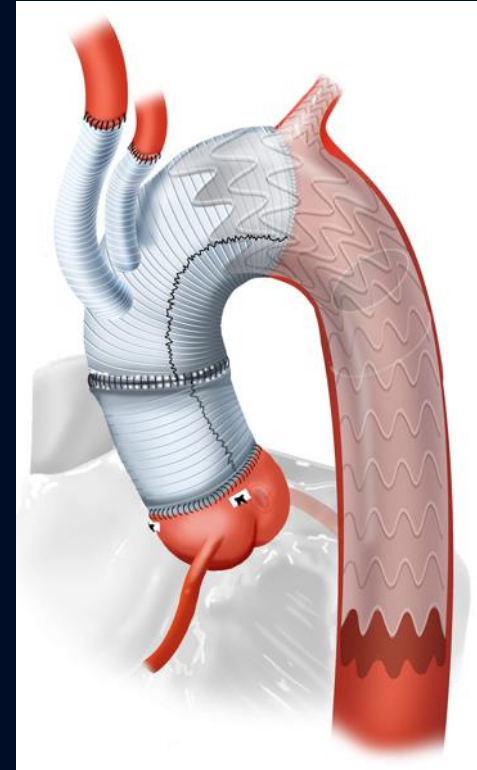
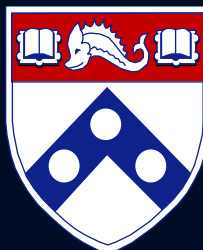


Aorta Live Essen 2016

# Endo Arch Repair: Gore perspective



Nimesh D. Desai, M.D., Ph.D.  
Co-Director, Thoracic Aortic and Vascular Center for Excellence  
University of Pennsylvania



# Who does NOT need Ascending /Arch TEVAR:

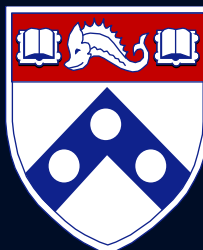
## Congenital Aortic Syndromes – Ascending only pathology



Ascending+Transverse 28%

Ascending Only 10%

Root Only 13%



# Arch Hybrid Concepts : Landing Zones



## I. Distal Arch Aneurysm

1. Zone 2 (carotid-subclavian bypass)
2. Zone 1 (Asc- L Carotid; Innominate-Carotid-subclavian bypass)



## II. Saccular Arch Aneurysm (Type I)

1. Classic “debranching” operation
2. Good Prox and Distal LZs

## III. Ascending / Arch Aneurysm (Type II)

1. No Prox LZ
2. Must reconstruct LZ o

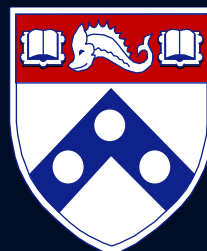
## IV. Mega Aortic Syndrome (Type III)

