APTUS ENDOSYSTEMS

ICD10-PCS Coding Proposal for Aptus® Heli-FX™ Procedure

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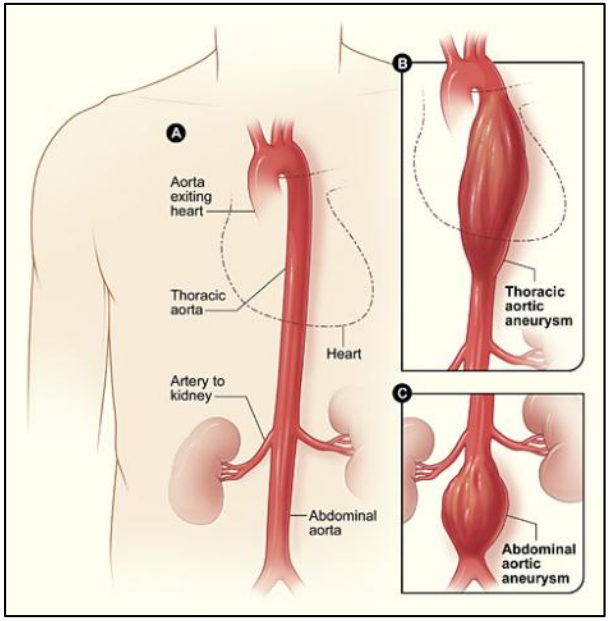
Baltimore, MD

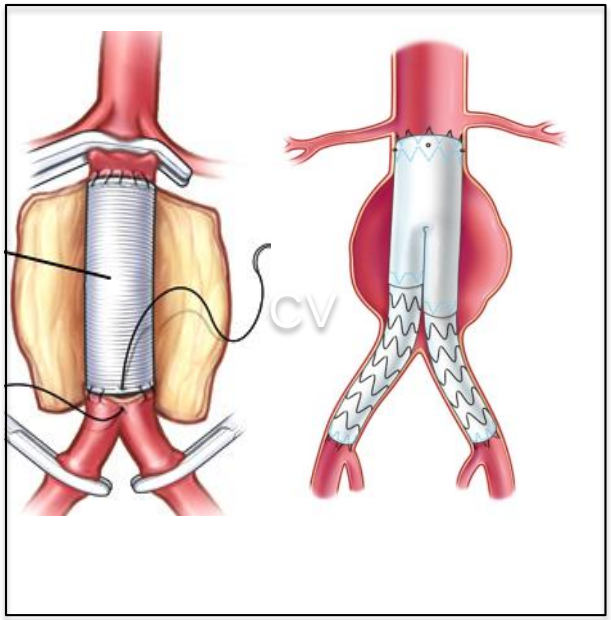
ICD10-PCS Coding Proposal: Aptus Heli-FX Procedure

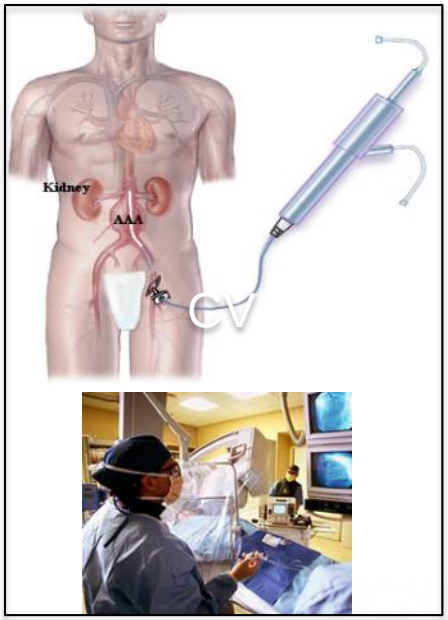
Agenda

- Heli-FX Clinical Benefit
- Heli-FX Procedure Overview
- Rationale for new ICD10-PCS Codes
- ICD10-PCS Coding Request

Aortic Aneurysms Have Two Treatment Options:
Open Surgical and Endovascular Aneurysm Repair







Aortic Aneurysms:
- Thoracic
- Abdominal

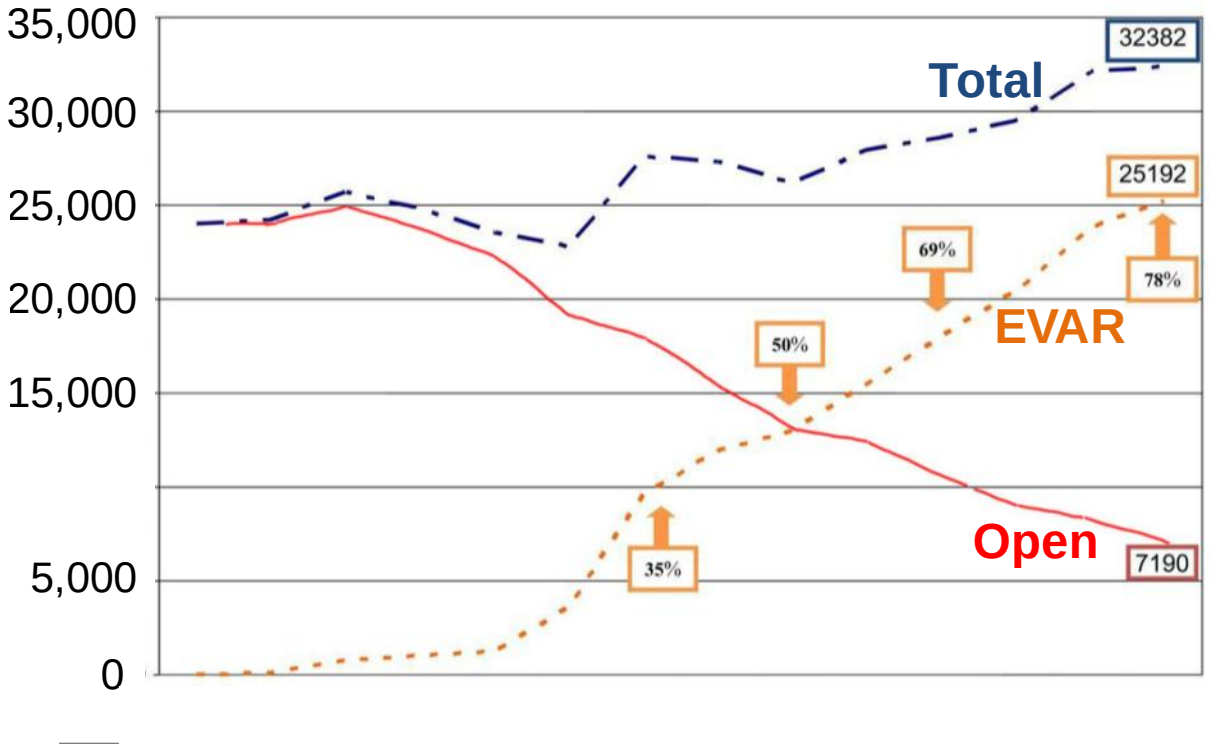
Repair:
- Open Surgical
- Endovascular

Endo Repair
- Less morbidity
- Durability?
- Anatomical limitations

Endovascular Aneurysm Repair (EVAR):
Now Most Common Procedure for Aortic Aneurysm Repair in US

By 2009, ≈45,000 elective aortic aneurysm repairs performed in US Medicare population.

Among > 30,000 infrarenal repairs ≈80% performed with EVAR.



Journal of Vascular Surgery

Sachs T , et al. *J Vasc Surg.* 2011;54:881–888

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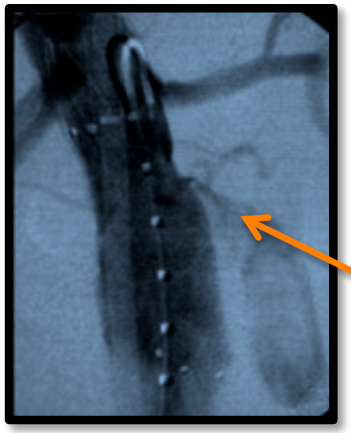
"Achilles Heel" of EVAR: Despite Advances in Endografts,
Late Failure Remains, Life Long F/U Still Required

- Loss of proximal neck seal and/or fixation = endoleaks, migration, aneurysm repressurization, enlargement, rupture
- Most failure and 2nd interventions occur at proximal aortic neck
- Presence of hostile prox neck increases risk of late complications, often contraindicates endo Tx option
- Risk of complications continues through each year of follow-up.

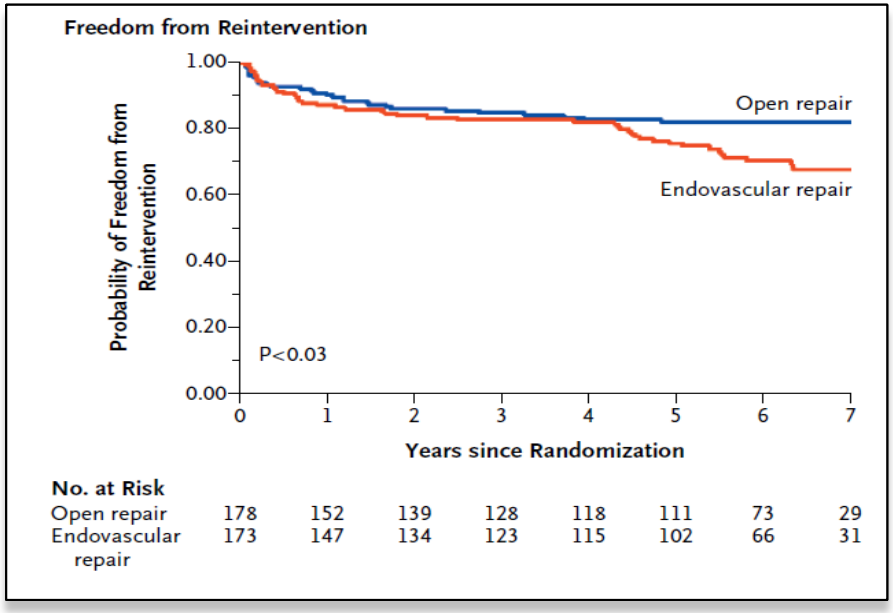


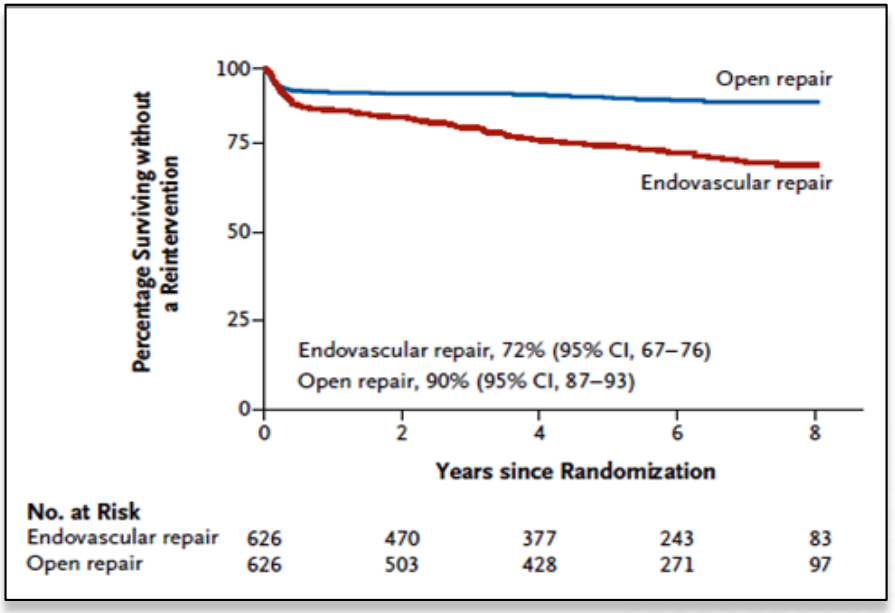
Type 1 Endoleak

Loss of fixation, seal due to migration

Landmark EVAR-1 & DREAM Trials:
Higher Complications & 2nd Interven. in EVAR vs. Open Repair

