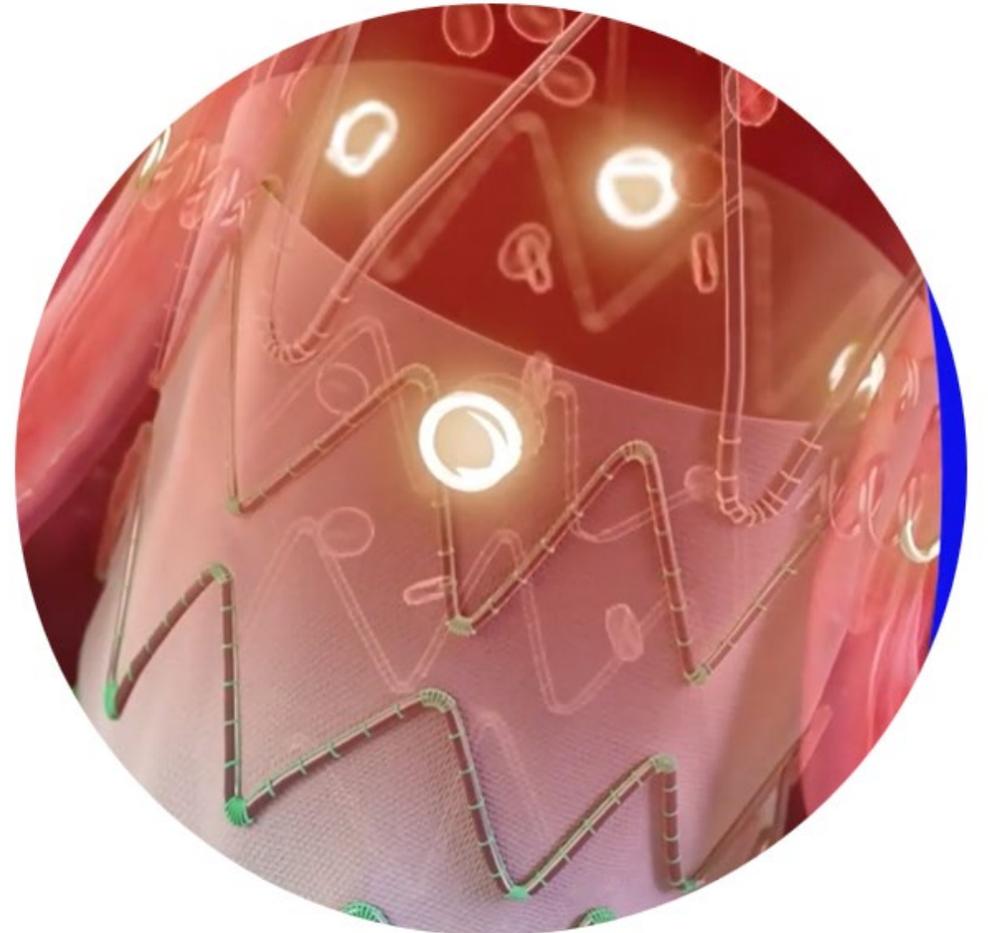


Insertion of Endovascular Anchors

**ICD-10 Coordination and Maintenance Committee Meeting
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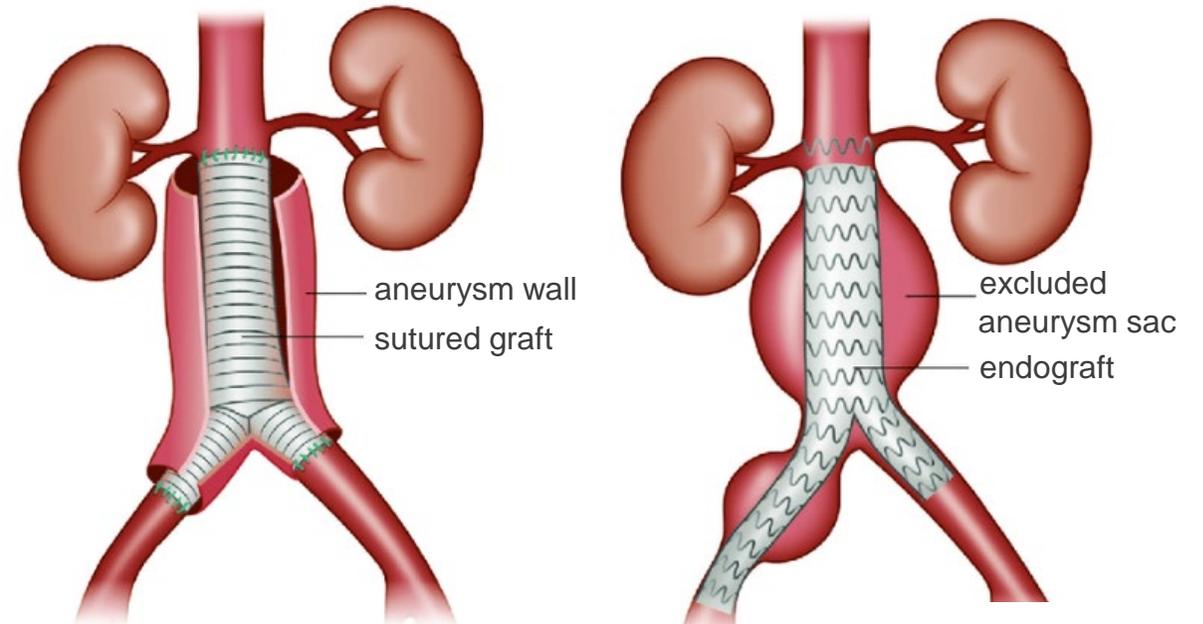
Aortic Aneurysm Overview

Diagnosis

- Aortic aneurysm is abnormal dilatation of a weakened segment of the aorta.
- Aneurysms are typically progressive and continue to enlarge, increasing the risk of dissection and rupture.

Treatment