1. No Prox and Distal LZs
2. Stent Elephant trunk with staged TEVAR

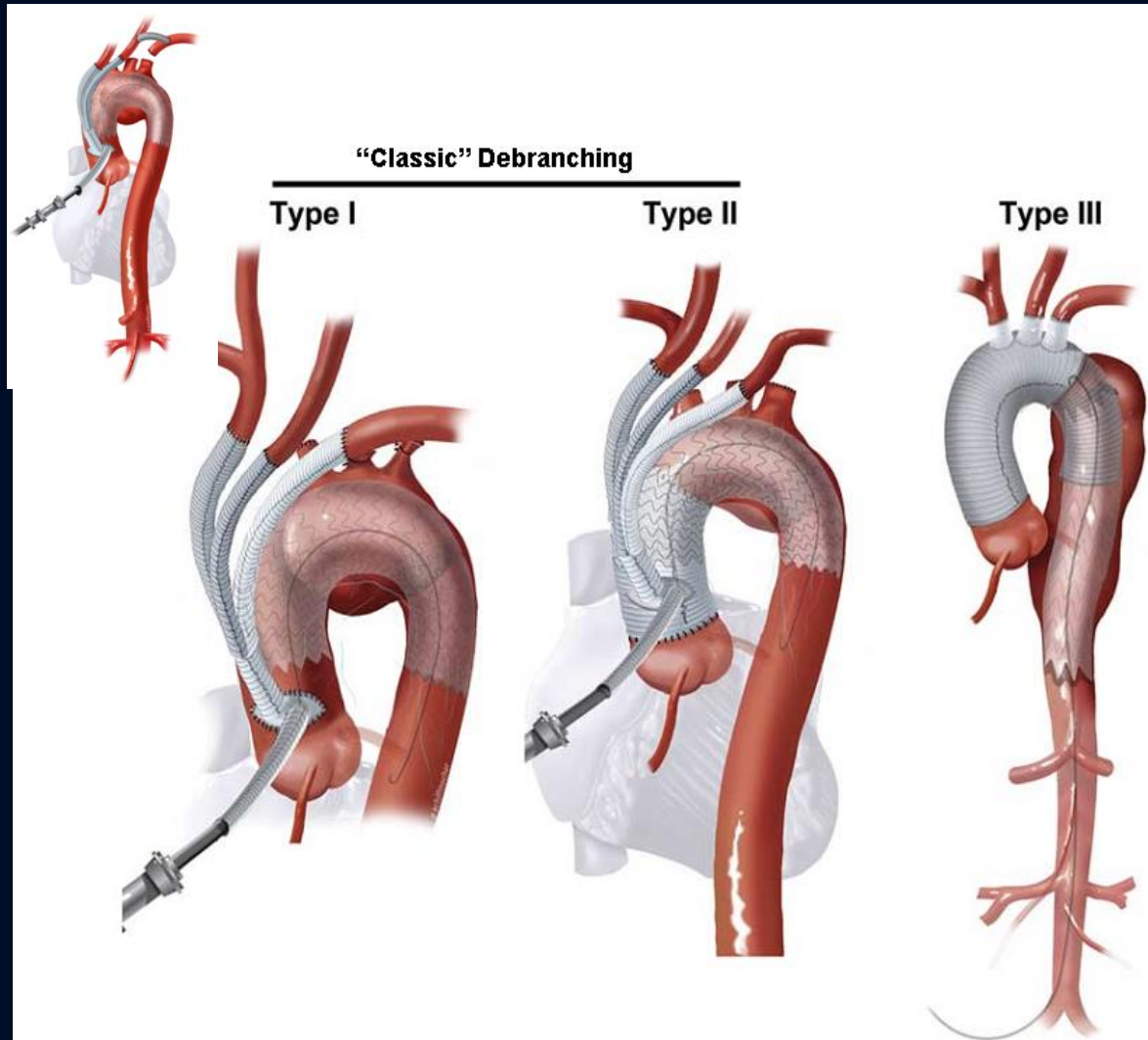
DEBRANCHING



Zone O

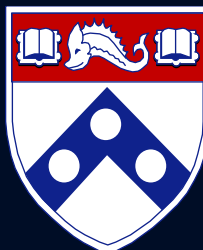


# Zone 0 Landing



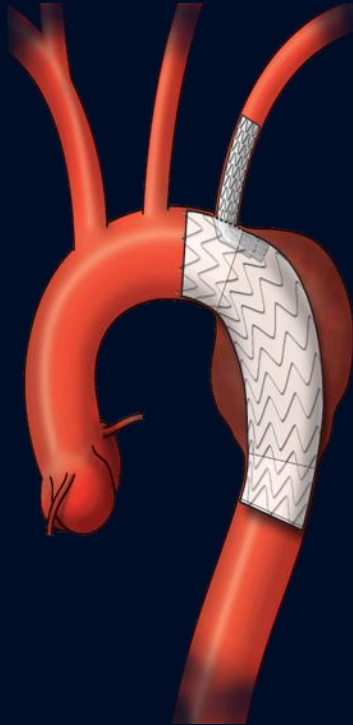
# Current treatment outcomes for aortic arch

- Open surgical repair
  - Longer hospital stays
  - Younger, healthier patients
- Endovascular Repair (parallel, branched, and fenestrated)
  - High risk for open repair
  - Not intended use of devices
- Hybrid Repair
  - High risk for open repair
  - Not intended use of devices
- Perioperative mortality
