

A nighttime photograph of a city skyline reflected in water. The lights from buildings and bridges are mirrored in the calm water. A prominent cylindrical building is illuminated in the center-right.

Challenging Complications of EVAR and Smart Solutions

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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.

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- Medtronic, Abbott, AngioScore, Speaker; and*
- Acist Medical Systems Grant*

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



Abdominal Aortic Aneurysm Rupture

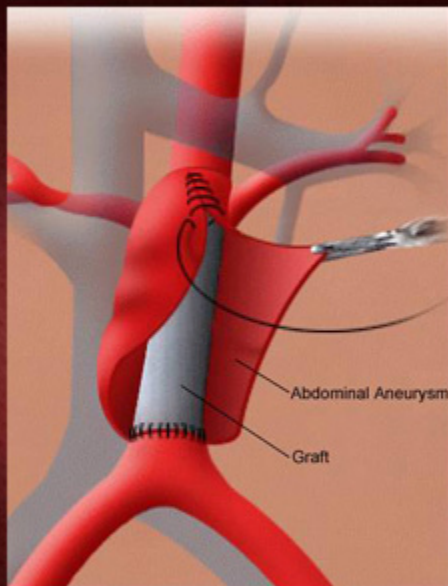
Annual Risk of Rupture

< 5 cm 1-2%

➤ 5-6 cm 10%

➤ >6 cm 25%





AAA

Surgical Repair



AAA Surgical Repair

- Resection and replacement with prosthetic graft is the preferred method of surgical repair



Abdominal Aortic Aneurysm

Scope of Problem

- 40,000 surgical repairs annually*
- Operative mortality 1-5% in good surgical risk patients*
- Operative mortality $\geq 10\%$ in higher risk surgical candidates*
- Significant operative morbidity: 15-30% incidence of major post operative complications*





EVAR



Endovascular Aneurysm Repair



- 1990 implanted the first Aortic Stent Graft in a high-risk pt with a symptomatic AAA
- Pt survived and died of pancreatic cancer nine years later
- 1991 Reported initial clinical results



- When patients undergo EVAR of AAA, there are increased rates of graft related complications and reinterventions (by a factor of 3-4) and EVAR is more costly

N. Engl J Med 2010;362:1863-1871. The United Kingdom. EVAR Trial Investigators.

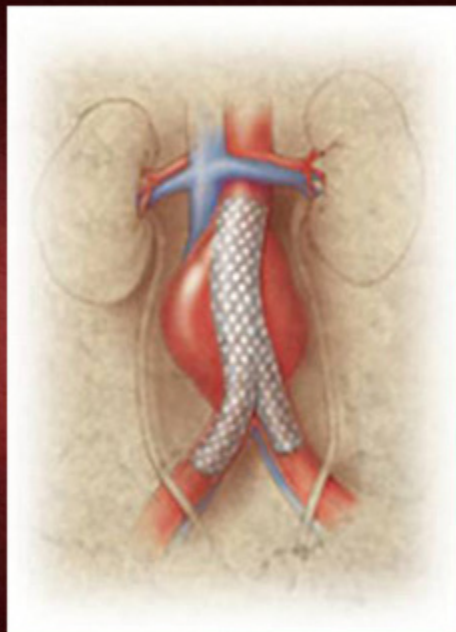






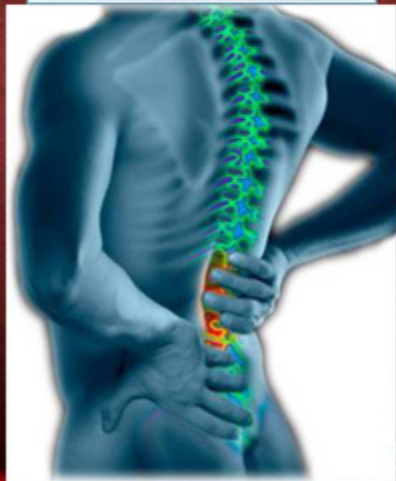
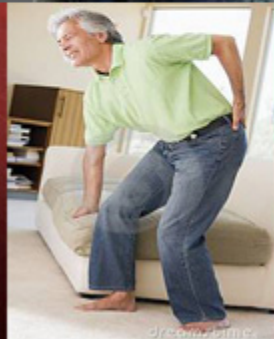
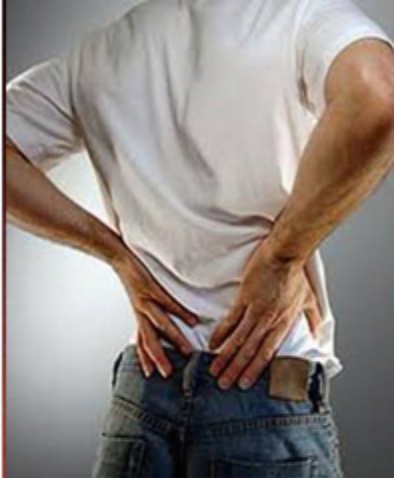






EVAR





Post Implant Syndrome

- Back pain
- Fever
- 50% of cases
- 2-3 days (up to 7)
- Negative cultures
- No increase in white blood count
- Usually benign



Endoleak

- Fix at the time of procedure
- Don't convert to open repair



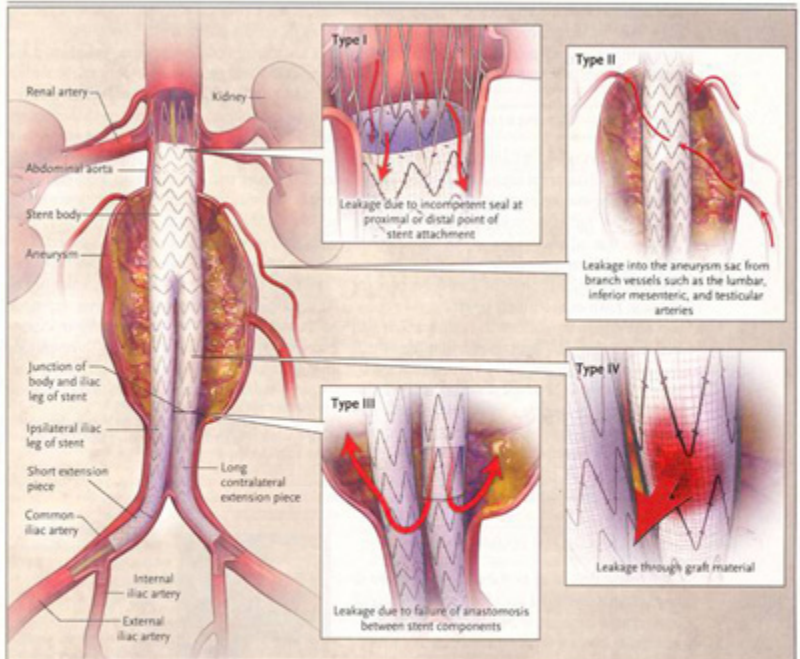


Figure 2. The Four Types of Leakage of Blood into the Aneurysm, or Endoleak.
Red arrows indicate blood flow.



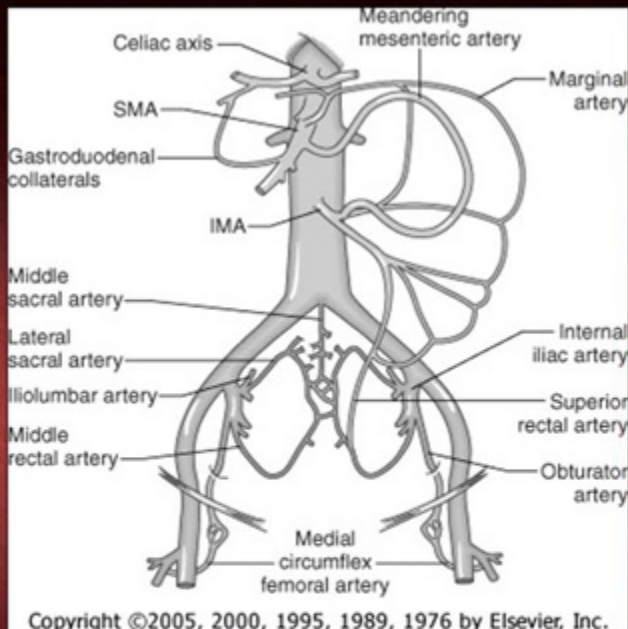


Figure 100-13 Important collateral pathways for the sigmoid colon and pelvis. IMA, inferior mesenteric artery; SMA, superior mesenteric artery. (From Bergman RT, Gloviczki P, Welch TJ, et al: The role of intravenous fluorescein in the detection of colon ischemia during aortic reconstruction. *Ann Vasc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



AAA Endovascular Repair Follow Up

- 1 month CT
- 6 month CT
- 12 month CT
- 18 month CT
- Yearly CT

What about MRI or Abdominal Ultrasound?



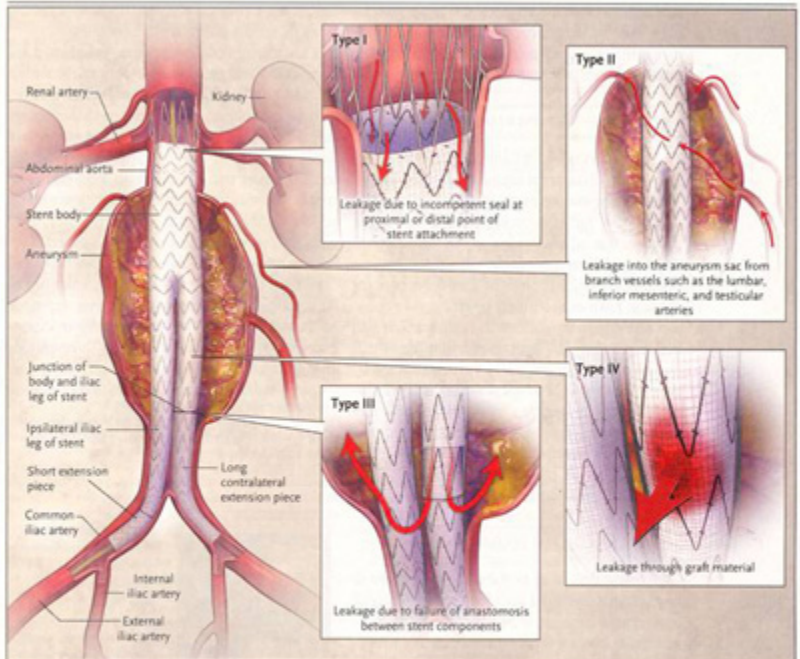


Figure 2. The Four Types of Leakage of Blood into the Aneurysm, or Endoleak. Red arrows indicate blood flow.



