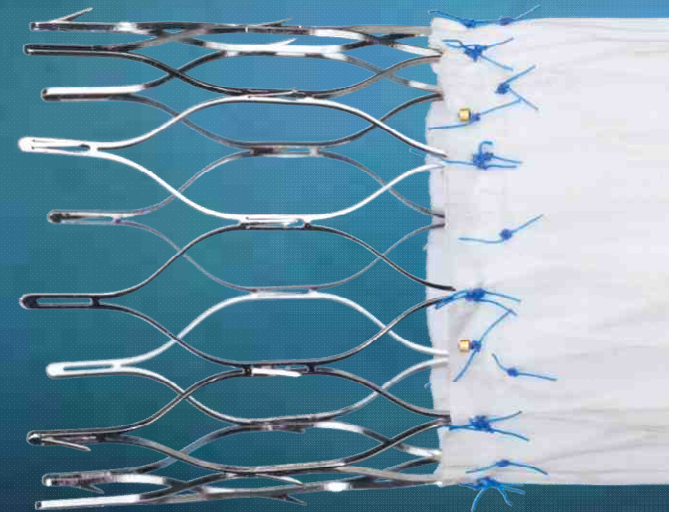
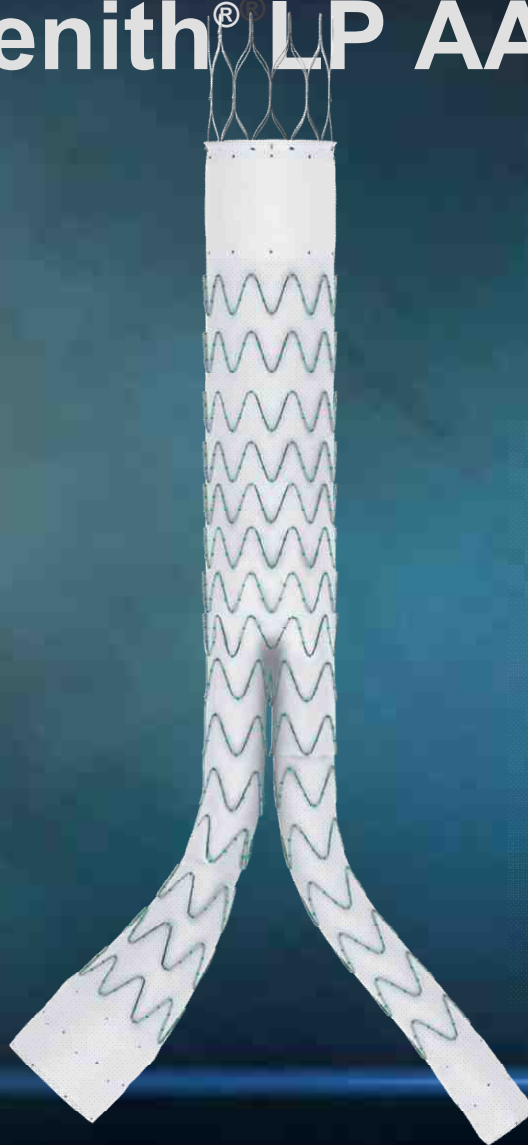
The Global EVAR Leader: Broadest Product Offering



All devices listed are approved in markets outside the U.S except the thoracic dissection system. This chart is for the U.S. only.

Zenith[®] LP AAA

- 16 Fr delivery
- MRI compatible

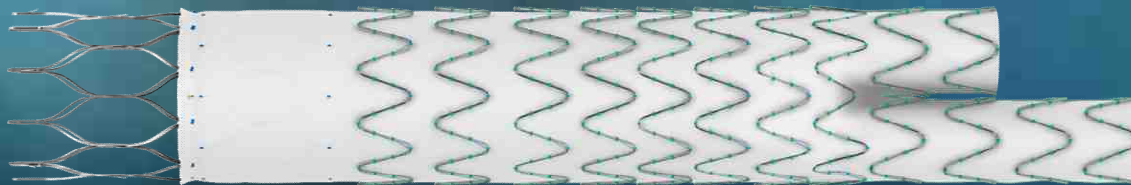


CAUTION – Investigational device. Limited by Federal (or United States) law to investigational use.

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Zenith[®] LP AAA

- Essential design features of standard AAA
- Enhanced deployment steps



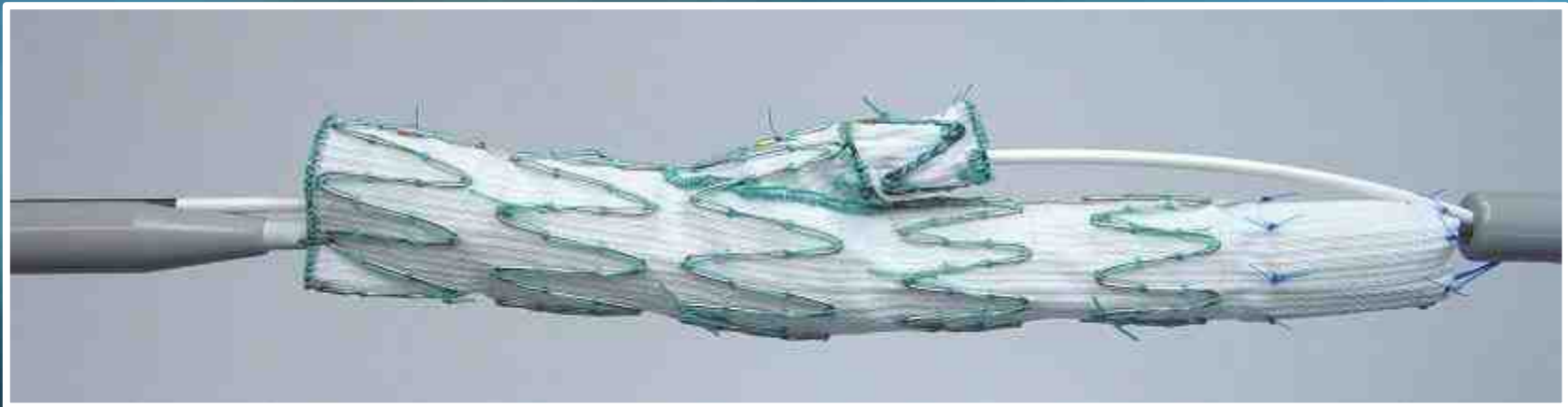
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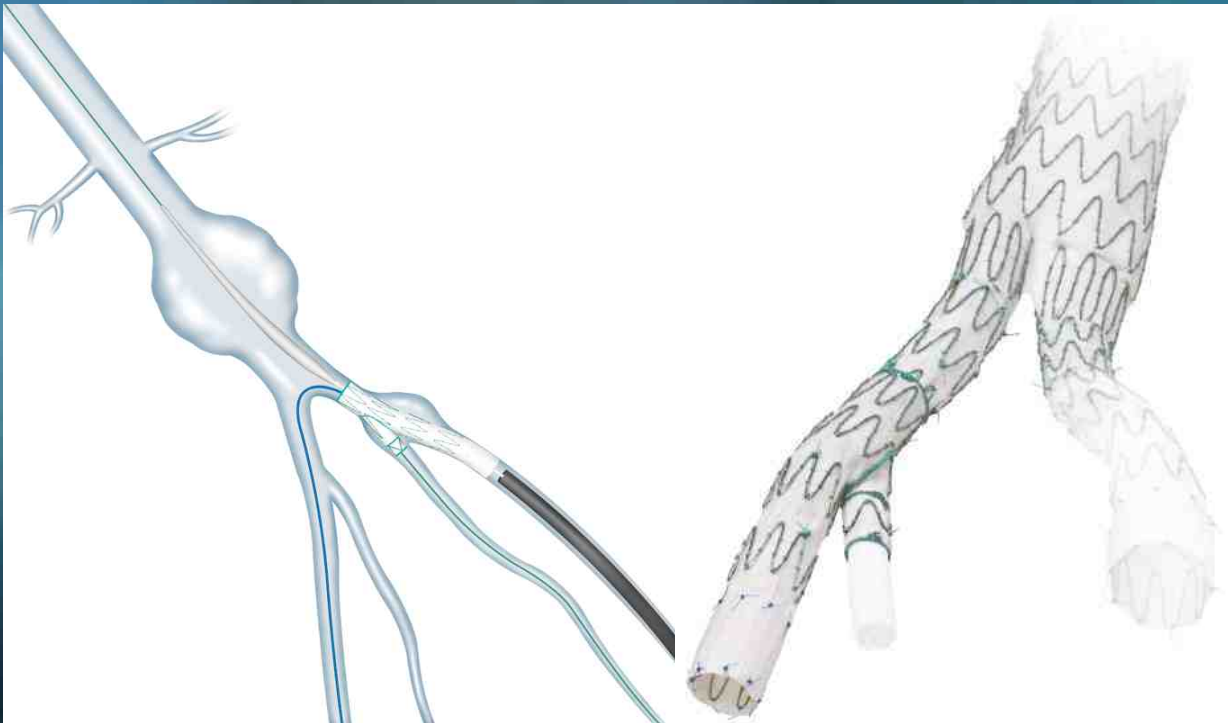
Common Iliac: Zenith® Branch Iliac Endovascular Graft