  - Open = 8.6% (Leshnower, 2011)
  - Parallel device = 4.8% (Moulakakis, 2013)
  - Hybrid = 10.8% (Cao, 2012)
- Stroke/neurological events
  - Open = 8.2% (Hiraoka, 2014)
  - Parallel devices = 4% (Moulakakis, 2013)
  - Hybrid = 6.8% (Cao, 2012)
- Reinterventions
  - Open = 9% (Sundt III, 2008)
  - Parallel = 30.8% (Mangialardi, 2014)

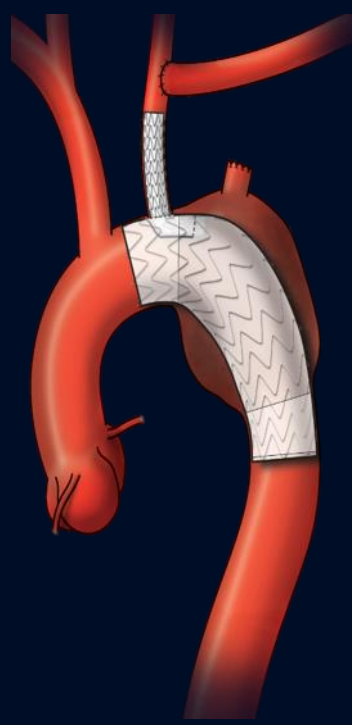


# GORE® TAG® Thoracic Branch Endoprosthesis (TBE)

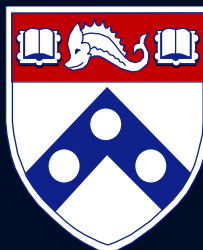
Zone 2



Zone 1

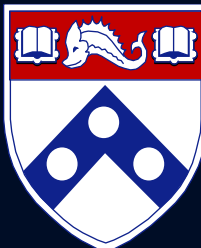
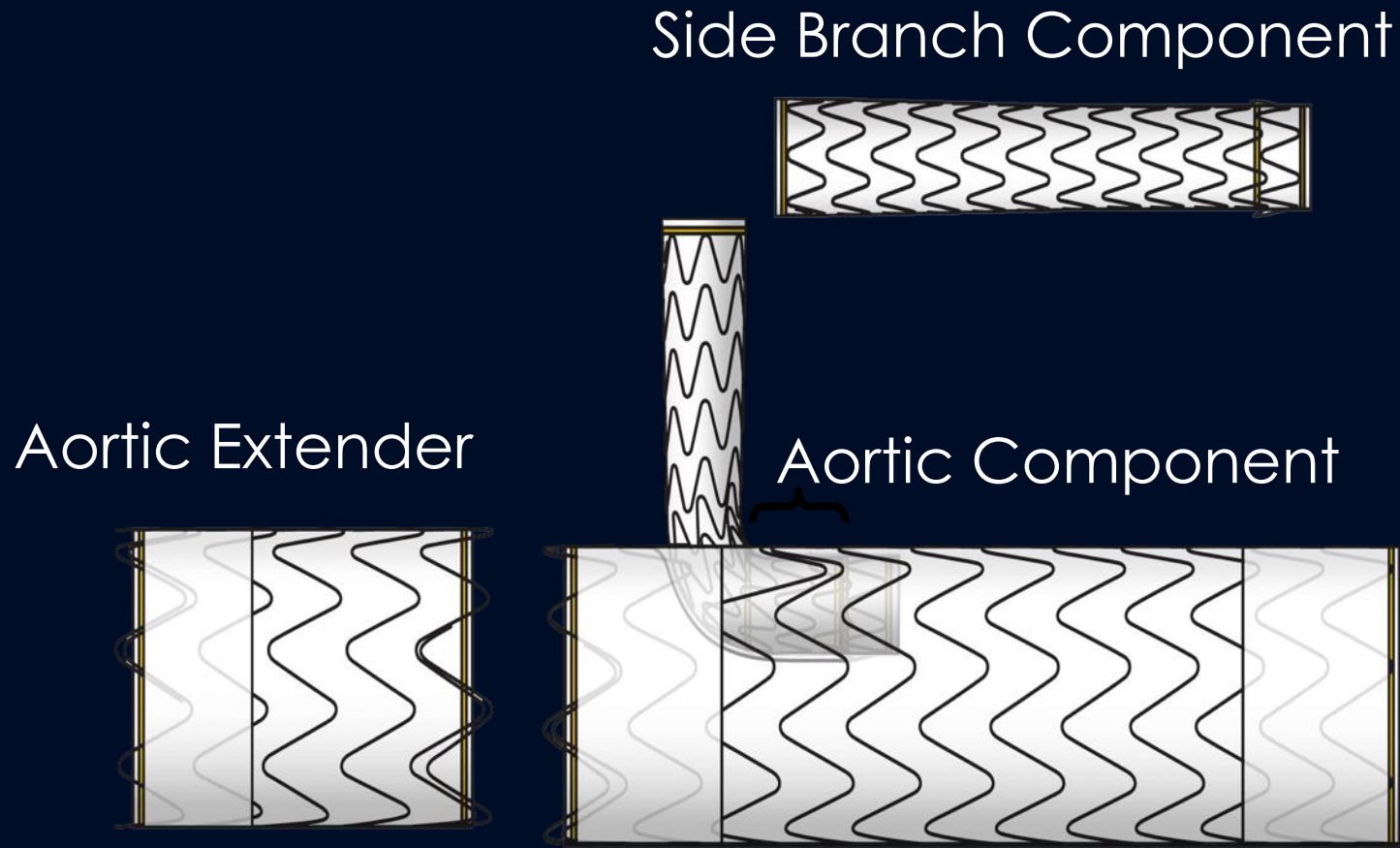