- Open repair of an aortic aneurysm consists of surgically removing the weakened segment and replacing it by suturing in a graft.
- Endovascular aortic aneurysm repair (EVAR) relines the lumen of the aorta to exclude the enlarged segment.



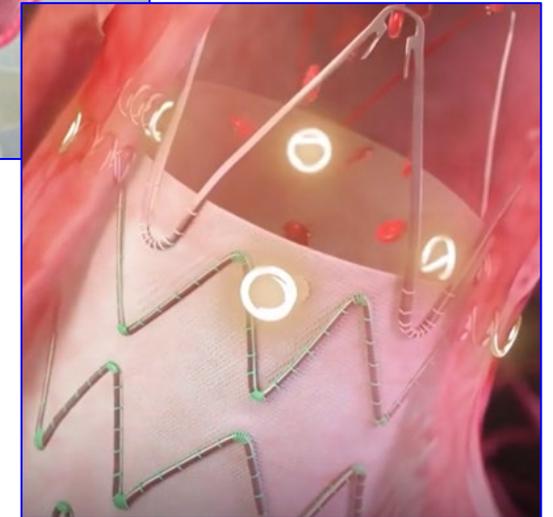
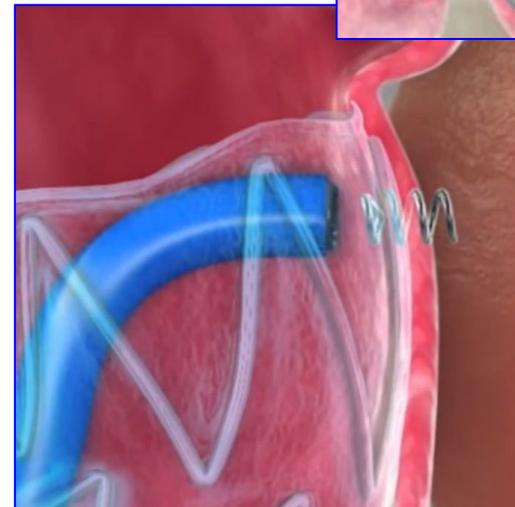
Endograft Mechanism of Action

Passive Outward Radial Fixation

- The large majority of endografts are held in place simply by the outward force of their own struts.