Type I Leak

All should be treated

- Extension cuff with noncompliant balloon
- When close to renal artery and persists a Palmaz stent
- Distal leaks can be repaired usually with extension limbs or cuffs (sometimes to the external iliac with coil embolization to the hypogastric)



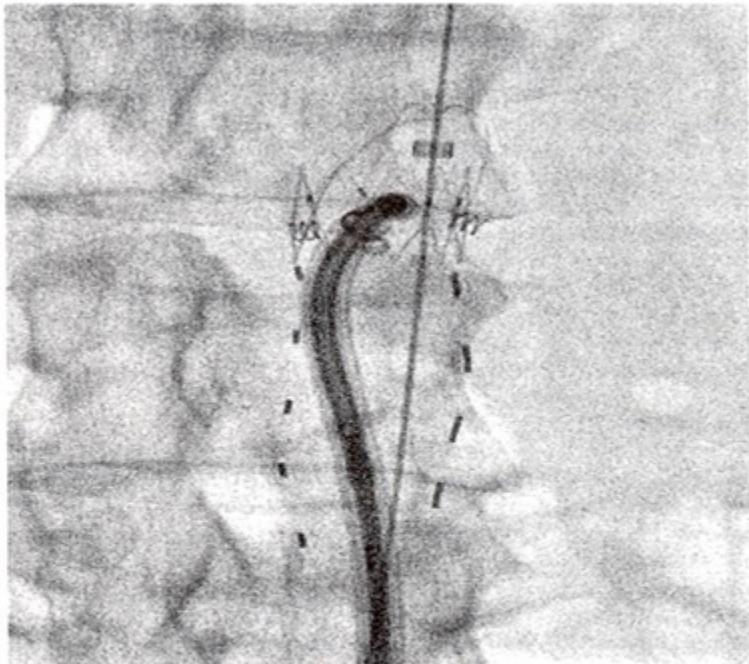
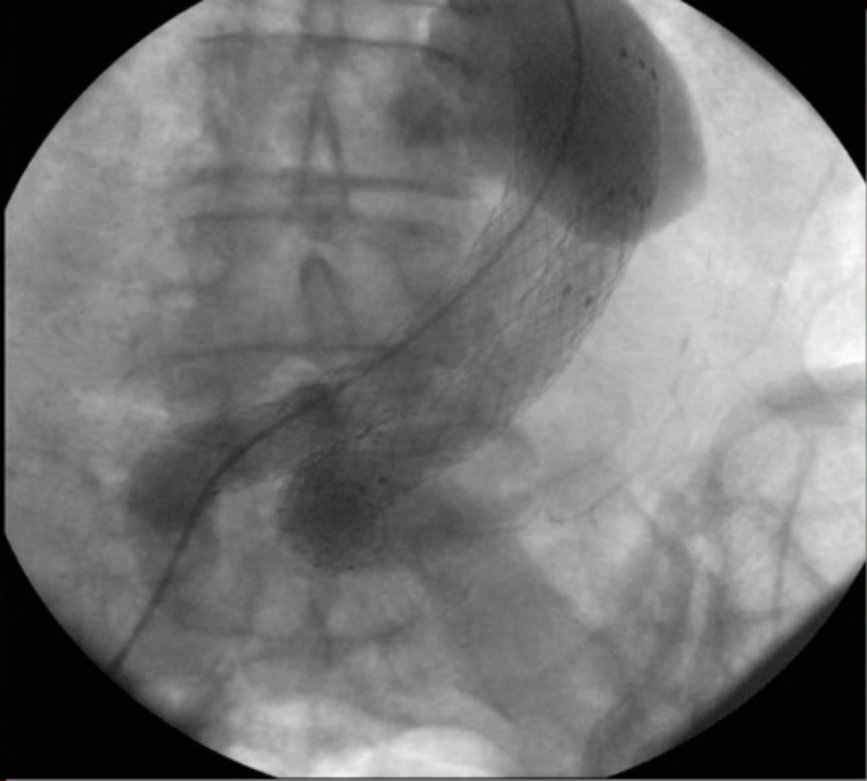
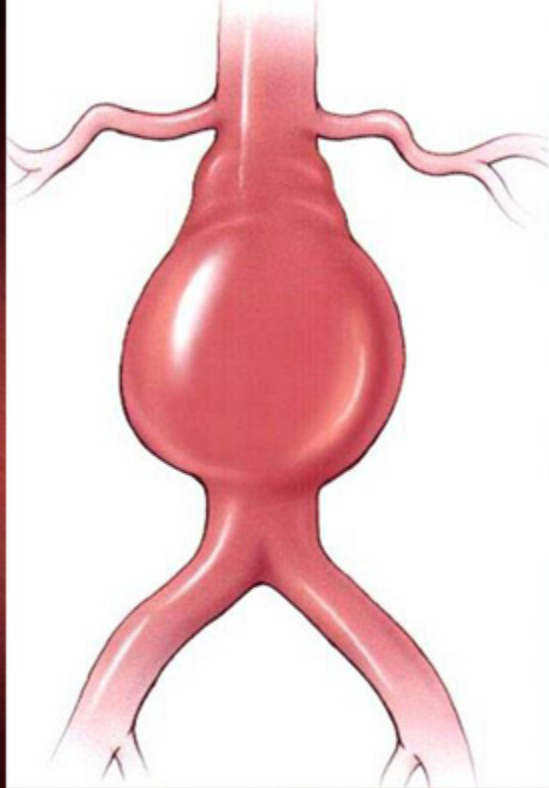
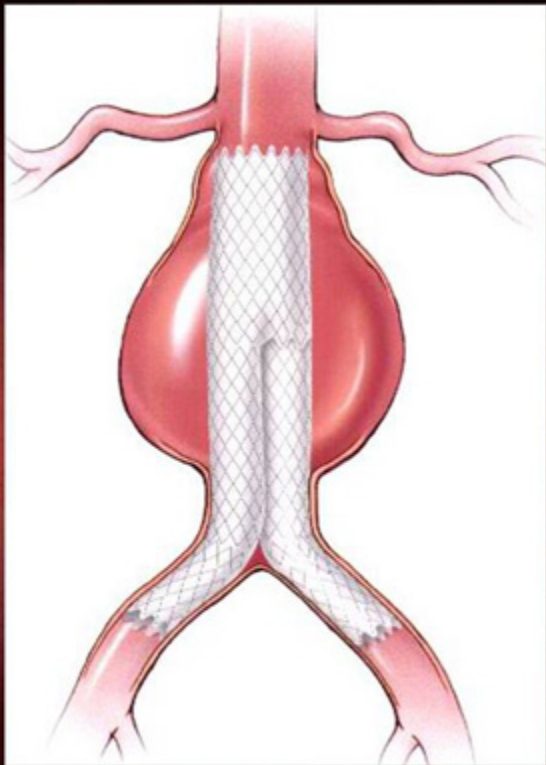


Fig. 9 Nitinol stent frame of the Aptus device in the infrarenal aorta. Endostaples can be seen affixing the graft to the vessel wall.







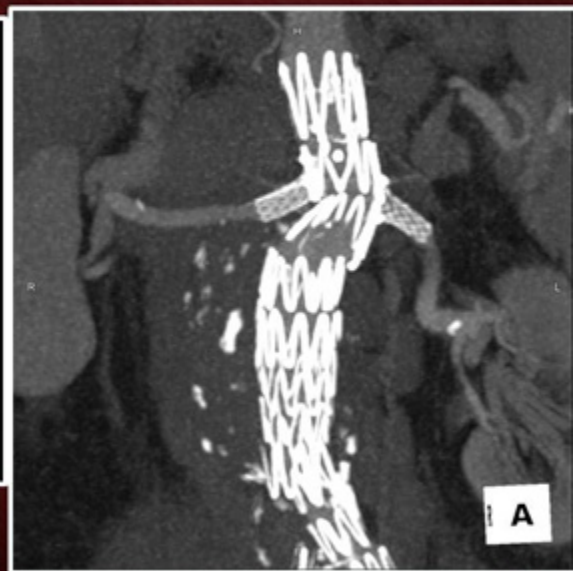




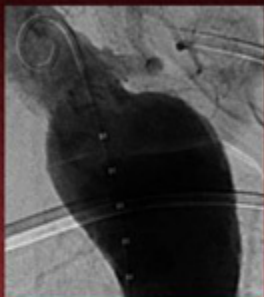
Juxtarenal: Zenith® Fenestrated



Juxtarenal: Zenith® Fenestrated



Challenging Infrarenal Aortic Neck Anatomy



Short neck



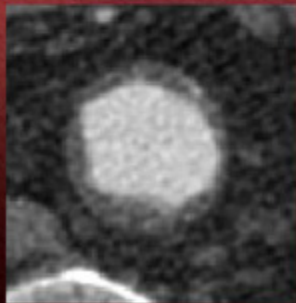
Angulated neck



Tapered neck



Reverse Taper



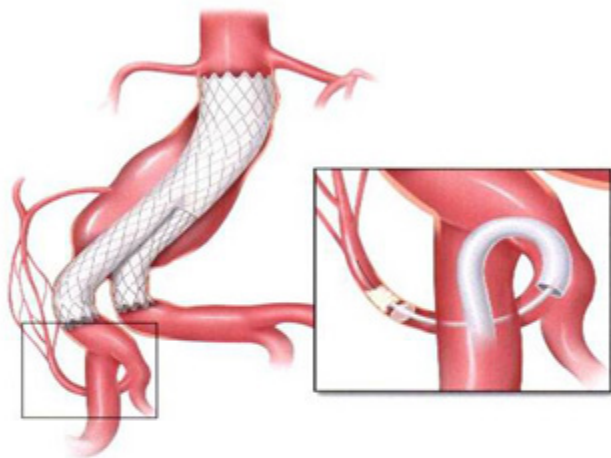
Thrombus

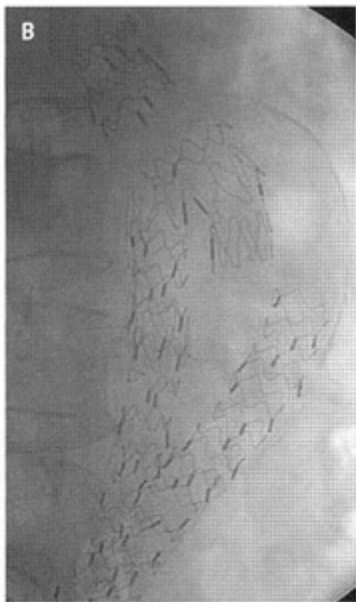
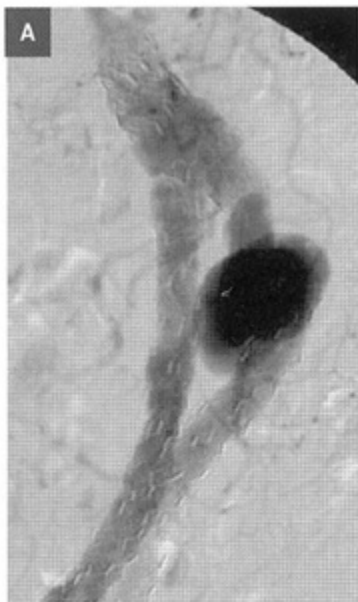