The NEW ENGLAND JOURNAL of MEDICINE





De Bruin *et al*. N Engl J Med 2010;362:1881-9

R.M. Greenhalgh *et al*. N Engl J Med 2010, 10.1056/NEJM 0909305

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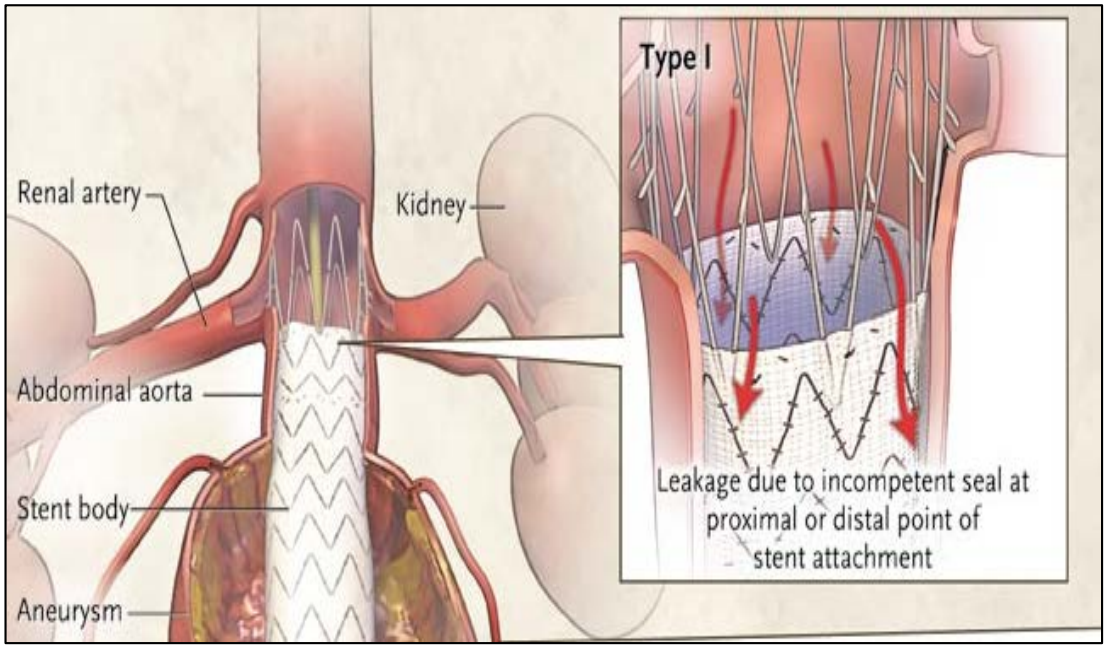
Proximal Neck Failure:
The Most Frequent Cause for 2nd Interventions and Explantation



Proximal neck issues occur early and late and ***must*** be corrected when detected

Journal of Vascular Surgery

Turney et al. *J Vasc Surg*. (30 December 2013)

ANNALS OF SURGERY

Wyss et al. *Ann Surg* 2010;252(5):805-12.

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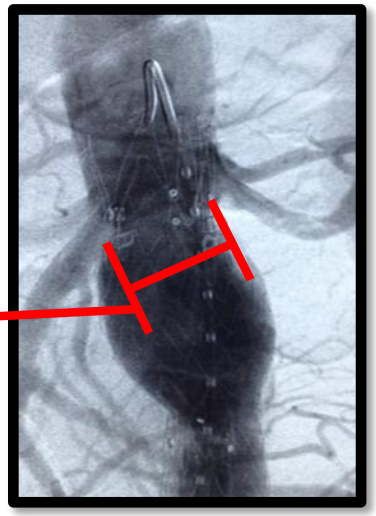
Hostile Prox Neck Compromises Acute, Early & Long Term

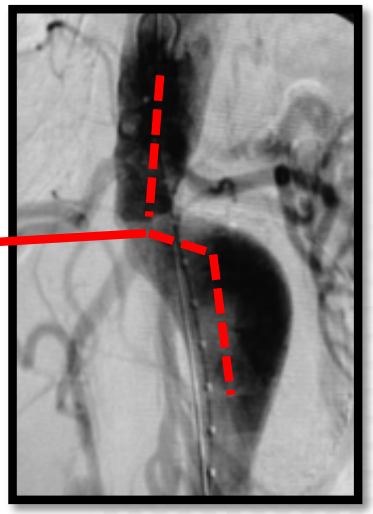
Seal & Fixation: Commonly Seen in EVAR Patients

Short <10-15mm (Length)



Large ≥28mm (Diameter)

Conical Shape

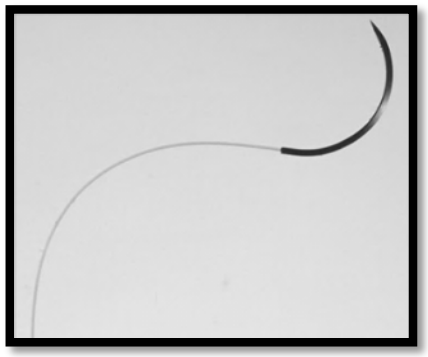


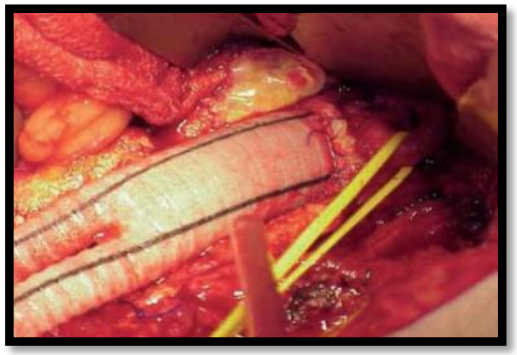
Angulated

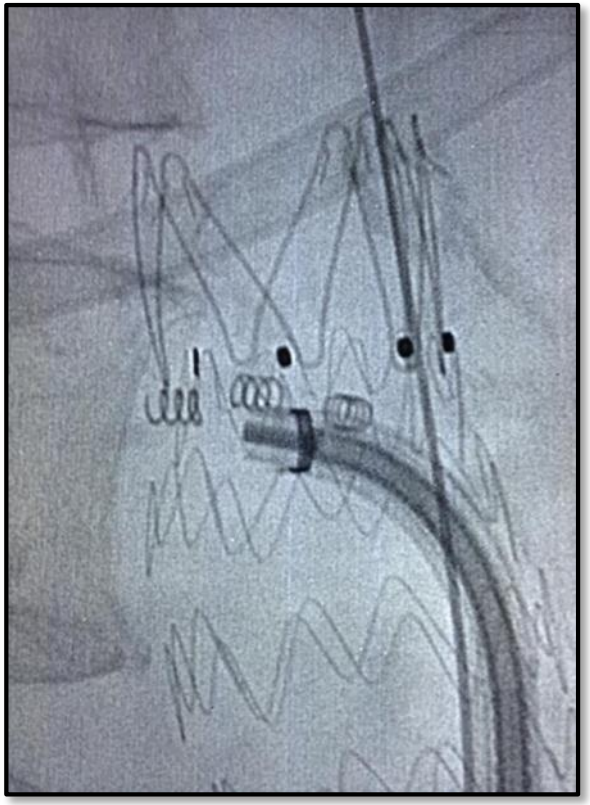
Excessive Thrombus & Calcium

Heli-FX Endovascular Procedure

Replicates the Gold Standard ‘Surgical’ Type Anastomosis

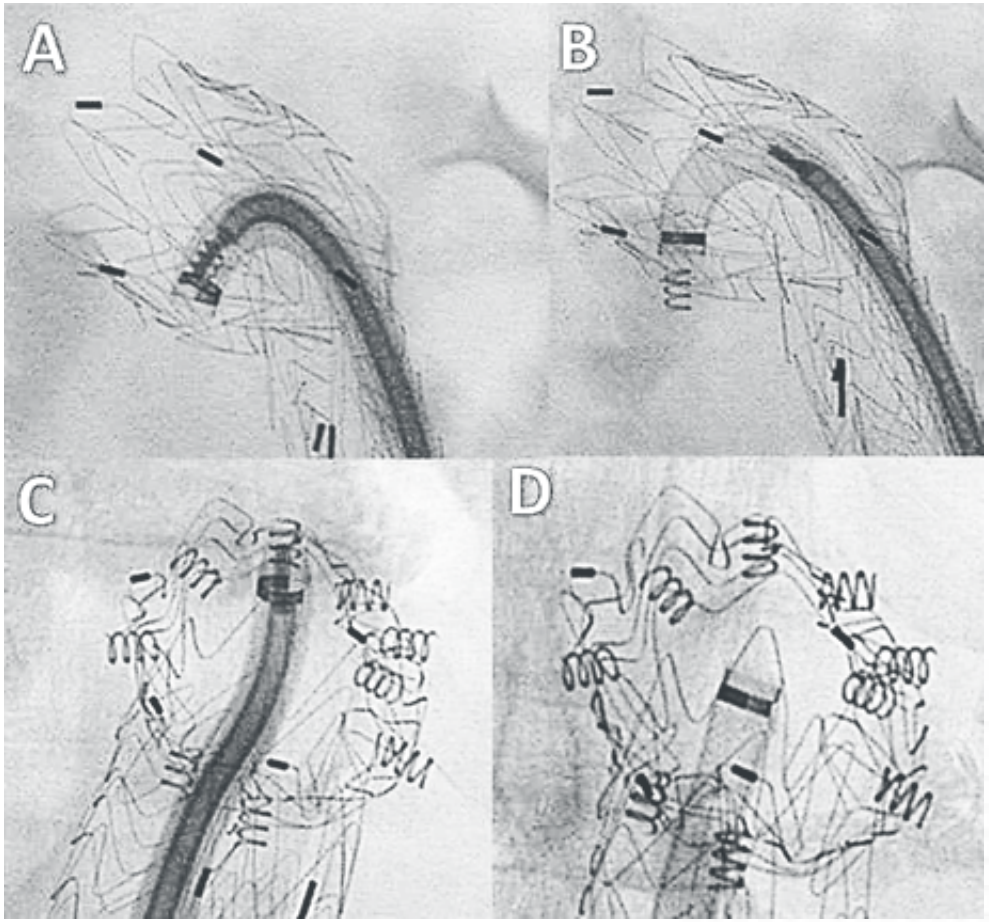






Heli-FX System includes Anchors, Applier, and Guide
Applier is Microprocessor Controlled, Guide is Steerable

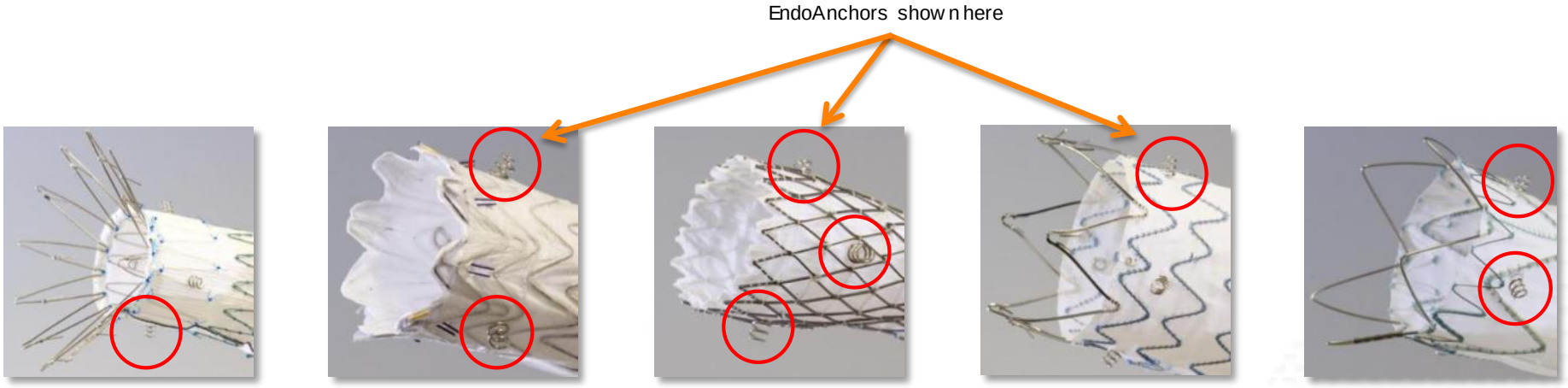
- Surgical-type anastomosis at proximal aortic neck (location of type Ia high-pressure endoleaks)
- Physician determined location and number of fixation points/anchors
- Similar versatility & limitations as open surgically sutured anastomosis (i.e. tissue strength, calcium, wall penetration)