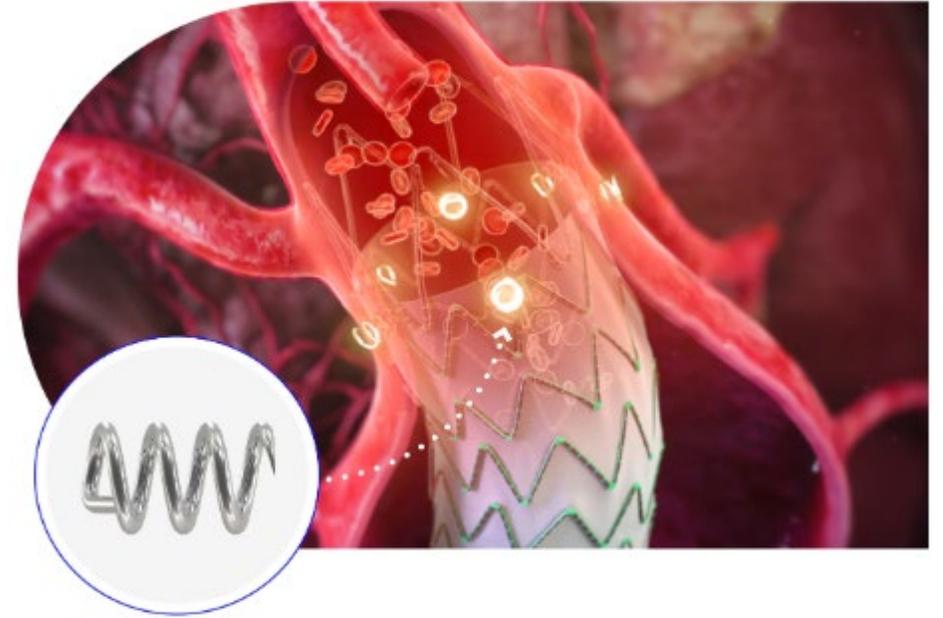
Active Transmural Radial Fixation

- In a select group, endografts are held in place by implanted endovascular anchors.
- Endovascular anchors extend across the endograft and the aortic wall, creating an active seal.



Endovascular Anchors

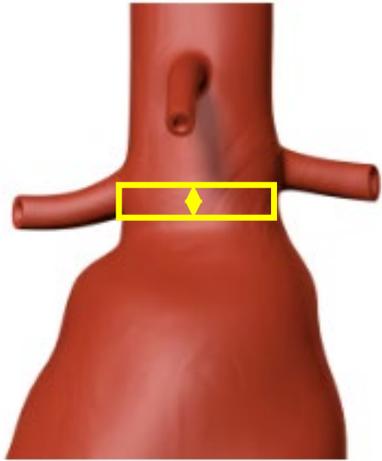
- Endovascular anchors are metallic helical implants that reinforce the endograft proximal seal zone.
- They can be used for repair of abdominal aortic aneurysms and thoracic aortic aneurysms.
- They are *not* routinely used or placed with most EVAR procedures.
- Typically, endovascular anchors are used in the subset of patients with hostile neck anatomy.



Fun Fact!

Endovascular anchors were initially designed to mimic the effect of surgical sutures used in open repair of aortic aneurysm, leading to the false impression that they are sutures.

