CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 25-27 2018

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER, PARIS, FRANCE

Technical tips and tricks and results of a PTFE branched graft

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Stanford University School of Medicine

Disclosure

Speaker name: Michael D. Dake

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- [x] I have the following potential conflicts of interest to report:
- [x] Consulting
- [ ] Employment in industry
- [ ] Shareholder in a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)
- [ ] I do not have any potential conflict of interest

GORE® TAG® Thoracic Branch Endoprosthesis[1]

- First Human Implant January 2014
  - Zone 0/1 and Zone 2 feasibility studies in US: Ongoing follow up
  - Pivotal trial experience accruing
- Modular Construction
  - Off-the-shelf components
  - Inner lumen for anchoring and sealing branch component
- Integrated system
  - Aortic and branch components designed for use in the arch
  - Accompanying accessory devices to facilitate delivery
- Ease of Use
  - Single femoral access
  - Pre-cannulated side branch wire

[1] **Caution:** Investigational Device. Limited by United States law to investigational use only

TBE Device Overview

TBE Device

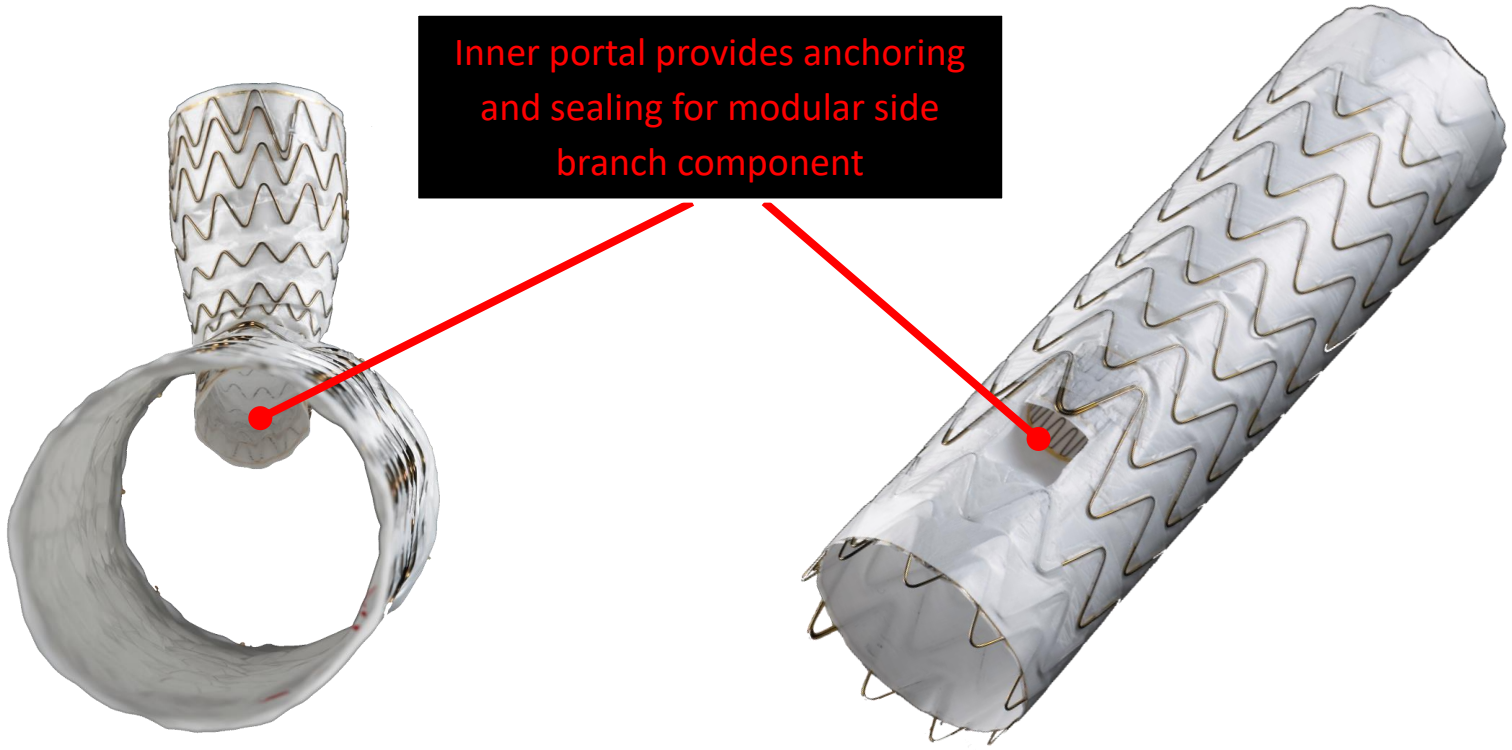
- Aortic Component
- Side Branch (SB) Component
- Aortic Extender (Optional)