Zone 0

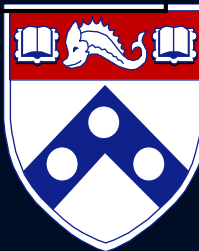
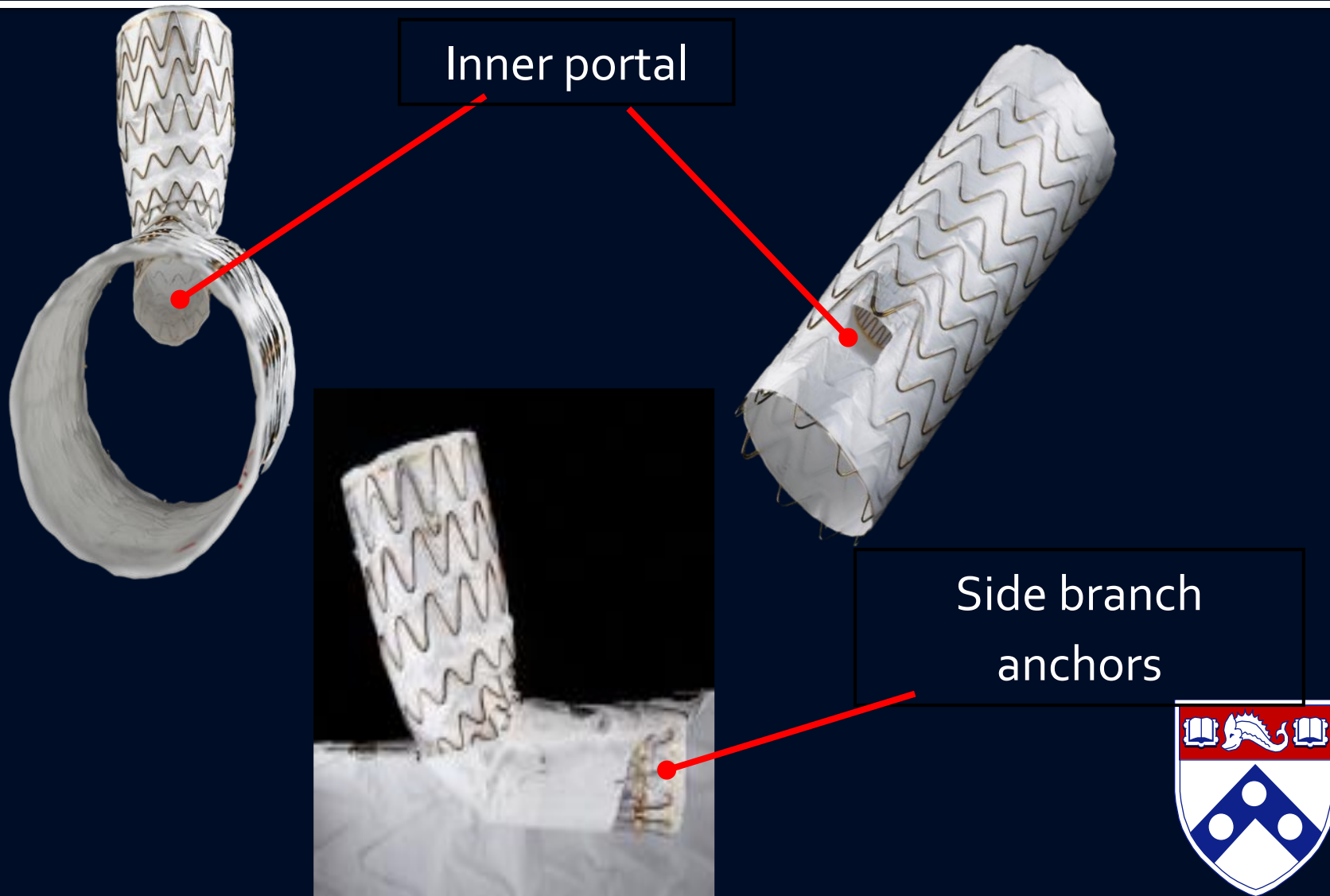