Hostile Aneurysm Neck Anatomy



Short aneurysm neck

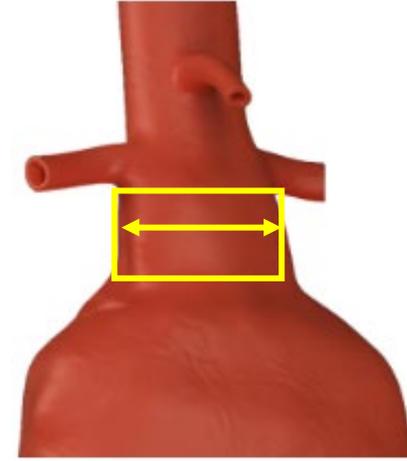
<15 mm

risk: leads to reduced infrarenal sealing zone

Wide aneurysm neck

≥28 mm

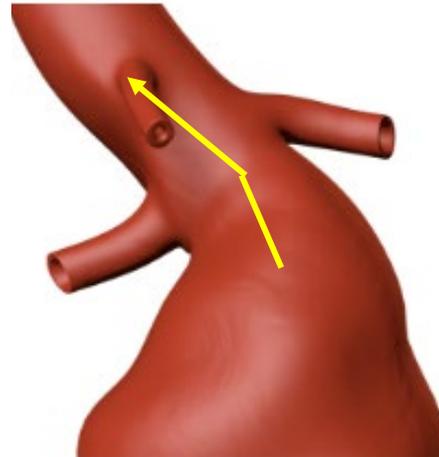
risk: more prone to endoleak



Angulated aneurysm neck

≥60%

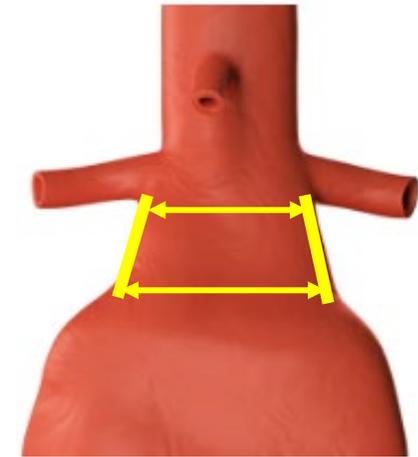
risk: bird-beaking interferes with proximal sealing



Conical neck aneurysm

progressive diameter

risk: more prone to graft migration and endoleak



Suboptimal Outcomes in Hostile Neck Anatomy

- Hostile neck anatomy increases the complexity of EVAR procedures.
- The risk of suboptimal outcomes and complications is significantly higher.

Hostile Neck Anatomy

- 4.5x increased risk of type Ia endoleak
- 10x increased risk of aneurysm-related mortality

Wide Aneurysm Neck

- 6.7x more likely to have type Ia endoleak
- 10x more likely to have aneurysm sac expansion
- 5.1x more likely to lead to aneurysm rupture

EVAR Risks and Indications for Endovascular Anchors

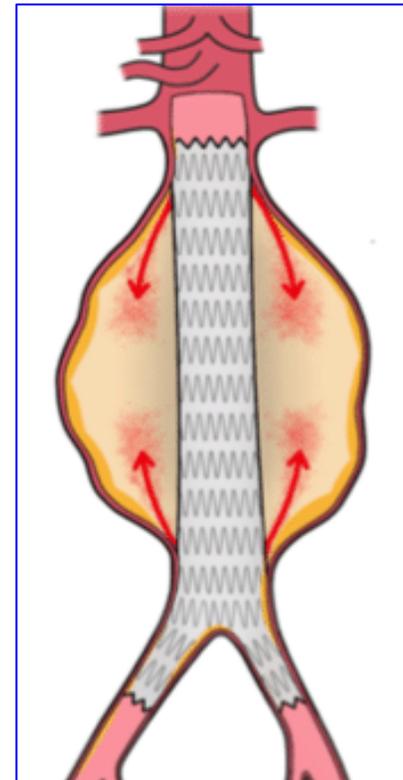
- Endograft migration, loss of seal (endoleak), and failure of the aneurysm to shrink are known complications of EVAR procedures.
- These can increase the risk of AAA rupture.