Additional TBE accessory

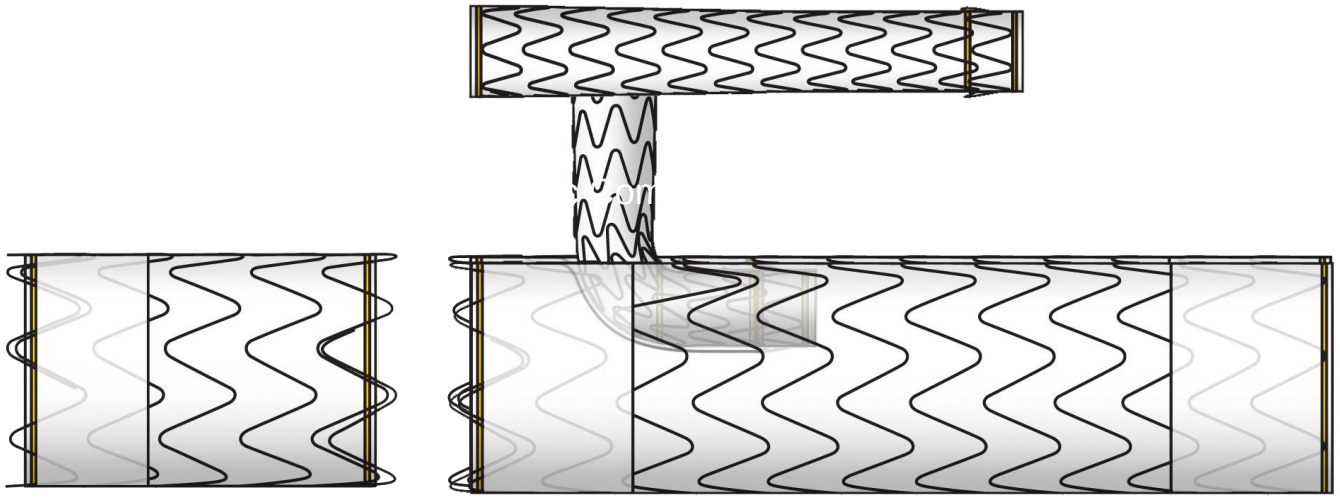
- GORE® DrySeal Side Branch Introducer Sheath (SBIS)

Caution: Investigational Device. Limited by United States law to investigational use only.

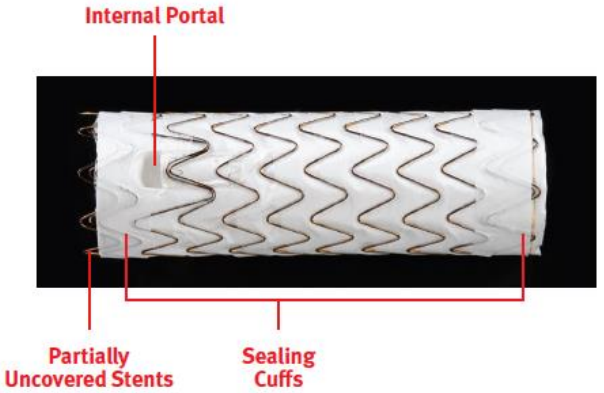
TAG® Branched Thoracic Endoprosthesis



TAG® Branched Thoracic Endoprosthesis



TBE Aortic Component



- Incorporates internal portal allowing seal and fixation of the SB Component
- Device diameters: 21 – 53 mm
- Aortic treatment range: 16 – 48 mm