- Bifurcated Branch



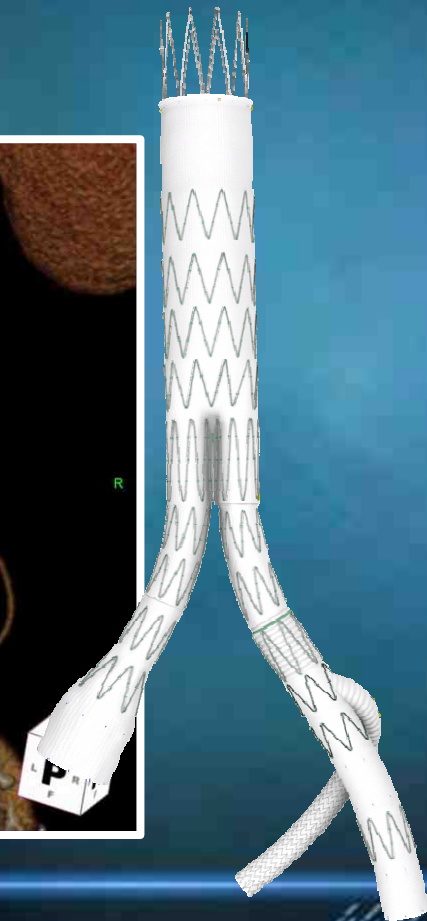
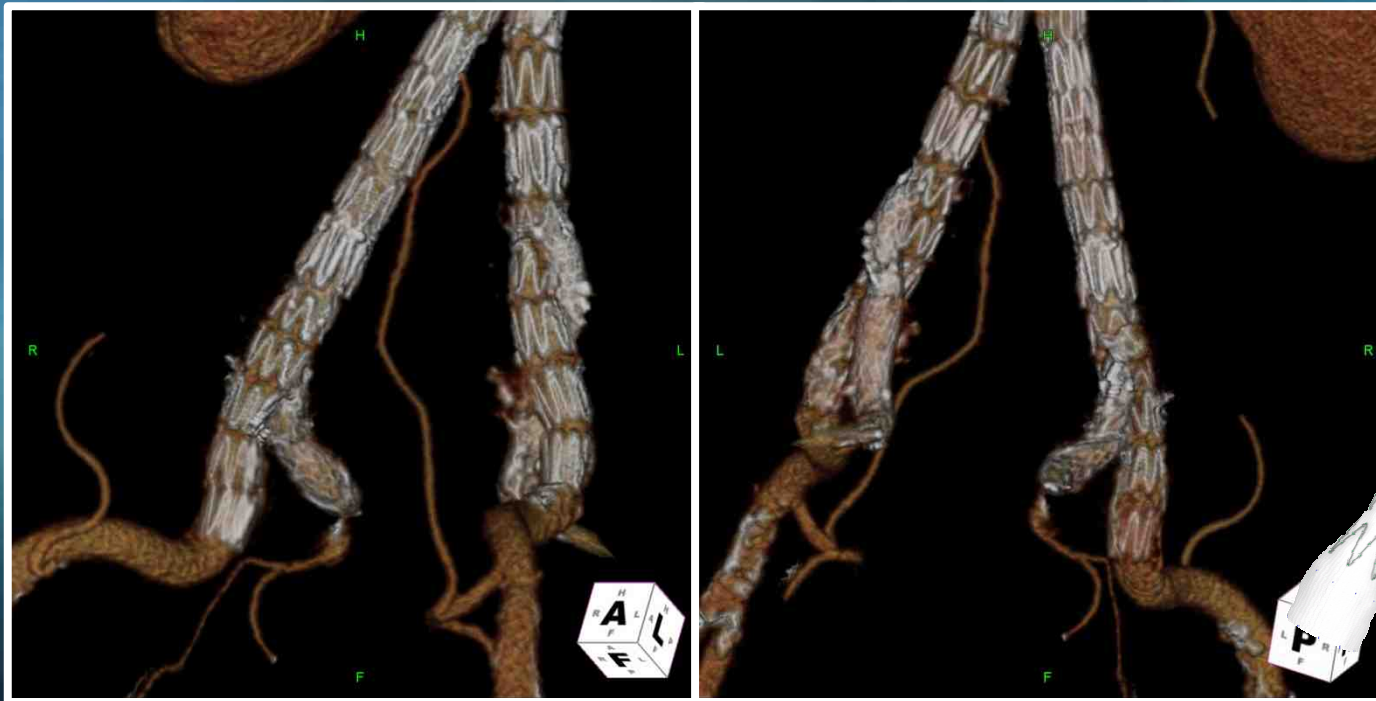
Common Iliac: Zenith® Branch Iliac Endovascular Graft

- Bifurcated Branch



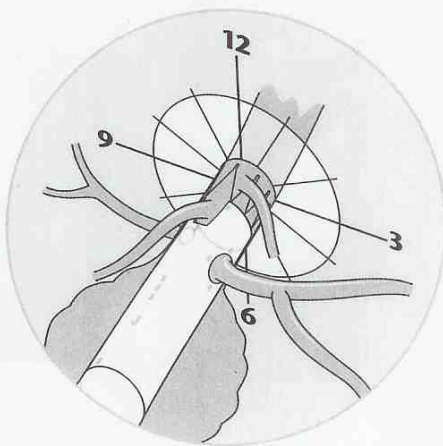
Common Iliac: Zenith® Branch Iliac Endovascular Graft

- Helical Branch

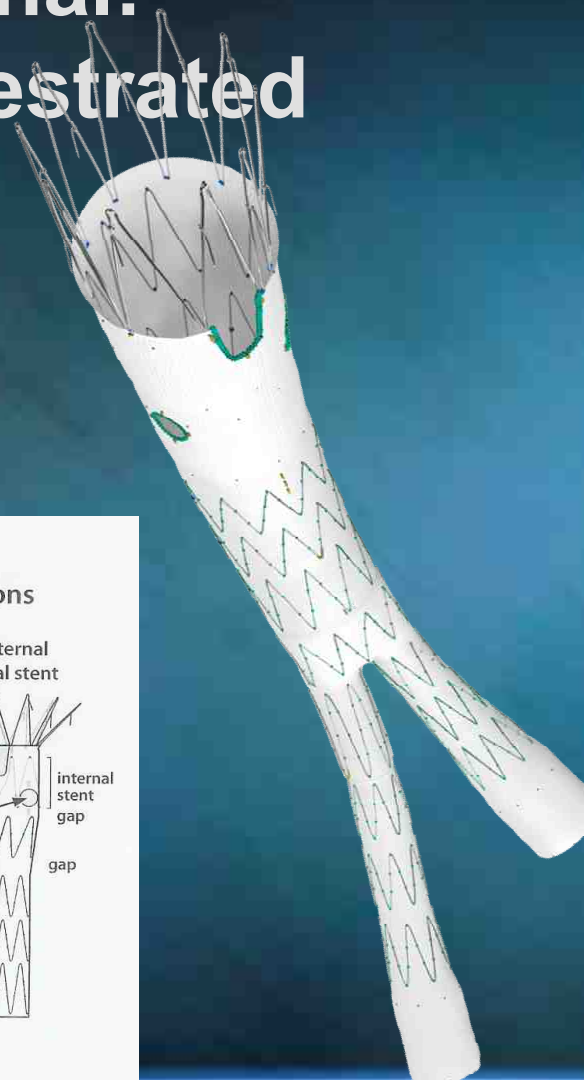
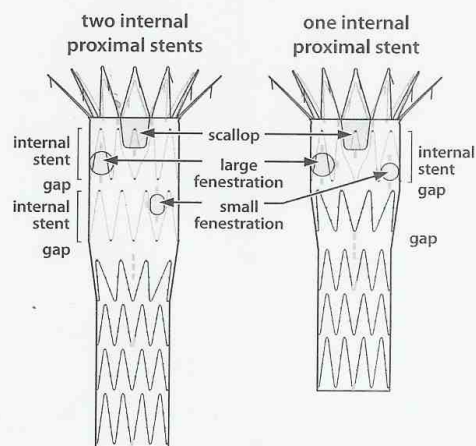


Juxtarenal: Zenith® Fenestrated

Fenestration Placement



Types of Fenestrations



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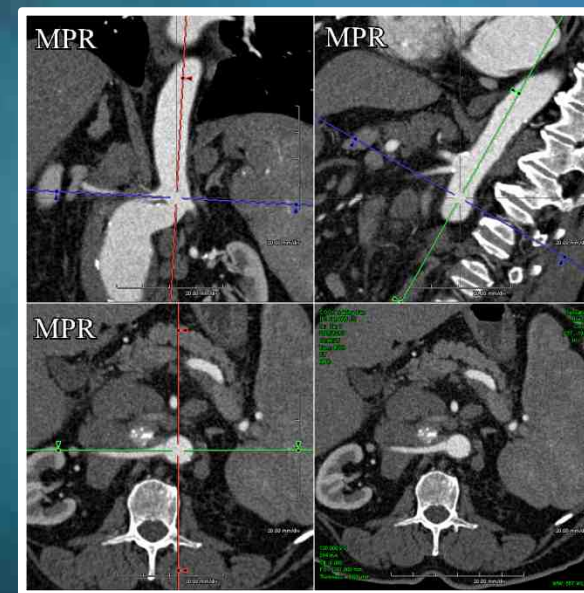
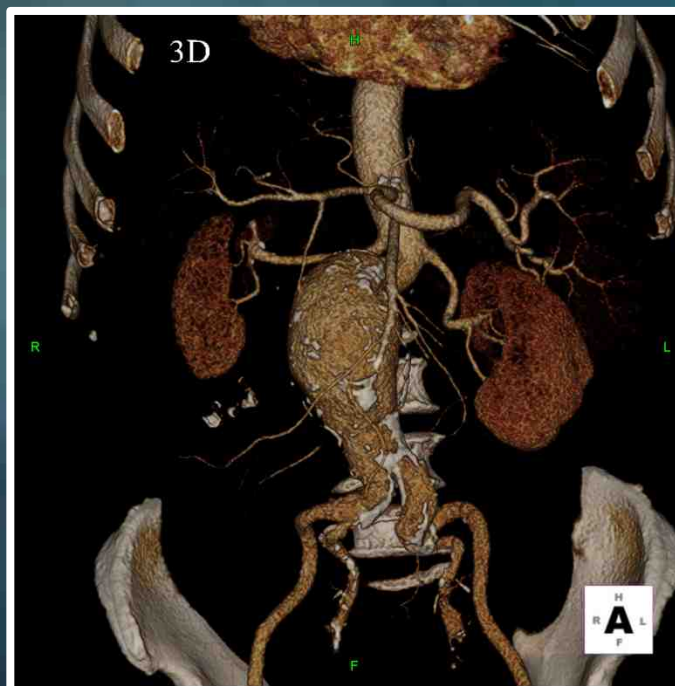
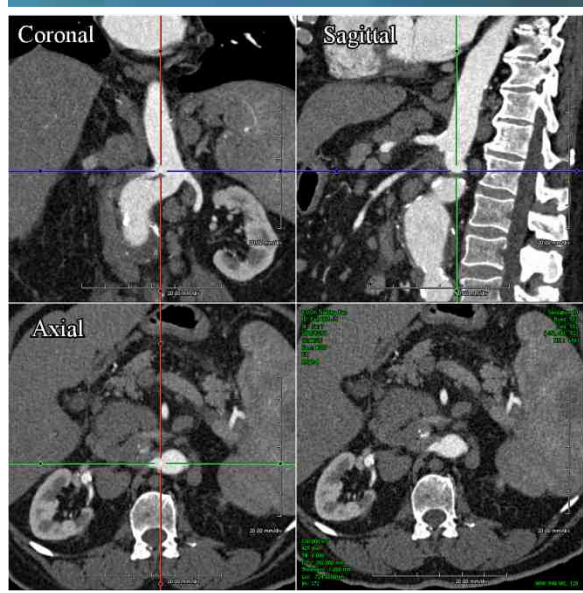
Juxtarenal: Zenith® Fenestrated



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Juxtarenal: Zenith® Fenestrated



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Juxtarenal: Zenith® Fenestrated