Initial EVAR Procedures

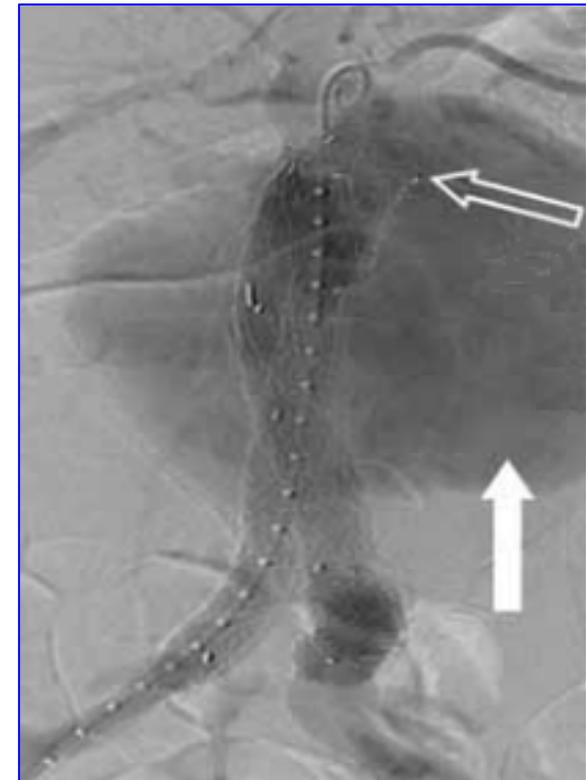
- Endovascular anchors are placed in patients at risk of these specific EVAR complications.

Revision EVAR Procedures

- Endovascular anchors are also used to treat patients currently experiencing these complications.