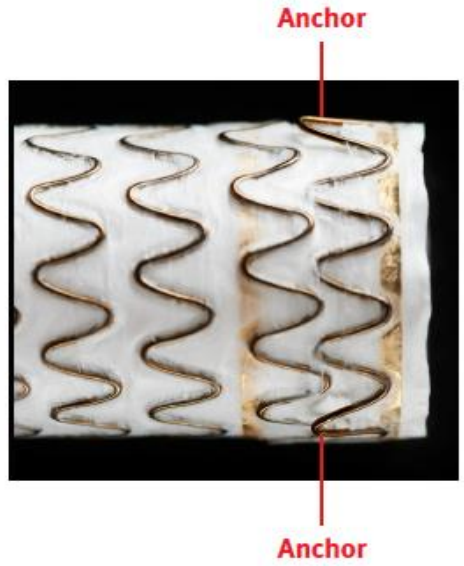
TBE Aortic Component

Delivery system

- Aortic lumen
- Side branch lumen
    - Removable Guidewire Tube (RGT)
        - Aids in passage of guidewire through internal portal

SB Component

- **Internal Portal Segment**
  - 3 “anchors” prevent SB migration into vessel
  - 8 or 12 mm diameter
    - Must use 12mm for Zone 0
- **Branch Vessel Segment**
  - Zone 1-2
    - Device diameters: 8 – 17 mm
    - Treatment range: 6 – 15 mm
  - Zone 0
    - Device diameters: 15 – 20 mm
    - Treatment range: 11 – 18 mm



Procedural Steps

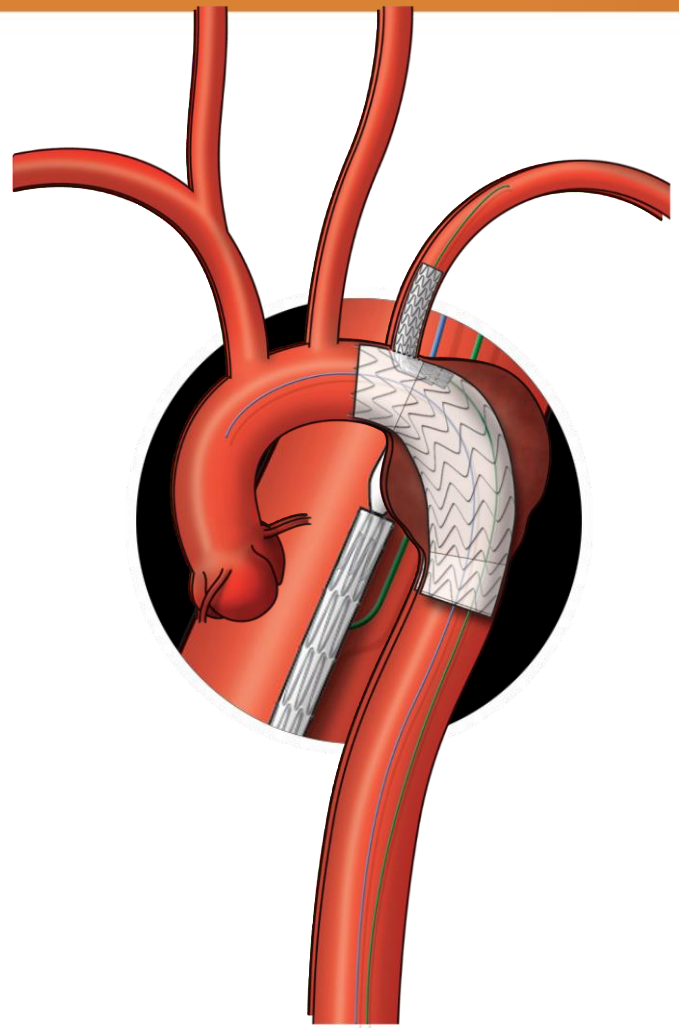
Step 1:
- Insert guidewires in aorta and branch vessel