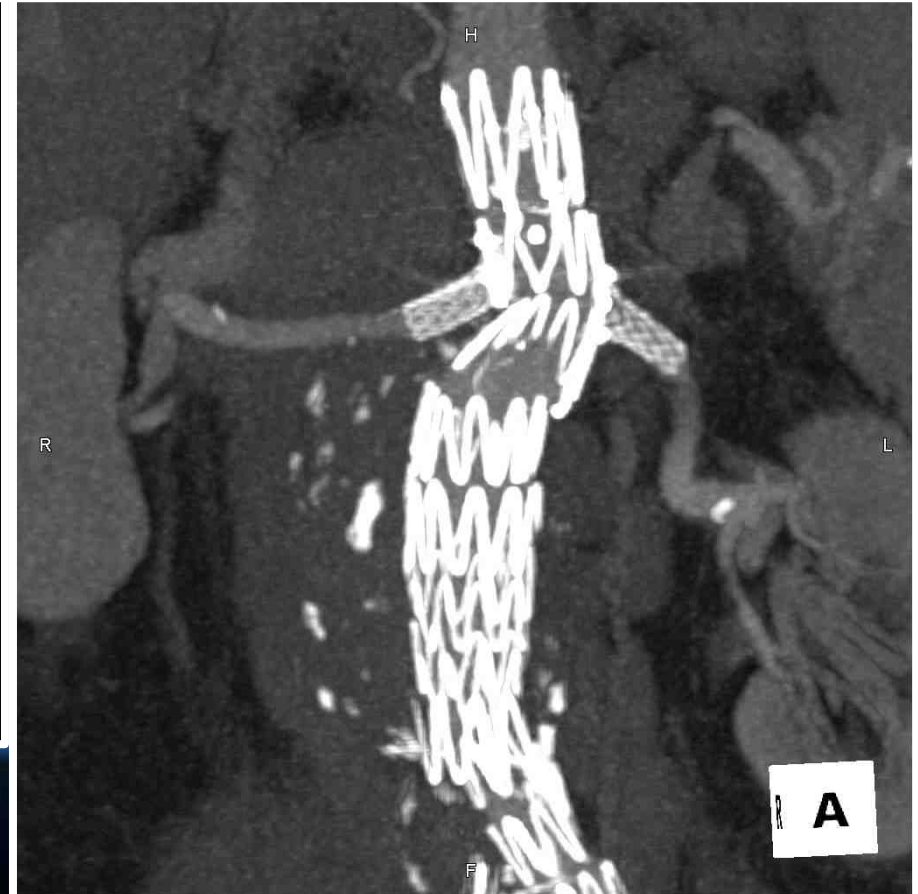
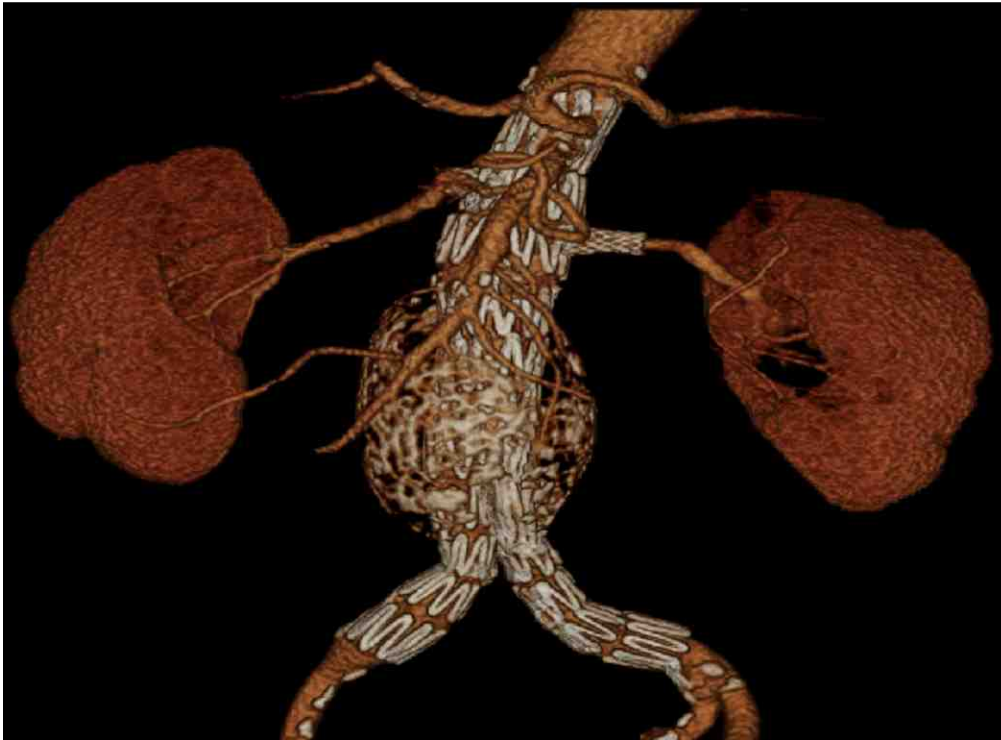


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Juxtarenal: Zenith® Fenestrated



CAUTION – Investigational device. Limited by Federal (or United States) law to investigational use.



TRIVASCULAR

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TriVascular Generation 1 Abdominal



- 79 Implants / Up to 7 years follow-up
- Aneurysms stable / shrinking
- Novel seal technology clinically demonstrated
- Fixation concept clinically demonstrated
- Some proximal stent fractures observed:
 - Root causes identified
 - Stent redesigned / testing completed
- **Proof-of-concept established**



New TriVascular Abdominal Endograft

- Tri-modular design
- Inflatable cuffs for optimal seal
- PTFE main body; majority 14F OD
- Majority of iliac limbs 13F OD
- Suprarenal stent with barbs
- Low viscosity, RO, biopolymer fibers



New TriVascular Abdominal Endograft Clinical Activity



- S. American Clinical Study - Ongoing
- Initiate CE Mark Trial – Q1 2010
- Initiate US Pivotal Trial – Q1 2010



The INCRAFT™ AAA Stent-graft System

“Real-time” customization for a more individualized solution and superior placement accuracy

- *without increasing procedural complexity*

Unmatched stent-graft delivery and **increased EVAR pool** for patients with small access vessels

- *without compromising device integrity*



Sac Anchoring Prosthesis: A New Method for EVAR

Mark Wholey M.D. UPMC Shadyside
Heart and Peripheral Vascular
Institute, Director, The Vascular
Institute



The Sac Anchoring AAA Prosthesis The Nellix System

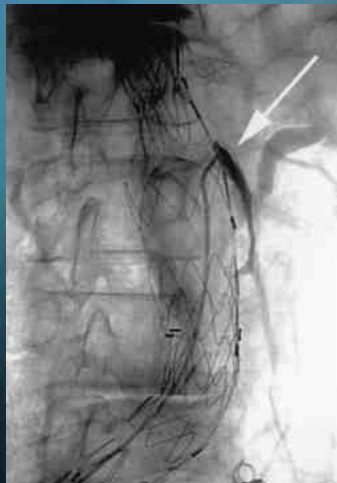
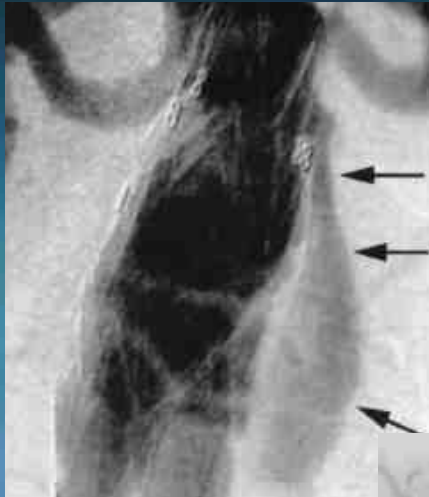
nellix
ENDO VASCULAR

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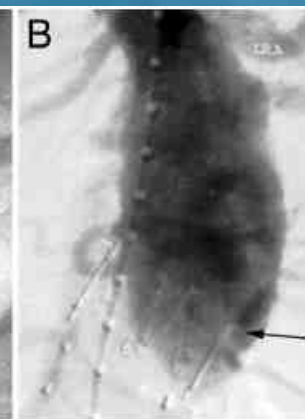
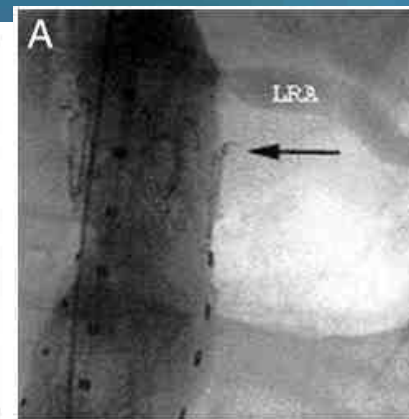
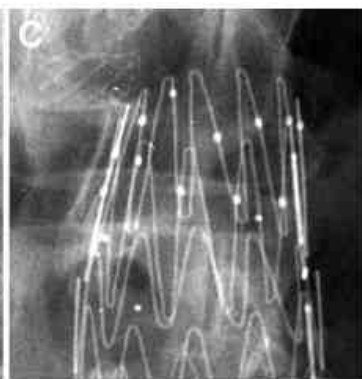
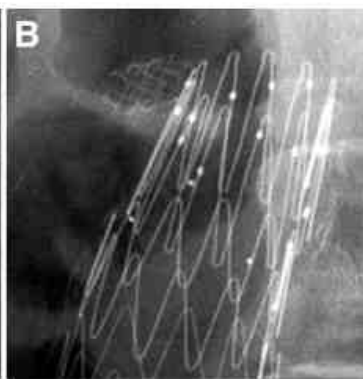
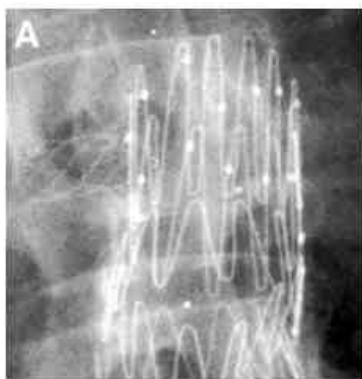
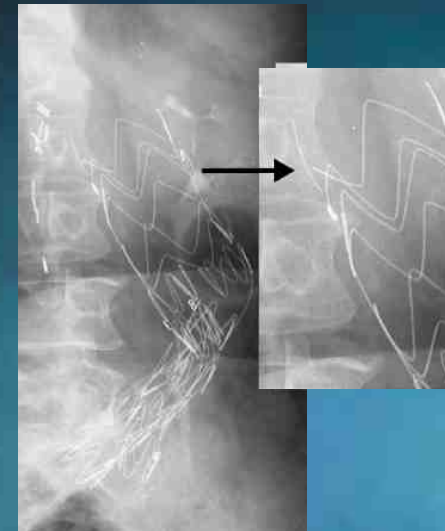
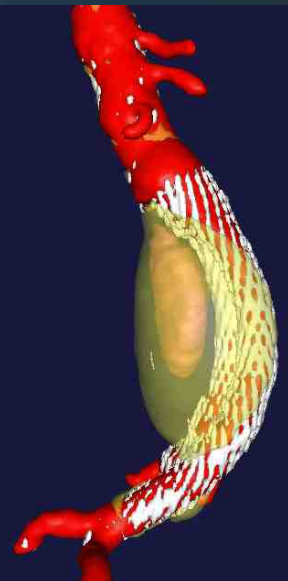
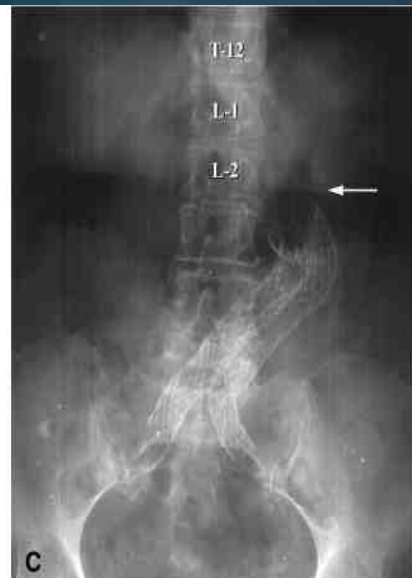
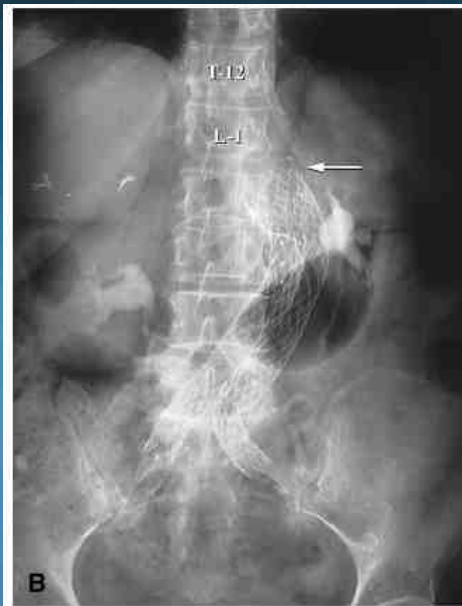


