



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

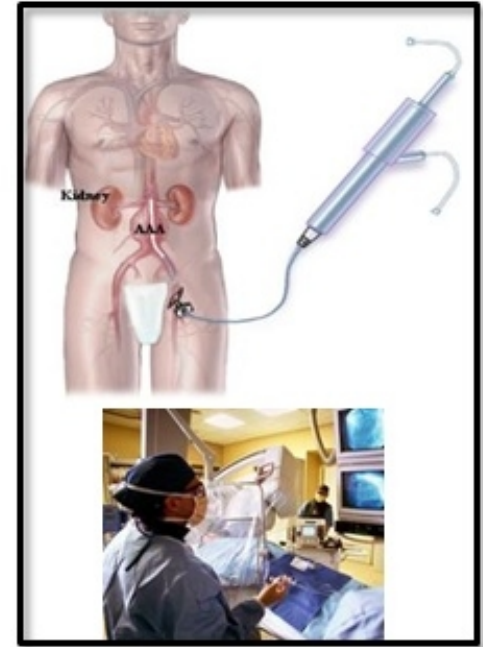
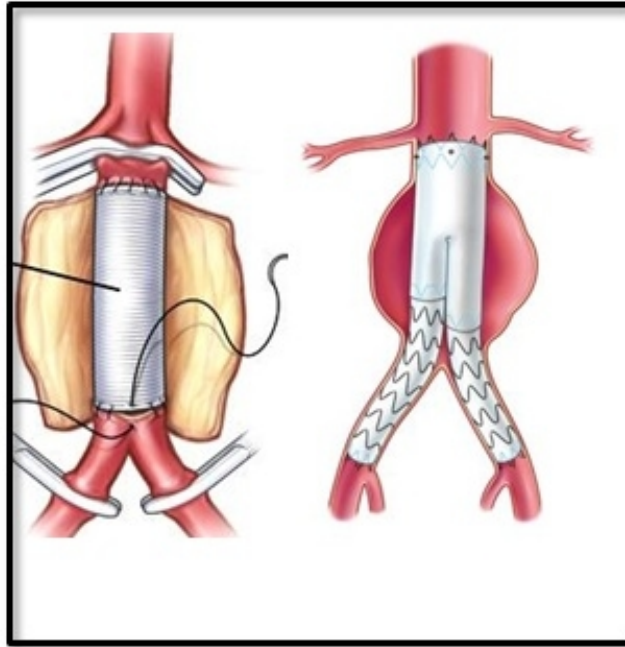
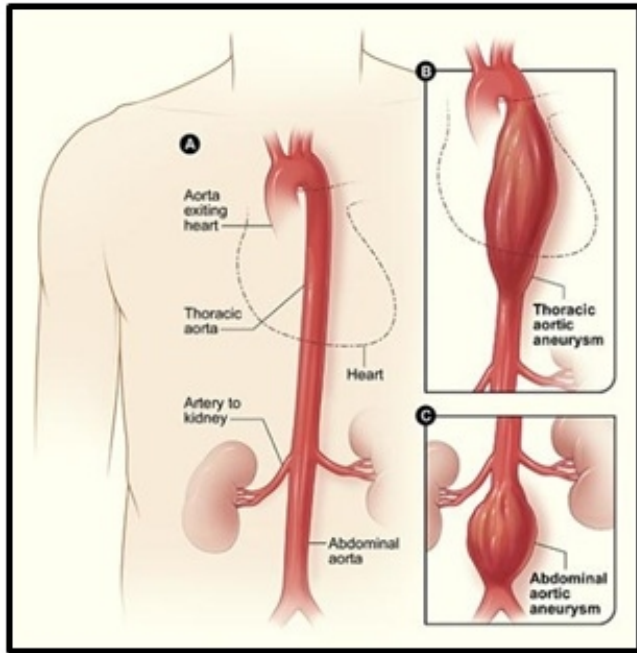
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Yale School of Medicine, New Haven CT

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Sr Coding & Reimbursement Analyst, Sue Rowinski Group LLC

March 19, 2014
Baltimore, MD



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



Aortic Aneurysms:

- Thoracic
- Abdominal

Repair:

- Open Surgical
- Endovascular

Endo Repair

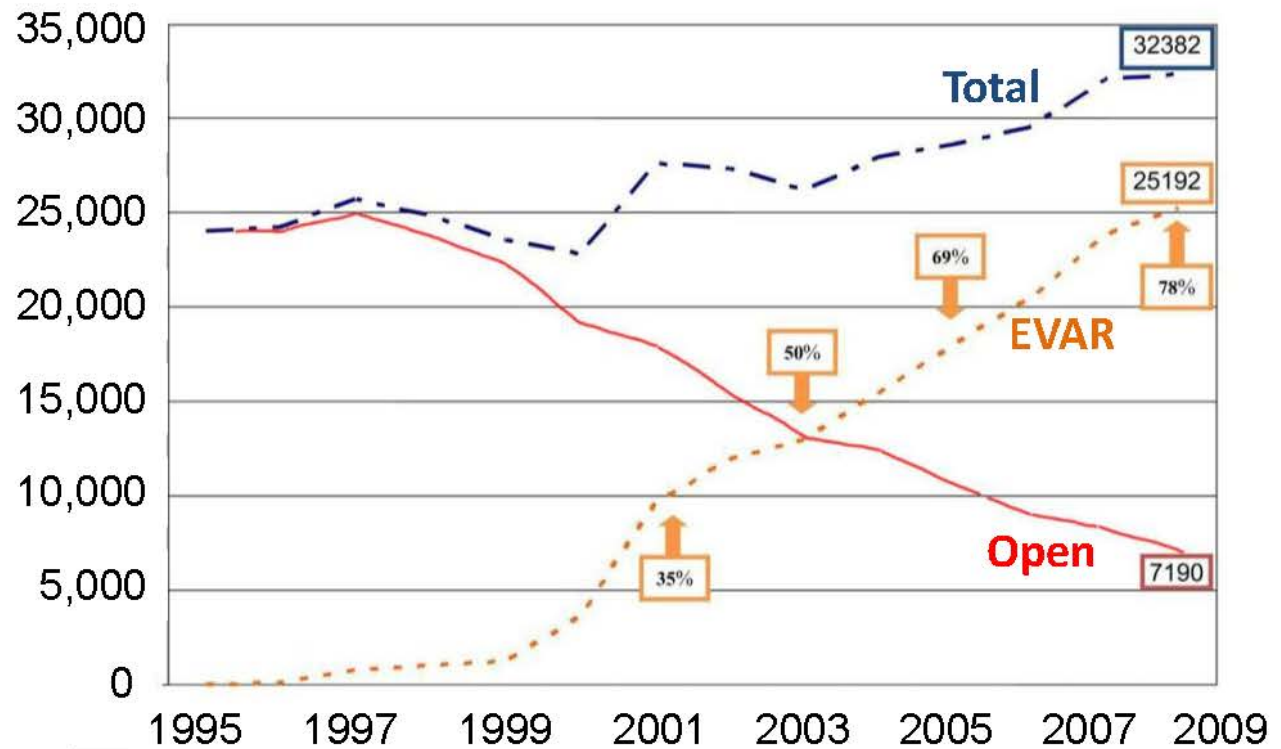
- Less morbidity
- Durability?
- Anatomical limitations