# GORE® TAG® Thoracic Branch Endoprosthesis



# GORE® TAG® Thoracic Branch Endoprosthesis





# Procedural Steps

## Step 1:

- Insert guidewires in aorta and branch vessel

## Step 2:

- Introduce aortic component over both guidewires into position within the arch

## Step 3:

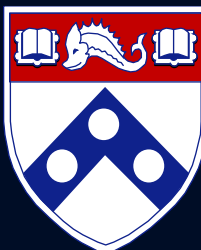
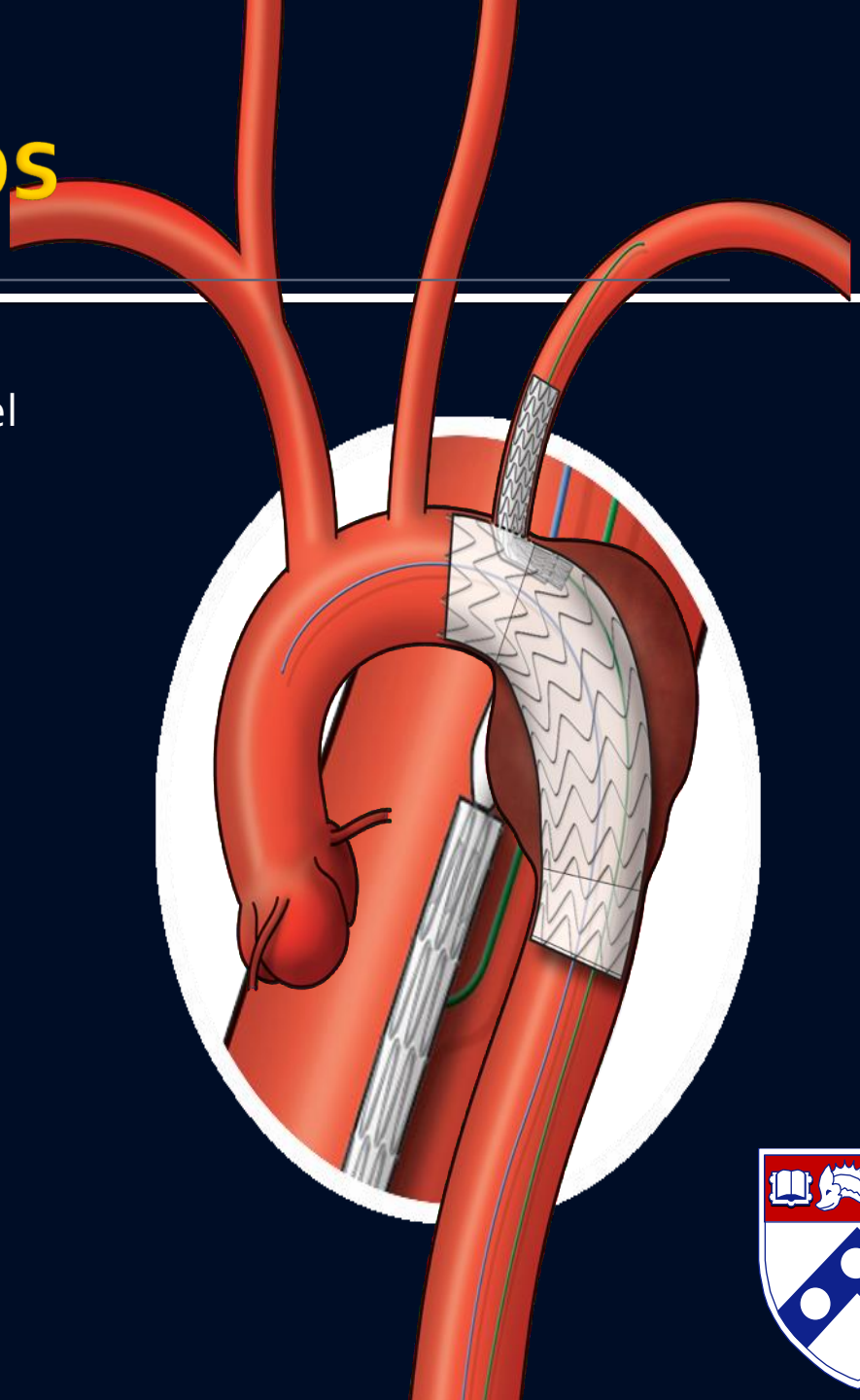
- Deploy aortic component and withdraw catheter

## Step 4:

- Advance introducer sheath and dilator

## Step 5:

- Advance and deploy branch component



# TBE Device Clinical Trials Overview

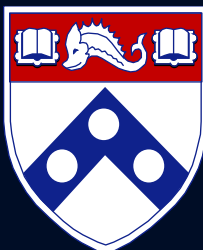
## Enrollment Complete

### ZONE 2 FEASIBILITY STUDY

- 31 patients enrolled
- Primary endpoints
  - Successful access and deployment of TBE
  - Primary patency of side branch assessed by angiography at conclusion of procedure
- Secondary endpoints
  - One month Core lab analysis
    - Side branch primary patency assessed
    - Device-related endoleaks

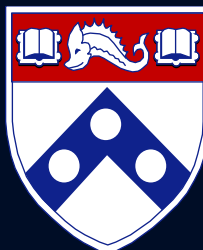
### ZONE 0/1 EARLY FEASIBILITY STUDY

- 9 patients enrolled
- Patients must be high risk for conventional open repair
- Primary endpoints
  - Successful access and deployment of TBE
  - Primary patency of side branch assessed by angiography at conclusion of procedure
- Secondary endpoints
  - One month Core lab analysis
    - Side branch primary patency assessed
    - Device-related endoleaks



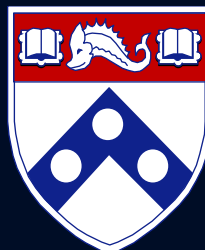
# Procedural Data

	Zone 2	Zone 0/1
Number of Enrolled Subjects	31	9
<b>Access Successful</b>	100%	100%
<b>Deployment Successful</b>	100%	100%
<b>Procedural Survival</b>	100%	100%
<b>Side Branch Patent at Conclusion of Procedure</b>	100%	100%
<b>Procedure Time (min)</b>		
Mean (Std Dev)	204.5 (111.6)	216.1 (89.5)
Range	(85, 560)	(95, 378)
<b>Length of Stay (days)</b>		
Mean (Std Dev)	5.1 (4.2)	15.0 (13.5)
Range	(1, 19)	(3, 43)



# Outcomes Data

1 month outcomes	Zone 2	Zone 0/1
Number of Enrolled Subjects	31	9
Patient Survival	100% (31/31)	100% (9/9)
Stroke	3.3% (1/31)	22.2% (2/9)
Spinal Cord Ischemia	3.3% (1/31)	0% (0/9)

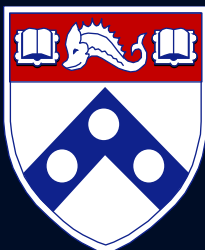


# Side Branch Patency

## ■ Side Branch Component Patency – Core Lab

Zone 2			
	1 Month	6 Months	12 Months
Number of Patients	29	19	16
Side Branch Patent	29	18	15

Zone 0/1			
	1 Month	6 Months	12 Months
Number of Patients	8	6	4
Side Branch Patent	8	6	4