Type II Leak

- Extension cuff with noncompliant balloon
- If persistent and greater than 5mm growth after implant should be treated
- TLA needle cyanoacrylate glue







Type III endoleak due to separation of the contralateral leg from the main body (a, b) treated by insertion of a stent graft (c).



Type III Leak

- Leak should be treated with a bridging endograft
- Relining if room between the renal arteries and bifurcation of the original endograft



Type IV Leak

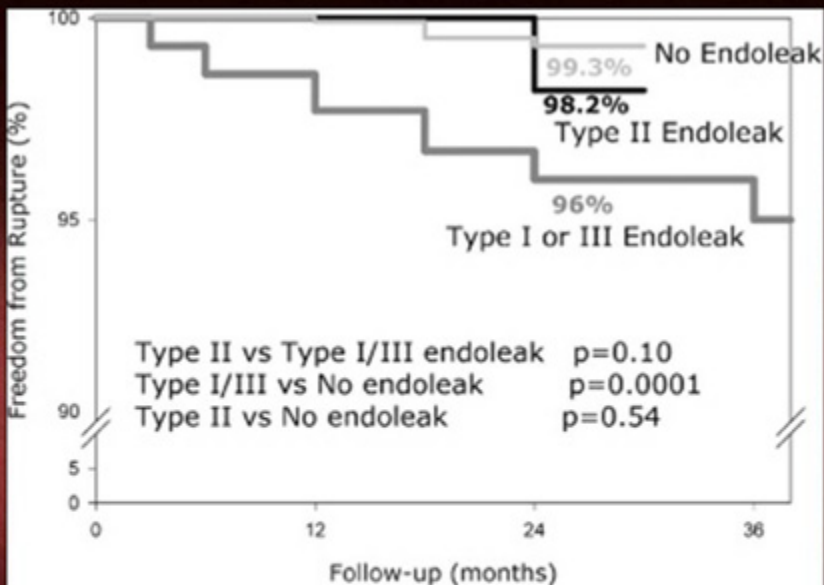
- Heparin off
- Usually no Rx



TYPES, ETIOLOGY, AND TREATMENT OF ENDOLEAKS

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



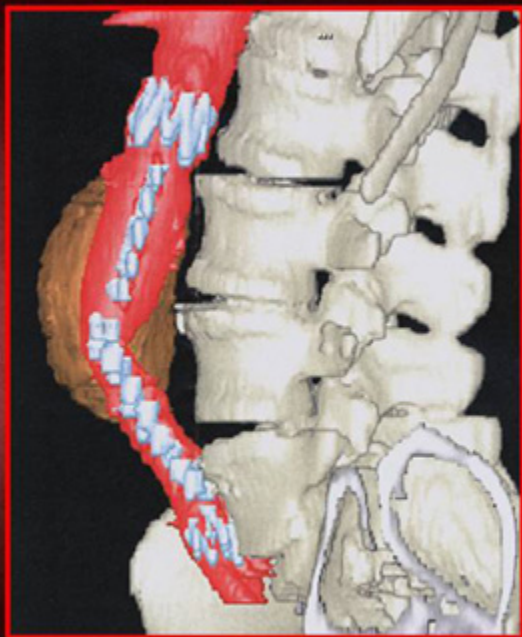
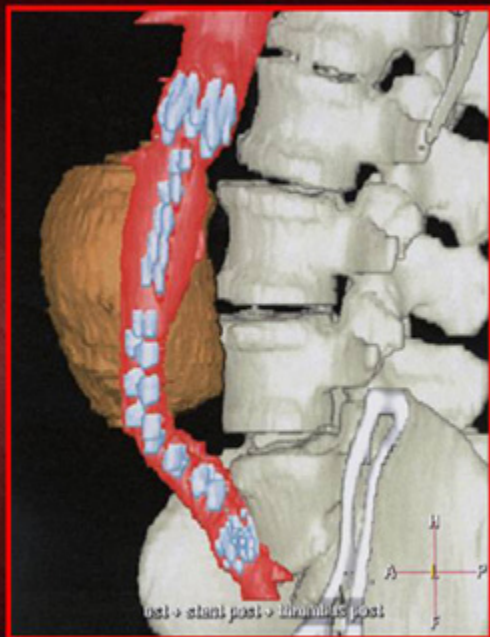


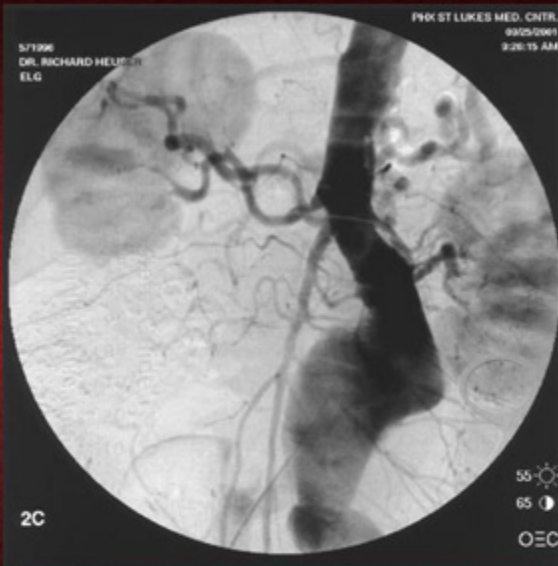
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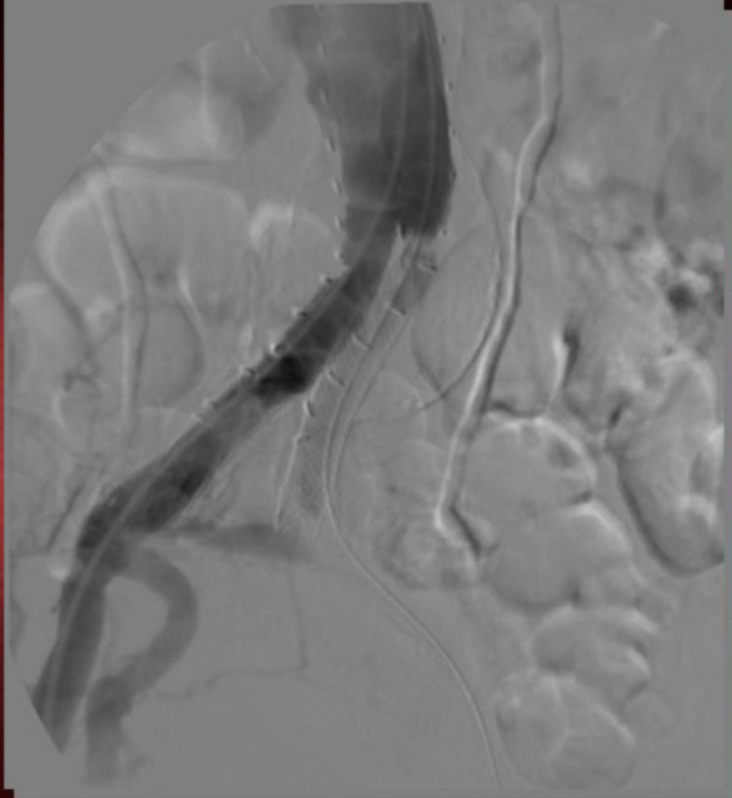
Figure 101-3 Freedom from aneurysm rupture after endovascular aneurysm repair in patients categorized according to endoleak: with isolated type II endoleak, with type I or type III endoleak, and without endoleak. (From Van Marrewijk C, Buth J, Harris PL, et al: Significance of endoleaks after endovascular repair of abdominal aortic aneurysms: The EUROSTAR experience. *J Vasc Surg* 35:461-473, 2002.)