Aptus Heli-FX System
510(k) Cleared, CE Marked: Indicated for Leading Endografts

- Intended to provide fixation and augment sealing between endovascular aortic grafts and aorta

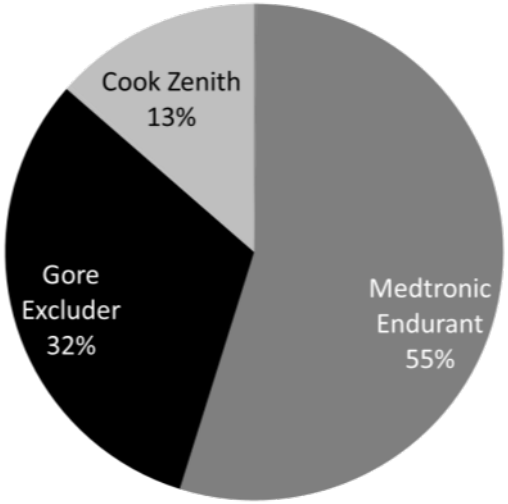
- Evaluated, determined compatible with Cook Zenith®, Gore Excluder®, Medtronic AneuRx®, Endurant® and Talent® (AAA), Cook Zenith TX2®, Gore TAG® and Medtronic Valiant® (TAA)



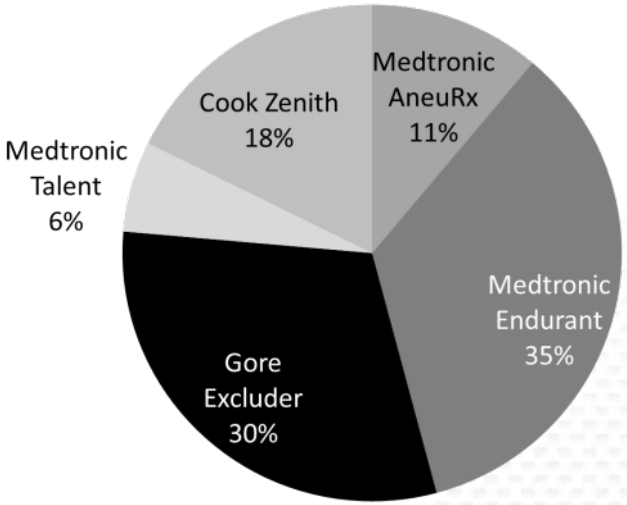
Heli-FX Procedure:
Experience Demonstrates Growing Adoption

Clinical & Commercial Experience	
Number of total Patients treated	> 2100
Number of EndoAnchors implanted	>10,000
Number of US Customers	>350 Hospitals
Specialties using Heli-FX	Vasc Surgeons, Int Radiologists & Cardiologists, CT Surgeons
AAA:TAA Case Ratio	Approx 10:1 to date

Primary EVAR*
77%

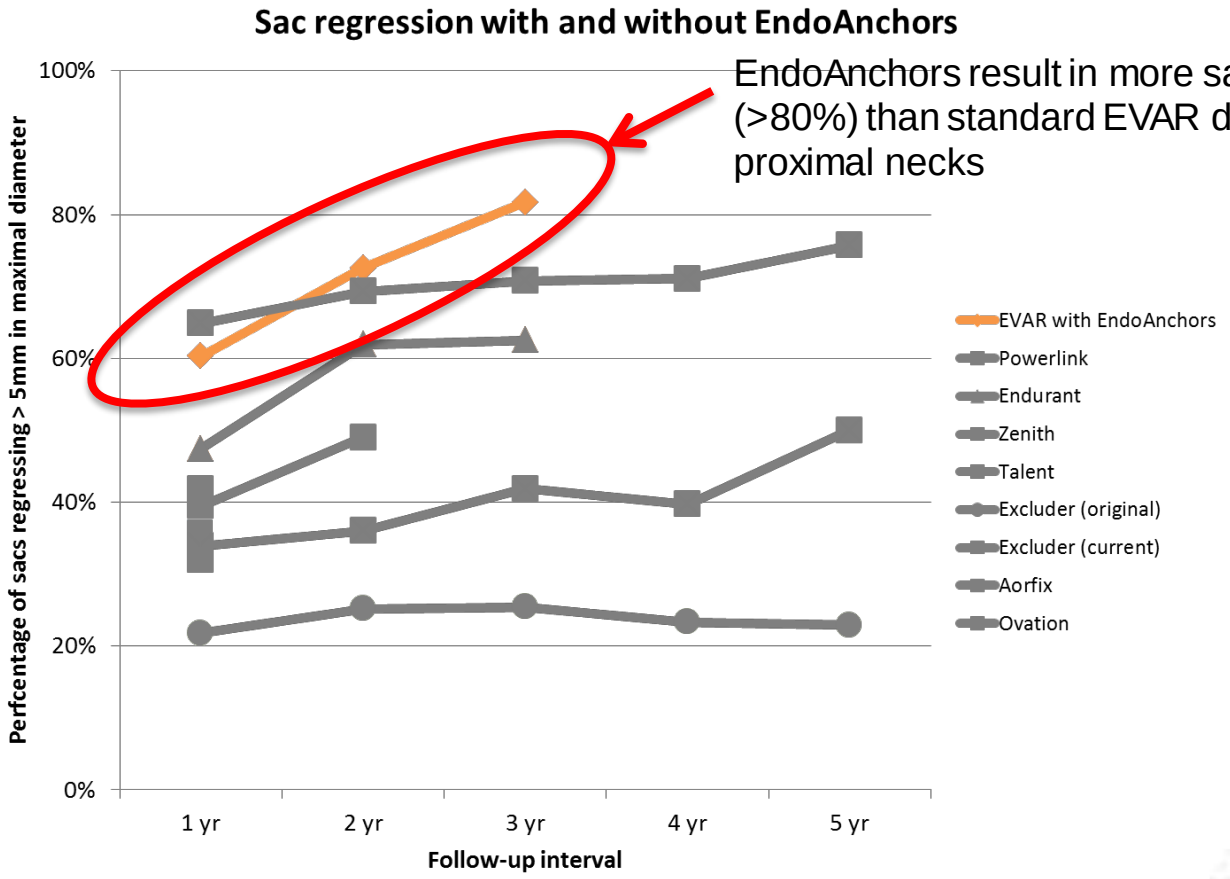


Revision EVAR*
23%



*US data only

Heli-FX-Related Outcomes from STAPLE-2:
EndoAnchors Result in More Sac Regression



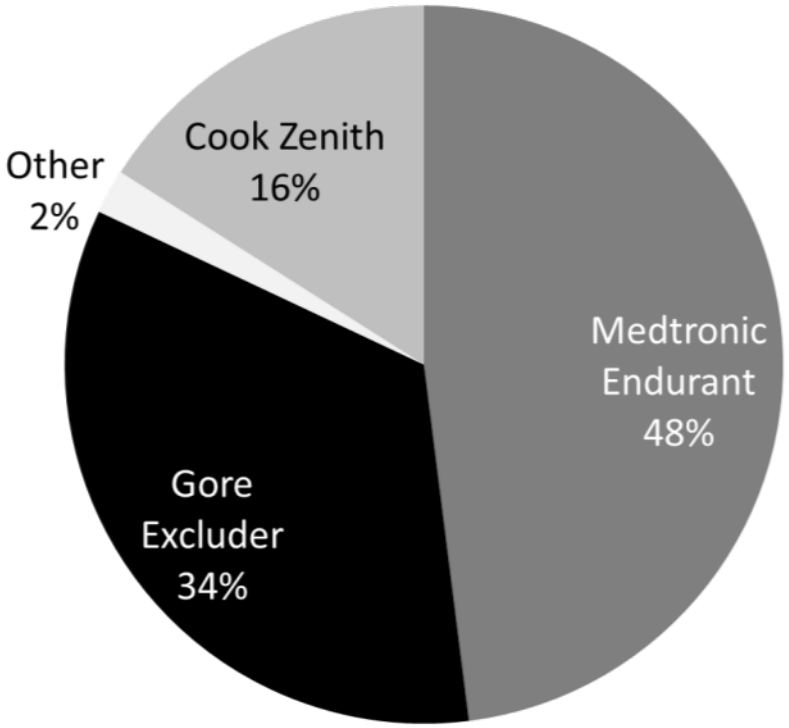
Sac stability is key determinant of success of EVAR

ANCHOR Post-Market Registry

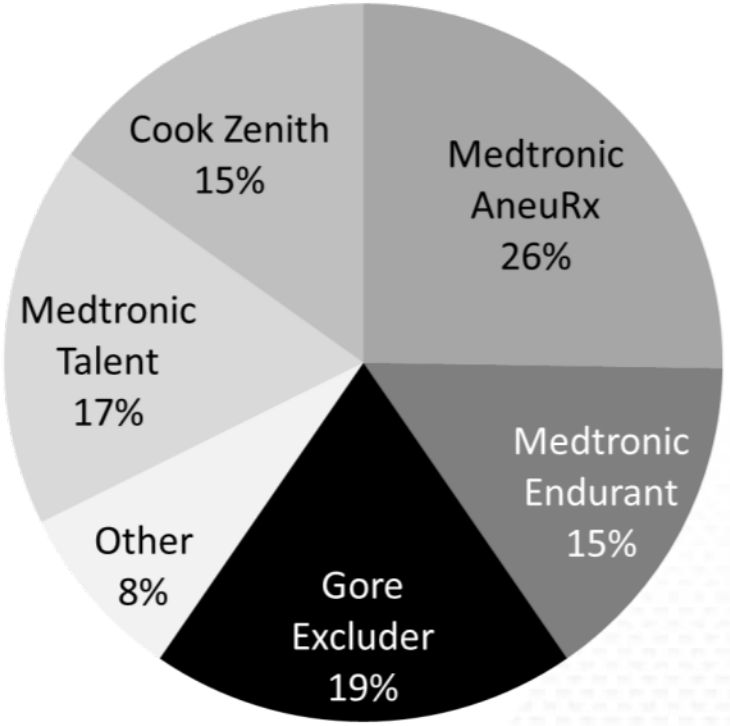
Principal Investigators	• Dr William Jordan, University of Alabama, Birmingham (US) • Dr Jean-Paul de Vries, St Antonius Hospital, Nieuwegein (NL)	
Design	Prospective, observational, international, dual-arm registry • Primary arm – EndoAnchors placed at time of endograft implant • Revision arm – EndoAnchors placed as part of a later revision procedure	
Protocol	EndoAnchor use per IFU, follow-up per standard of care	
Duration	Five years follow-up	
Primary Endpoints	Effectiveness	Successful implantation + freedom from migration / type Ia endoleak at one year
	Safety	Freedom from device (Heli-FX) or procedure-related SAE at one year
Sites	37 US / 18 EU	
Patients Enrolled	345 as of 1/31/14 (continuing up to 1,000 per study arm)	

ANCHOR Registry:
Case Mix Shows Widely Varied Usage & Endograft Types

Primary
N=260 (76%)