Endoleak

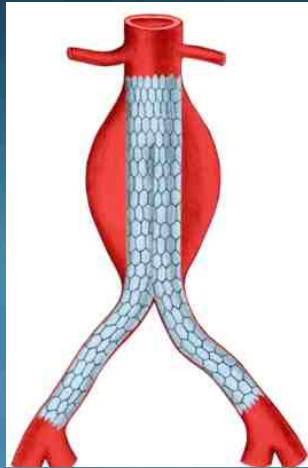
Persistent and New Endoleak is the most common reason for secondary procedures following EVAR



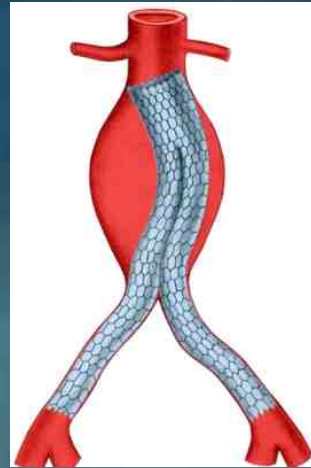
Stent Graft Migration



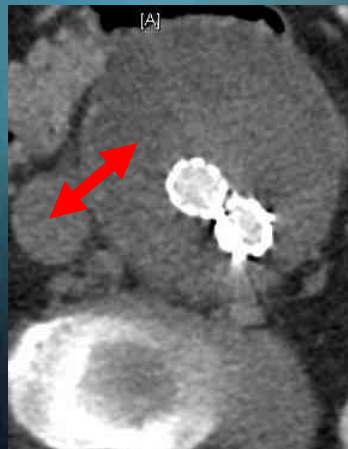
Stability: Lateral Movement & Device Migration



Post-op CT



One year CT



Post-op



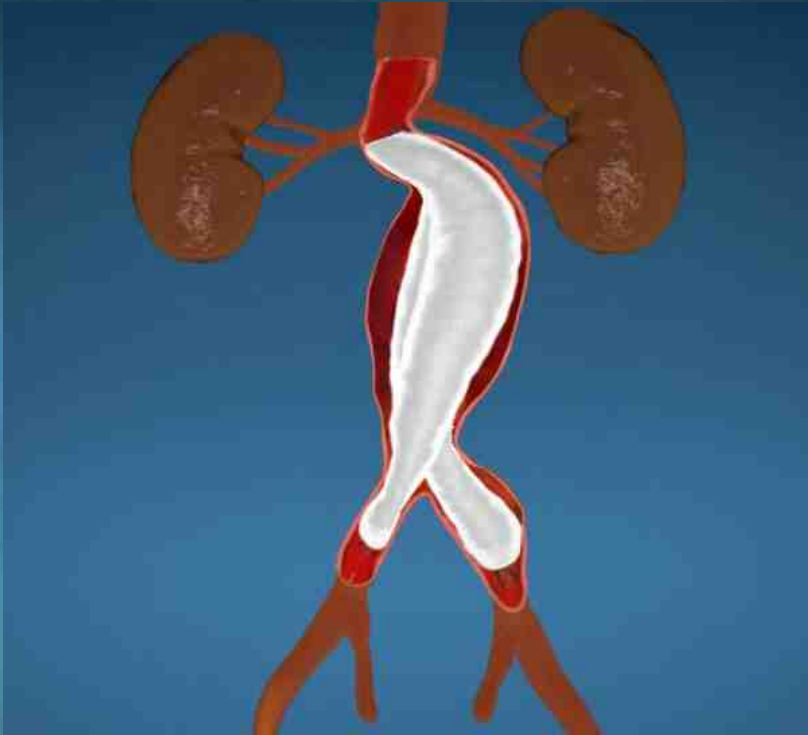
1 year



Difficult Anatomies



Nellix System Components & Design Objectives



- **POLYMER**
 - BioStable and BioDurable
 - Optimal Weight, Density and Modulus (Neutrally Buoyant)
- **ENDO BAG**
 - Sealed Containment System
- **ENDOFRAME**
 - Flexible
 - Anatomic Support, and Not Anchoring
- **DELIVERY SYSTEM**
 - Low Profile, Easy to Use
 - Controlled Filling

The Nellix System is fixed in place by polymer-filled bags, designed to

- Oppose endograft displacement force for long-term positional stability
- Obliterate Endoleaks: Tissue contact/Wall apposition
- Conform to patient specific anatomy (Large and Angulated Necks)

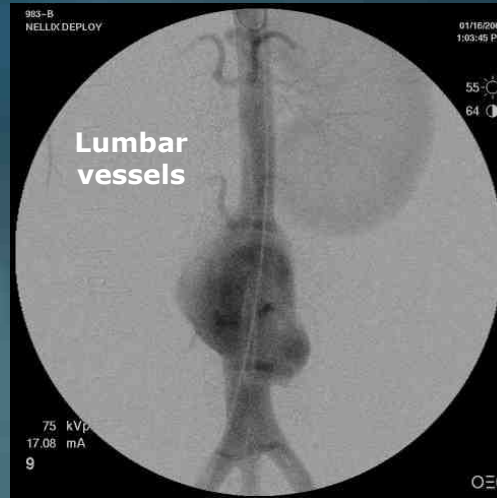
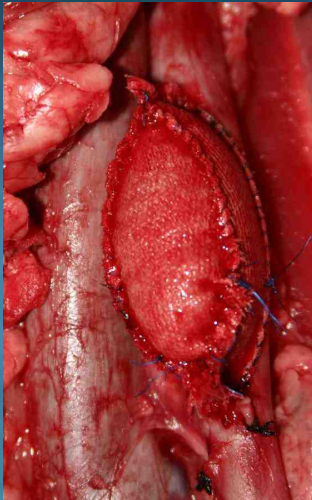
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Nellix CONFIDENTIAL: Investigational Device - Not available for Commercial

Pre-Clinical Animal Studies

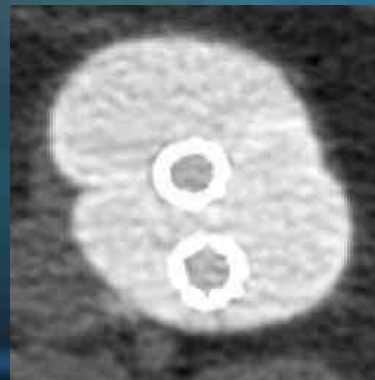
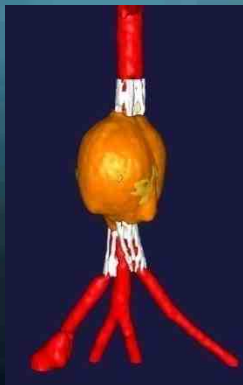
Pre Treatment



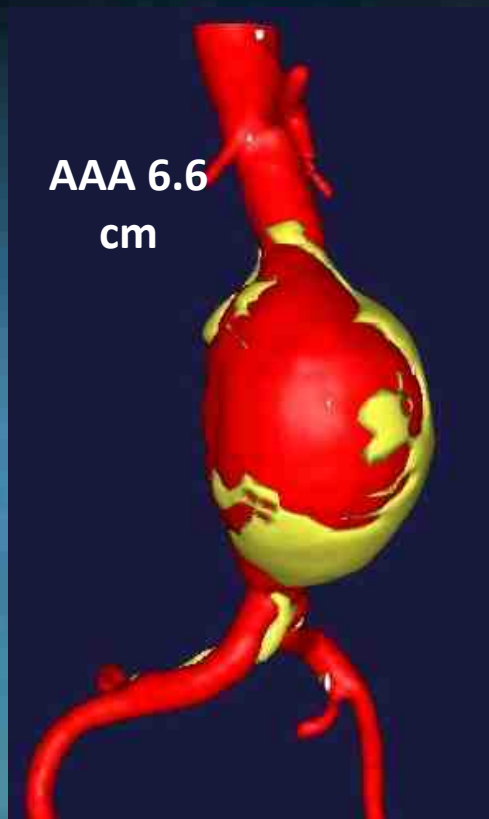
Summary

- **Ovine Model**
 - Dacron Patch Aneurysm
 - Multiple Configurations
- **>40 Animals**
- **Good Long Term Results**
 - > 2 Years Durability

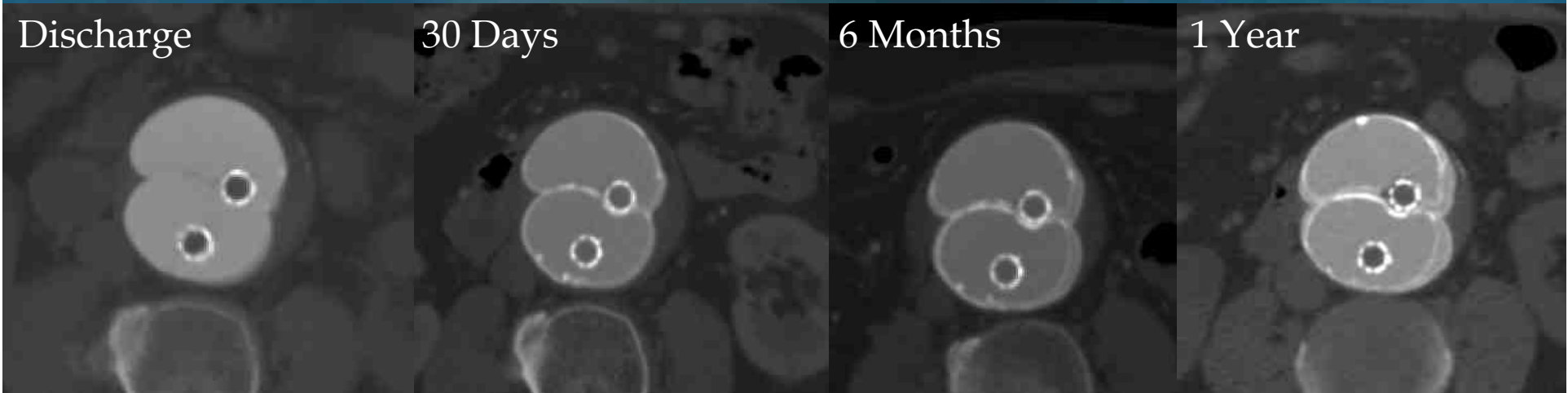
Post Treatment: 3 Months



Clinical Case: Large AAA with Minimal Thrombus



1 Year Patient Follow Up



- Thrombus Reduction
- No Type II Endoleaks
- No Device Migration
- Contrast Dissipation
- No Change in Polymer Volume
- Fully Patent Lumens



Elimination of Type II Endoleaks



Conformable Implant (Hypogastric Preservation)



Nellix CONFIDENTIAL: Investigational Device - Not available for Commercial Use R. Heuser