BUSINESS/FINANCIAL DESK | June 17, 2003, Tuesday

Medical Concern Will Halt Sales Of Artery Device Linked to Deaths

By MELODY PETERSEN (NYT) 746 words

Late Edition - Final , Section C , Page 1 , Column 5

ABSTRACT - Guidant Corp to stop selling device that helps treat weakened abdominal aorta after admitting it concealed thousands of problems linked to product; says 18,000 patients who already have device are safe because problems center on system used to insert it, not device itself; says it will continue to support those patients over years; group chairman Jay Graf says potential liability from dozen suits filed on behalf of patients who died or were injured by device is 'manageable' because product liability insurance will help pay costs (M)



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Arizona Medical Systems

Four devices developed
to deal with common
complications of EVAR







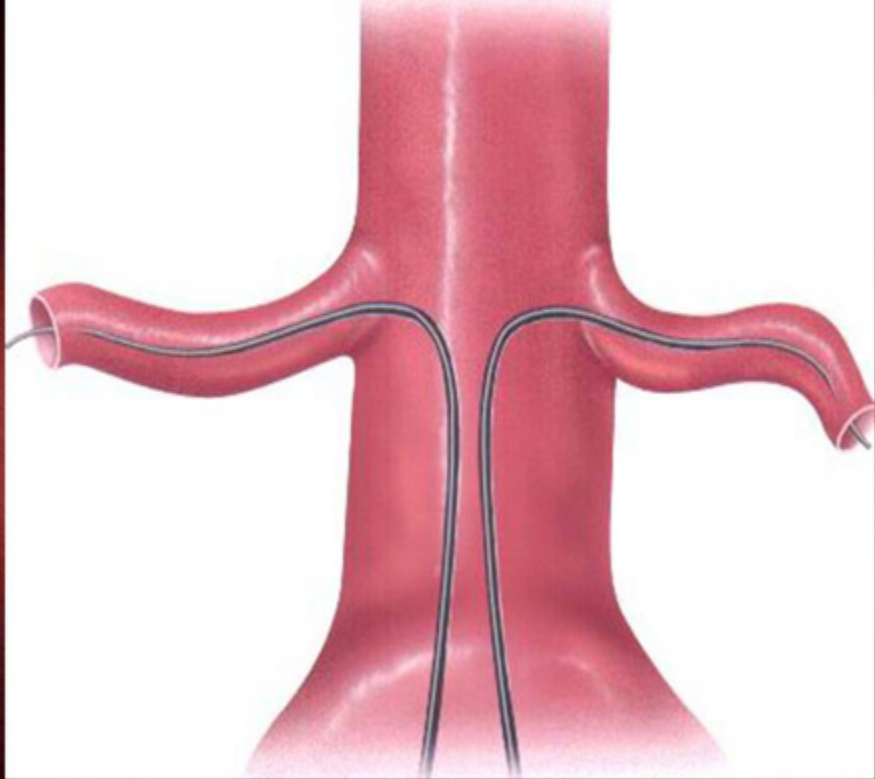
Catheter Introducer System
Patent # 7,166,088
Issue Date 1/27/07

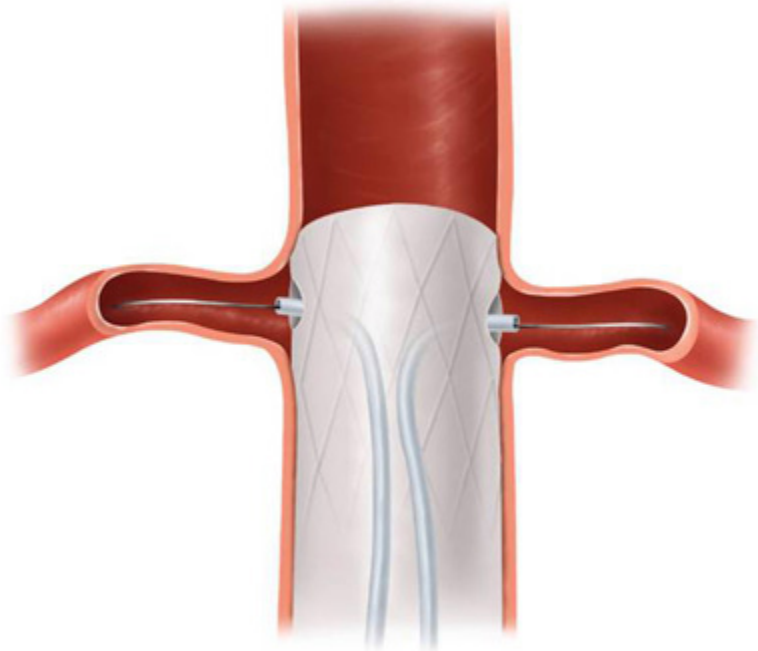


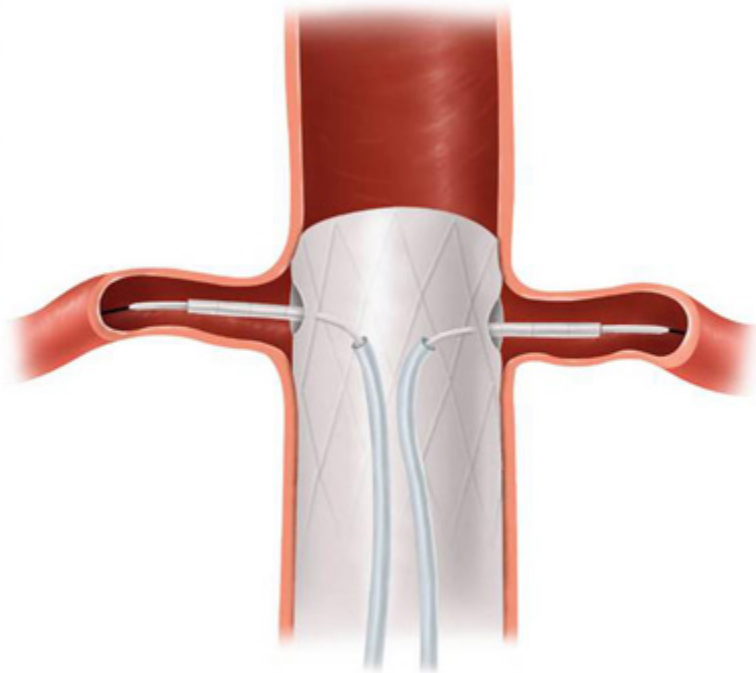


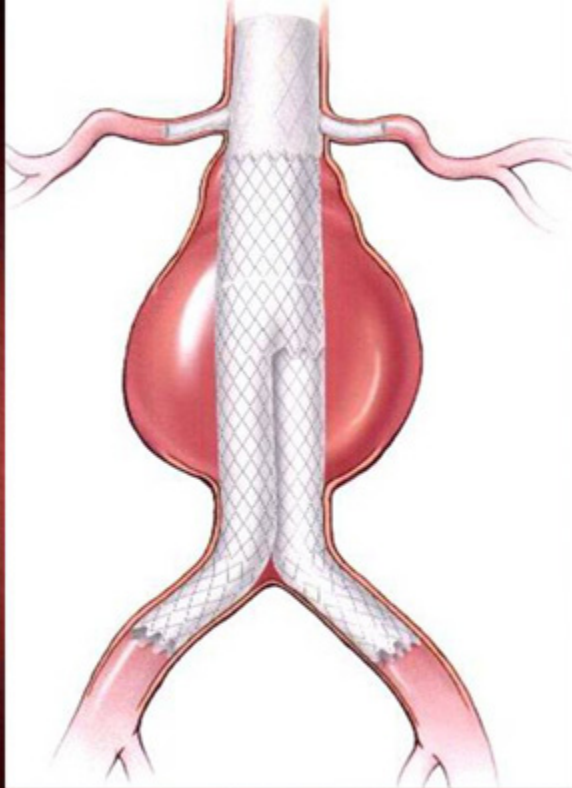
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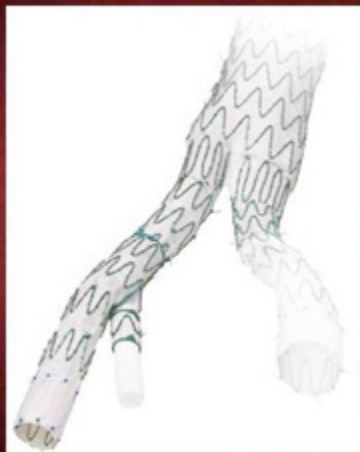


*Common Iliac:
Zenith® Branch Iliac Endovascular Graft*

- Bifurcated Branch

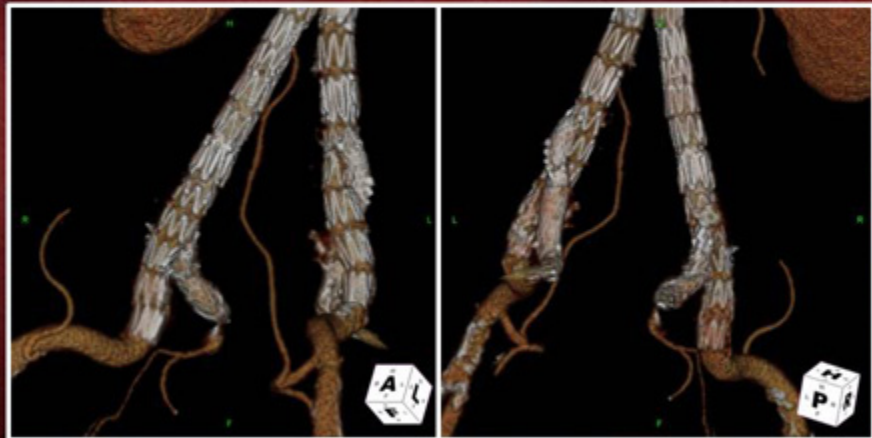


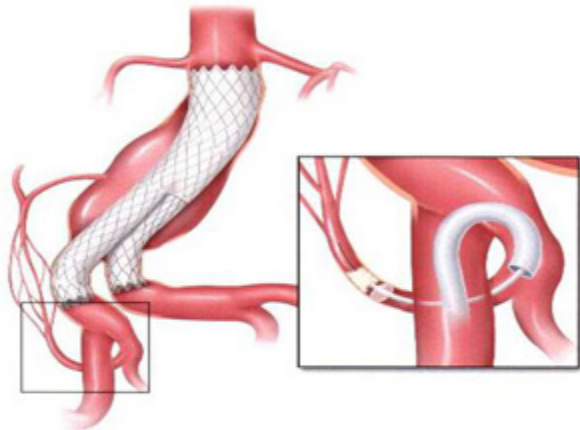
Common Iliac: Zenith® Branch Iliac Endovascular Graft