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

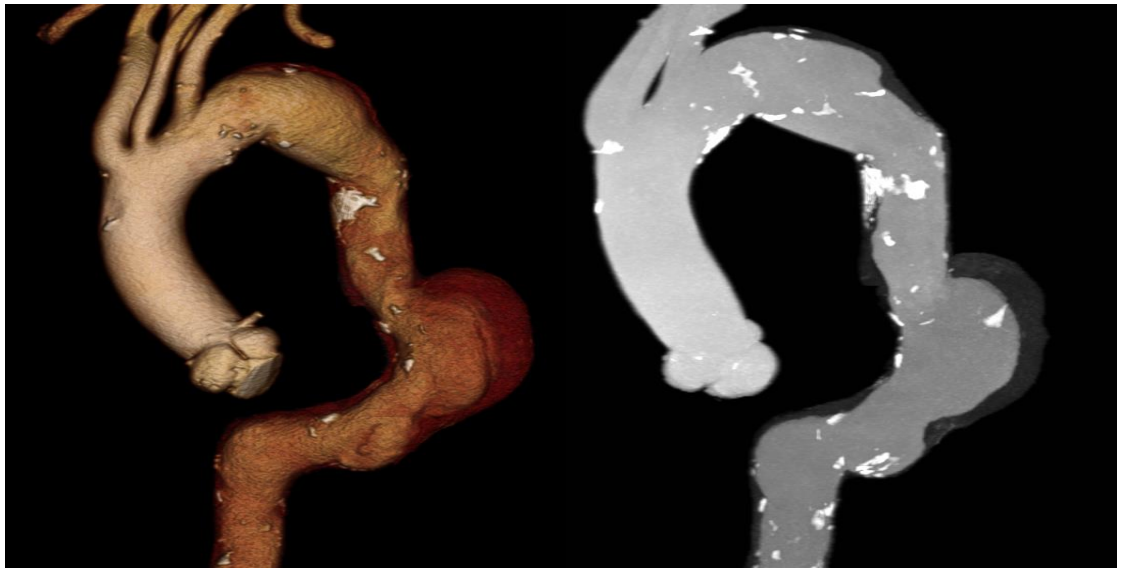


Zone 2

Stanford GORE® TAG® TBE Case

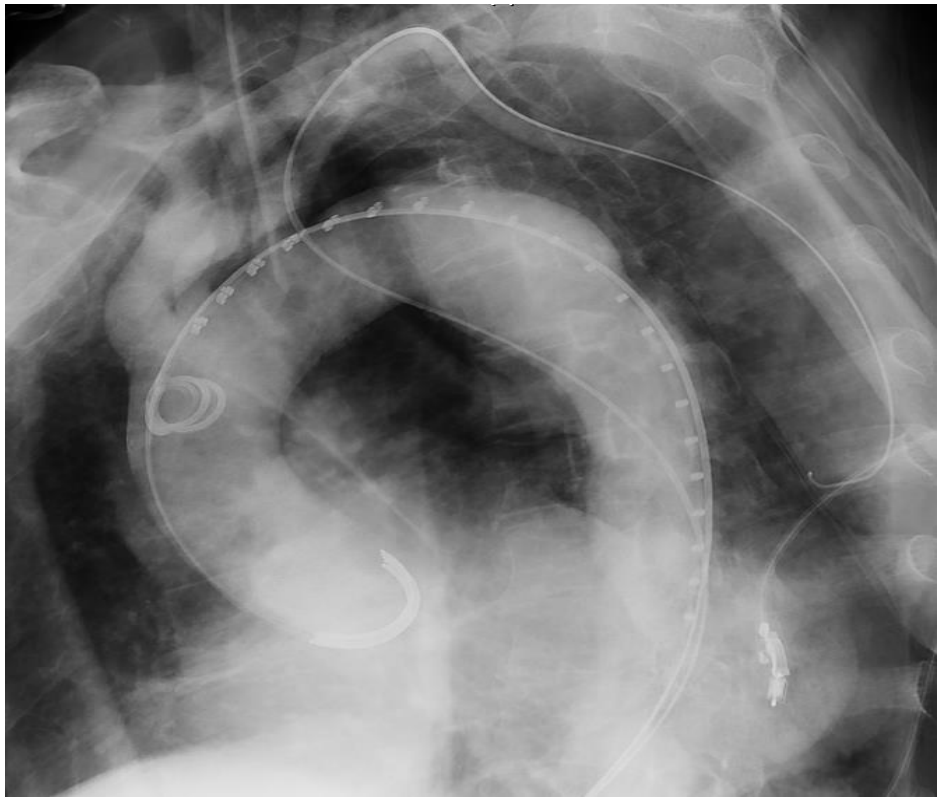