CONCLUSIONS

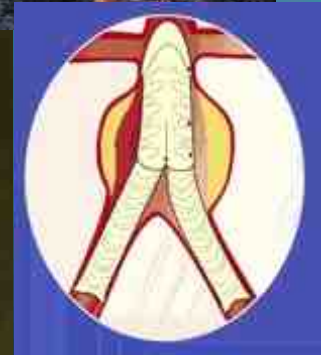
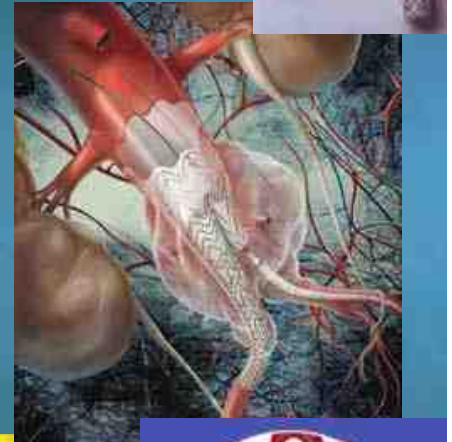
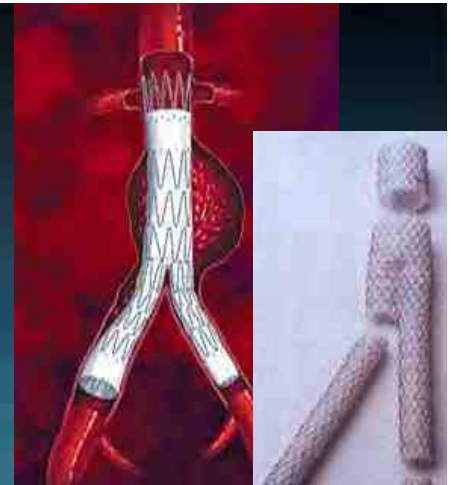
AAA Stent Grafts

Exciting alternative to open surgery

Continued interest despite product setbacks

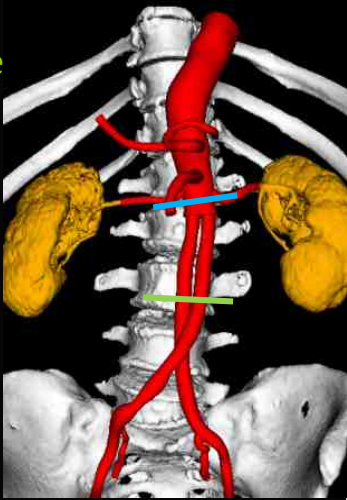
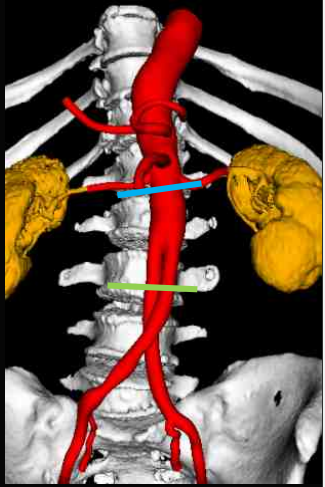
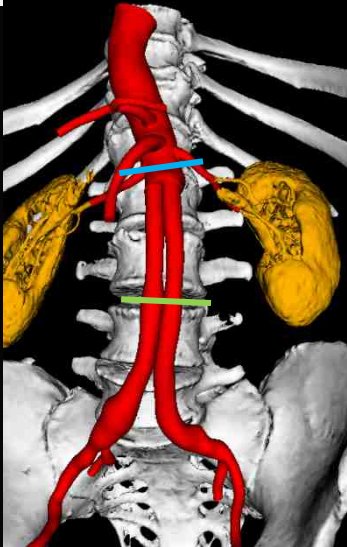
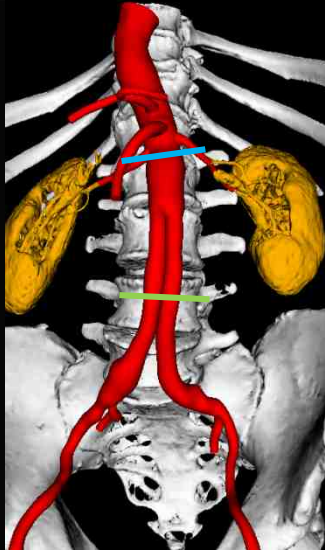
Industry responding with design changes

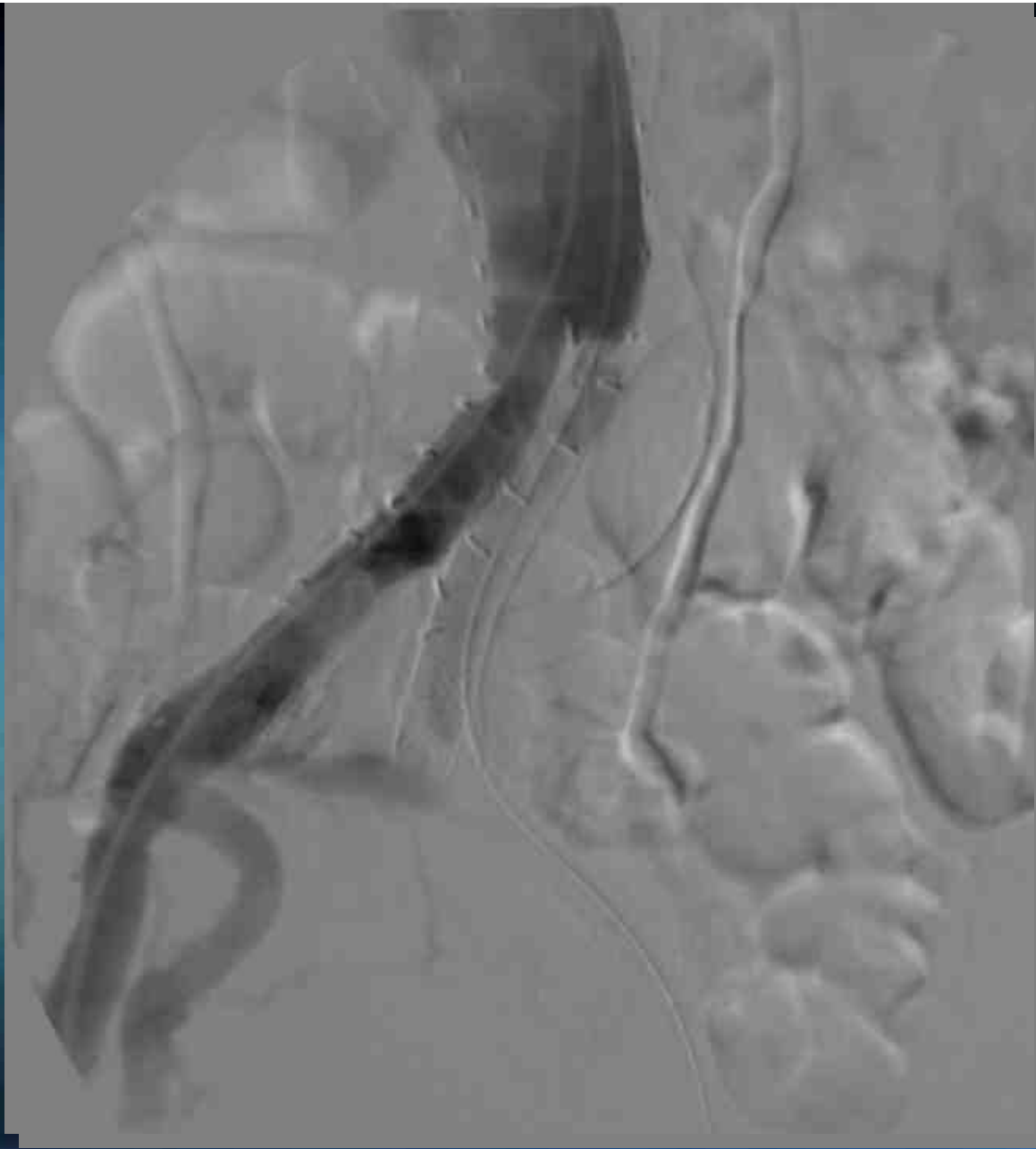
Various design approaches





Time Averaged Pressure Drop

	Nellix Device	Standard EVAR
#1	<p>No Significant Difference</p> <p>Infrarenal: 97.58 mmHg</p> <p>Iliacs: 97.17 mmHg</p> <p>Difference: 0.41 mmHg</p> 	<p>Infrarenal: 97.22 mmHg</p> <p>Iliacs: 96.79 mmHg</p> <p>Difference: 0.43 mmHg</p> 
#2	<p>No Significant Difference</p> <p>Infrarenal: 100.36 mmHg</p> <p>Iliacs: 99.97 mmHg</p> <p>Difference: 0.57 mmHg</p> 	<p>Infrarenal: 100.57 mmHg</p> <p>Iliacs: 99.99 mmHg</p> <p>Difference: 0.67 mmHg</p> 



Potential Endoluminal Graft Complications

- *Dissection/Perforation*
- *Device malfunction/failure*
- *Thromboembolic Event*
- *Prosthetic Occlusion*
- *Prosthetic Migration*
- *Prosthetic Leak*
- *Limb Ischemia*
- *Ischemic Bowel*
- *Renal Failure*
- *Wound Infection*
- *Coagulopathy*
- *MI*
- *Arrhythmias*





Conclusions

- Sac anchoring prosthesis is an innovative platform technology for endovascular treatment of aneurysms.
- Preclinical bench and animal results have established the feasibility of this novel approach.
- Initial clinical experience has been successful with the potential to treat challenging anatomies