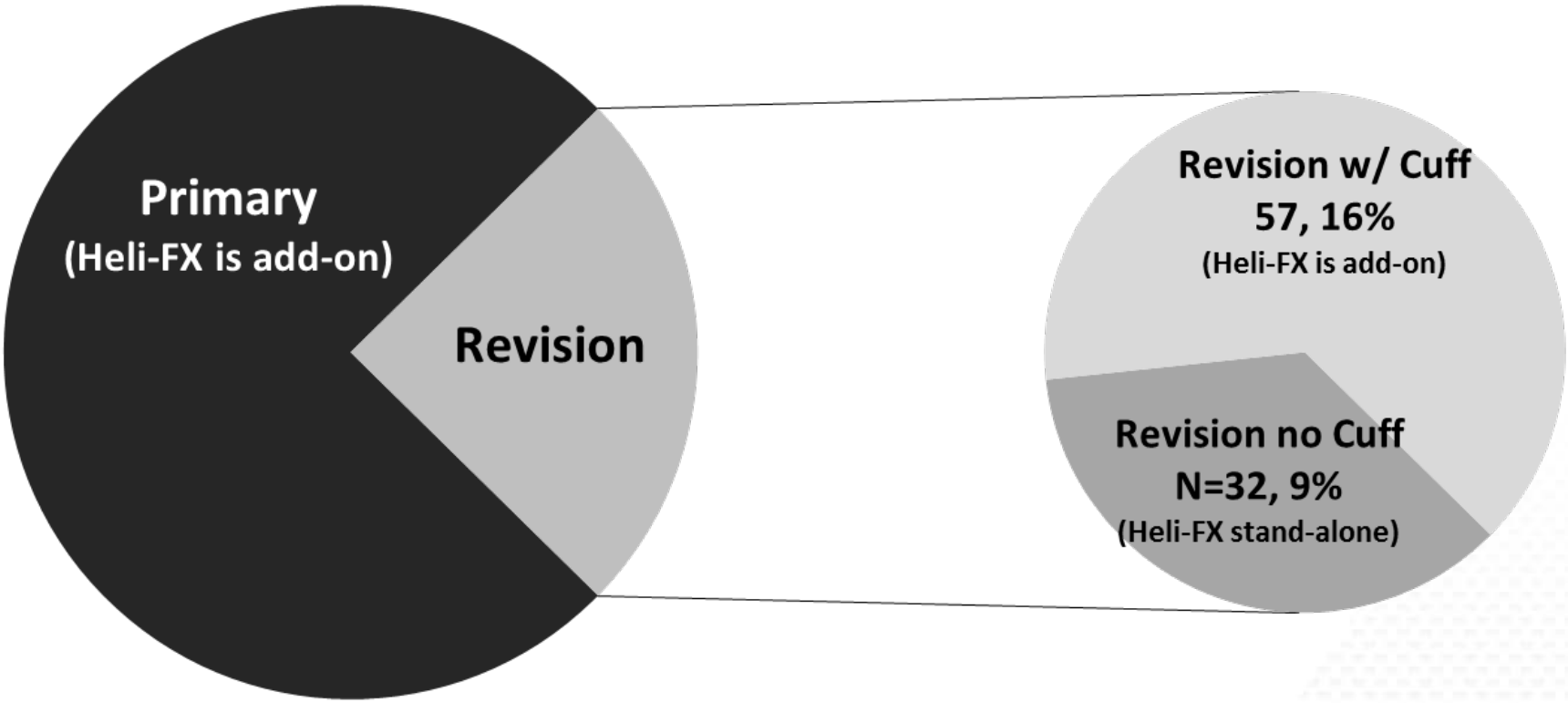


Revision
N=84 (24%)



ANCHOR Registry – EndoAnchor Usage
Add-on to EVAR and Stand-Alone

Procedure break-down:



ANCHOR Registry - Anatomical Characteristics*

Indicates Some of Most 'Challenging' Anatomy Studied in EVAR

	All	Primary	Revision
Max Aneurysm Diameter [mm], mean (range)	58.0 (24-98)	55.9 (24-98)	65.3 (34-93)
Neck Length [mm], mean (range)	15.9 (0-57)	16.3 (0-57)	14.5 (2-44)
Necks ≤10mm Length, N (%)	**43%**	**42%**	**45%**
Neck Diameter[1] [mm], mean (range)	27.0 (17-45)	26.2 (17-45)	29.5 (21-44)
Conical Necks[2], N (%)	**60%**	**59%**	**61%**

(1) At most distal renal artery
(2) >10% increase in diameter from most distal renal artery to 15mm below most distal renal

* Analysis based on available Core Laboratory data

ANCHOR Registry - Reason for EndoAnchoring

Prevention & Treatment of Late Failure Verifies Clinical Need

Primary (n=260)	Concern for Late Failure	147 (56.5%)
	Treatment of Type 1a Endoleak	**59 (22.7%)**
	Prevention of Neck Dilation	42 (16.2%)
Revision (n=84)	Type 1a Endoleak	42 (50%)
	Migration & Endoleak	21 (25%)
	Migration	11 (13.1%)

Median # EndoAnchors Implanted*	
Primary Arm:	**5**
Revision Arm:	**6**
Total Combined:	6

***EndoAnchors are permanently implanted; patients need to be followed long term**

ANCHOR Registry – Acute Technical Success

Favorable Results Suggest Improvement Over 'Standard of Care'

Arm	N	Success	% Successful
Primary	260	257	**98.8%**
Revision	84	78	**92.9%**

- No EndoAnchor related SAEs or re-interventions
- 50% of type 1 endoleaks treated w/EndoAnchors also used Cuffs (53/106)

Reasons for Unsuccessful Results:

- Primary: 3 Unresolved type 1a endoleak at final angio, 2 resolved (1 @1-M & 1 @3-M F/Us respectively)
- Revision (N=6): Persistent Type 1a endoleak at final angio, 2 Pts outside Aptus IFU

ANCHOR Results Compare Favorably to Alternative Tx

Patients with Persistent Type 1a Endoleak at End of Primary EVAR procedure	
Studies	Type 1a Endoleak
Byrne J et al.* (Patients treated with Palmaz Stent)	8.6% (14/162)**
ANCHOR Registry	**1.6%** (1/59)***

Meta-analysis of outcomes in AAA Endo Repair with hostile anatomy		Type 1 Endoleaks
Studies	Median Follow-Up	Hostile Necks
Meta-analysis, Antoniou et al*	12-Months	9.8% (20/205)**
ANCHOR Registry	10.4-Months	**1.5%** (3/189)***

* Byrne J et al. *Ann Vasc Surg* 2013 May;27(4):401-11
** Rate includes both emergent and elective patients receiving Palmaz stents during primary EVAR procedure.
*** N = 59, 1 out of 59 Patients had an acute Type I endoleak unresolved at final angio

* Antoniou GA et al. A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy. J Vasc Surg 2012
** Hostile neck criteria: neck length <15 mm and neck angulation > 60 degrees
*** Hostile as determined by physician in Primary Arm

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ANCHOR Registry:
Favorable Conclusions from Early Results

- EndoAnchors show favorable results as prophylaxis for late proximal seal complications
  - 99% technical success
  - No Type 1a Endoleaks in 10-mo median F/U, despite high proportion of hostile necks
  - Data consistent with STAPLE-2 IDE trial where all pts had EndoAnchors placed primarily
- EndoAnchors show high effectiveness in treating acute and late Type 1a endoleaks (98% & 90% respectively)
- Low re-intervention rates (0.4%) in the Primary Arm despite hostile anatomy
  - Low Type 1a Endoleak rates (1.5%) in Primary compared to ~10% in hostile necks per meta analysis by Antoniou et al

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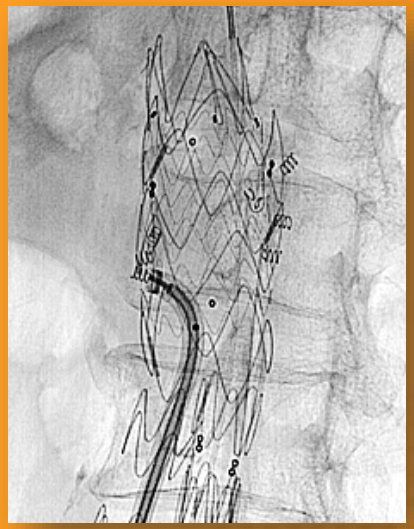
The EndoAnchoring Procedure



Heli-FX Procedure Duration: Implant Time Varies
with # of Anchors, Complexity of Anatomy, Familiarity of Physician

Recommended # EndoAnchors:	• 4 EndoAnchors recommended for ≤29mm dia aortas • 6+ EndoAnchors recommended for >29mm dia aortas EndoAnchor locations should avoid severe thrombus and calcium
Avg EndoAnchors Implanted:	During a Primary or Revision EVAR or TEVAR is 5 to 6
Add'l Operating Room Time:	30-45 min (not including set up) required to implant EndoAnchors
Heli-FX Procedure:	EndoAnchor Procedure has its own distinct beginning, middle & end separate from the Endograft insertion & implantation May also be performed as a stand alone procedure (Repair without Endograft Extension Cuff)

Image Guided, Resource Intensive Procedure Completed in OR, Cath Lab or Interventional Suite

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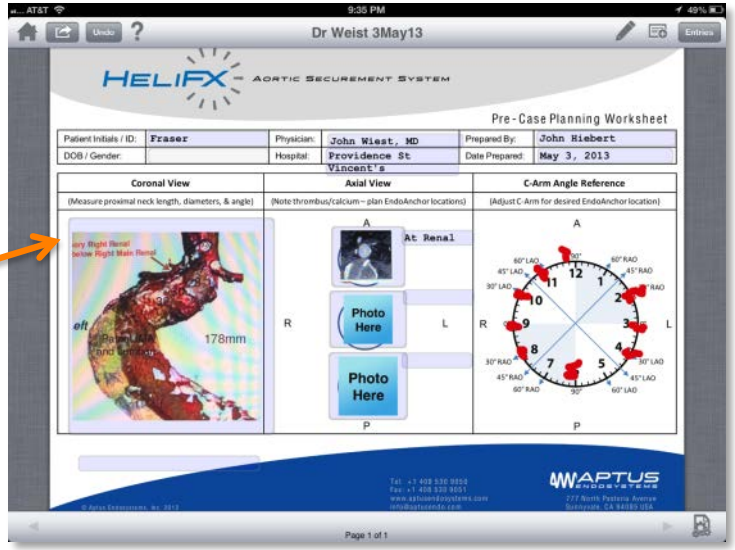
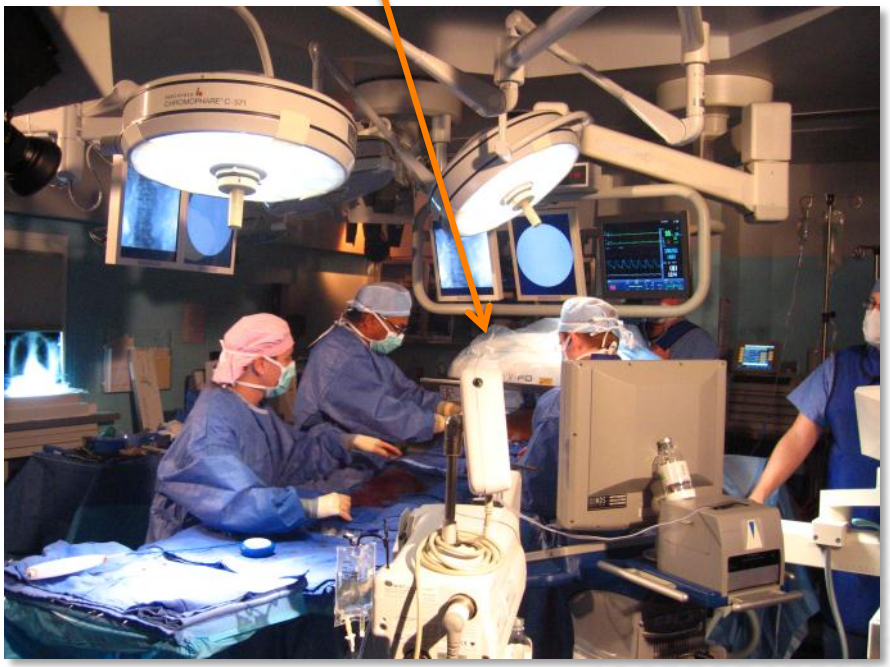
Anchoring Requires Advance Planning:
Location(s) and C-Arm Angles for Fluoroscopy & Implant