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



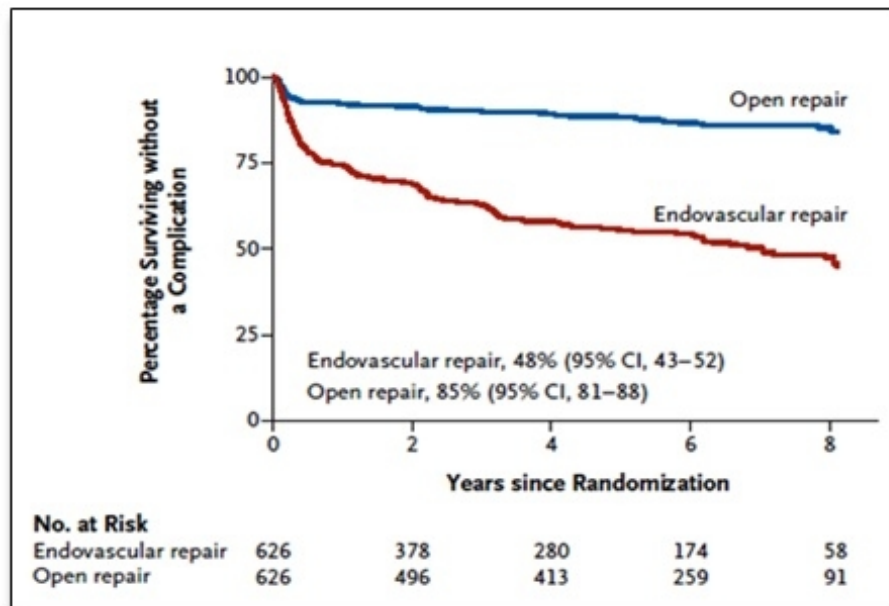
By 2009, ≈45,000 elective aortic aneurysm repairs performed in US Medicare population.

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

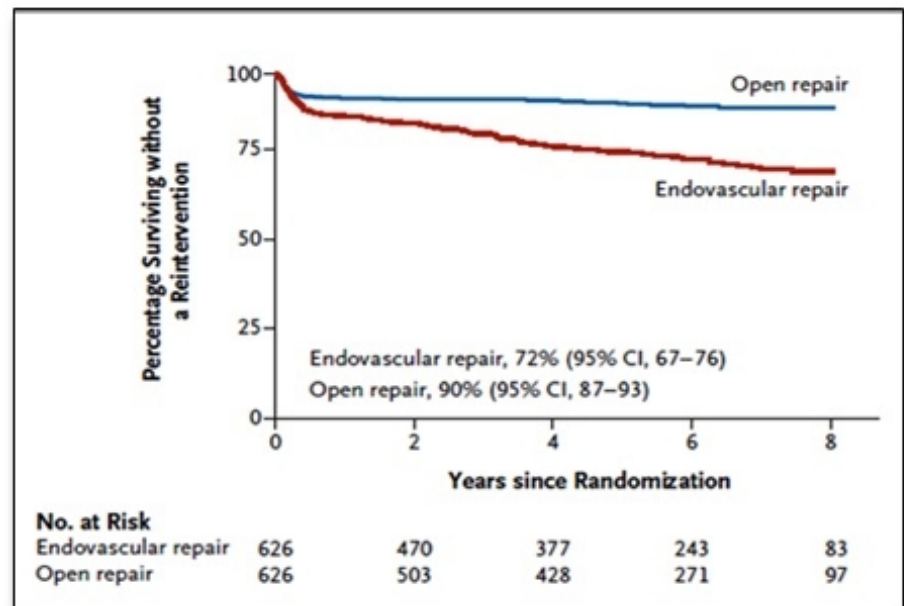


Sachs T, et al. *J Vasc Surg.* 2011;54:881-888

EVAR Has Higher Complications than Open Aneurysm Repair: EVAR-1 & DREAM Trials

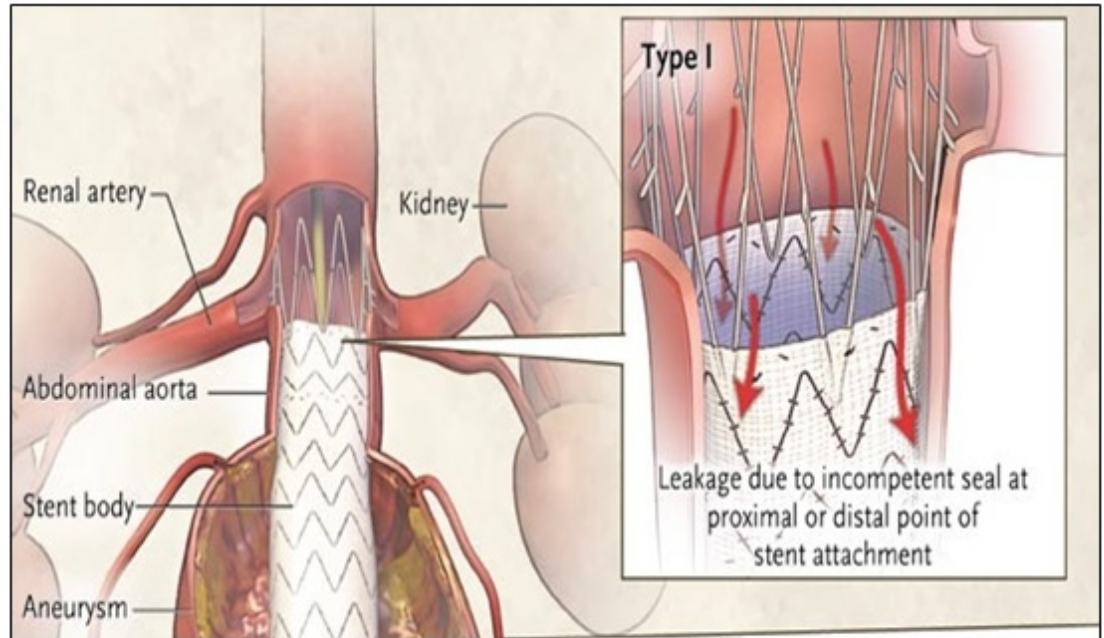
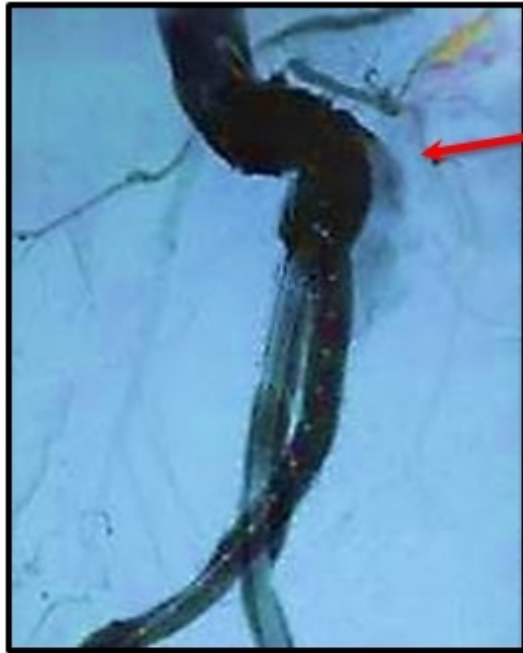