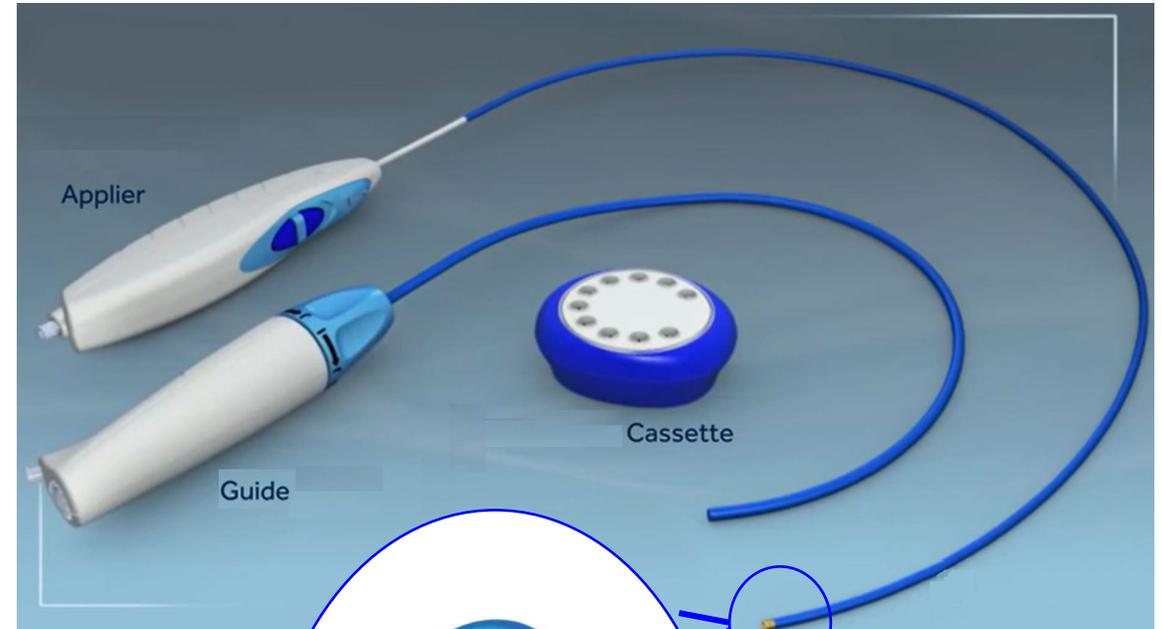
type Ia endoleak



endograft migration with AAA rupture

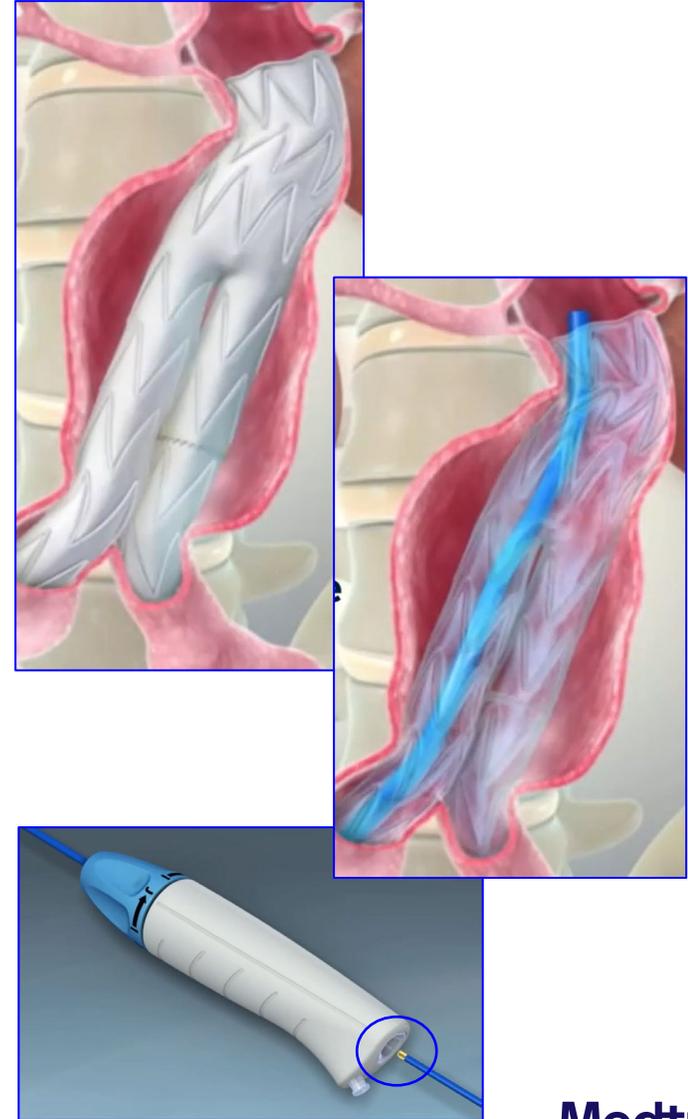
Endovascular Anchor System

- The system has three components:
 - guide catheter through which the applier is advanced
 - applier which delivers the anchors
 - endovascular anchors in a pre-loaded cassette
- The system is compatible for use with aortic aneurysm endografts from multiple manufacturers.
- The anchors are the only permanent implants.