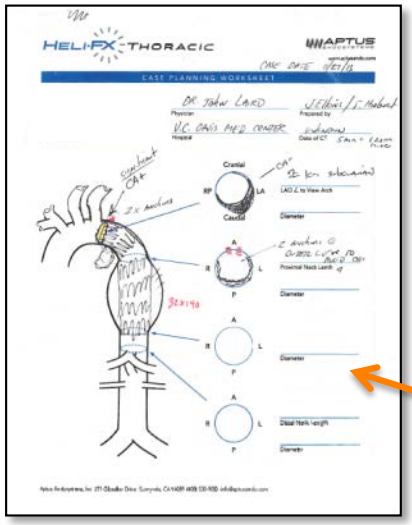
AAA Case – iPad used for Case Planning



C-Arm Used for EndoAnchoring Positioning & Angulation



Case Planning:
Case planning by physician includes CT scan review, measurements, review of 3D recon & planning for EndoAnchor implantation location(s) – iPad or hard copy



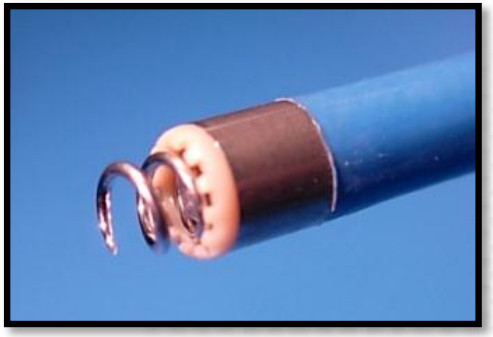
TAA Case - Hard Copy Worksheet used for Case Planning

Heli-FX Device Preparation (Pre-Insertion)

Device Packaging:
Product is unpacked &
Provided to sterile field

Device Preparation:
- Saline flush all components
- Turn Applier on

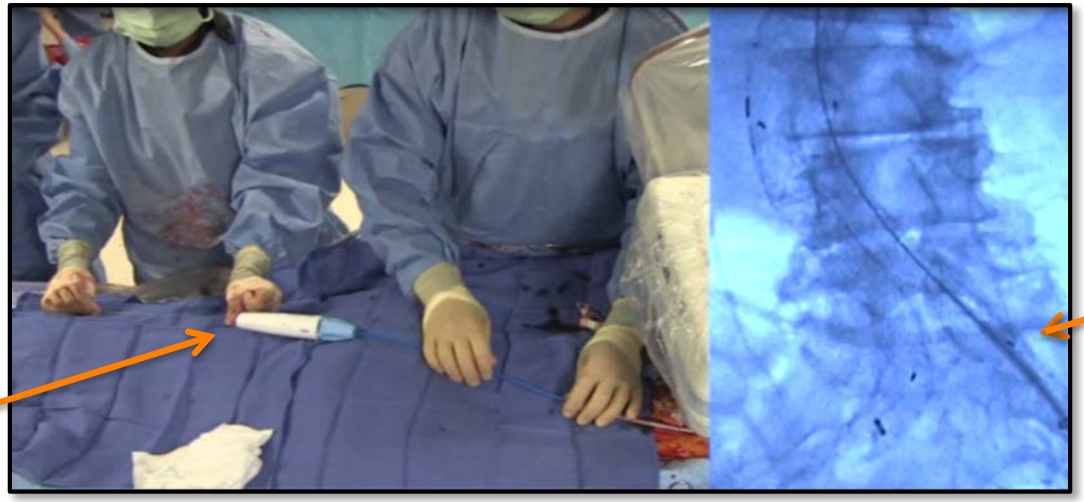
EndoAnchor Loading:
- Load EndoAnchor
- Verify loading



Heli-FX Device Insertion:
After Prep/Loading, Guide is Inserted

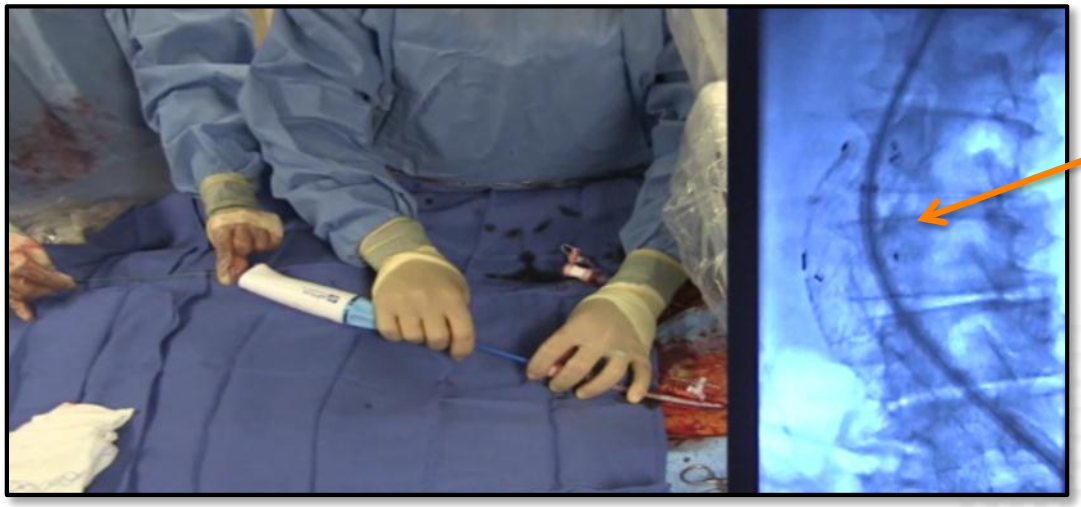
Insert Guide & Dilator into femoral artery

Heli-FX Guide



Dilator & Guide entering Iliac

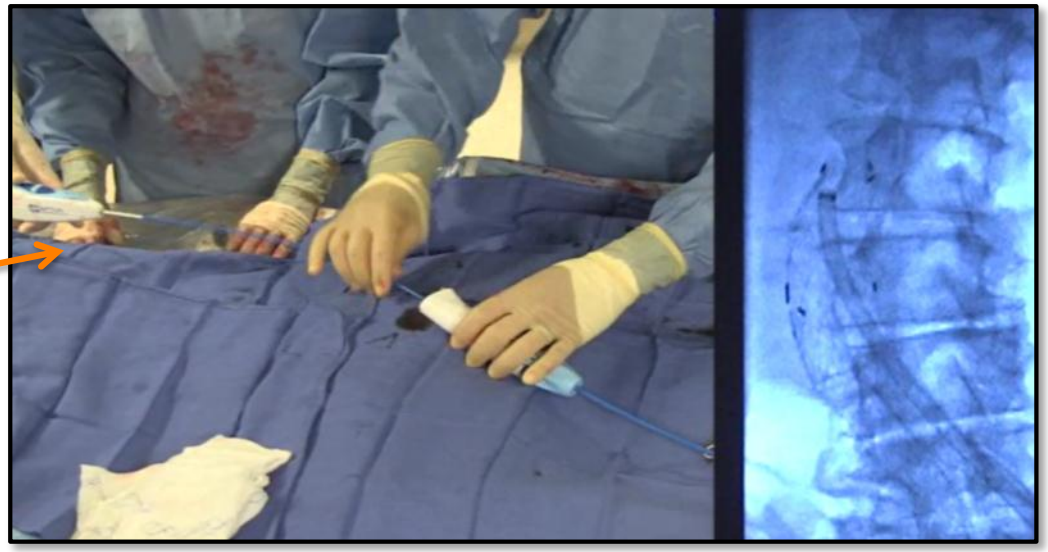
Advance & position Into Guide at Proximal Neck of Aorta

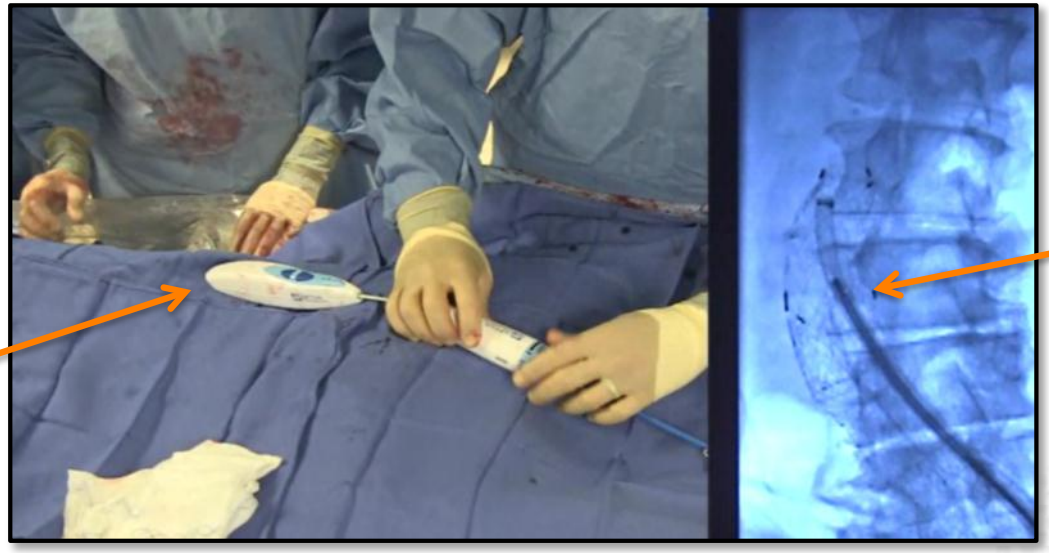


Dilator & Guide At Proximal Neck

Guide is Positioned, Applier is then Inserted and Advanced

Applier inserted into Guide





Anchor Applier

Applier is advanced to proximal neck

Heli-FX Implantation: Proper Positioning Highly Critical

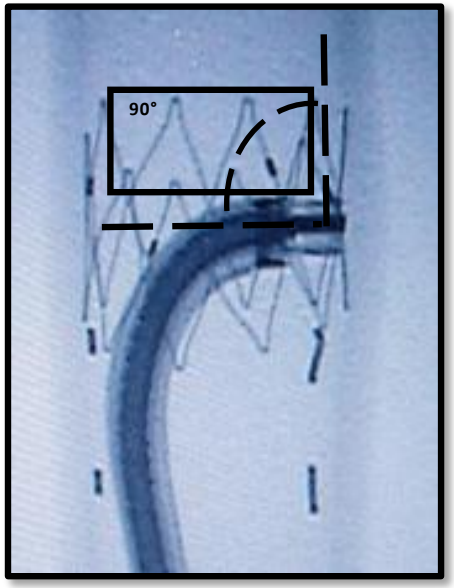
Perpendicular Positioning
- Rotate Guide to visualize “C” marker
- Position Guide & Applier 90° relative to endograft

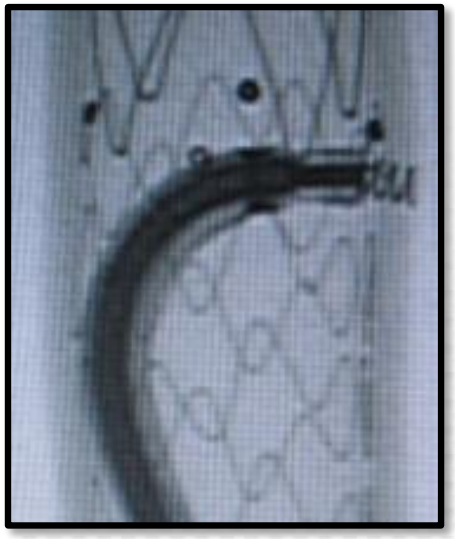
Apposition
- Stabilize Guide. Advance Applier until resistance is felt against endograft & aortic wall.
- Confirm perpendicular positioning & Guide recoiling against opposite wall under fluoro

Stage 1
- Press Applier Forward once to implant EndoAnchor halfway.
- Confirm EndoAnchor tip penetrated thru endograft & Guide/Applier position remained stable
- If acceptable, proceed to Stage 2. Otherwise, press Reverse button & attempt again. Re-position if necessary.

Stage 2
- Maintain constant position & pressure throughout deployment sequence.
- Press Applier Forward button again to fully implant EndoAnchor
- Slowly retract Applier under fluoro to ensure EndoAnchor is fully released.