De Bruin *et al.* N Engl J Med 2010;362:1881-9



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

Most EVAR Complications at Proximal Neck of Aneurysm



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



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

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

Heli-FX System Designed to Treat Neck Issues: Unique Instruments Navigate & Implant the Heli-FX System



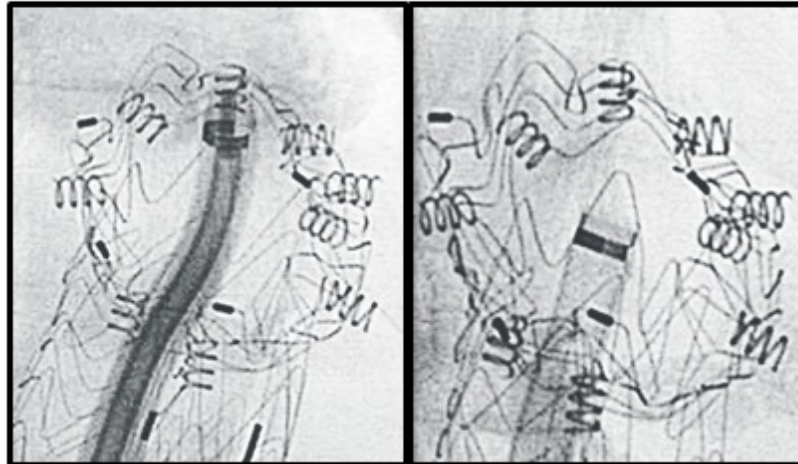
Tip of Applier



Applier & Guide



Cassette with EndoAnchors

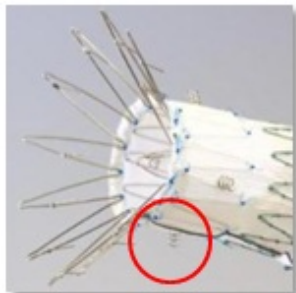


Heli-FX System 510(k) Cleared as Medical Device: Indicated for Use in Variety of Commercial Endografts



- Provides fixation, augments seal between endovascular graft and aorta. Indicated for patients at risk for or experiencing endoleak or migration.
- Determined compatible with Cook Zenith® & TX2®, Gore Excluder® & TAG®, Medtronic AneuRx®, Endurant®, Talent® (AAA) & Valiant® (TAA)

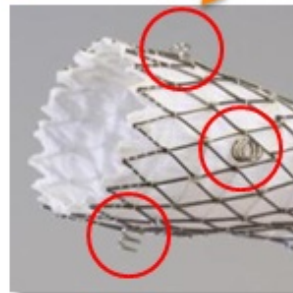
EndoAnchors shown here



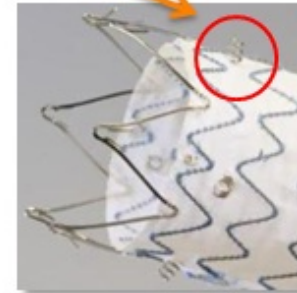
**Cook
Zenith®**



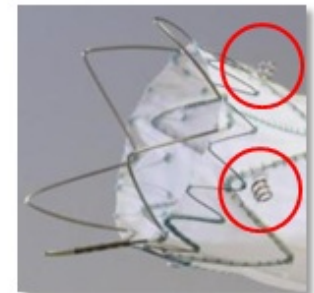
**Gore
Excluder®**



**Medtronic
AneuRx®**



**Medtronic
Endurant®**



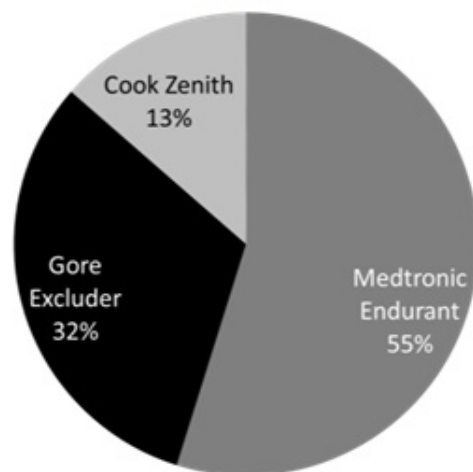
**Medtronic
Talent®**

Despite Being a New Technology, Heli-FX Usage Growing

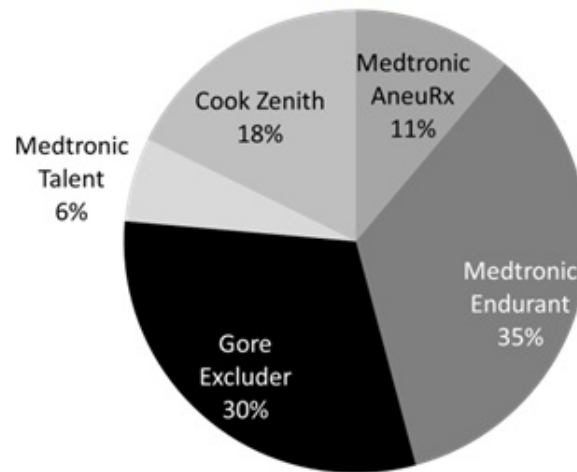
Clinical & Commercial Experience

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

STAPLE-2 IDE: Positive Outcomes in Short Necks



STUDY OUTCOMES

Endpoint	Outcome
Primary Safety (30 day):	98.1% (152/155)
Primary Effectiveness (1 year):	97.4% (151/155)
No EndoAnchor-related adverse events; no late ruptures, Type I Endoleaks, EndoAnchor Dislocation or Fractures	

Proximal Neck Length

≤ 15mm	n=42 (27%)
≤ 10mm	n=18 (12%)