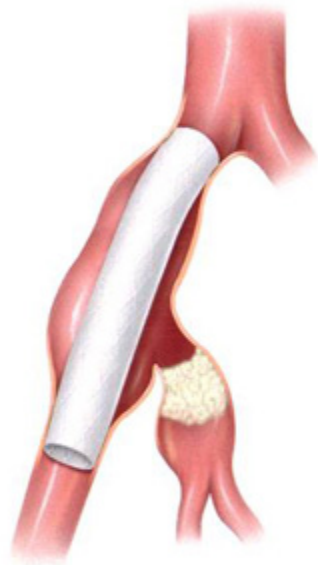
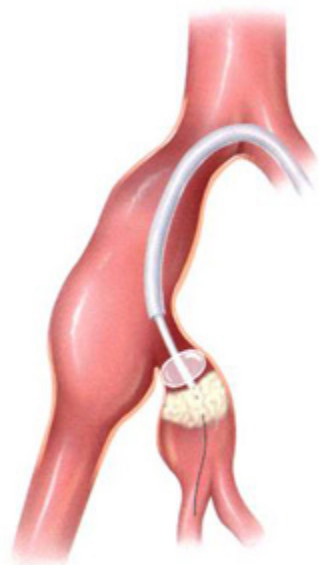
Common Iliac: Zenith® Branch Iliac Endovascular Graft