Repeat the above steps for each EndoAnchor (Avg. 5-6 per case)





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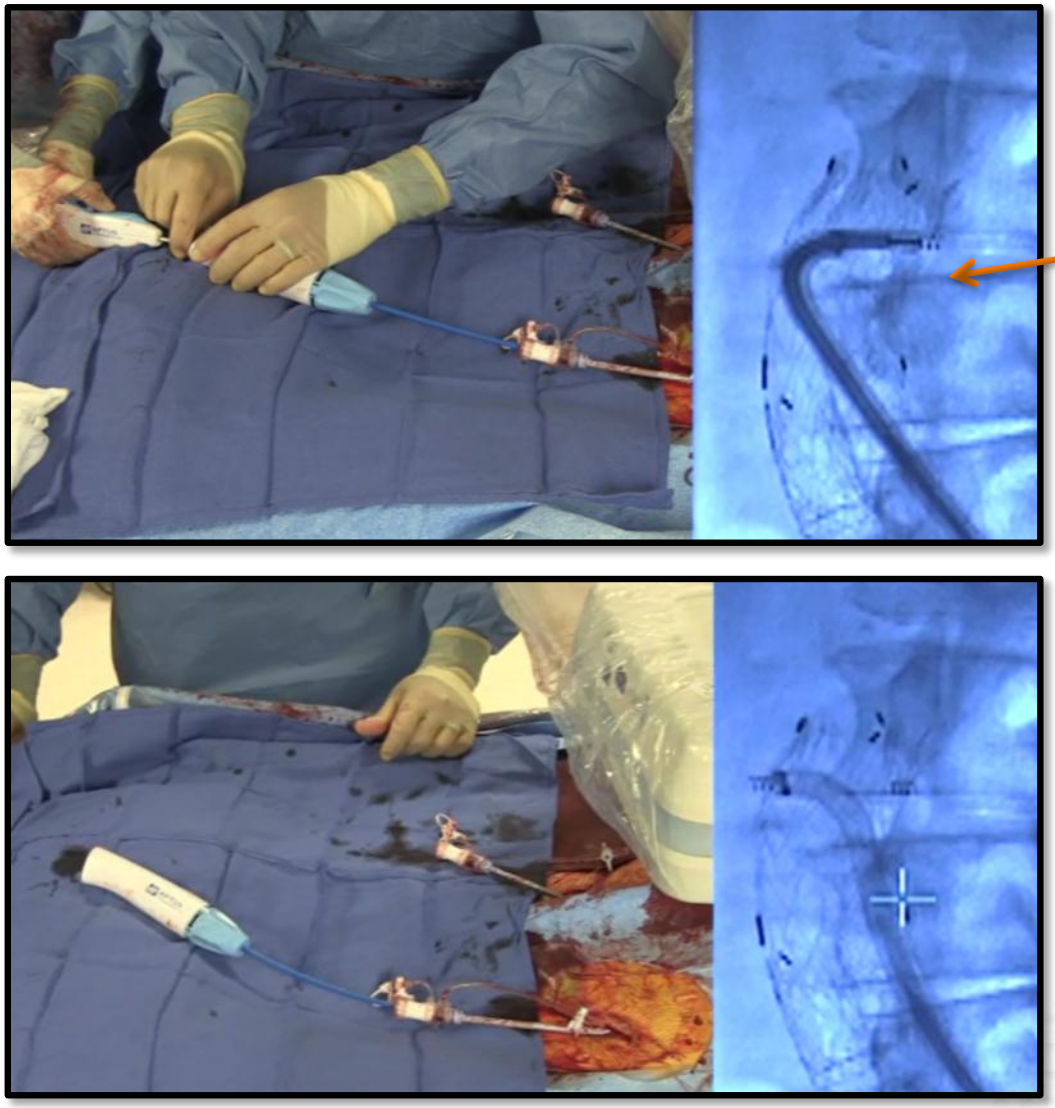
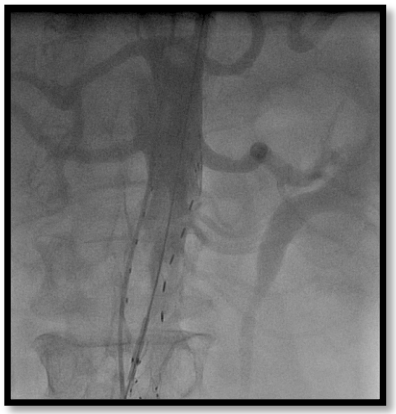
Heli-FX Device Insertion & Implantation of EndoAnchors

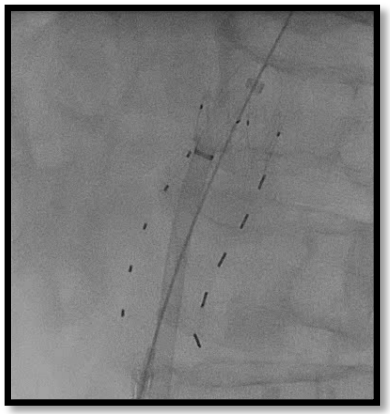


Guide is 'deflected' into position, Anchor implanted

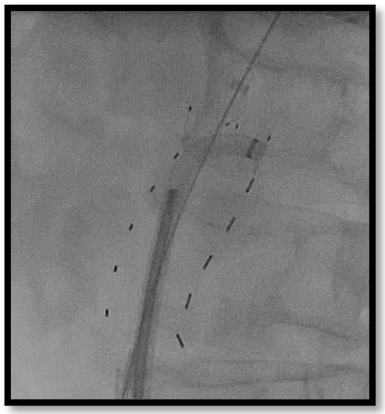
Heli-FX Procedure as Add-On to EVAR (Parent Procedure)



Angiogram prior to EndoAnchoring Ensuring Proper Graft Location



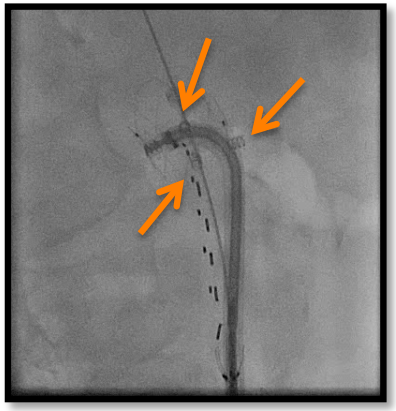
Heli-FX Guide Advancement



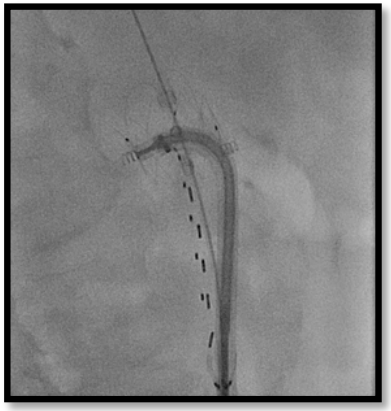
1st Anchoring Location Selected w/ Guide (C-Arm LAO 45°)

Heli-FX Applier Ready to Implant 1st EndoAnchor

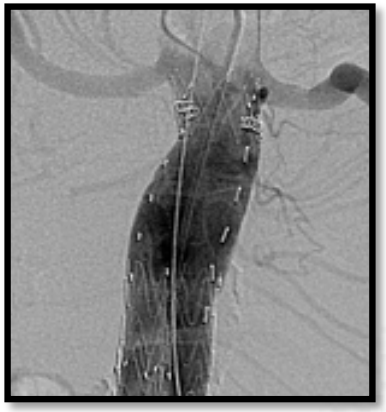
Arrows Denote Implanted 3 EndoAnchors



Applier Ready to Implant 4th EndoAnchor (C-Arm RAO 45°)



4th EndoAnchor Implanted



Final Angiogram after EndoAnchoring

Images courtesy of Dr. Burkhart Zipfel, Deutsches Herzzentrum Berlin

FDA Classification

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER H--MEDICAL DEVICES
PART 870 CARDIOVASCULAR DEVICES

Subpart D--Cardiovascular Prosthetic Devices

§ 870.3250 - Vascular clip.
§ 870.3260 - Vena cava clip.
§ 870.3300 - Vascular embolization device.
§ 870.3375 - Cardiovascular intravascular filter.
§ 870.3450 - Vascular graft prosthesis.
§ 870.3460 - Endovascular Suturing System.
§ 870.3470 - Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.
§ 870.3535 - Intra-aortic balloon and control system
§ 870.3545 - Ventricular bypass (assist) device.
§ 870.3600 - External pacemaker pulse generator.
§ 870.3610 - Implantable pacemaker pulse generator.
§ 870.3620 - Pacemaker lead adaptor.
§ 870.3630 - Pacemaker generator function analyzer.
§ 870.3640 - Indirect pacemaker generator function analyzer.
§ 870.3650 - Pacemaker polymeric mesh bag.
§ 870.3670 - Pacemaker charger.
§ 870.3680 - Cardiovascular permanent or temporary pacemaker electrode.
§ 870.3690 - Pacemaker test magnet.
§ 870.3700 - Pacemaker programmers.
§ 870.3710 - Pacemaker repair or replacement material.
§ 870.3720 - Pacemaker electrode function tester.
§ 870.3730 - Pacemaker service tools.
§ 870.3800 - Annuloplasty ring.
§ 870.3850 - Carotid sinus nerve stimulator.
§ 870.3925 - Replacement heart valve.
§ 870.3935 - Prosthetic heart valve holder.
§ 870.3945 - Prosthetic heart valve sizer.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=870.3460

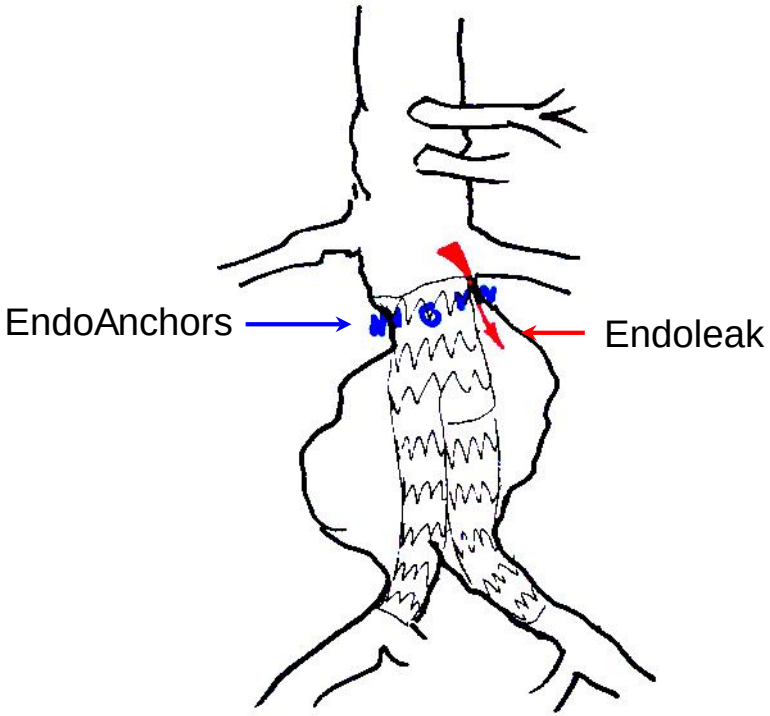
Heli-FX Clinical Scenarios Vary According to Patient Need

Six (6) procedural use cases

		EVAR (Body Section: Lower Artery)	TEVAR (Body Section: Heart & Great Vessel)
Heli-FX as Add-On	Primary	Control of acute Endoleak and/or Hostile anatomy	Control of acute Endoleak and/or Hostile anatomy
	Revision	Control of Endoleak / repair of migration	Control of Endoleak / repair of migration
Heli-FX as Stand-Alone	Revision of previous aneurysm repair	Control of Endoleak	Control of Endoleak