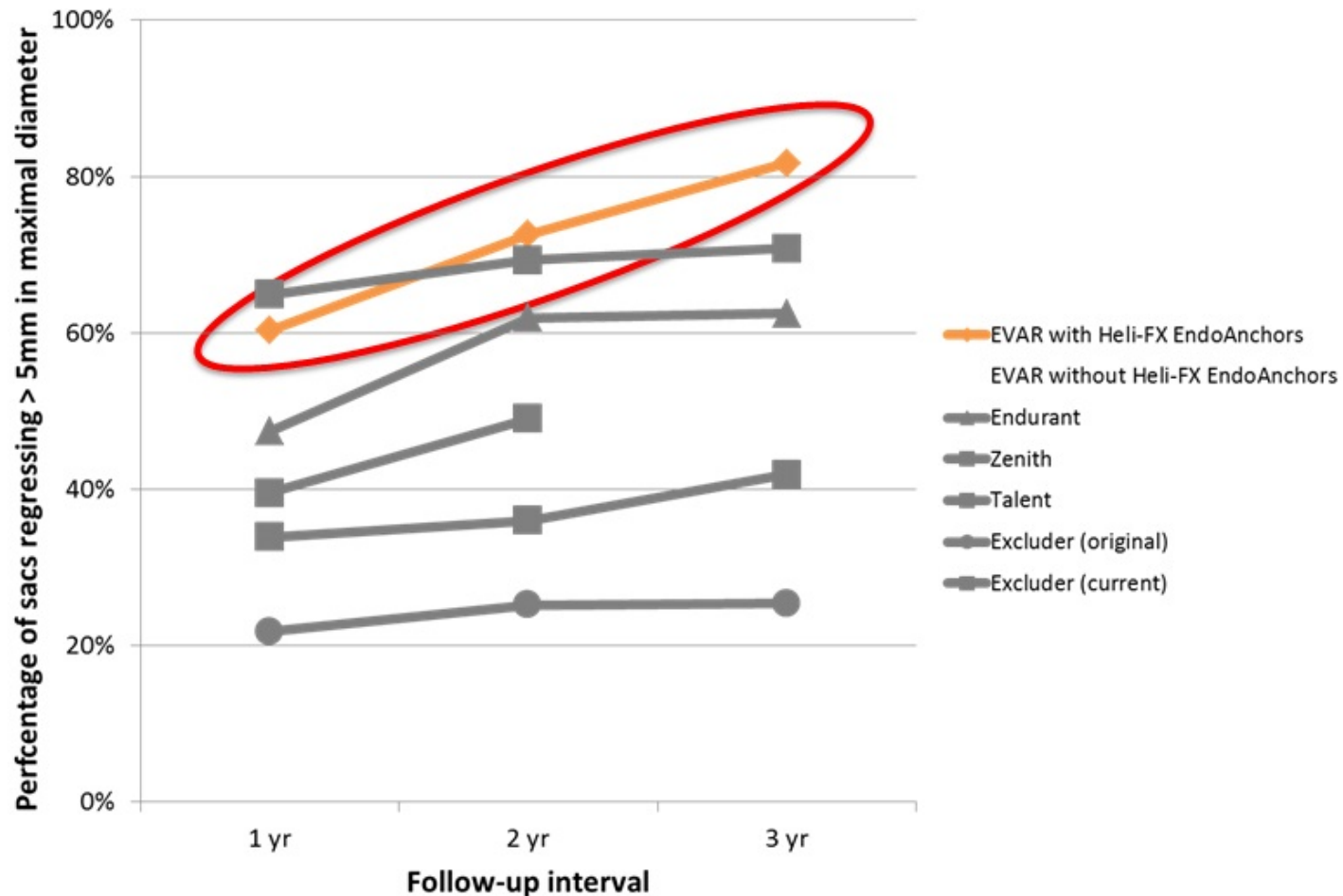


Short <10-15mm (Length)

STAPLE-2: Heli-FX Yields Best Aneurysm Regression, Despite High Prevalence of Hostile Proximal Neck



Aneurysm regression with and without Heli-FX EndoAnchors



ANCHOR Post-Market Registry:

Large, Prospective, Real World, US/EU Study



Design	Prospective, 5-year, dual-arm registry • Primary arm – EndoAnchors placed at time of endograft implant • Revision arm – EndoAnchors placed as part of a later revision procedure	
	Enrollment	
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
Heli-FX	• Used with a variety of commercial endograft • As a stand-alone procedure	
Usage	• 5-6 EndoAnchors per Heli-FX procedure (Median) • Reason for EndoAnchoring: – Treatment of Type 1a Endoleak – Concern for Late Failure	

ANCHOR Registry:

Highly Favorable Results in Difficult to Treat Population



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

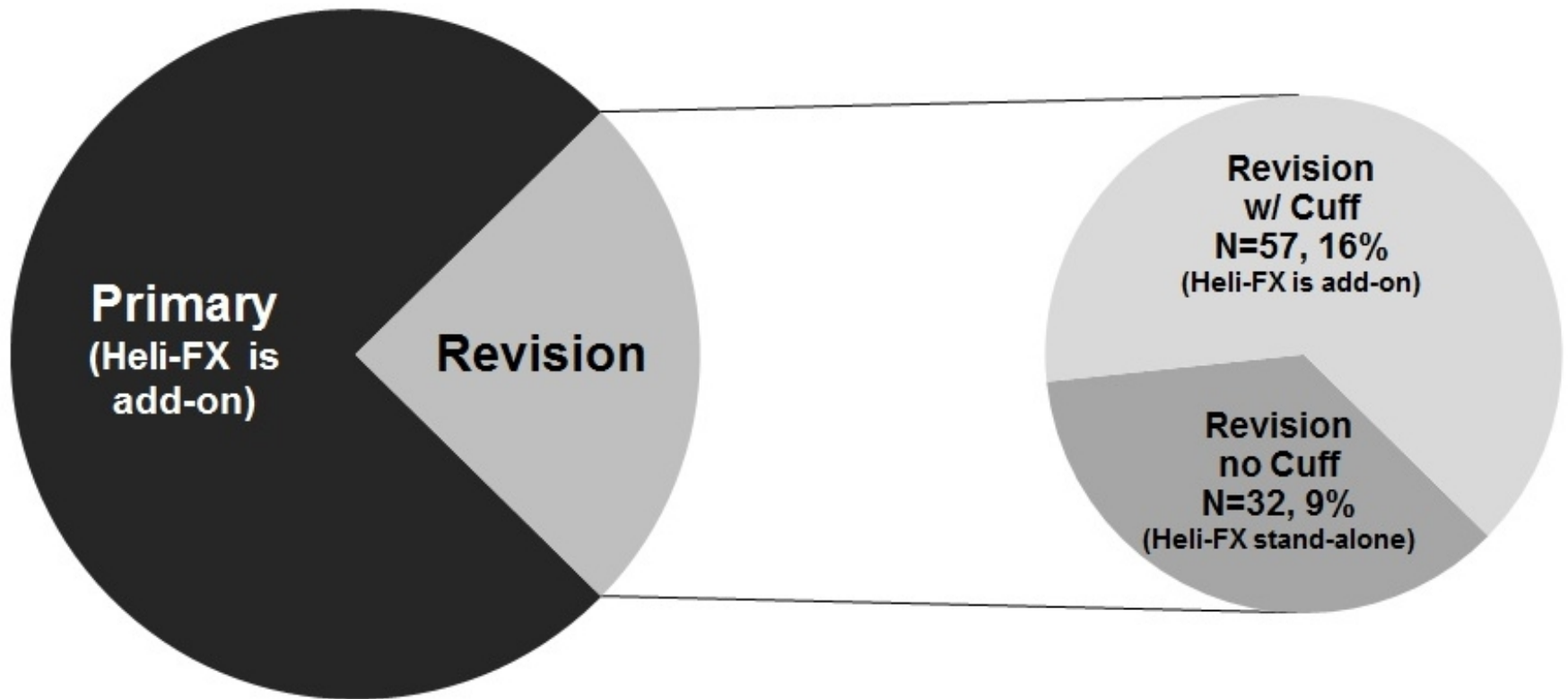
- No EndoAnchor related SAEs or re-interventions
- 50% of type 1 endoleaks treated w/EndoAnchors also used Cuffs (53/106)
- Results compare favorably to published data on endografts without Anchors

ANCHOR Registry – EndoAnchor Usage

Add-on to EVAR and as Stand-Alone



Procedure break-down:





The EndoAnchoring Procedure



Heli-FX Procedure Duration: Varies with # of Anchors, Complexity of Anatomy, Difficulty of Procedure



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

Heli-FX Procedure: Preparation (Pre-Insertion)



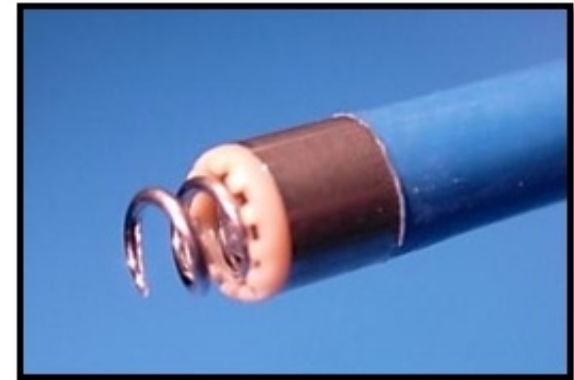
System Preparation:

- Saline flush all components
- Turn Applier on



Loading Applier:

- Verify loading



Heli-FX Procedure:

Guide Inserted & Positioned, Applier Inserted & Advanced



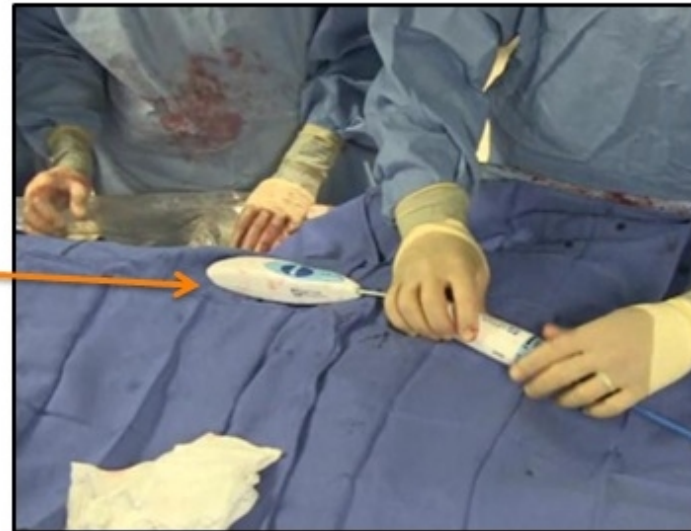
Heli-FX Guide



Dilator & Guide
at Proximal Neck



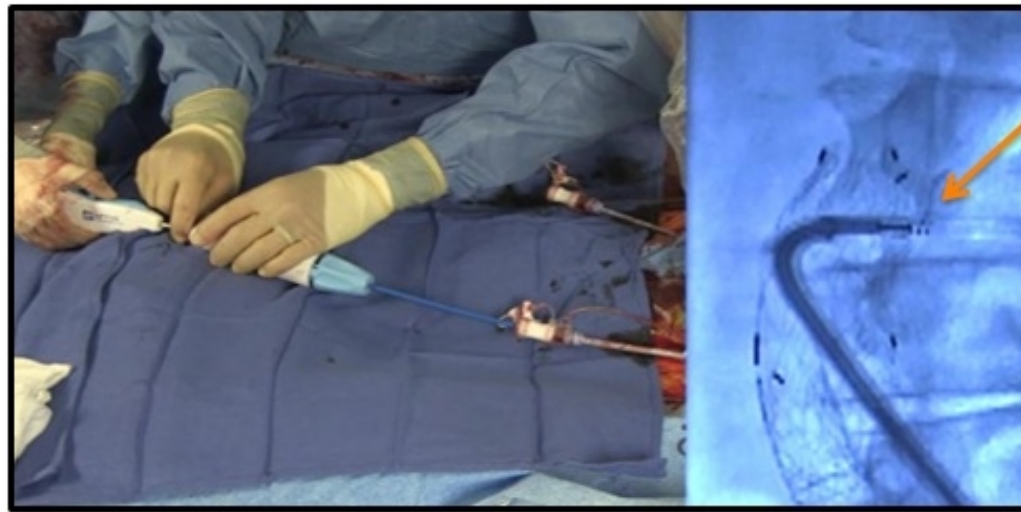
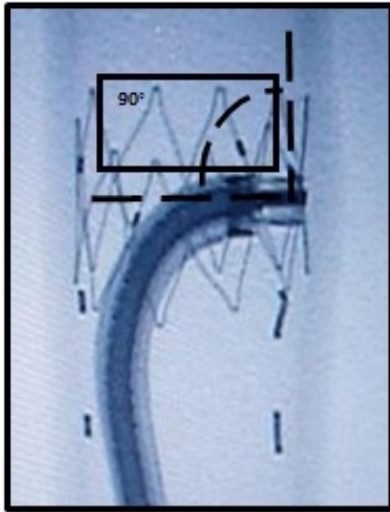
Applier Inserted
into Guide



Applier is
Advanced to
Proximal Neck



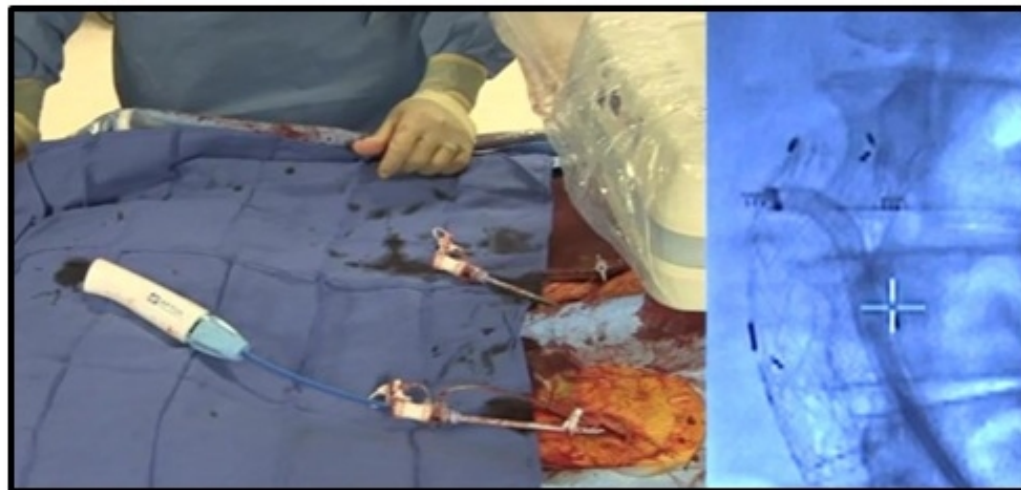
Heli-FX Procedure: Positioning & Implantation