Patient Info

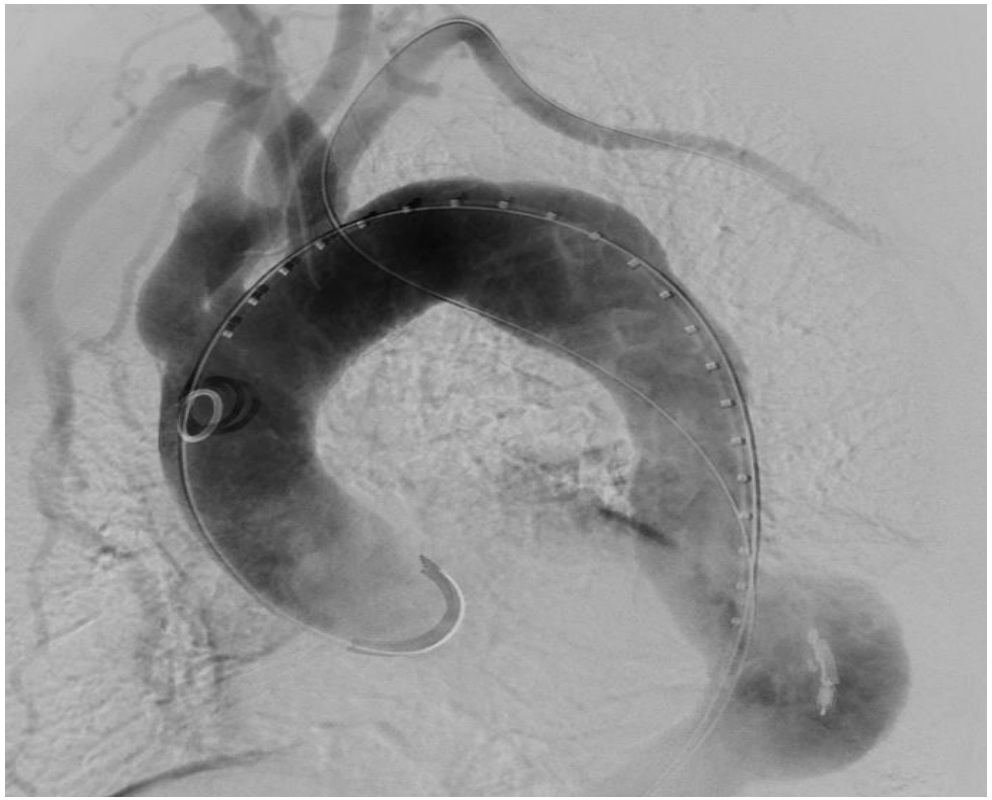
- 84 yo male
- 48mm fusiform aneurysm

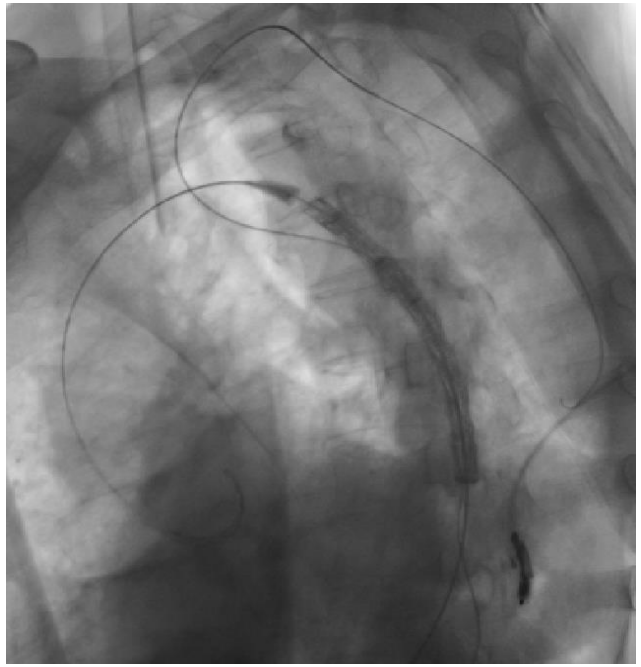
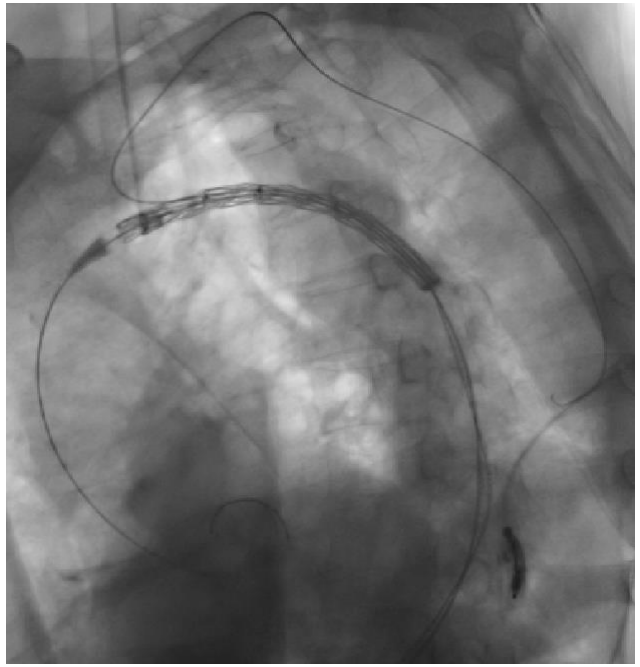