# Summary of Preliminary Results

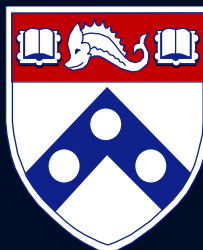
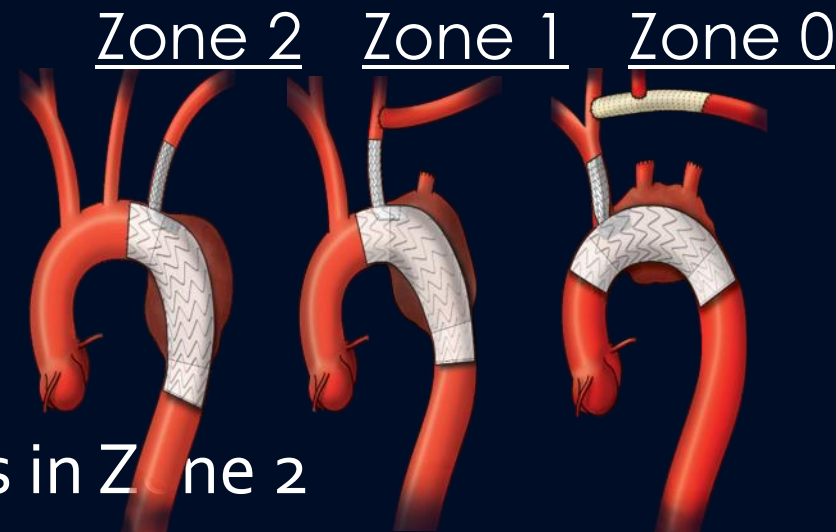
- 100% Technical success for Zones 0-2
- 100% Survival at 1 month for Zones 0-2

- Peri-procedural Stroke

- 1 strokes in Zone 2
- 2 strokes in Zone 0

- Side Branch Patency

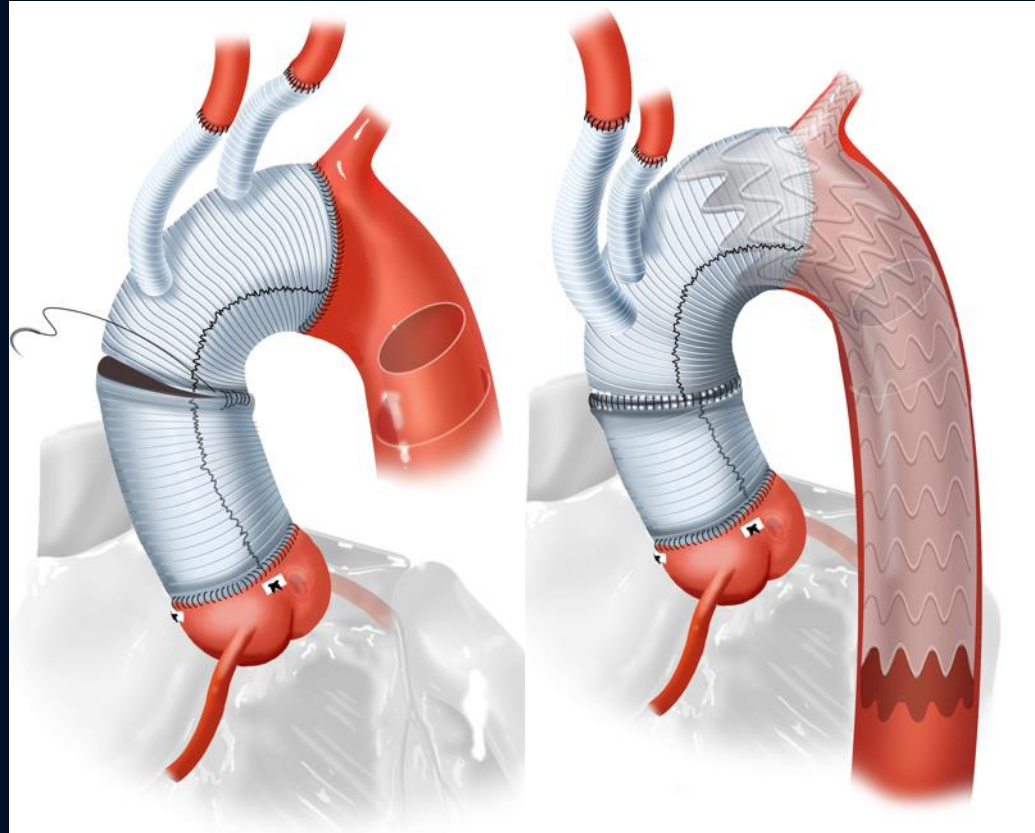
- 1 loss of patency at 6 months in Zone 2
- No loss of patency in Zone 0



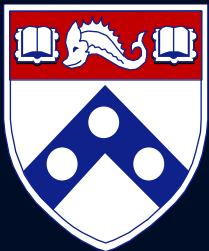


# *ZONE 2 Arch with Branched TEVAR completion for Acute Type A with large DTA tear*

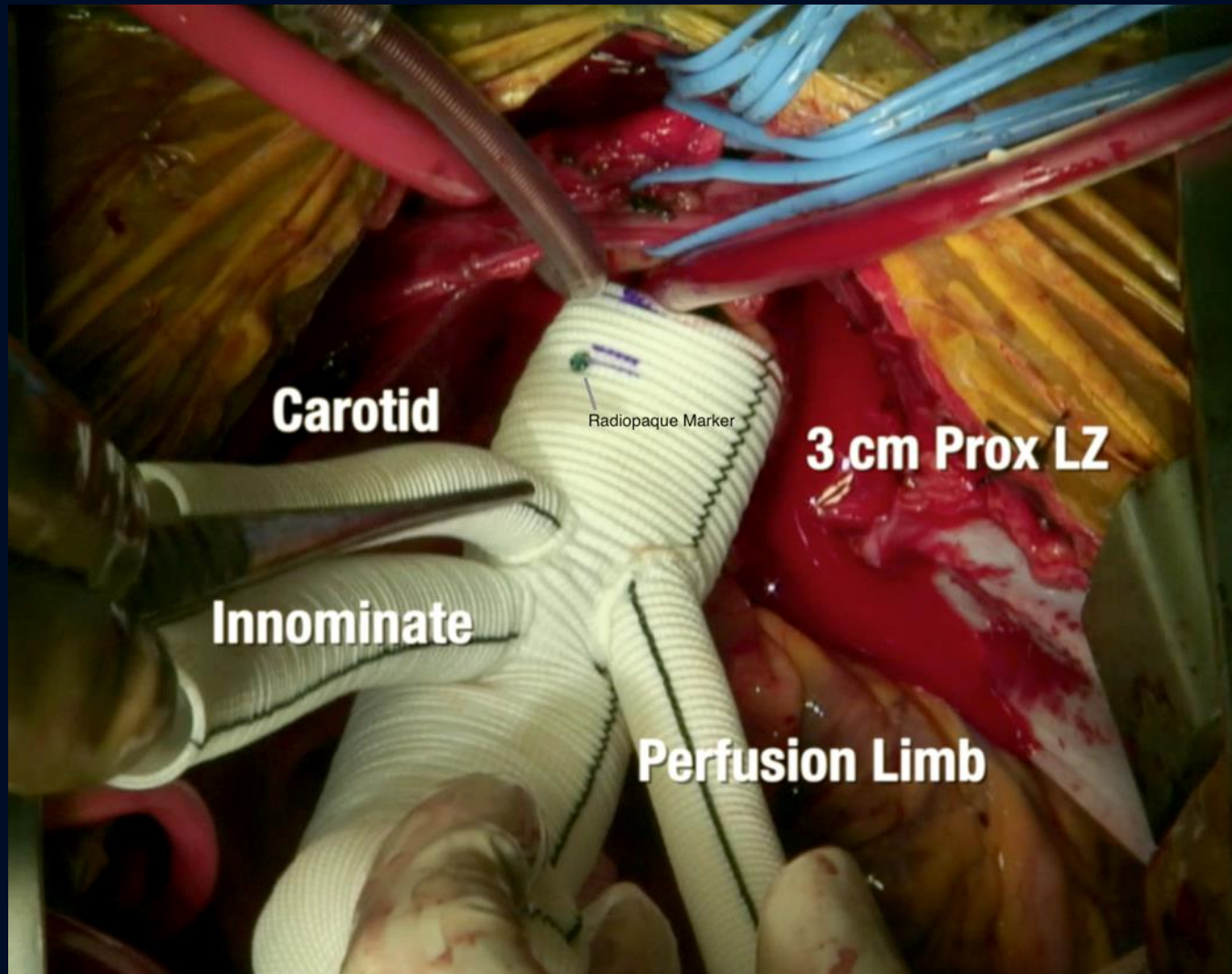
- Advantages
  - Simpler Distal Anastomosis
  - Can address most complex arch tears and eliminate flap in proximal head vessels
  - Shorter ACP times
  - Definitive TEVAR options
  - Less risk of Recurrent laryngeal nerve injury