Maneuver repeated for each implant

Proper alignment
imperative

Implant procedure
repeated for each
EndoAnchor

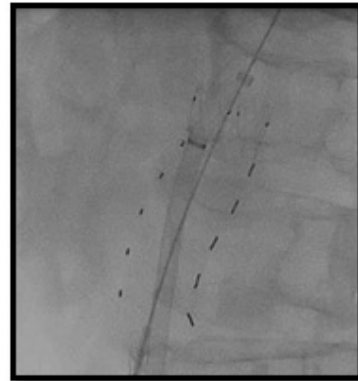


Heli-FX Procedure Fluoroscopic View

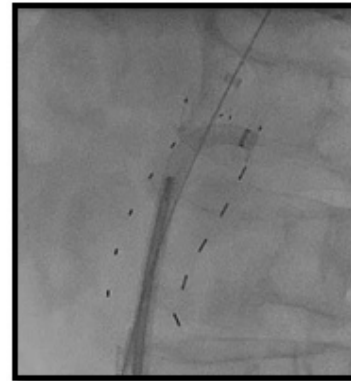
Adjunct to Primary EVAR



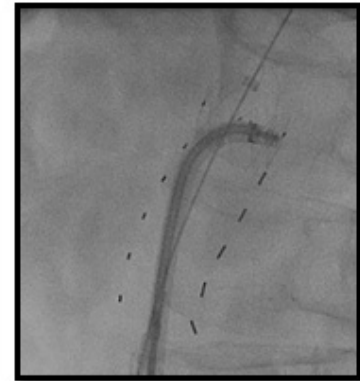
Angiogram prior to EndoAnchoring Ensuring Proper Graft Location



Heli-FX Guide Advancement

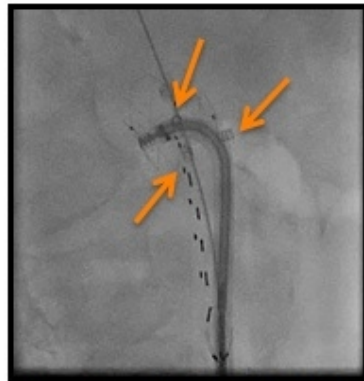


1st Anchoring Location Selected w/ Guide (C-Arm LAO 45°)

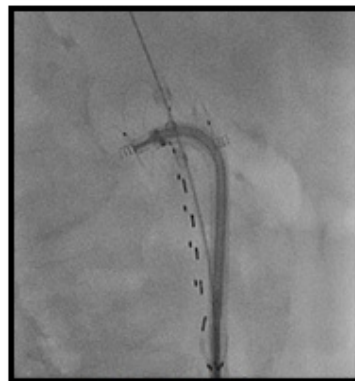


Heli-FX Applicator Ready to Implant 1st EndoAnchor

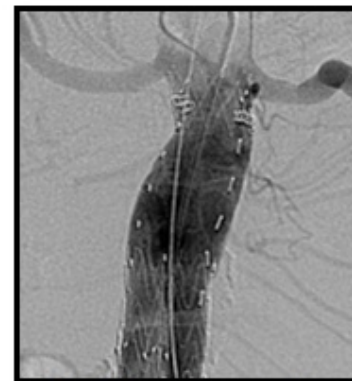
Arrows Denote Implanted 3 EndoAnchors



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



4th EndoAnchor Implanted



Final Angiogram after EndoAnchoring

Images courtesy of Dr. Burkhard Zipfel, Deutsches Herzzentrum Berlin

Heli-FX Clinical Scenarios Vary According to Patient Need:

Six Procedural Applications

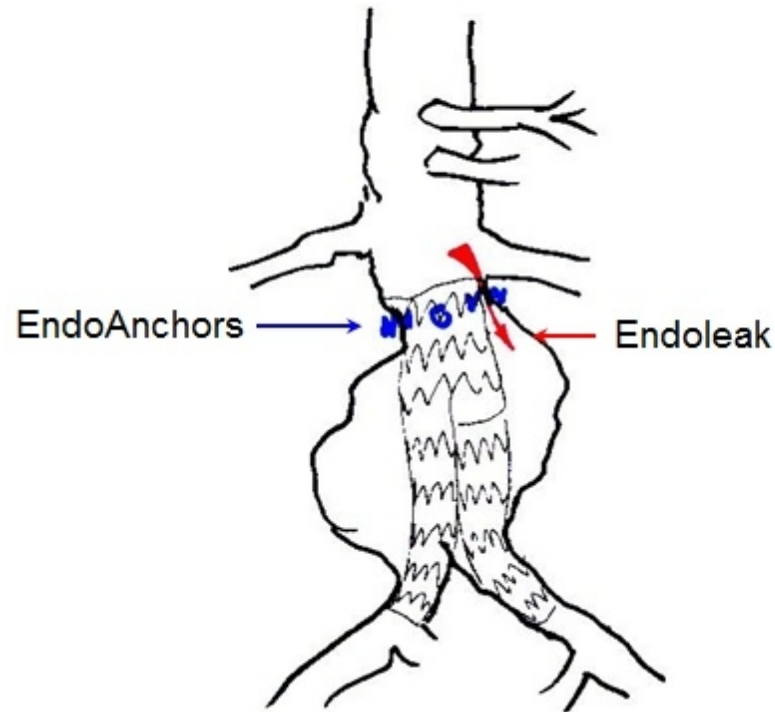


		EVAR (AAA)	TEVAR (TAA)
Heli-FX as Add-On Procedure	Primary	Control of acute Endoleak and/or Hostile anatomy	Control of acute Endoleak and/or Hostile anatomy
	Revision	Control of Endoleak / repair of migration	Control of Endoleak / repair of migration
Heli-FX as Stand-Alone	Revision with only Heli-FX	Control of Endoleak	Control of Endoleak

Heli-FX Shown as Stand Alone Procedure in AAA



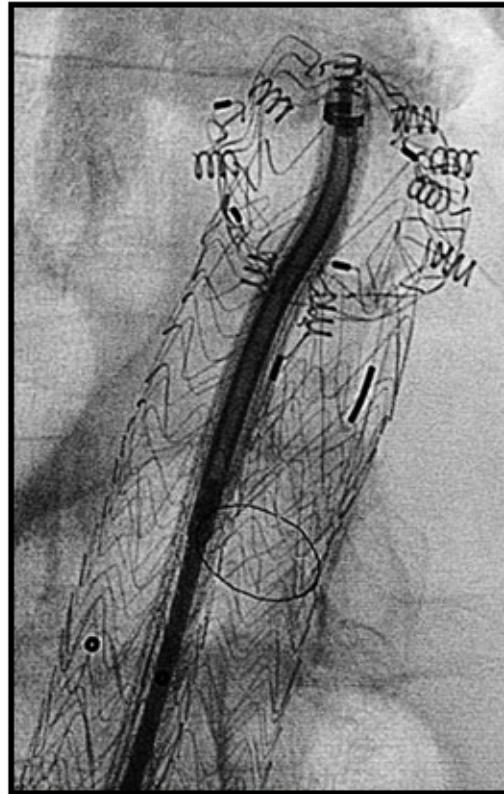
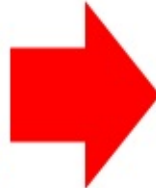
EndoAnchoring Stand Alone Procedure to Repair Endoleak



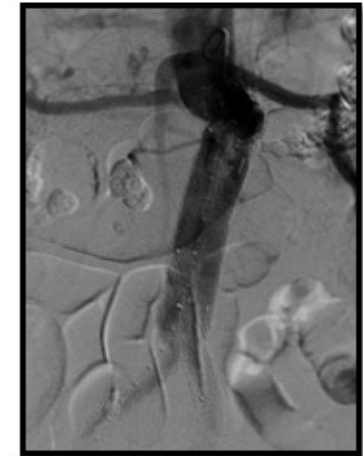
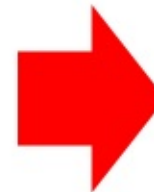
Heli-FX Shown as Stand Alone Procedure in AAA Revision Case with Type 1a Endoleak