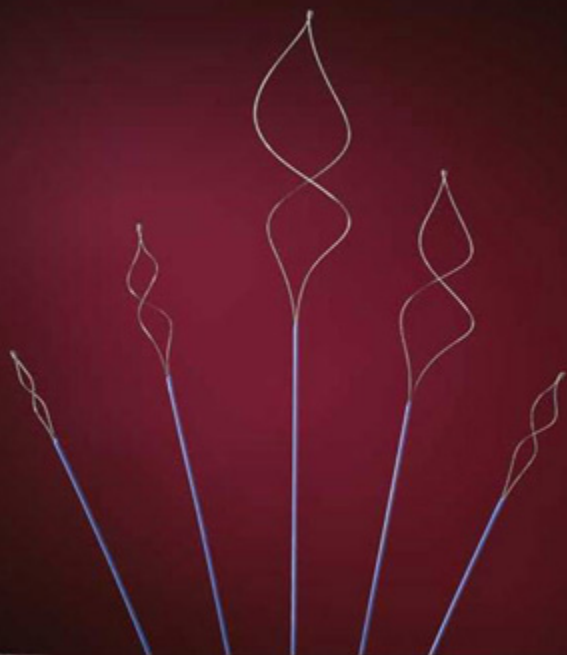
- Helical Branch

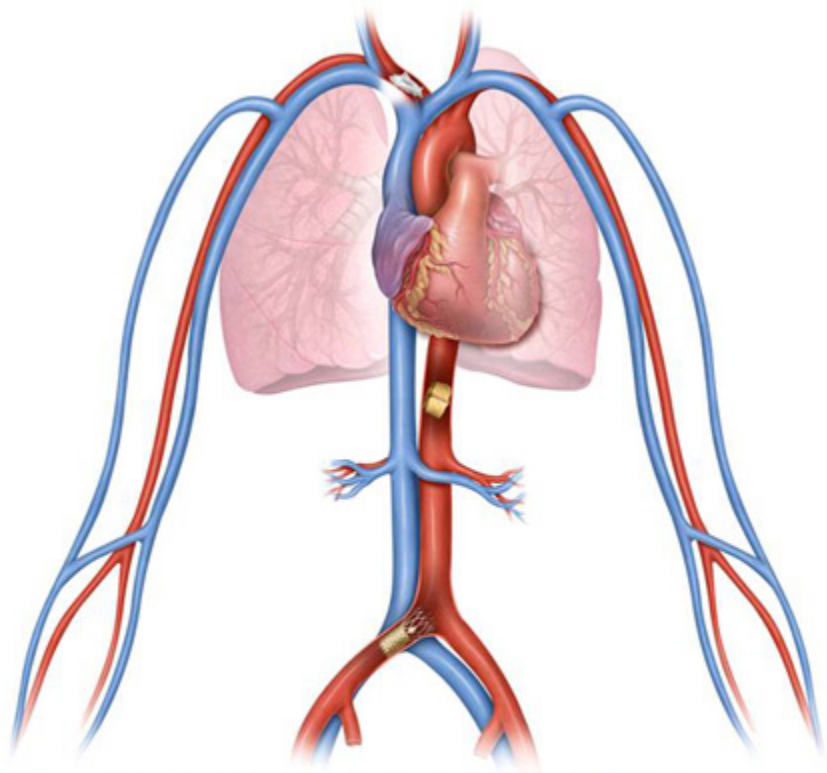


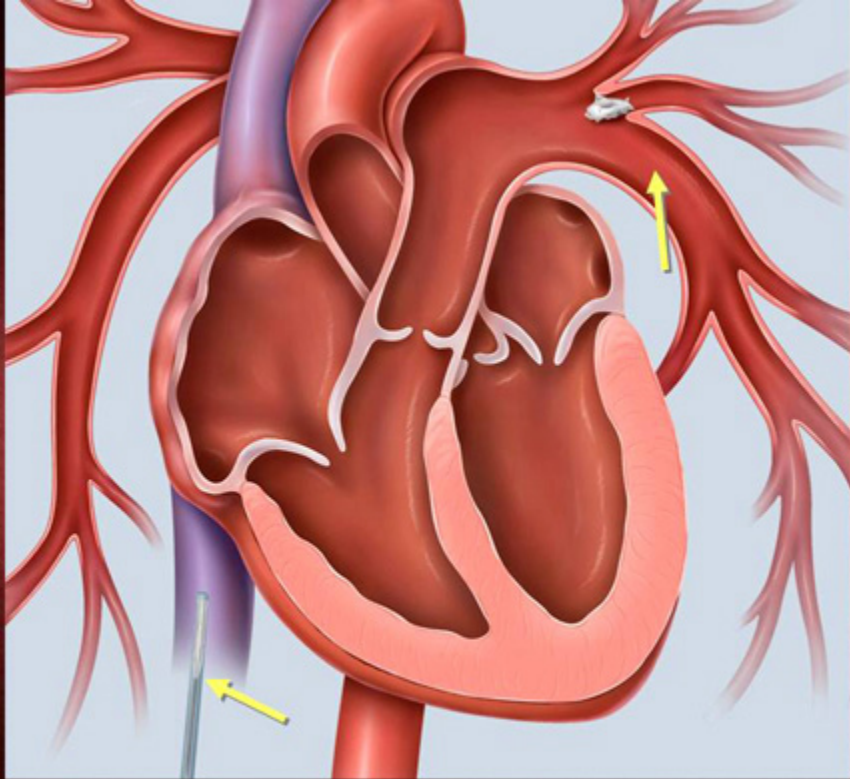


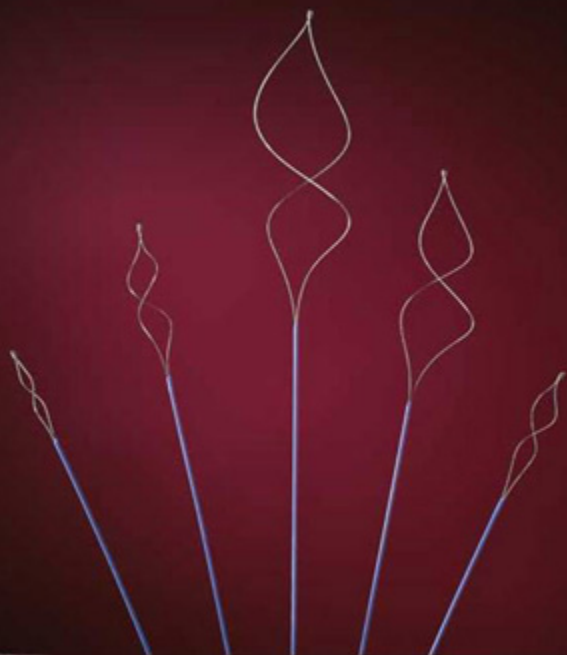


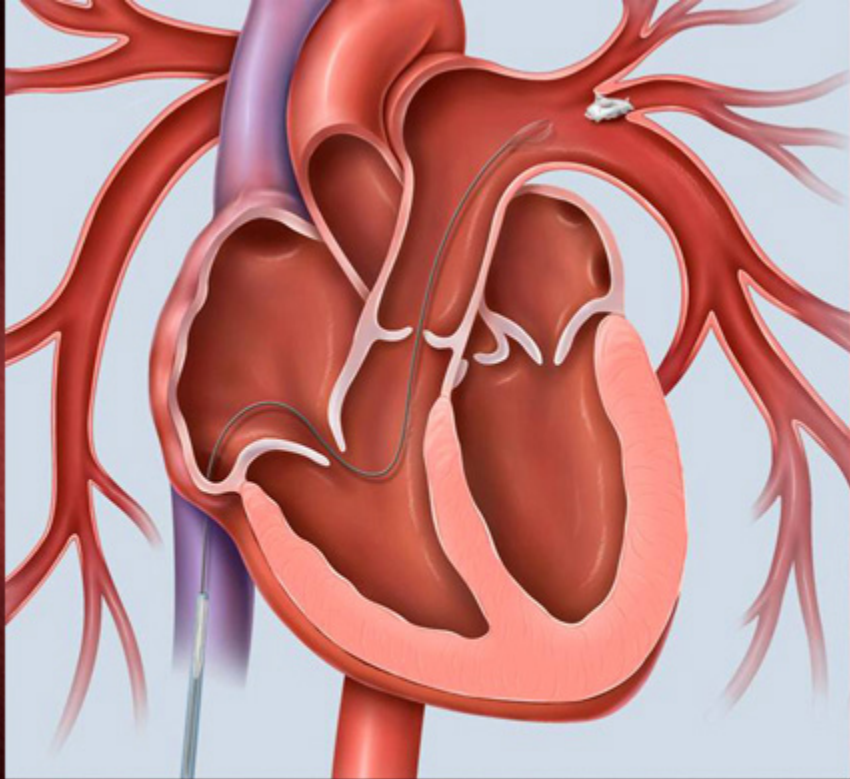


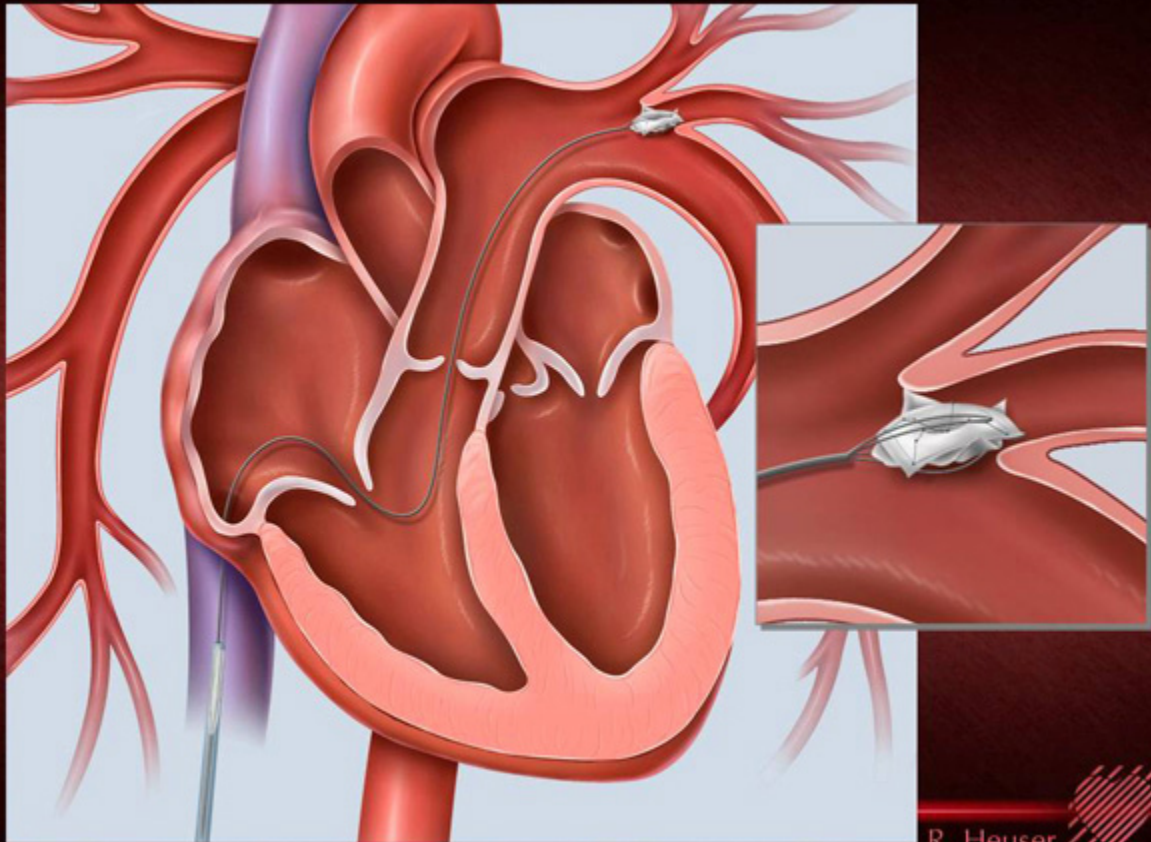


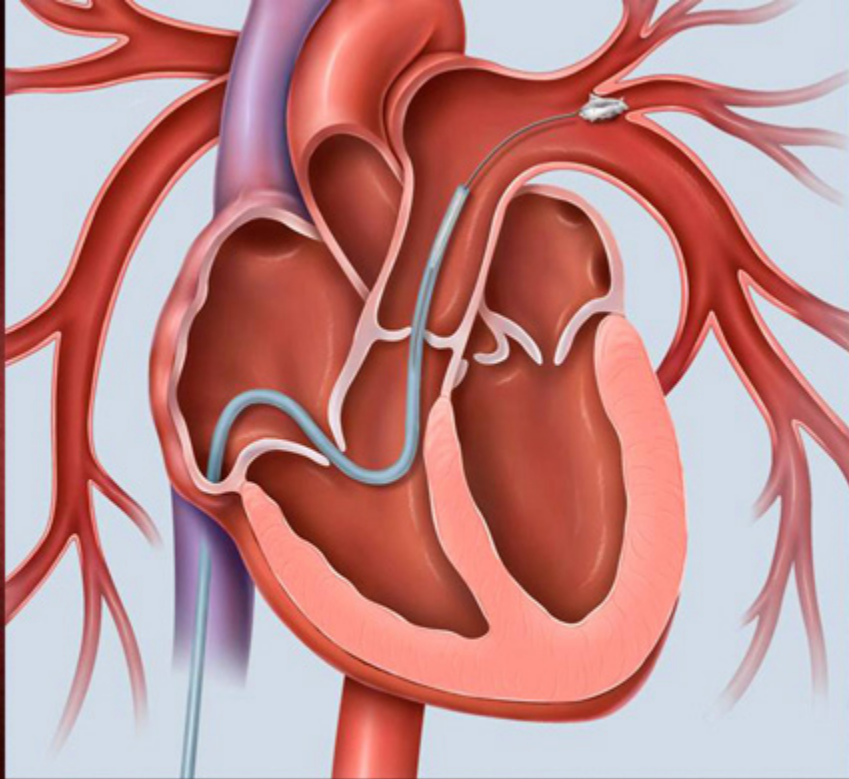


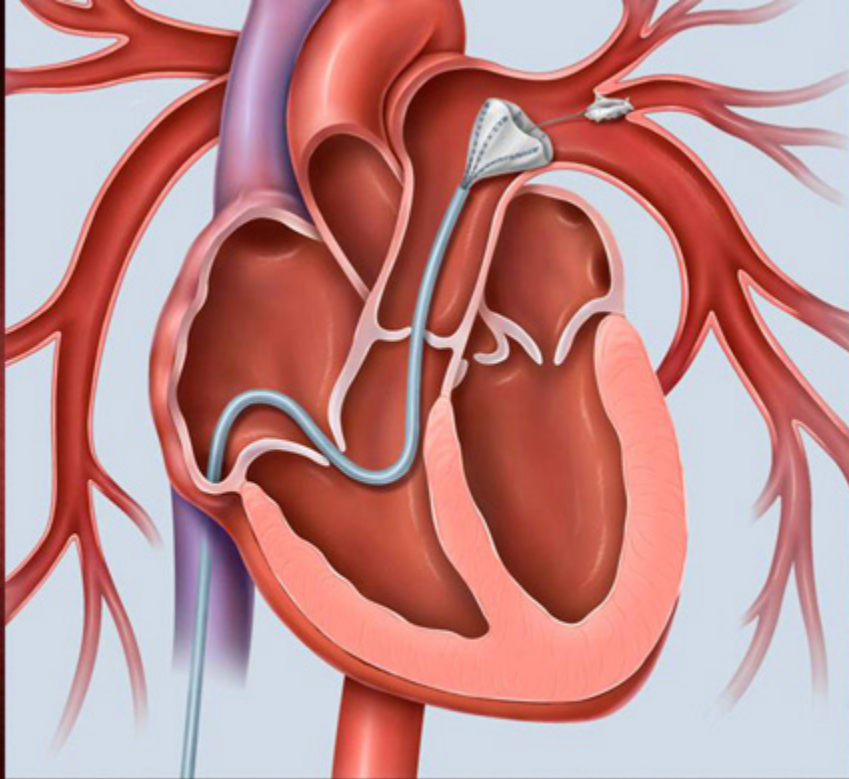


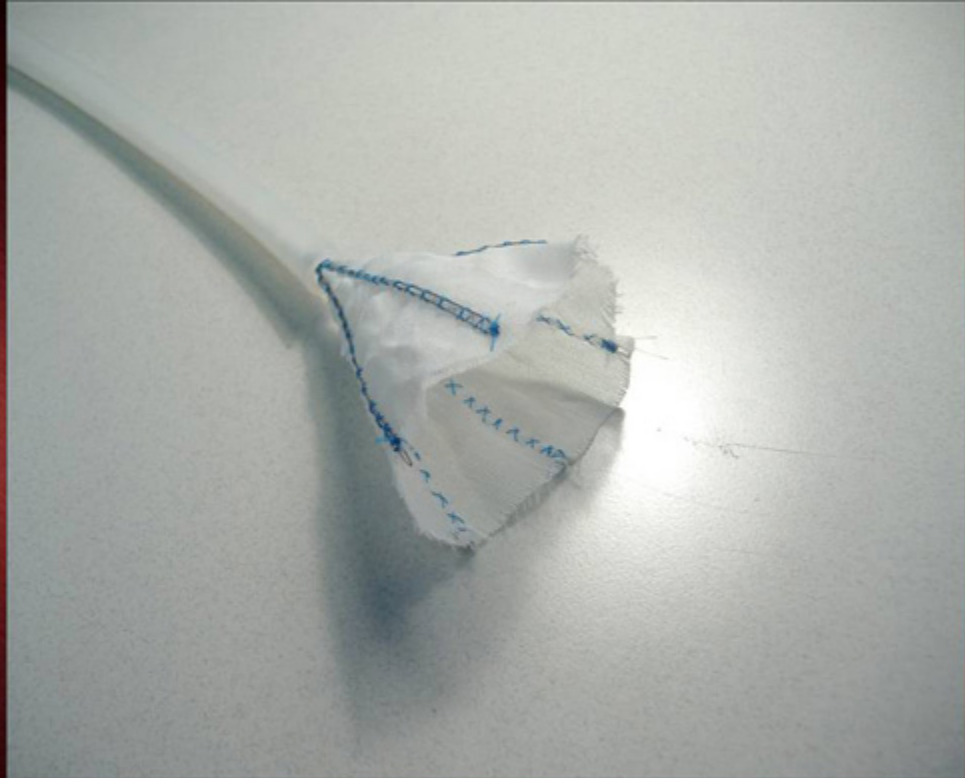


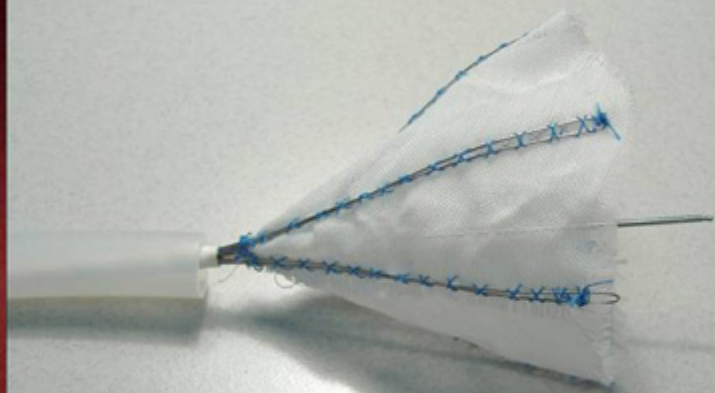


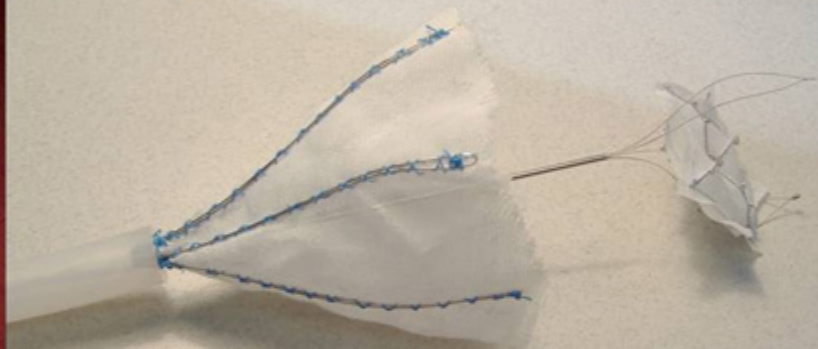


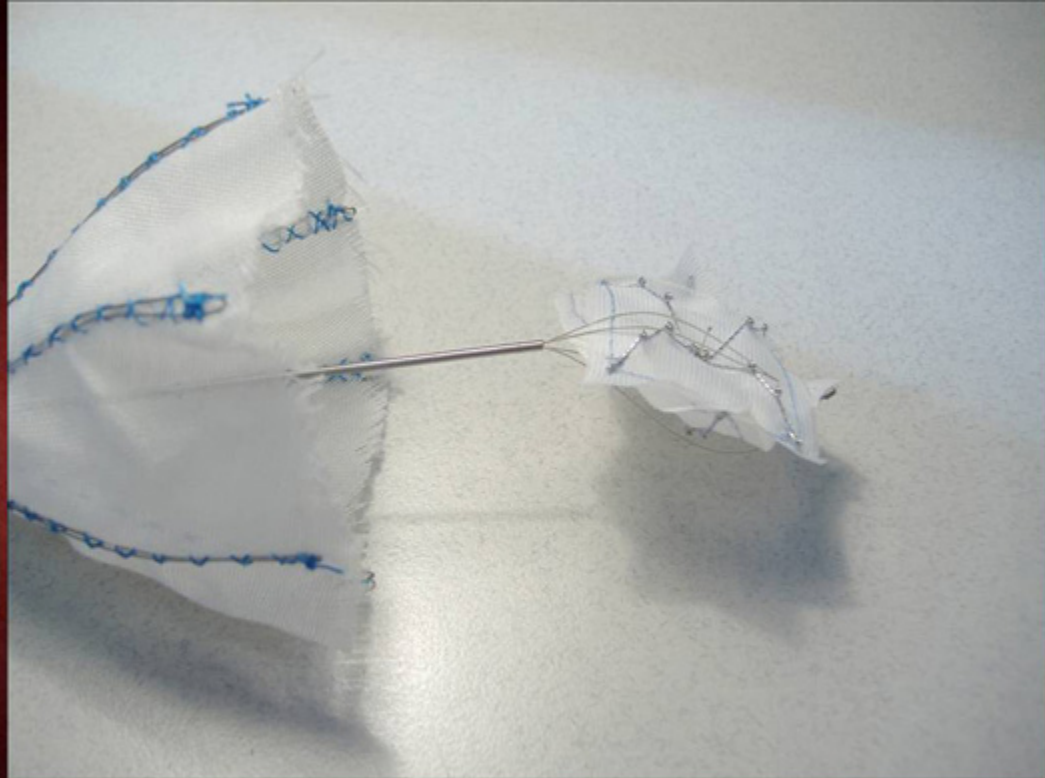




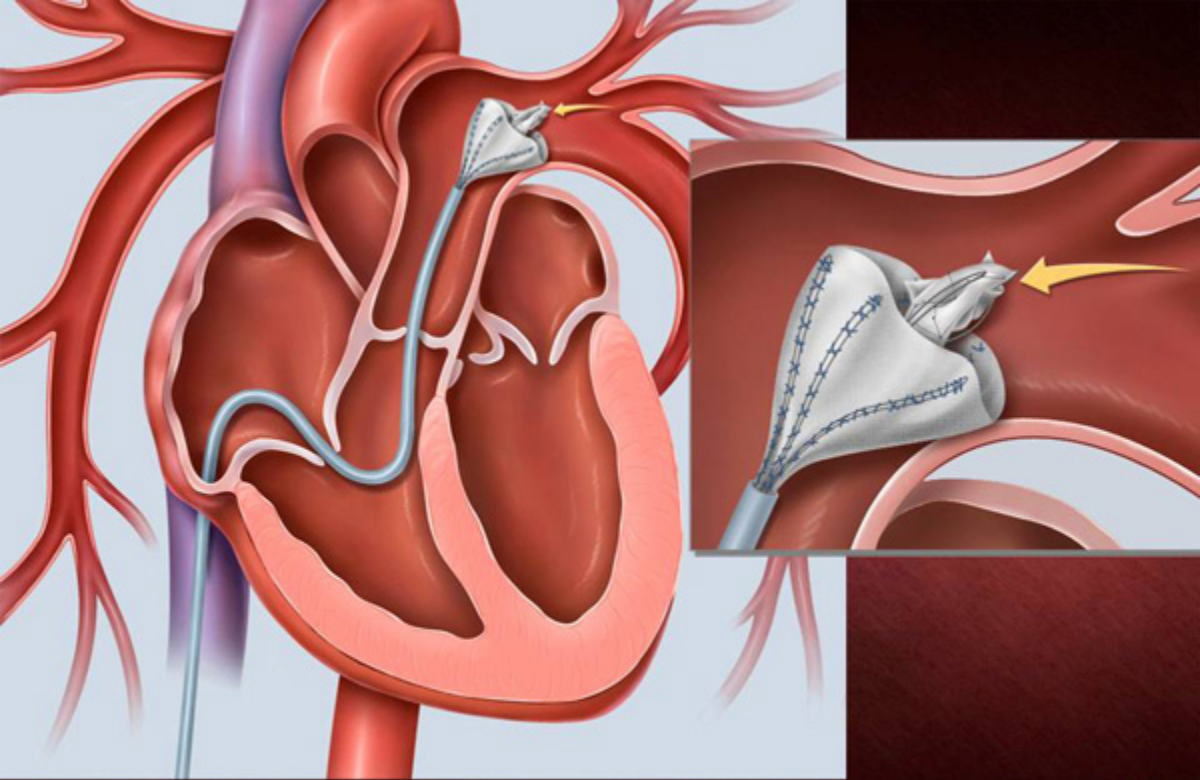


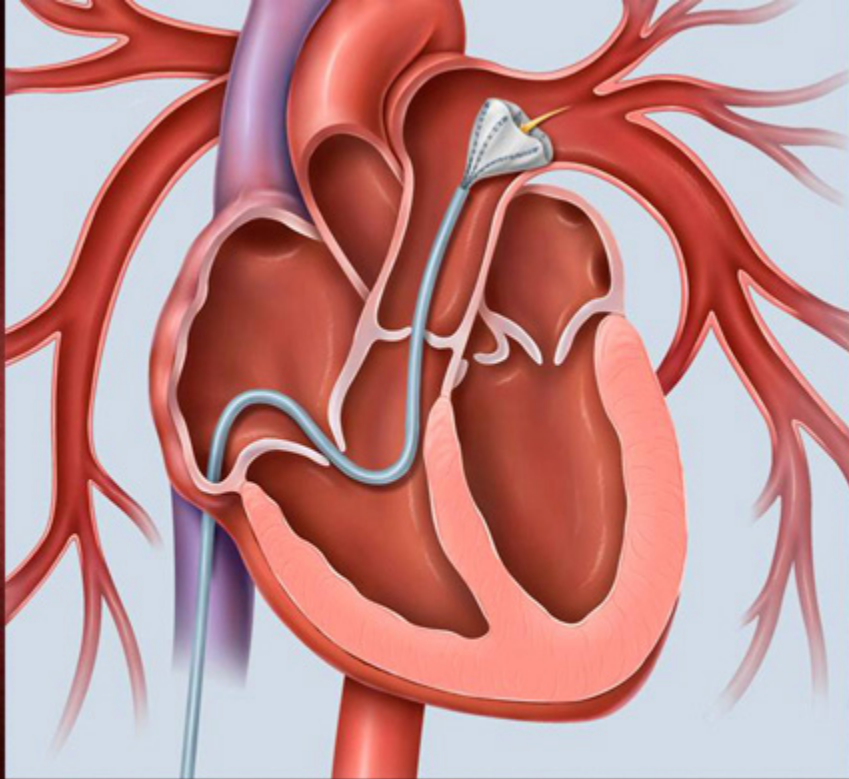


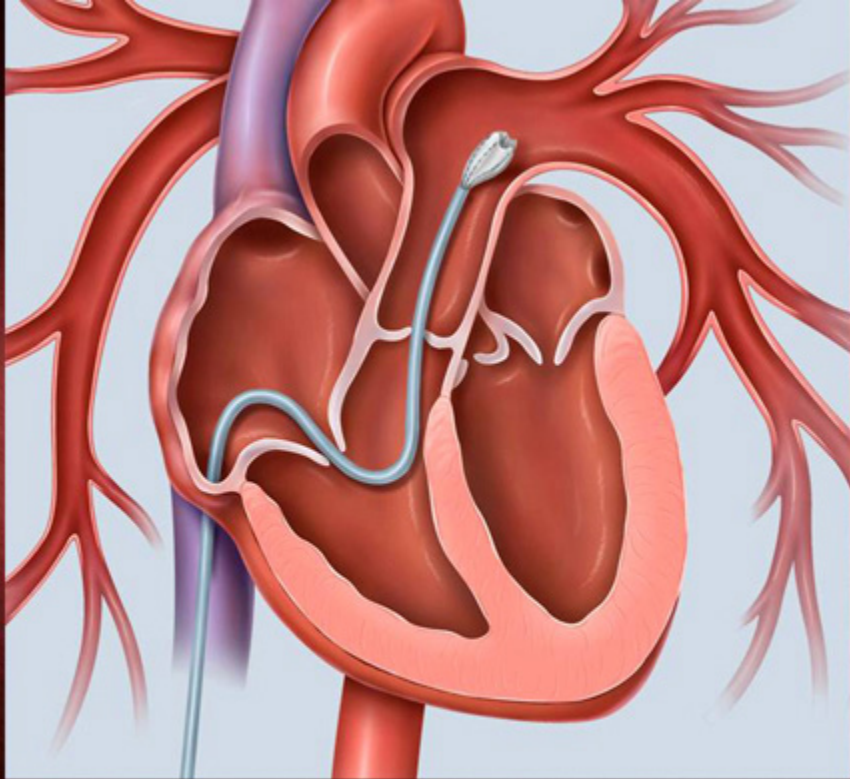


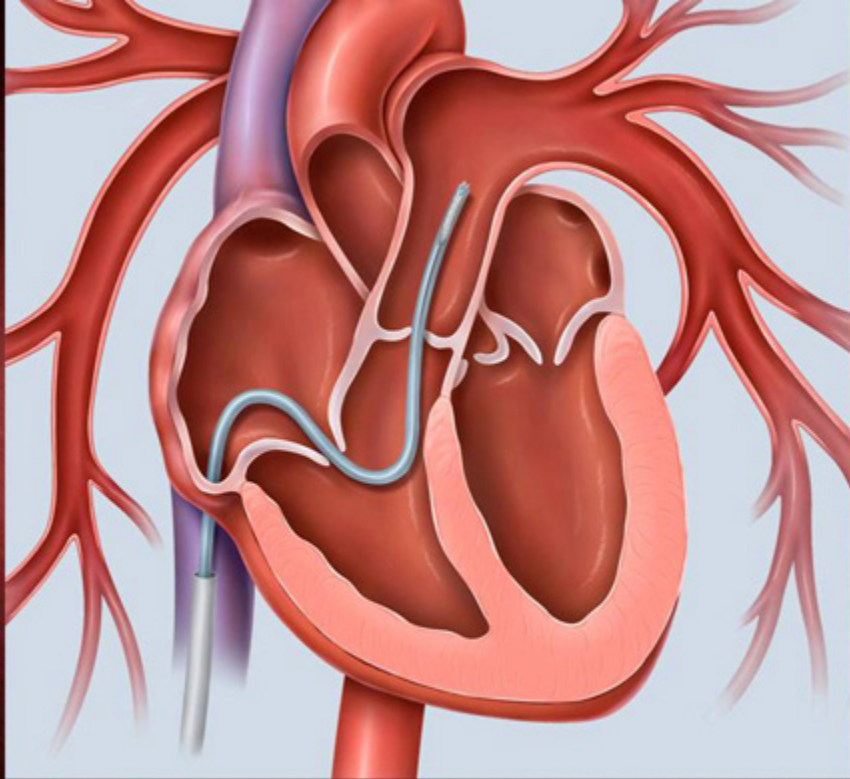


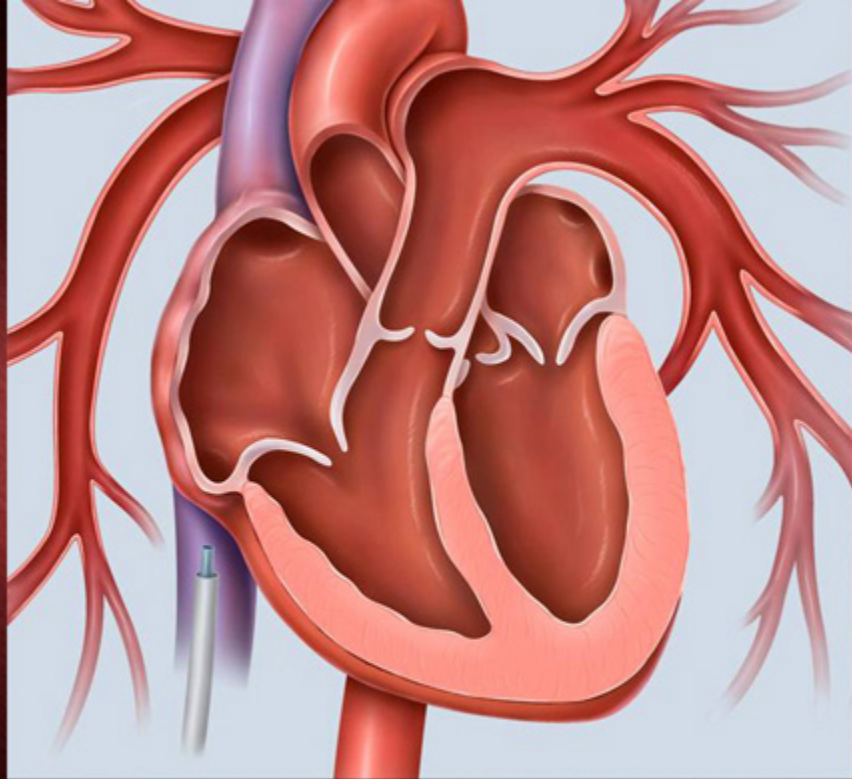


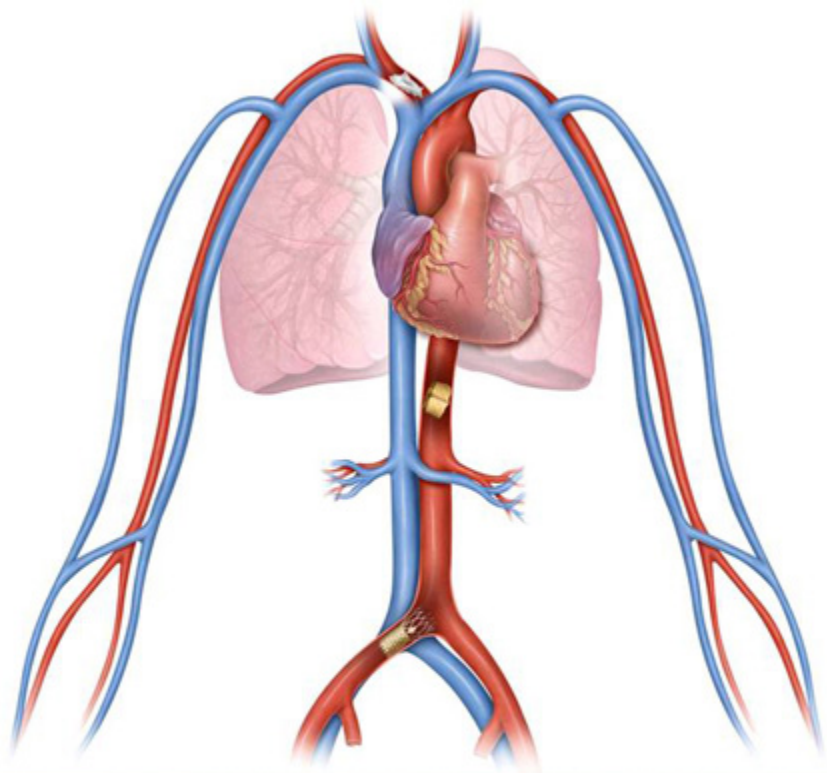














Outcome of Patients After Transcatheter Aortic Valve Embolization

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J Am Coll Cardiol Intv 2011;4:201-207. © 2011 American College of Cardiology

OBJECTIVE This study aims to assess the clinical outcomes for acute aortic valve embolization at the time of transcatheter aortic valve implantation (TAVI).

BACKGROUND Transcatheter heart valve (THV) embolization is a rare but serious complication during TAVI. Although various techniques have been developed to manage acute complications and reduce periprocedural morbidity, notably, long-term clinical and hemodynamic consequences for these