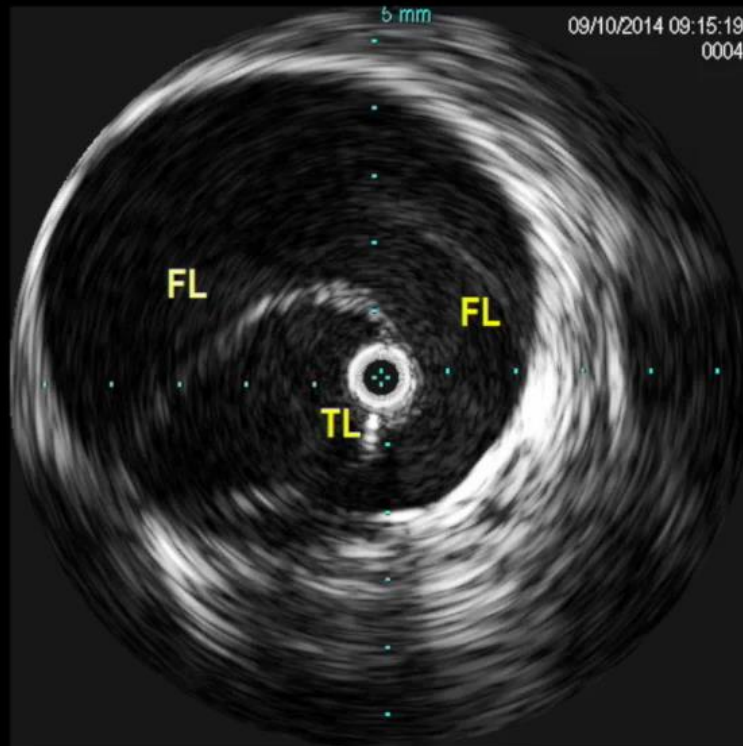
Desai STS 2015



# Zone 2 Arch



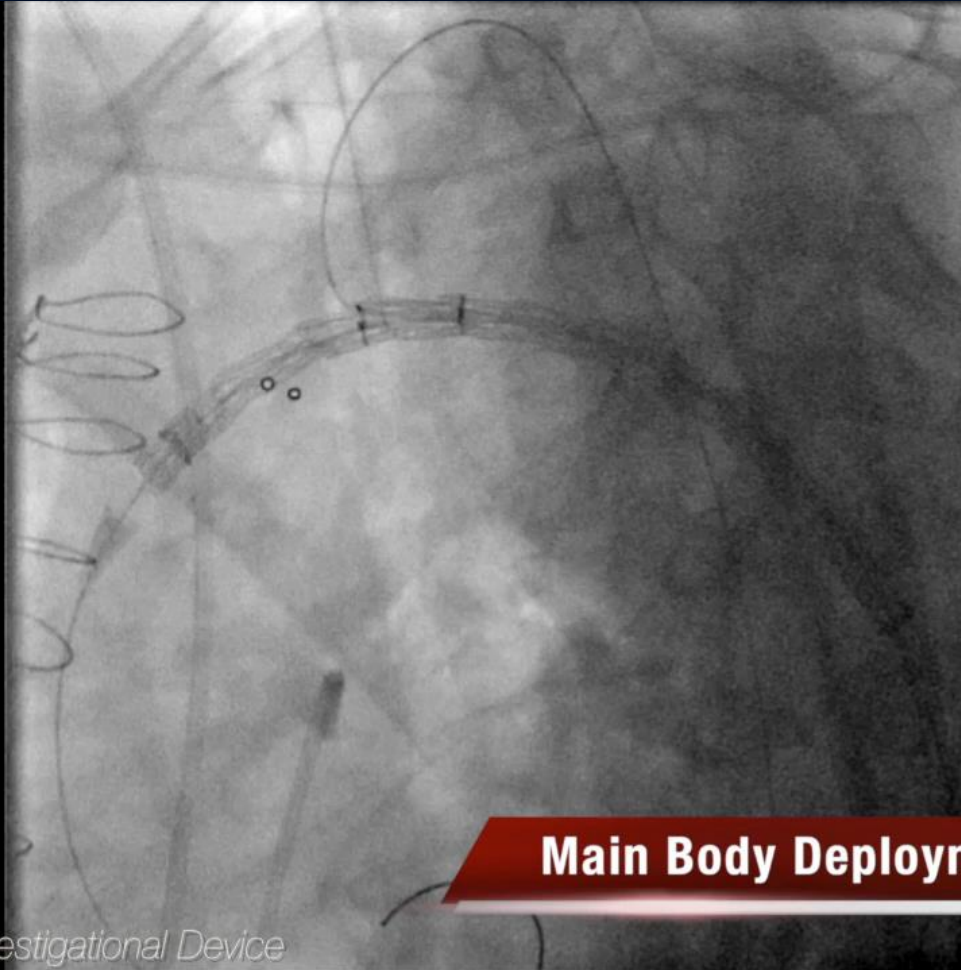
# Branched TEVAR – wire access



**Anatomic Assessment with IVUS**



# Branched TEVAR – Main Body



**Main Body Deployment**

*Emergency Use of Investigational Device*

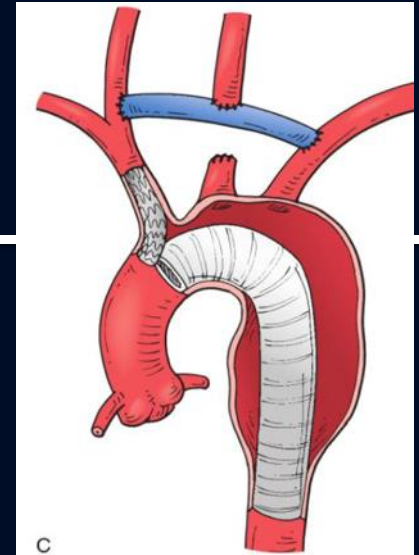
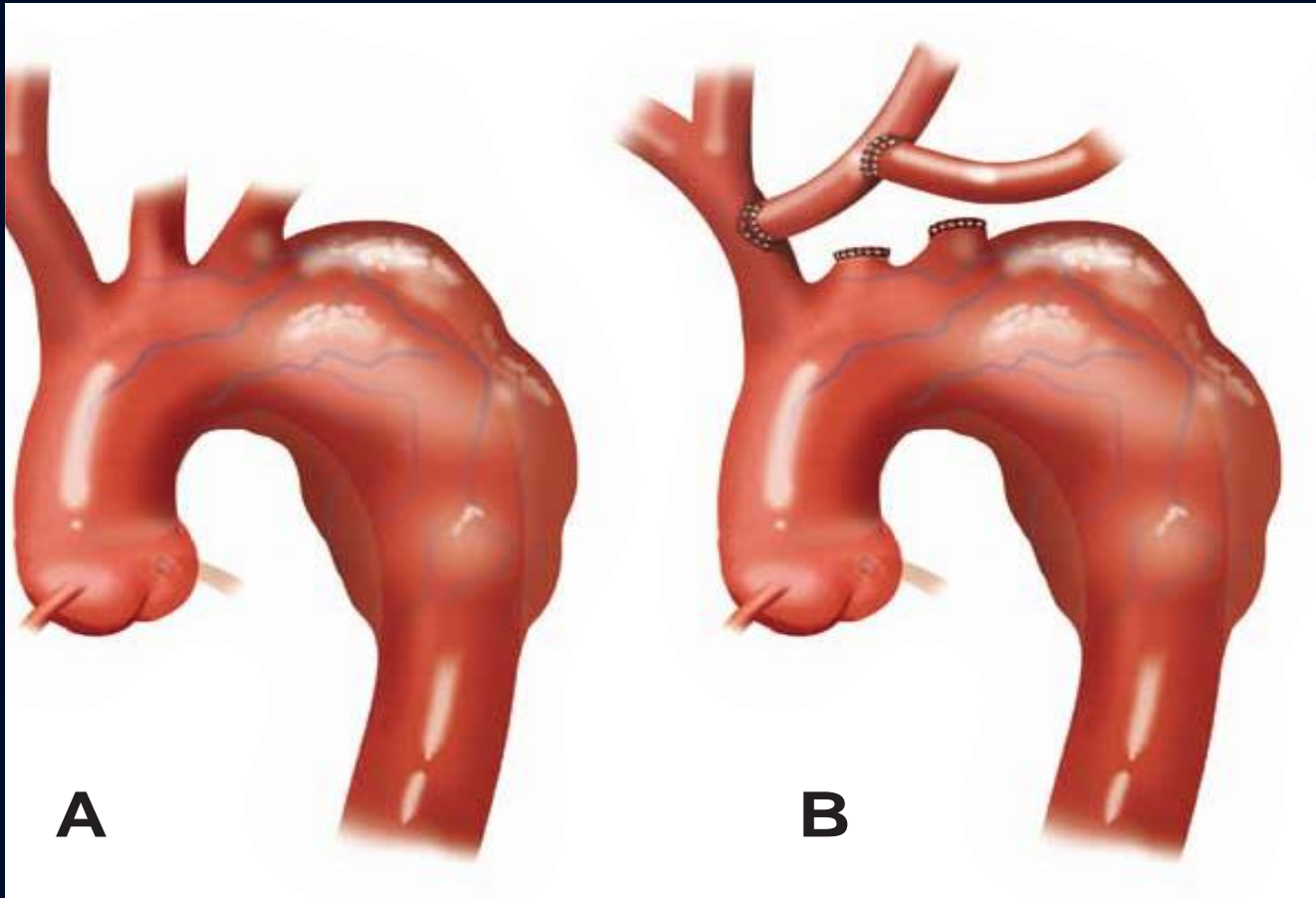