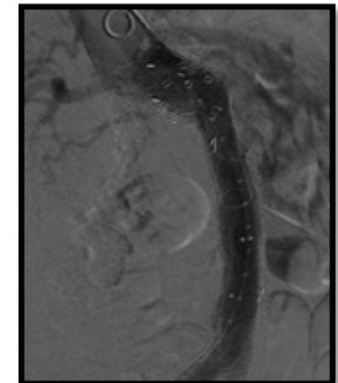
Type 1a Endoleak
One week post implant



Nine Heli-FX EndoAnchors implanted



Type 1a Endoleak
Resolved without cuff

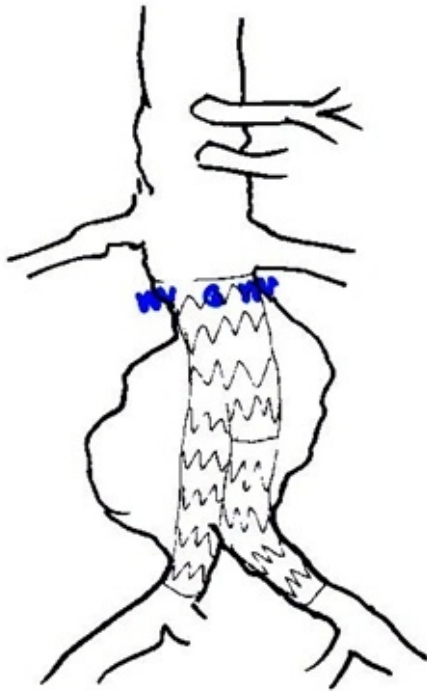


Images courtesy of Bart Muhs, MD & John Aruny, MD
Yale New Haven Medical Center

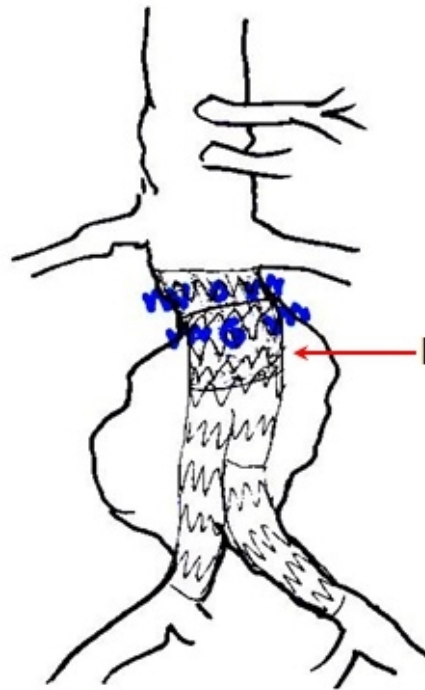
Heli-FX Shown as Add-On Procedure in AAA



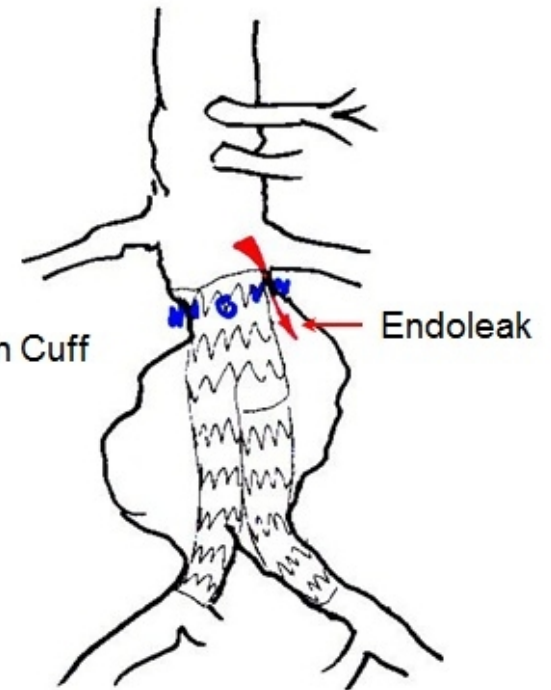
Primary Challenging
Neck Anatomy
with EndoAnchors



Revision
with Cuff
+ EndoAnchors



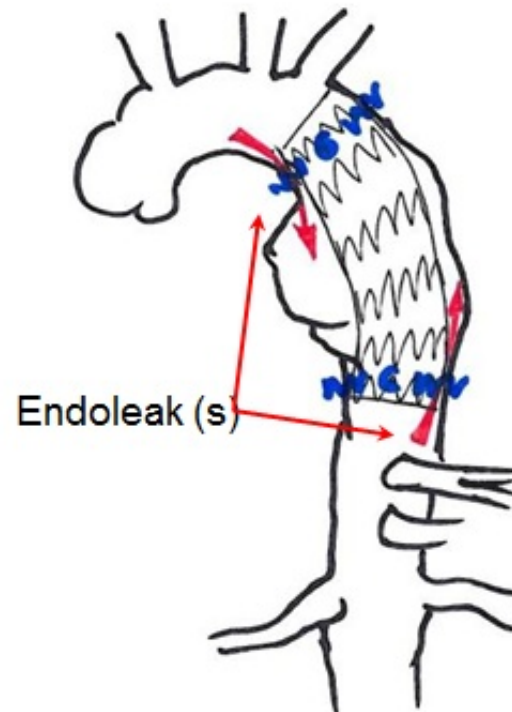
Treatment of Acute Endoleak
with EndoAnchors



Heli-FX Shown as Stand Alone Procedure in TAA



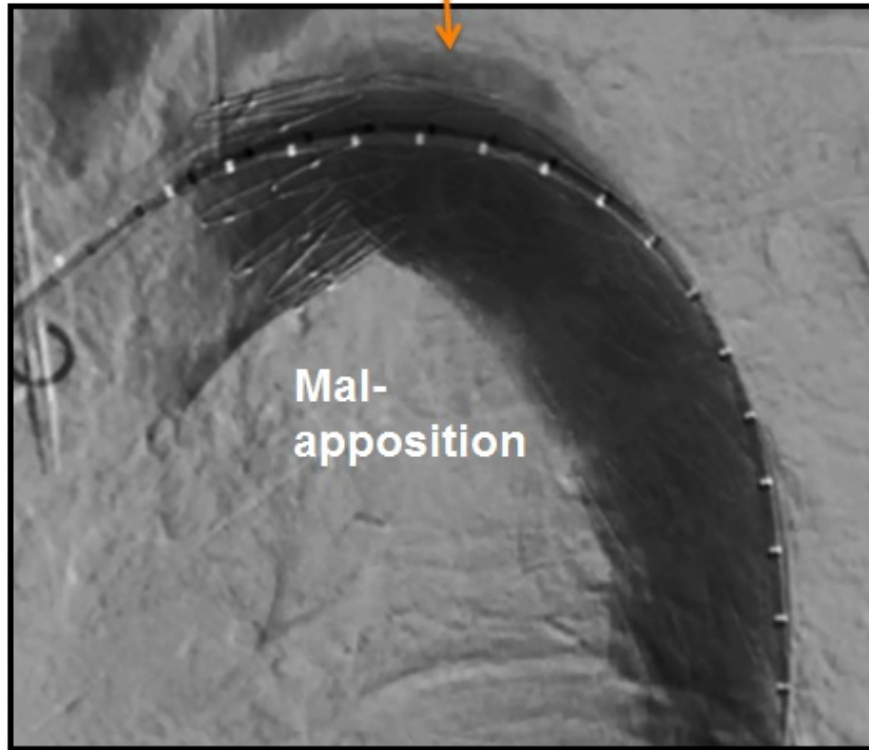
EndoAnchoring Stand Alone Procedure to Repair Endoleak