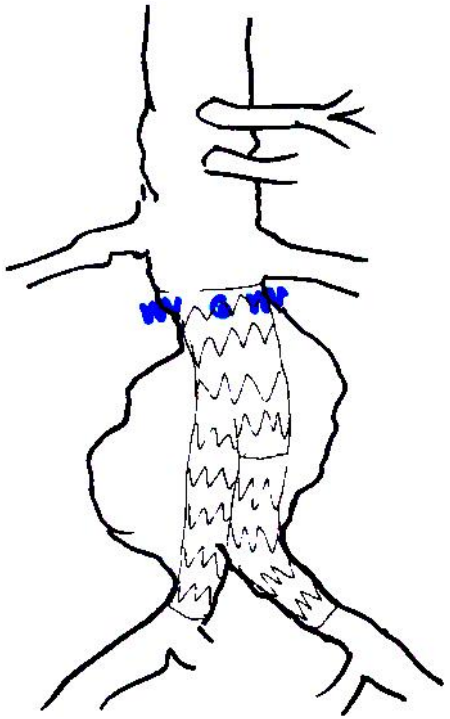
Heli-FX Procedure as Stand Alone (Parent Procedure)

EndoAnchoring Stand Alone Procedure
to Repair Endoleak

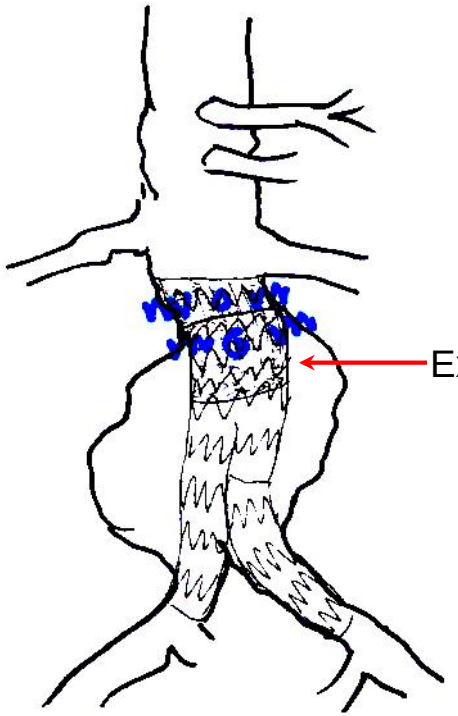


Heli-FX as Add-On to EVAR (Parent Procedure)

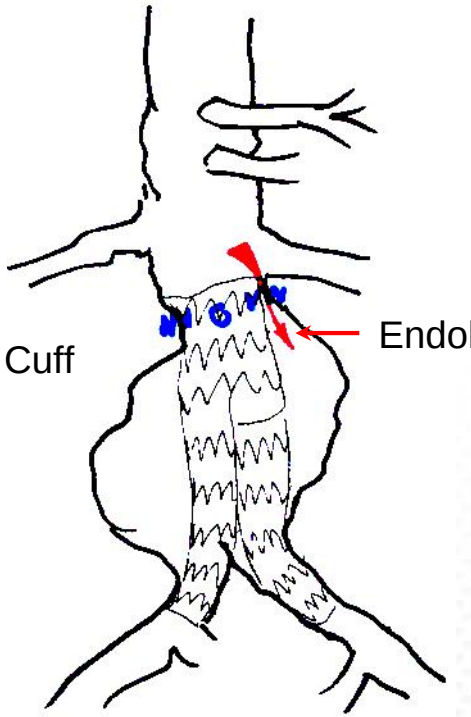
Primary Challenging Neck Anatomy + EndoAnchors



Revision with Cuff + EndoAnchors

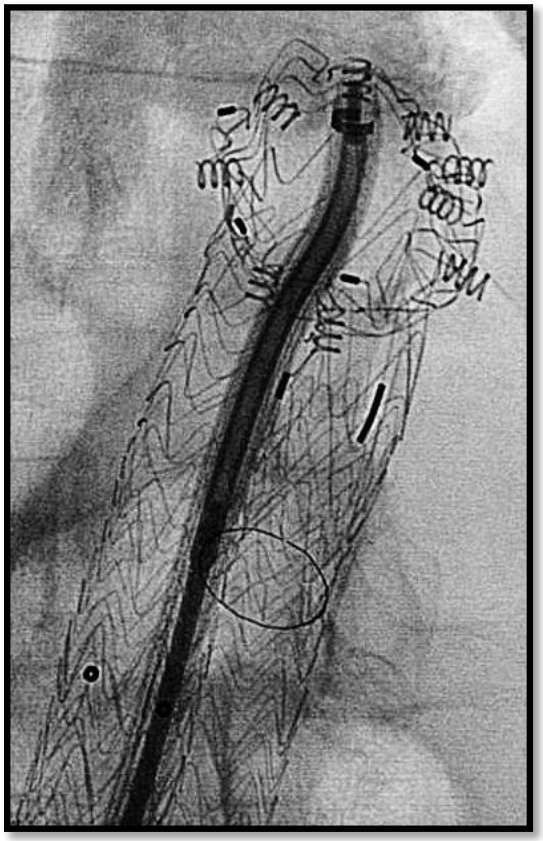


Primary or Revision with Endoleak + EndoAnchors



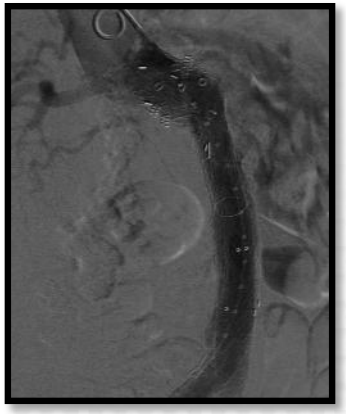
Revision Case w/a Type 1a Endoleak, Anchors

Type 1 Endoleak 1 week post implant



9 Heli-FX EndoAnchors implanted

Type 1 Endoleak Resolved without cuff



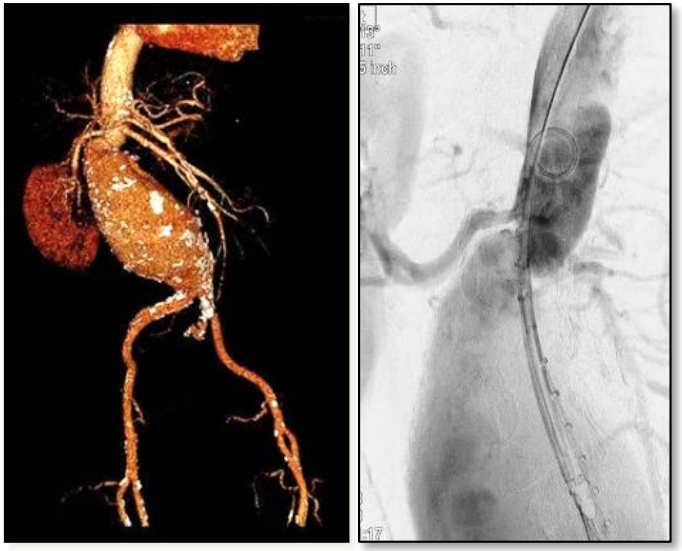
Images courtesy of Bart Muhs, MD & Scott Aruny, MD
Yale New Haven Medical Center

Primary Endograft Case w/Acute Type 1a Endoleak

Pre-Op
- 9.5cm asymptomatic AAA, female
- Reason for anchoring: highly angulated, short neck

Intra-Op
- First completion with type Ia endoleak

Final Angio
- Proximal cuff and 4 EndoAnchors
- No endoleak at final angio or 30-day CTA



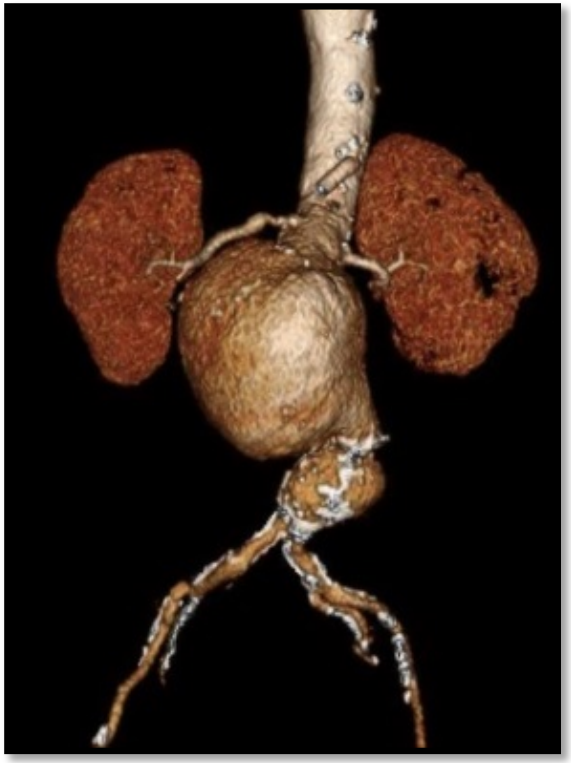
Final Angio

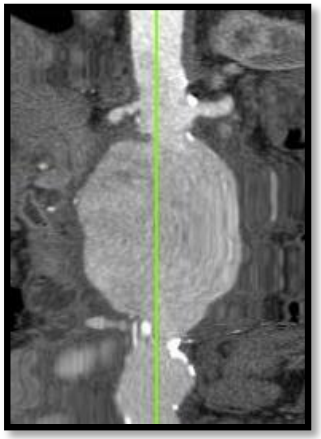
30-day CTA

Case images courtesy of Will Jordan, MD, Univ. of Alabama

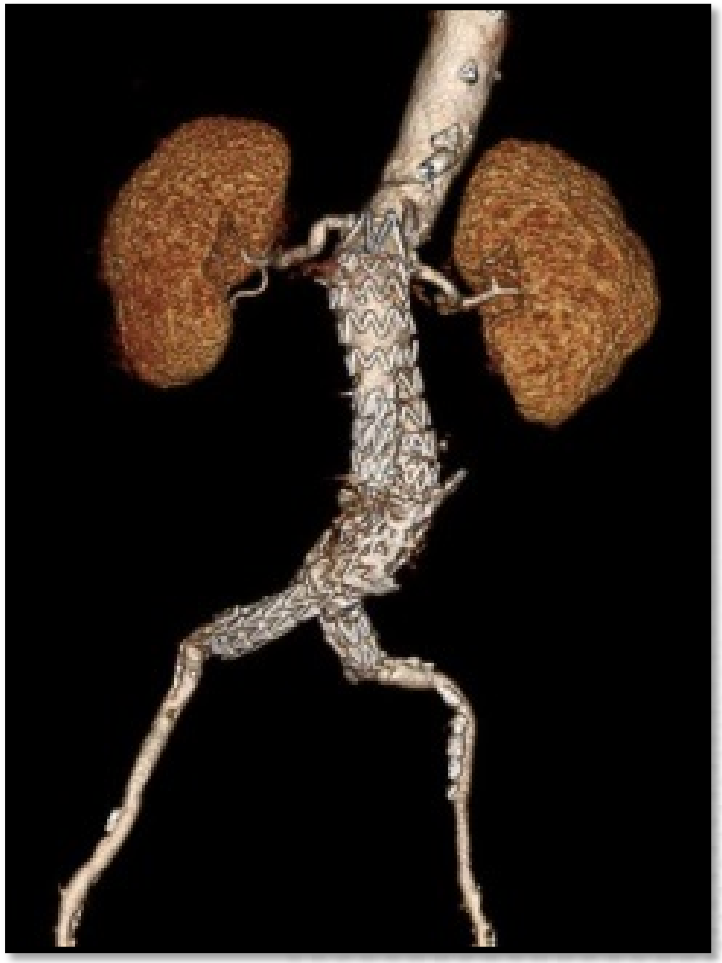
Primary Endograft Case with Challenging Anatomy