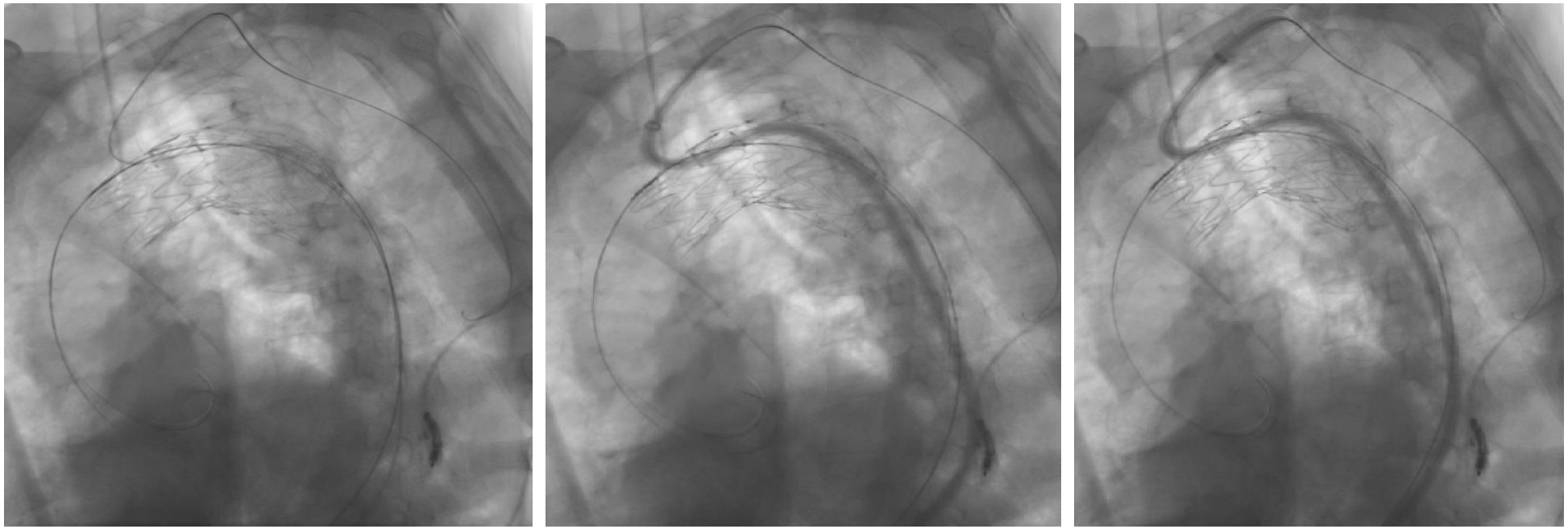
Case Plan

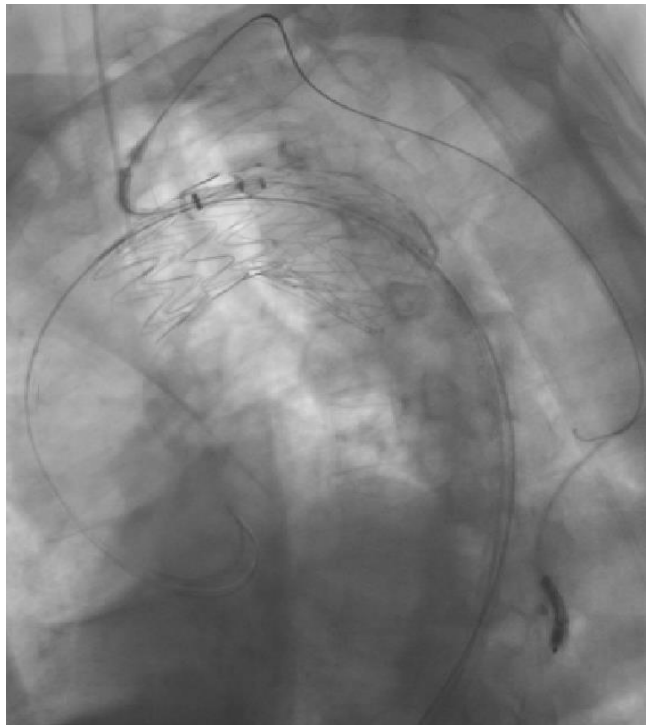
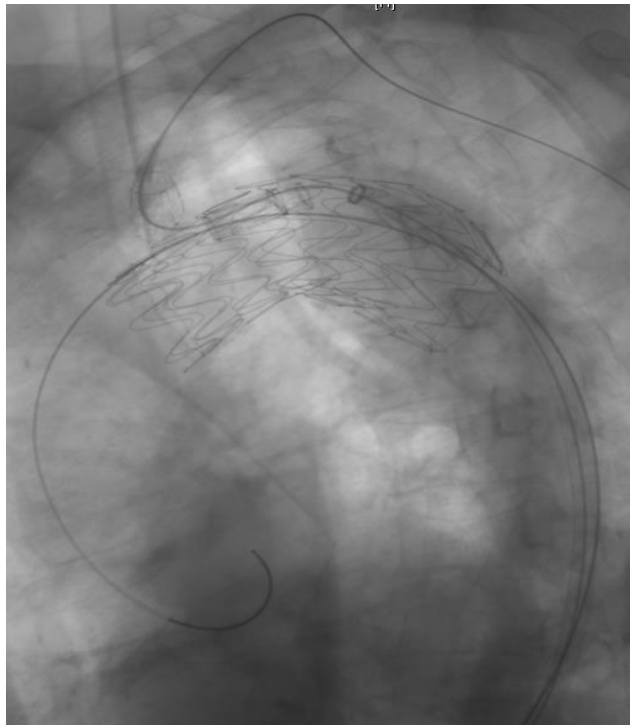
1. TBE Aortic Component (37mm x 10cm)
2. TBE Side Branch Component (8mm x 12mm x 6cm)
3. Distal CTAG (34mm x 20cm)
4. Bridging CTAG (40mm x 10cm)