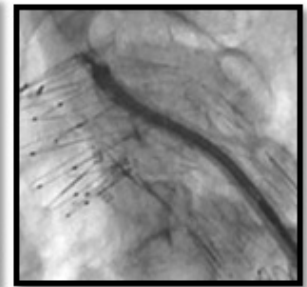
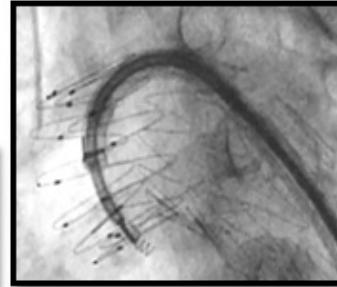
Heli-FX Shown as Stand Alone Procedure in TAA: Primary TEVAR – Short Proximal / Distal Necks



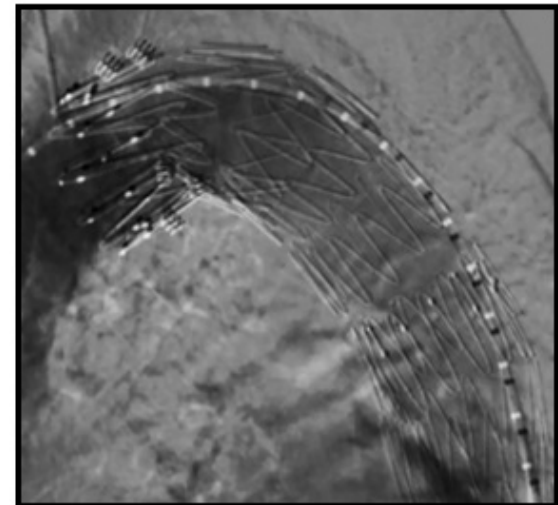
Type 1a Endoleak



Mal-
apposition



4 EndoAnchors implanted



Final Angio, leak resolved

Case images courtesy of P Kasprzak MD, Regensburg

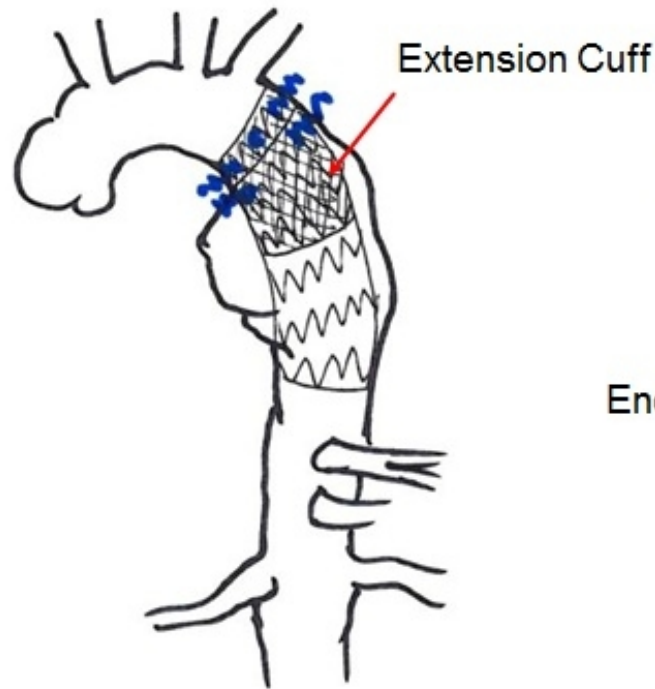
Heli-FX Shown as Add-On Procedure in TAA



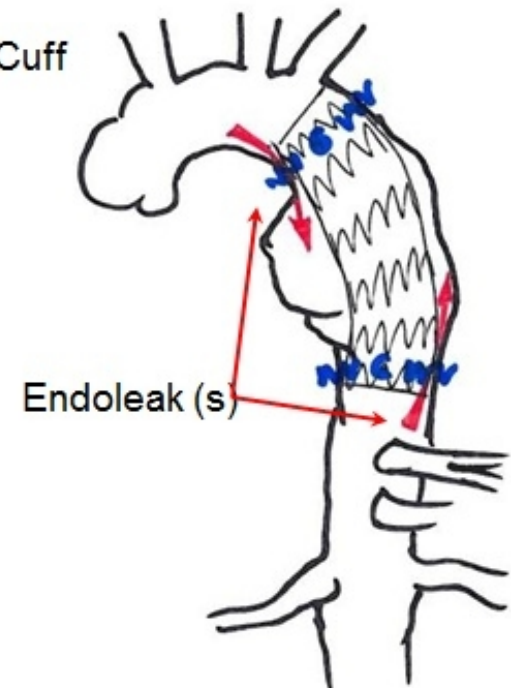
Primary Prophylactic
Proximal &
Distal shown



Primary or Revision
with Cuff



Treatment of Acute Endoleak
with EndoAnchors





Coding





There no ICD9-CM and ICD10-PCS codes to describe the placement and implantation of the Heli-FX Stand-alone and Add-on procedures during EVAR and TEVAR

		EVAR (AAA)	TEVAR (TAA)
Heli-FX as 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 as Stand-Alone	Revision with only Heli-FX	Control of Endoleak	Control of Endoleak



- NTAP Application is under consideration for FY2015
- Cleared by the FDA as a Medical Device to repair and prevent endograft complications in the abdominal and thoracic aorta
- Distinct procedure with its own beginning, middle & end from that of the endovascular graft procedure
- Use of distinct instruments are required for the deployment of the Heli-FX System
 - Cassette and Heli-FX EndoAnchors
 - Deflectable Guide and Obturator
 - Heli-FX Applier
- Requires additional operating room time (excluding pre-planning time) of (30) minutes during EVAR and (45) minutes during TEVAR for the surgeon to implant 5-6 Heli-FX EndoAnchors into the wall of the abdominal or thoracic aorta

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>

Rationale for new Heli-FX Procedure ICD10-PCS Codes (cont'd)



- Versatile because the Heli-FX system can be used with most commercially available endografts in an Adjunctive or Stand-alone manner
- Need to 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 and as a result;
 - No comparable ICD9-CM, ICD10-PCS codes exist because there is no other FDA approved implantable device which serves the same function as the Heli-FX System

Heli-FX Procedure ICD10-PCS Proposal



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

- Create a new device character
- Add the Heli-FX System to the Device Key because it is a new technology



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

Thank you

Q & A