techniques remain unknown. The aim of this study was to describe the clinical and hemodynamic outcomes of a novel THV embolization technique, which were compared to those of a conventional technique. The acute results of the embolization technique and TAVI were compared to those of aortic valve replacement. The THV migration and strut fractures/degeneration were assessed by computed tomography.

RESULTS A total of 7 patients had THV embolization, all of which occurred immediately after valve deployment. The embolized THV was repositioned in the aortic arch proximal to the left subclavian artery ($n = 2$), immediately distal to the left subclavian artery ($n = 2$), and in the abdominal aorta ($n = 3$). Successful repositioning was achieved in all cases. There were no deaths and at the time of a second TAVI, the embolized THV was completely covered by the new valve. The procedure was performed in 1 patient of whom the valve was deployed 2 days. Complications of the embolization were similar to those of aortic valve replacement. The embolized THV was covered by the new valve in all cases I or II at final follow-up. Mid-term computed tomography follow-up ($n = 4$; 591 to 1,548 days) showed that the leaflets of the embolized THV remain open in all phases of the cardiac cycle. There was also no strut fracture or migration of these valves.

CONCLUSIONS Clinical outcomes remain good when THV embolization is managed effectively. The embolized THV was covered by the new valve in all cases. There were no deaths and at the time of a second TAVI, the embolized THV was completely covered by the new valve. The embolized THV was covered by the new valve in all cases I or II at final follow-up. Mid-term computed tomography follow-up ($n = 4$; 591 to 1,548 days) showed that the leaflets of the embolized THV remain open in all phases of the cardiac cycle. There was also no strut fracture or migration of these valves.

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All aortic valves were dilated in the aorta (left in place)
What happens in the future?



Aneurysms

- 1st successful open repair of aneurysm repair was in 1951 by Dr. John Freeman's group as iliac vein graft

Charles Dubost used an aortic homograft to replace the aneurysm

- 1st Complete Repair Occurred September 2, 1954 -- Michael DeBakey

SUBJECTED TO LEVEL 1 EVIDENCE



OPEN REPAIR

- Does Require Intensive Follow Up and Surveillance
- 51.8% **WHO HAD OPEN REPAIRS** Have Endoleaks or Pseudoaneurysms
- Only 64% Fully Ambulatory Post Open Repair **WOULD NOT HAVE IT AGAIN**



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



CONCLUSION

- Endograft repair of abdominal aortic aneurysm should be considered in all patients who present with a significant AAA
- The results appear to be relatively safe
- Endoleaks and late complications can occur, but can usually be managed effectively non-surgically