# Branched TEVAR – Side Branch



*Emergency Use of Investigational Device*

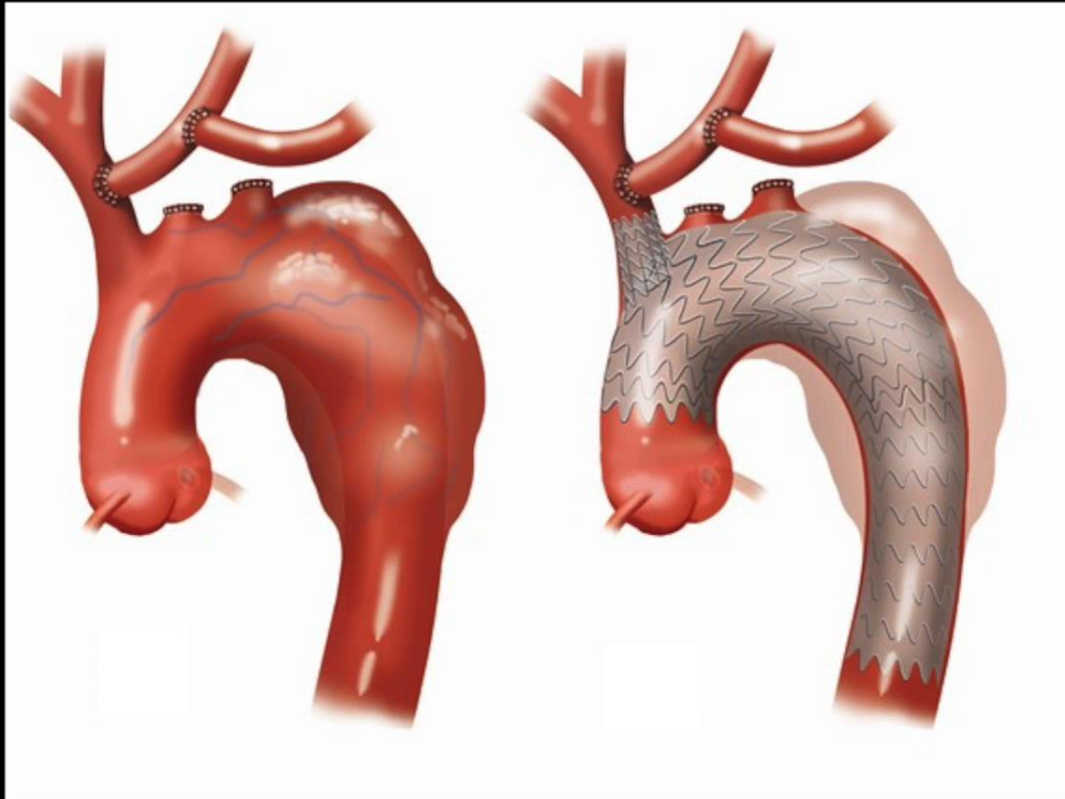
# Zone 0 - Debranching



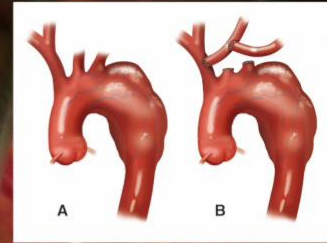
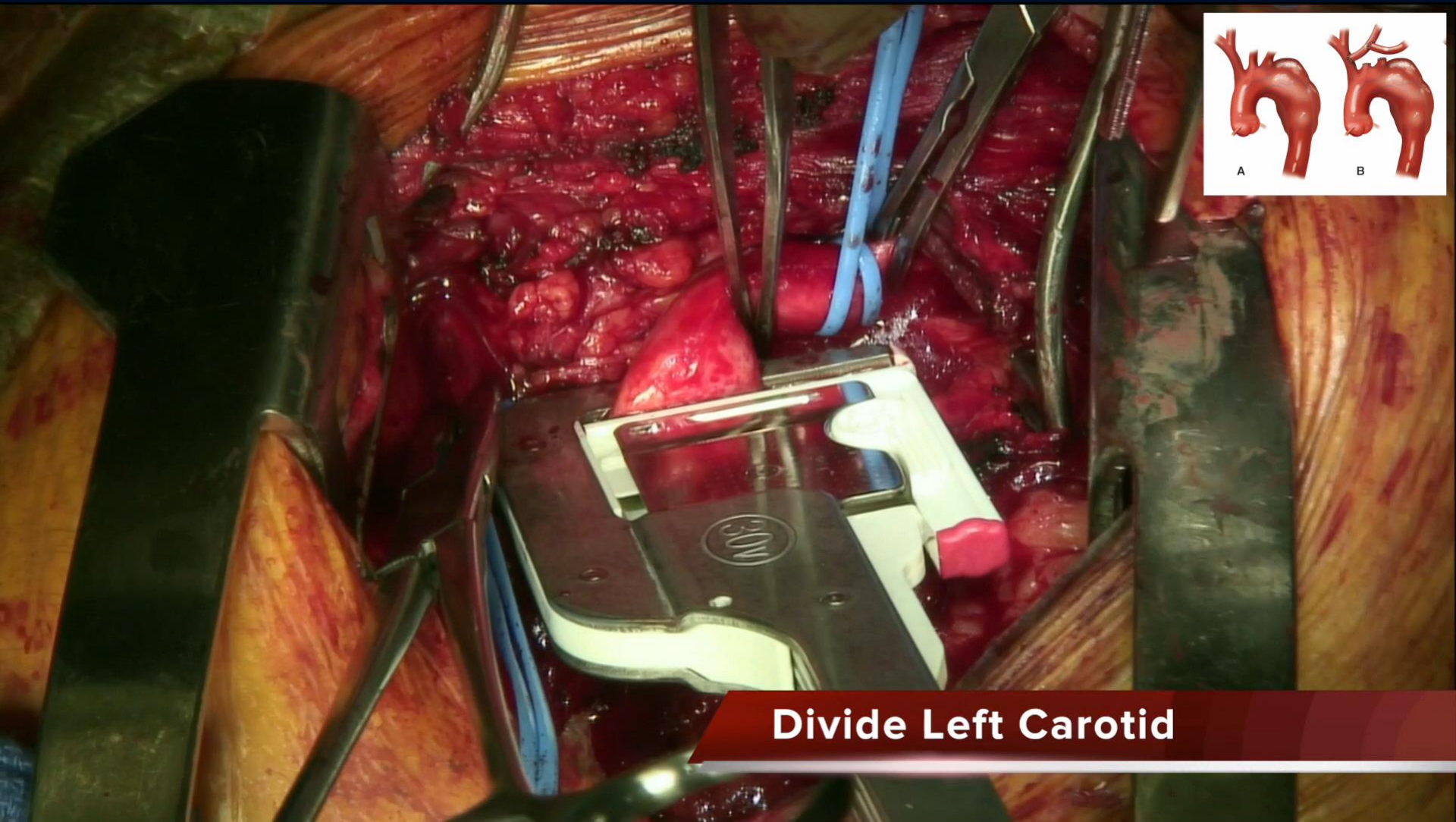
- No Graft Material
- All vessels are behind the sternum
- No retro-esophageal course, no dysphagia, erosion risk



# Zone o Gore TBE



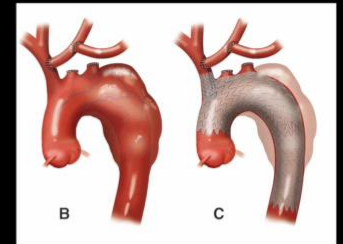
# Zone o Gore TBE



**Divide Left Carotid**

# Zone 0 Gore TBE

Brachial Wire is  
Externalized in Groin  
and loaded in to  
Side branch Portal  
of Gore TBE graft



**Gore TBE Zone 0 Device**

# GORE Single Branch Pivotal Trial

- **Patients:**
  - Aortic arch aneurysms requiring placement of the proximal extent of the aortic stent graft in Zone 0, 1 or 2
  - First implant expected in fall 2016
- Up to 40 sites
- Minimum 175 patients, Maximum 435 patients
- 5 year follow-up

# Pivotal Clinical Trial Design