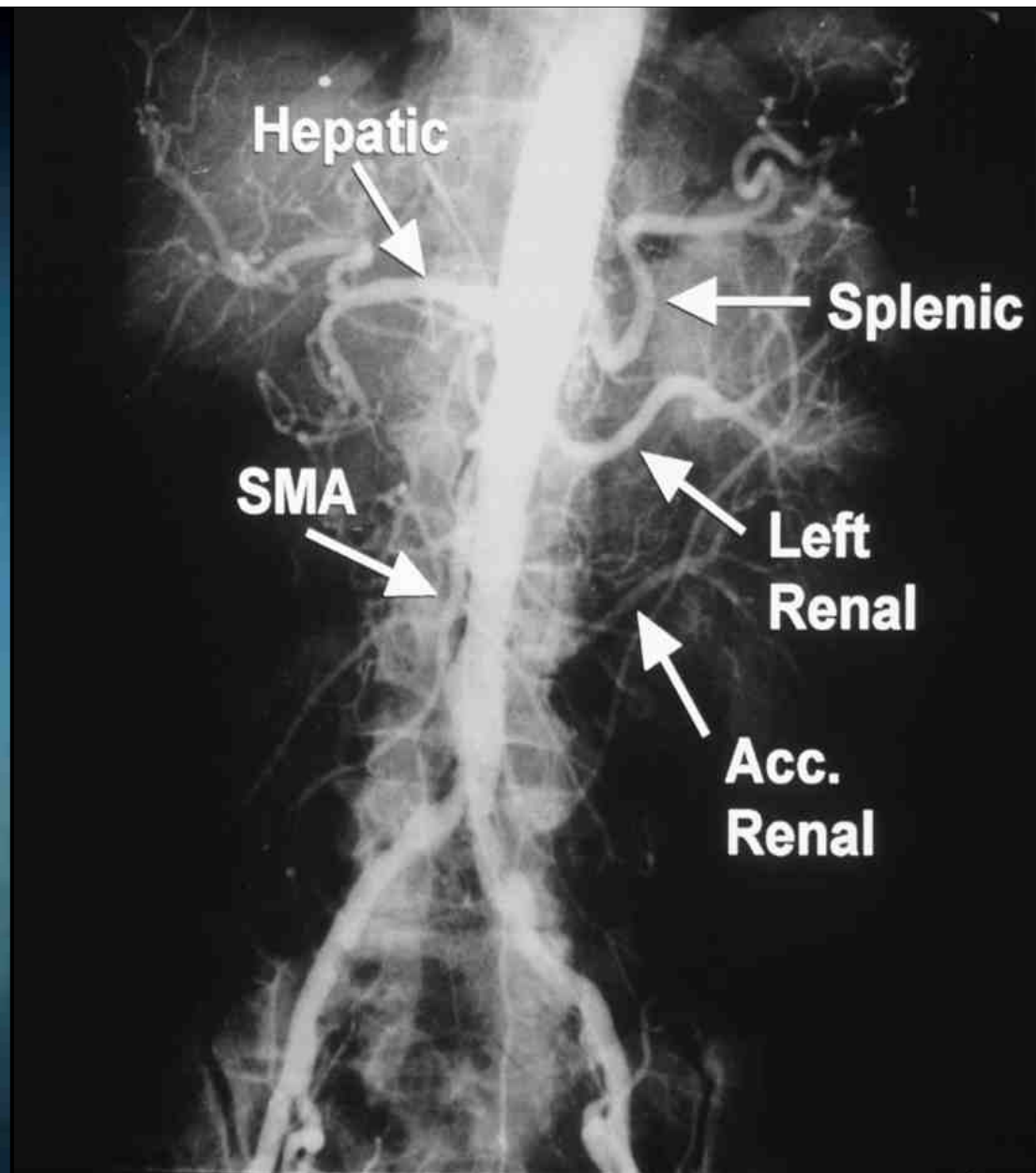


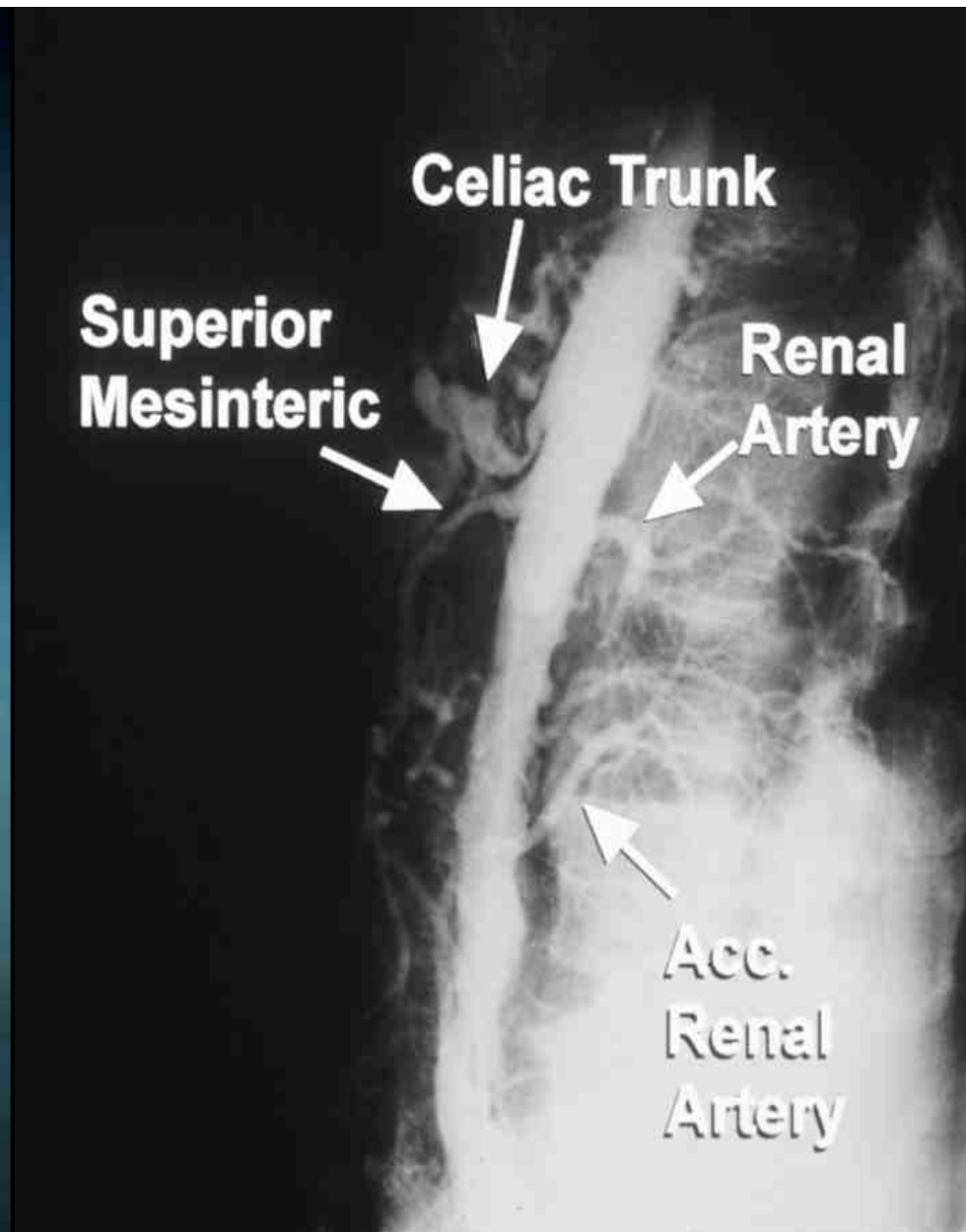


What You Need to Know to do about Peripheral Intervention

- *Know the disease*
- *Know the anatomy*
- *Know the patients' symptoms*
- *Know and understand the non-invasive testing*
- *Know the alternatives*
- *Know the anticipated results*
- *Known the potential risks*







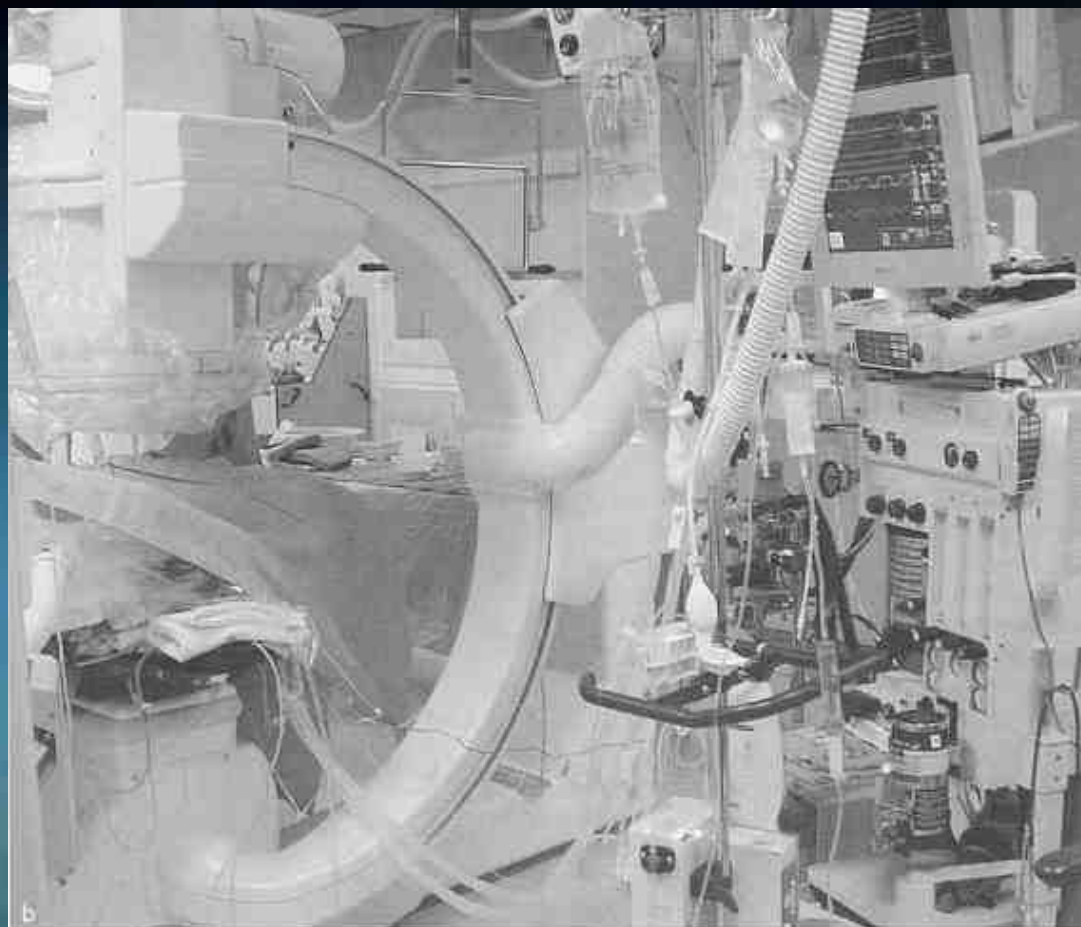
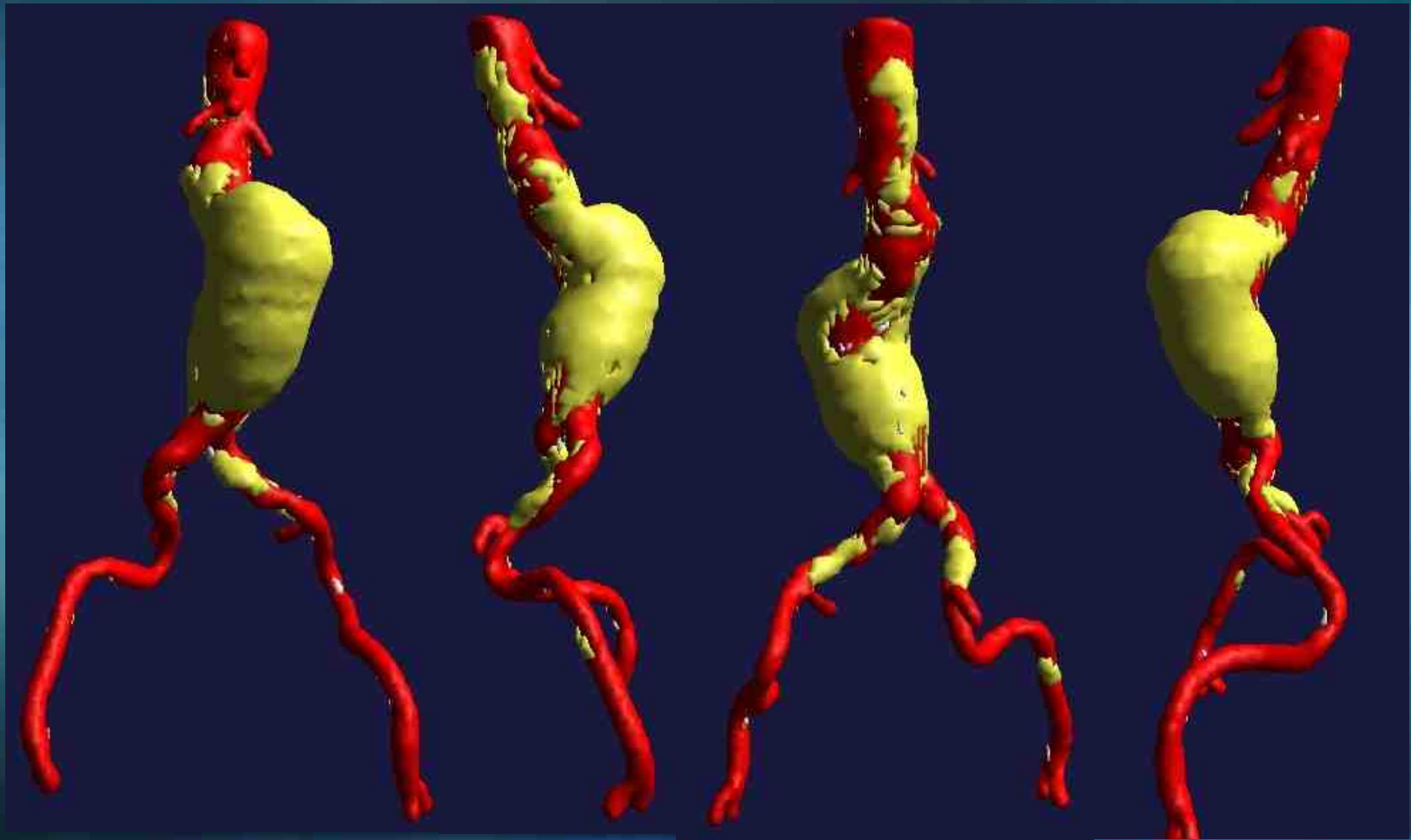


Fig. 5.3 Continued (b) The endovascular suite must be large enough to accommodate all the equipment needed to perform complex interventions.