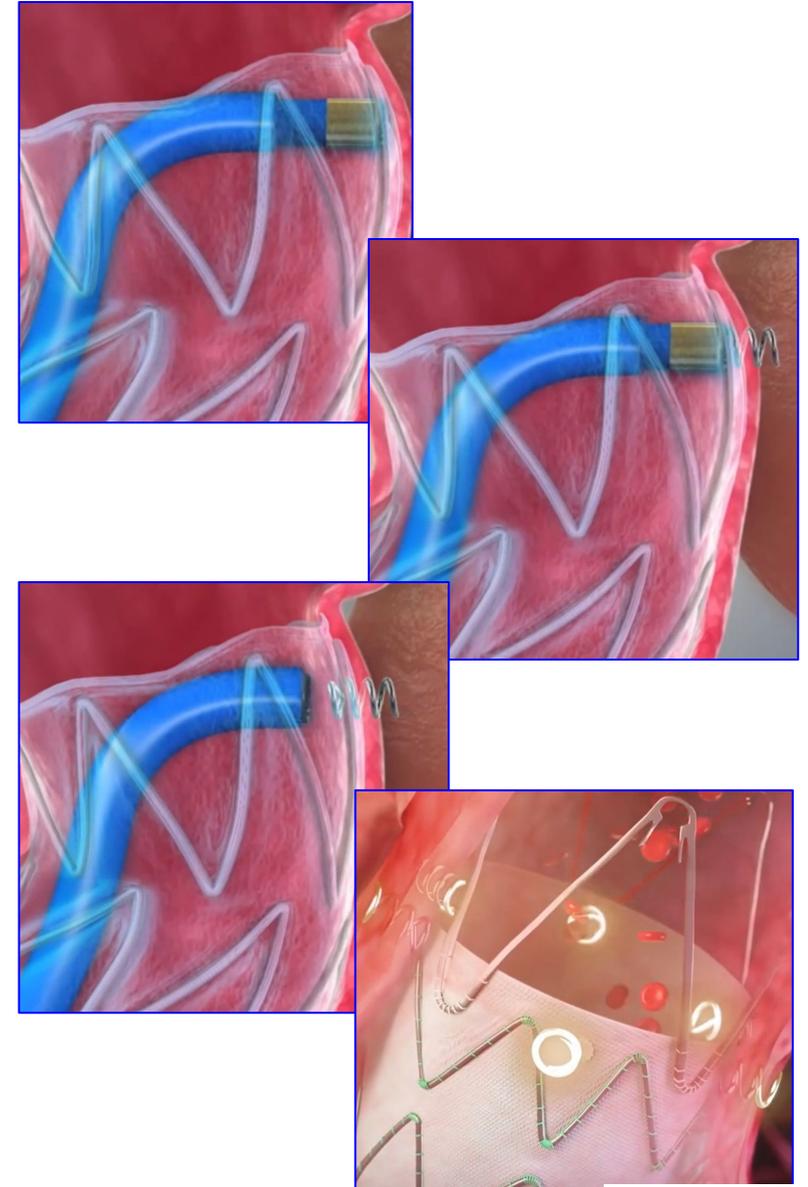
Procedural Steps to Implant Endovascular Anchors

- Access is via the femoral artery:
 - initial EVAR procedure: access for the endograft is also used for the endovascular anchors
 - revision EVAR: new access is established
- Under fluoroscopic guidance, the guide catheter is advanced to the aorta and through the endograft
- It is then positioned in the endograft proximal seal zone.
- Each endovascular anchor is loaded onto the applicator delivery catheter.



Procedural Steps

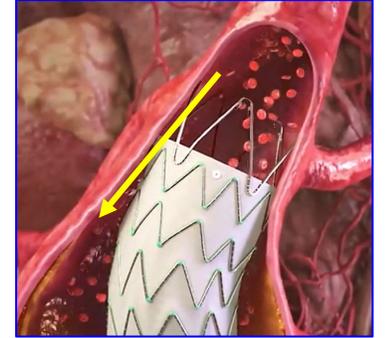
- The applicator delivery catheter carrying the endovascular anchor is advanced through the working channel of the guide catheter.
- After positioning is checked, the endovascular anchor is individually deployed through the inner wall of the endograft and across the aorta.
- As needed, the endovascular anchor can be retracted and repositioned prior to final deployment.
- Each endovascular anchor is individually delivered and deployed using the applicator delivery catheter.