- 77 year old female
- 95mm saccular AAA
- Short proximal aortic neck





- Deployment of Medtronic Endurant
- 4 EndoAnchors
- No endoleak at 30-day CT

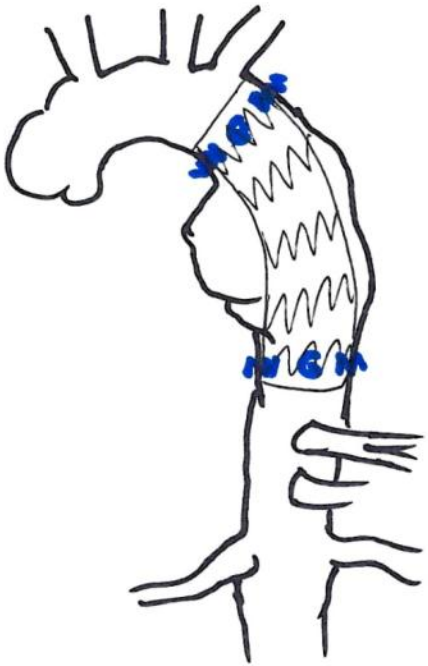


Case images courtesy of Dr. Manish Mehta,
Albany Vascular

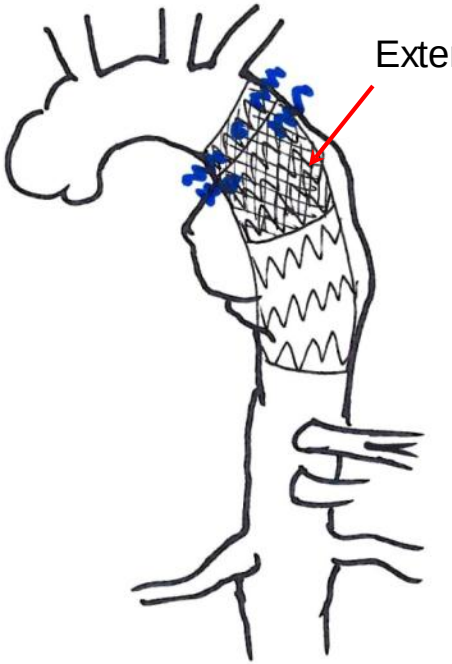
APTUS ENDOSYSTEMS

Heli-FX TAA Procedures

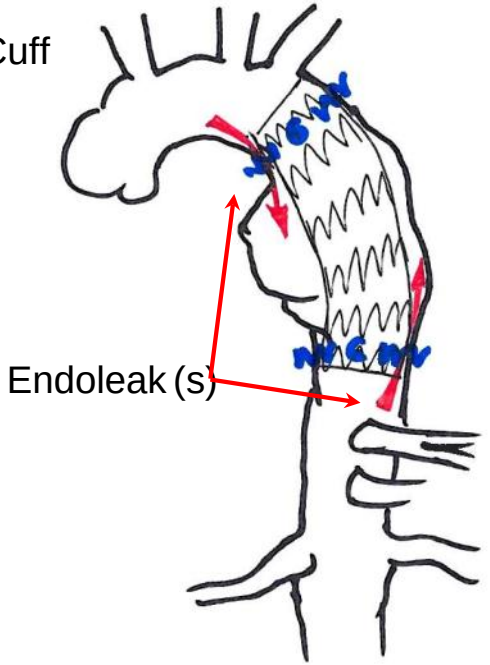
Primary Prophylactic
Proximal &
Distal shown



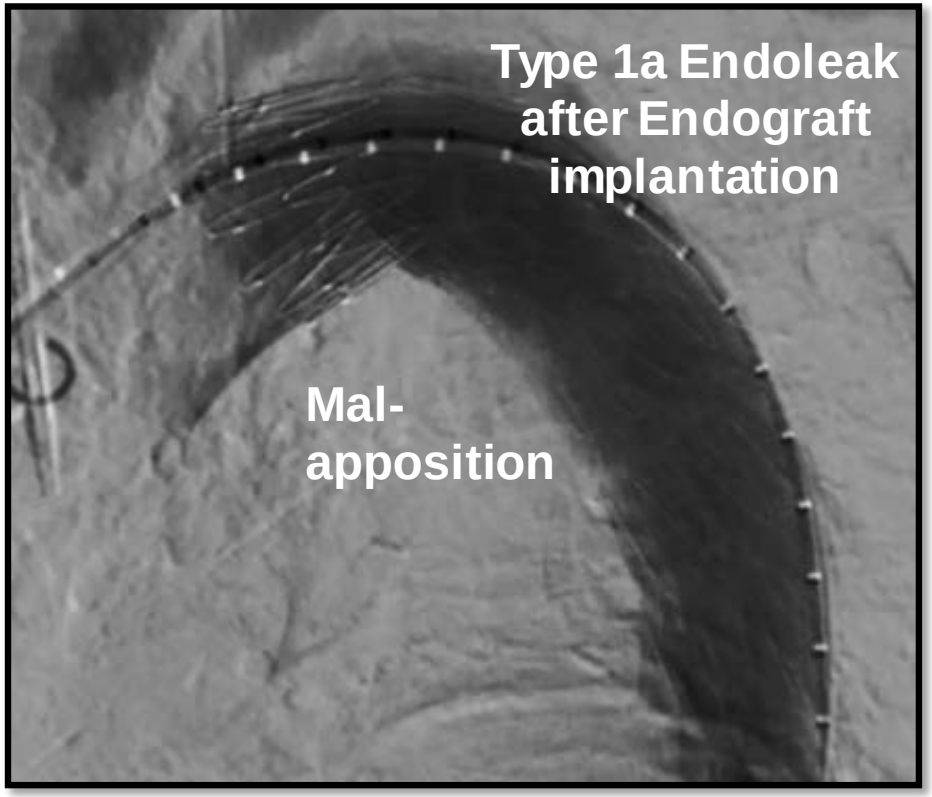
Primary or Revision
with Cuff

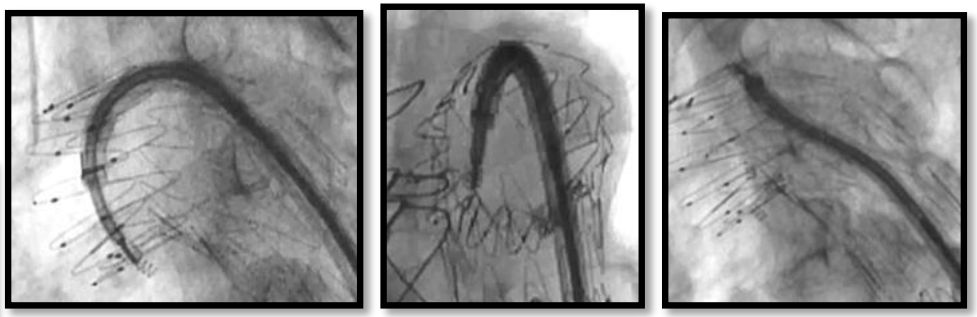


Primary or Revision
with Endoleak

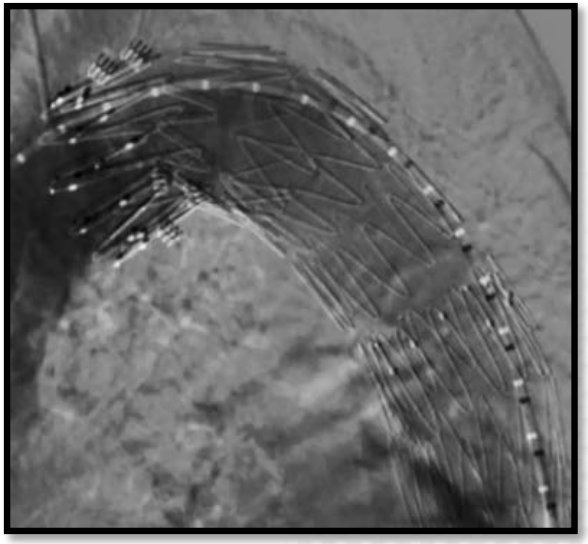


Primary TEVAR – Short Proximal / Distal Necks





4 EndoAnchors implanted



Final Angio, leak resolved

Case images courtesy of P Kasprzak MD, Regensburg

APTUS ENDOSYSTEMS

Rationale for New ICD10-PCS Qualifier & Codes

- NTAP Application is under consideration for FY2015
- Cleared by the FDA *not as a suture* but as a Medical Device to:
  - Repair failed endografts
  - Improve an endograft's inherent fixation and sealing mechanisms, especially in patients with challenging neck anatomy
- Distinct procedure with its own beginning, middle & end from that of the endovascular graft procedure
- Requires unique & patented instruments for EndoAnchor deployment
  - EndoAnchor
  - Heli-FX Guide
  - Heli-FX Applier
- Requires additional operating room time of 30-45 minutes (not including set up time) to implant 5-6 EndoAnchors into the wall of the abdominal or thoracic Aorta

Rationale for New ICD10-PCS Qualifier & Codes

- Used with most commercially available endografts as a Supplement or in a Repair
- Need to address the multiple root operations occur during Primary & Revision EVAR and TEVAR
  - Implantation of multiple intraluminal devices (graft, cuff, Heli-FX),
  - Each serving different purposes during the same surgical session
- No distinct ICD9 -CM codes, therefore it is not possible to convert to ICD10 -PCS using GEM mapping
- Heli-FX is a new technology:
  - No comparable ICD9-CM, ICD10-PCS codes exist because there is no other FDA approved implantable device which serve the same function

ICD10-PCS Coding Proposal Summary

- Proposing the creation of (1) qualifier and new and separate codes for the Heli-FX when performed in the abdominal and thoracic regions. Root Operations for these regions could be:
  - Lower Artery body section
    - **Supplement -** Heli-FX is an add-on procedure during primary/revision EVAR
    - **Repair -** Heli-FX is the parent procedure during revision EVAR
  - Heart and Great Vessel body section
    - **Supplement** - Heli-FX is an add-on procedure during primary/revision TEVAR
    - **Repair -** Heli-FX is the parent procedure during revision TEVAR (emerging procedure)
- Establish the Qualifier T, **EndoVascular Graft Fastener**
- To help coders quickly locate the new ICD10-PCS qualifier and codes
  - Place in the Medical/Surgical Section
  - Add the Heli-FX EndoAnchor System to the Device Key because it is a new technology

Coding Issue

Currently there no ICD9-CM and ICD10-PCS codes to capture the Heli-FX Stand-alone and Add-on procedures during EVAR and TEVAR

		EVAR	TEVAR
Heli-FX Add-On Procedure	**Primary**	Control of acute Endoleak and/or Hostile anatomy	Control of acute Endoleak and/or Hostile anatomy
	Revision	Control of Endoleak / repair of migration	Control of Endoleak / repair of migration
Heli-FX Stand-Alone Procedure	**Revision of previous aneurysm repair**	Control of Endoleak	Control of Endoleak

Rationale for new ICD10-PCS Codes

- Heli-FX is used with most commercially available endografts in multiple operations as outlined in Options 2-4 and initial ICD10 Application.
  - Operations are Introduction, Supplement, in a Revision or in a Repair
- Distinguish and capture the Heli-FX Stand-alone and Add-on procedures.
- There are no distinct ICD9-CM codes for Heli-FX Stand-alone and Add-on procedures, therefore conversion into ICD10-PCS using GEM mapping is not possible
- Heli-FX is a new technology:
  - No comparable ICD9-CM, ICD10-PCS codes which exist because there is no other FDA approved implantable device which serves the same function as the Heli-FX system.

ICD10-PCS Coding Request Summary

- Option 4

Heli-FX Procedure	Lower Artery, Abdominal	Heart and Great Vessels, Thoracic	Section
Stand-alone during Revision EVAR or TEVAR	Operation: Revision	Operation: Revision	Medical- Surgical
Add-on during Primary EVAR and EVAR	Operation: Supplement,	Operation: Supplement	Medical -Surgical
Add-on during Revision EVAR and TEVAR	Operation: Revision	Operation: Revision	Medical-Surgical

- Create a new device character
- Because Heli-FX is a new technology add the Heli-FX System to the Device Key

Conclusion

- Heli-FX is a new & unique technology with significant clinical benefit as a stand alone and as an add-on in EVAR & TEVAR
- There are no other existing codes which are applicable to Heli-FX
- Heli-FX requires additional planning, operative steps, additional time, resources, and associated risks & therefore warrants its own specific coding

APTUS ENDOSYSTEMS

Thank you