***Heuser, Biamino, Peripheral Vascular Stenting Second Edition,
2005 Taylor & Francis, an imprint of the Taylor & Francis group***

Early Clinical Evaluation



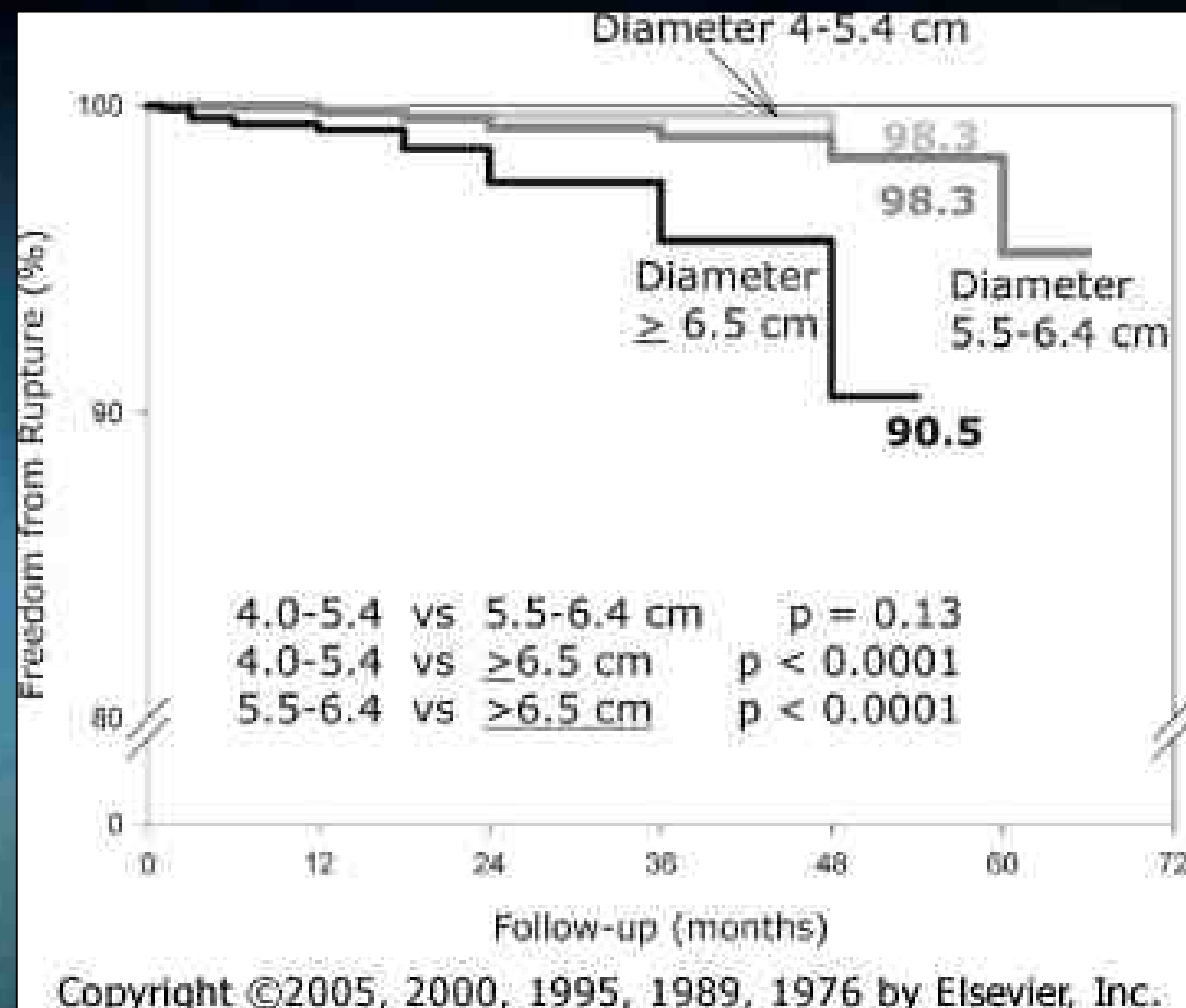
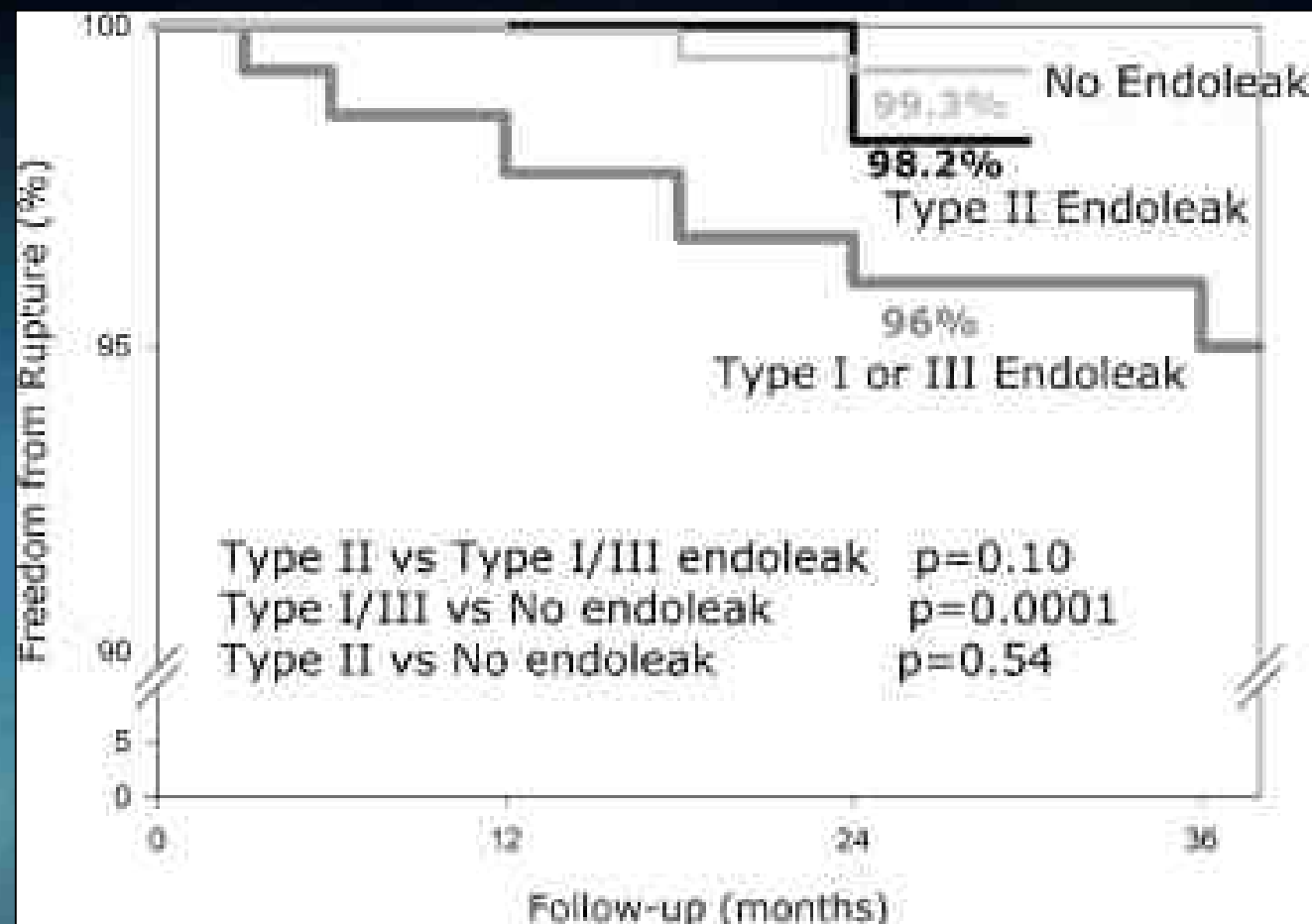


Figure 101-9 Cumulative freedom from rupture after endovascular aneurysm repair in patients with aneurysms measuring 4 to 5.4 cm, 5.5 to 6.4 cm, and more than 6.5 cm. (From Ouriel K, Clair DC, Greenberg RK, et al: Endovascular repair of abdominal aortic aneurysms: Device-specific outcome. J Vasc Surg 37:991-998, 2003.)

TYPES, ETIOLOGY, AND TREATMENT OF ENDOLEAKS

Type	Etiology	Treatment
1	Attachment Site	PTA, Balloons, Stents
2	Collaterals	Embolization
3	Graft Failure	Graft Repair
4	Porousity	No Treatment Needed





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Figure 101-8 Freedom from aneurysm rupture after endovascular aneurysm repair in patients categorized according to endoleak: with isolated type II endoleak, with type I or type III endoleak, and without endoleak. (From Van Marrewijk C, Buth J, Harris PL, et al: Significance of endoleaks after endovascular repair of abdominal aortic aneurysms: The EUROSTAR experience. *J Vasc Surg* 35:461-473, 2002.)