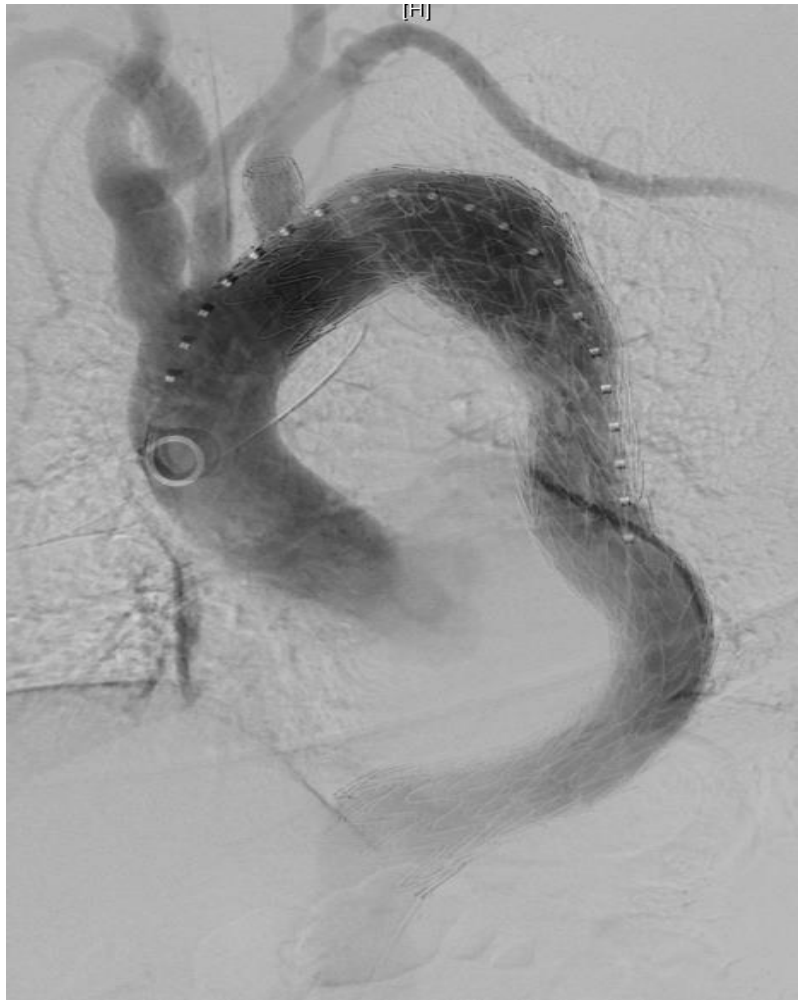