Distinct Therapeutic Outcomes of Endovascular Anchors

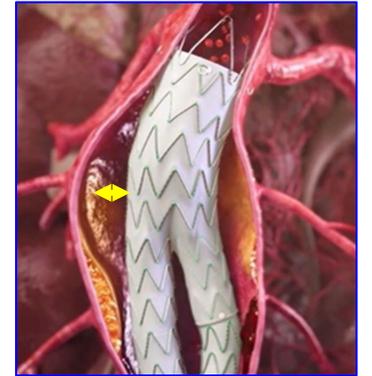
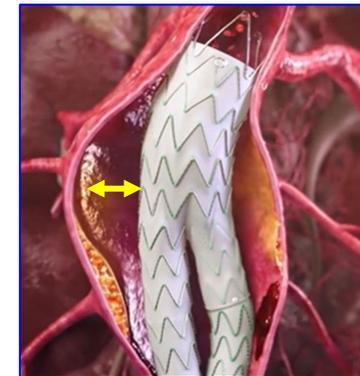
Arrest of progressive aneurysm neck dilatation

- Due to the heart's continual pulsing, dilatation of aortic aneurysms may continue post-EVAR for endografts without transmural radial fixation.
- Endovascular anchors prevent progressive neck dilatation.
- This is associated with significant reduction in type Ia endoleaks.



Regression of aneurysm sac

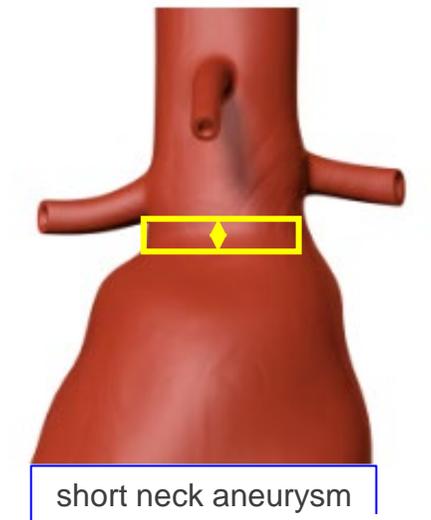
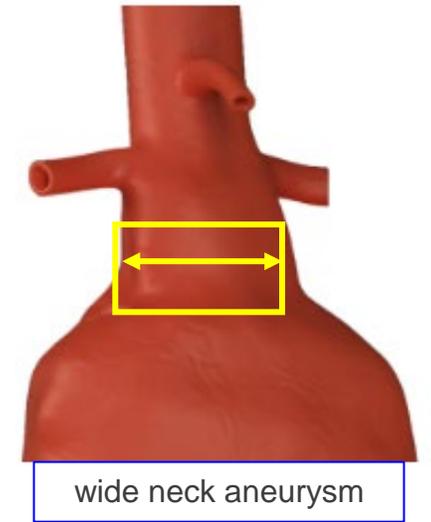
- Use of endovascular anchors markedly improves regression of the existing aneurysm sac.
- Sac regression is associated with lower mortality and morbidity and reduced need for reintervention.



Medtronic

Improved Outcomes in Hostile Aneurysm Neck Anatomy

- Registry data for use of endovascular anchors over 3 years demonstrate multiple improved outcomes for wide neck aneurysms:
 - 98.5% freedom from type Ia endoleaks
 - 100% freedom from endograft migration
 - 100% freedom from aneurysm rupture
 - 60% aneurysm sac regression and 30% aneurysm sac stability
- Similarly, registry data for use of endovascular anchors over 5 years demonstrate multiple improved outcomes for short neck aneurysms:
 - 90% freedom from aneurysm-related mortality
 - 77% freedom from reinterventions
 - 68% aneurysm sac regression and 13.6% aneurysm sac stability



Procedure Documentation

- Placement of endovascular anchors is documented in the procedure report.
- Endovascular anchors may be referred to using various terms:
 - endoanchors
 - endostaples or endosutures
 - Aptus screws or Aptus implants
 - Heli-FX

FDA Status

- Endovascular anchors have been FDA approved as cardiovascular devices since 2011.

Clinical Data

In the 10+ years since endovascular anchors have been used, mid-term and long-term clinical data on their effects have been developed and analyzed.

Significant evidence supports their efficacy in bringing about unique therapeutic outcomes in selected patients, warranting unique identification in the encoded data.

Clinical questions?