DISCLOSURES

Mark H. Wholey, MD

- **Consulting Fees**
 - Abbott Vascular, Medrad, Inc., Cordis, a Johnson & Johnson company, Covidien, AccessClosure, Inc.
- **Board Membership**
 - CarMell Therapeutics



Percutaneous Mitral Valve

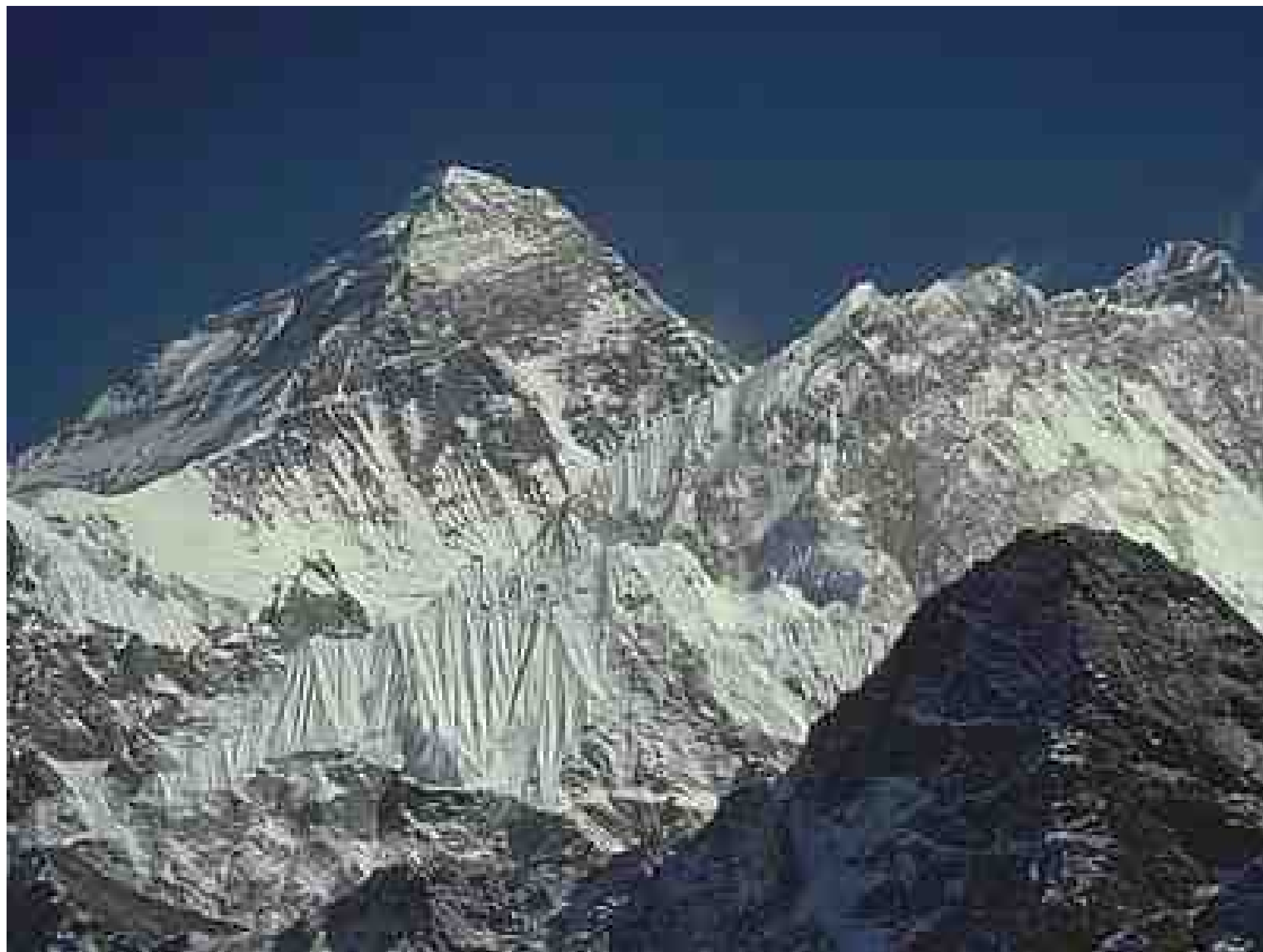
Treatment will need to be:

- Direct valve approach;
- Annular approach;
- Repeatable;
- Cannot preclude future mitral valve repair







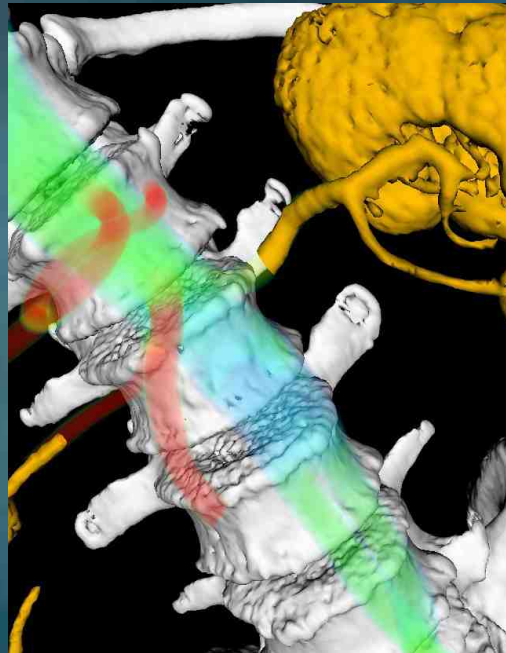




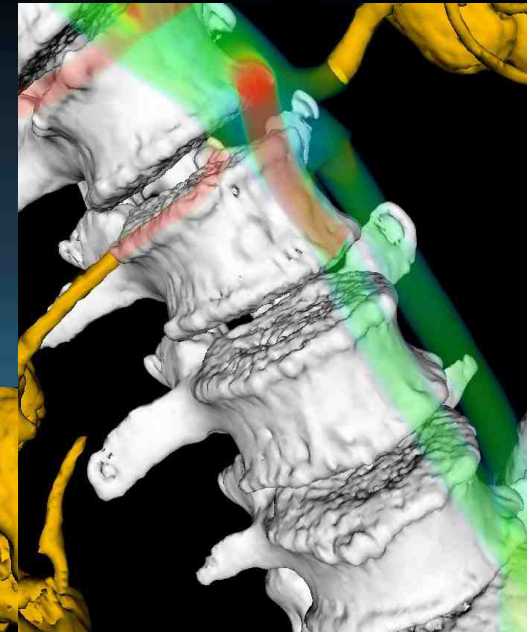
Treatment

- Modeled the Effect of EVAR Treatment on Blood Flow Using Computational Methods
 - Pulsatile Flow
 - Anatomical Geometry
 - Compared Nellix and Standard EVAR Implants
- Preliminary Results Equivalent to Standard EVAR Implant
 - Pressure Drop
 - Wall Shear Stress

Nellix
Treated



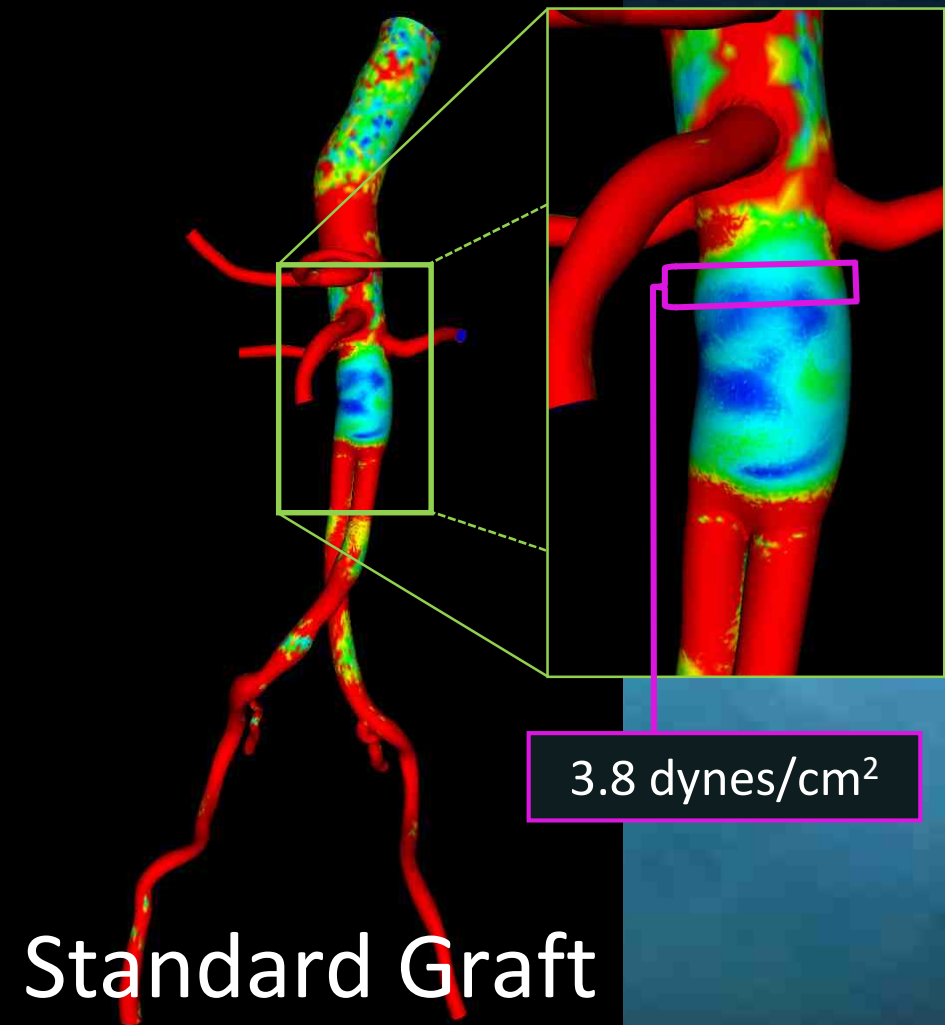
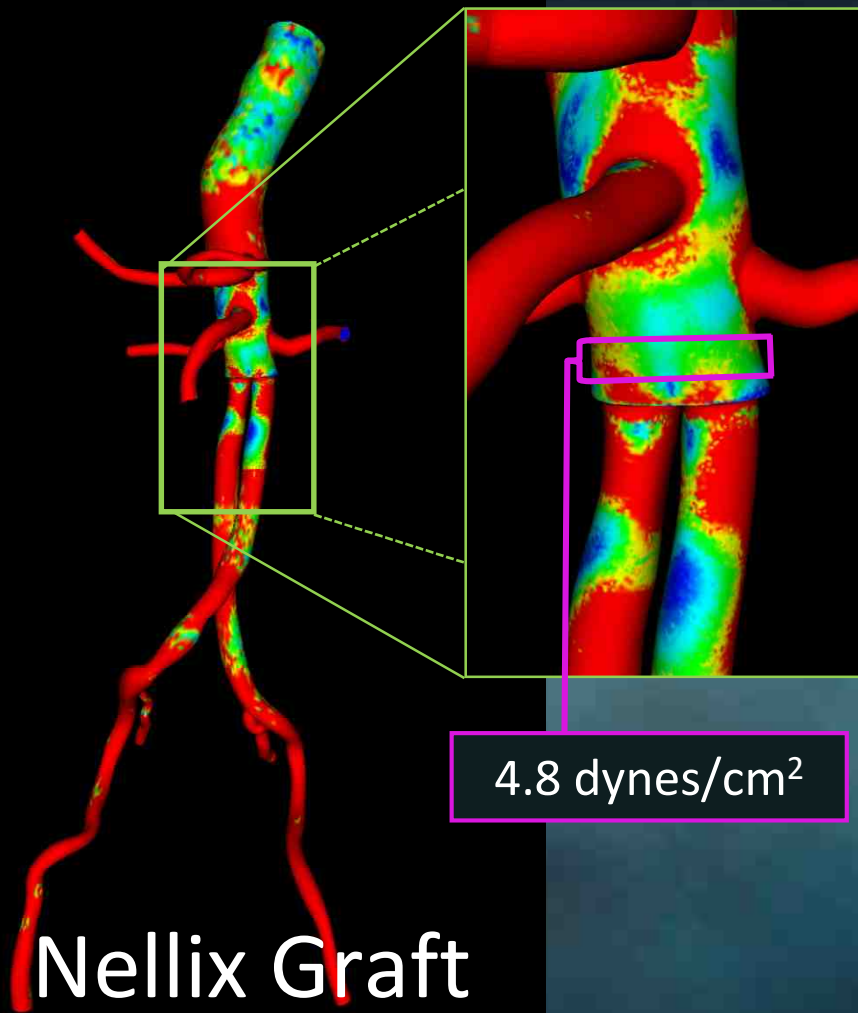
Standard
EVAR



**Charles Taylor, PhD and Nathan Wilson, PhD,
Cardiovascular Simulation Inc. 2008*



Shear Stress, Hemodynamics (Flow & Pressure)



- Nellix Pressure & Flow Rates Comparable to Normal Aorta
- No Statistical Difference Between Nellix and Standard Graft. Normal is 5 dynes. Too high (turbulence), to low (platelet aggregation)