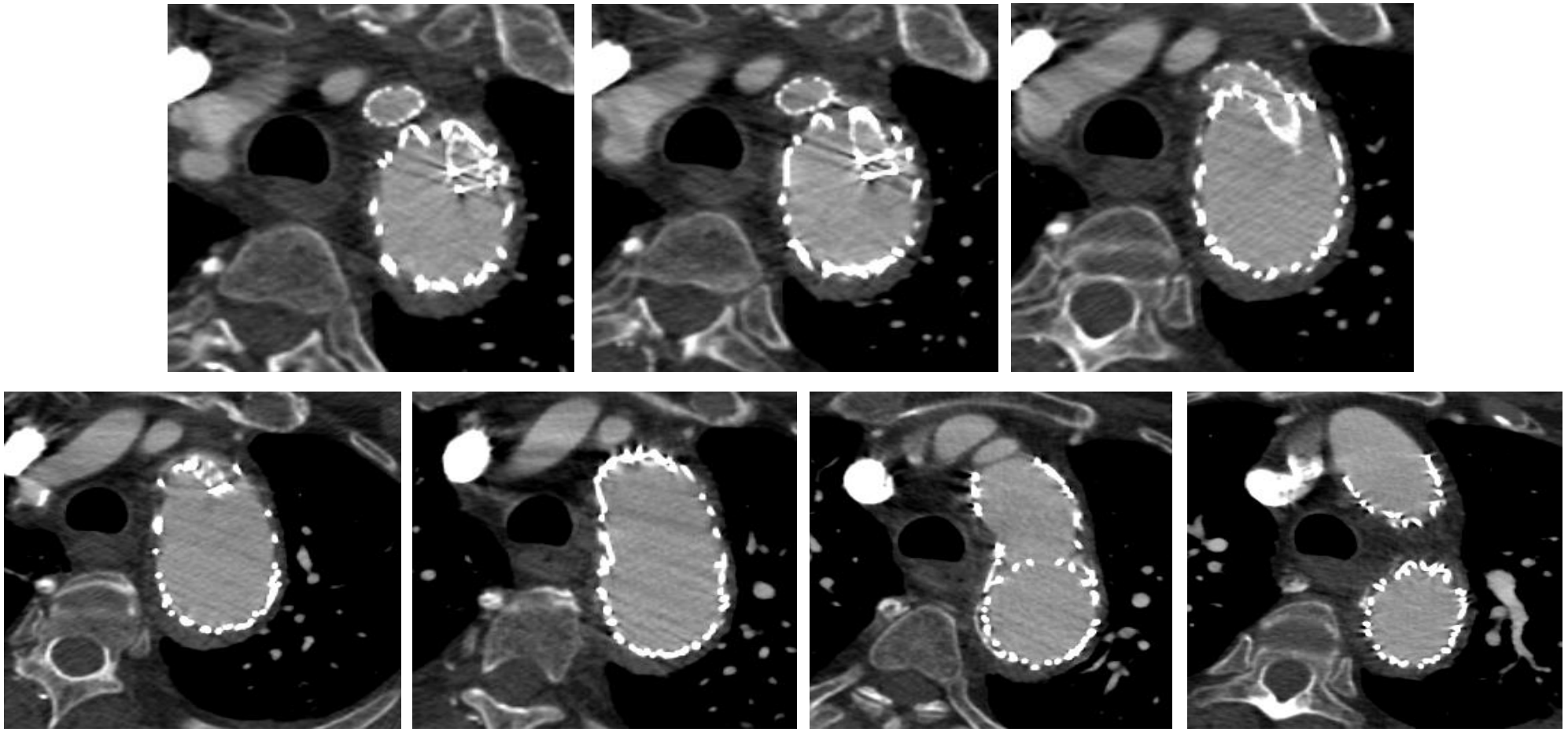


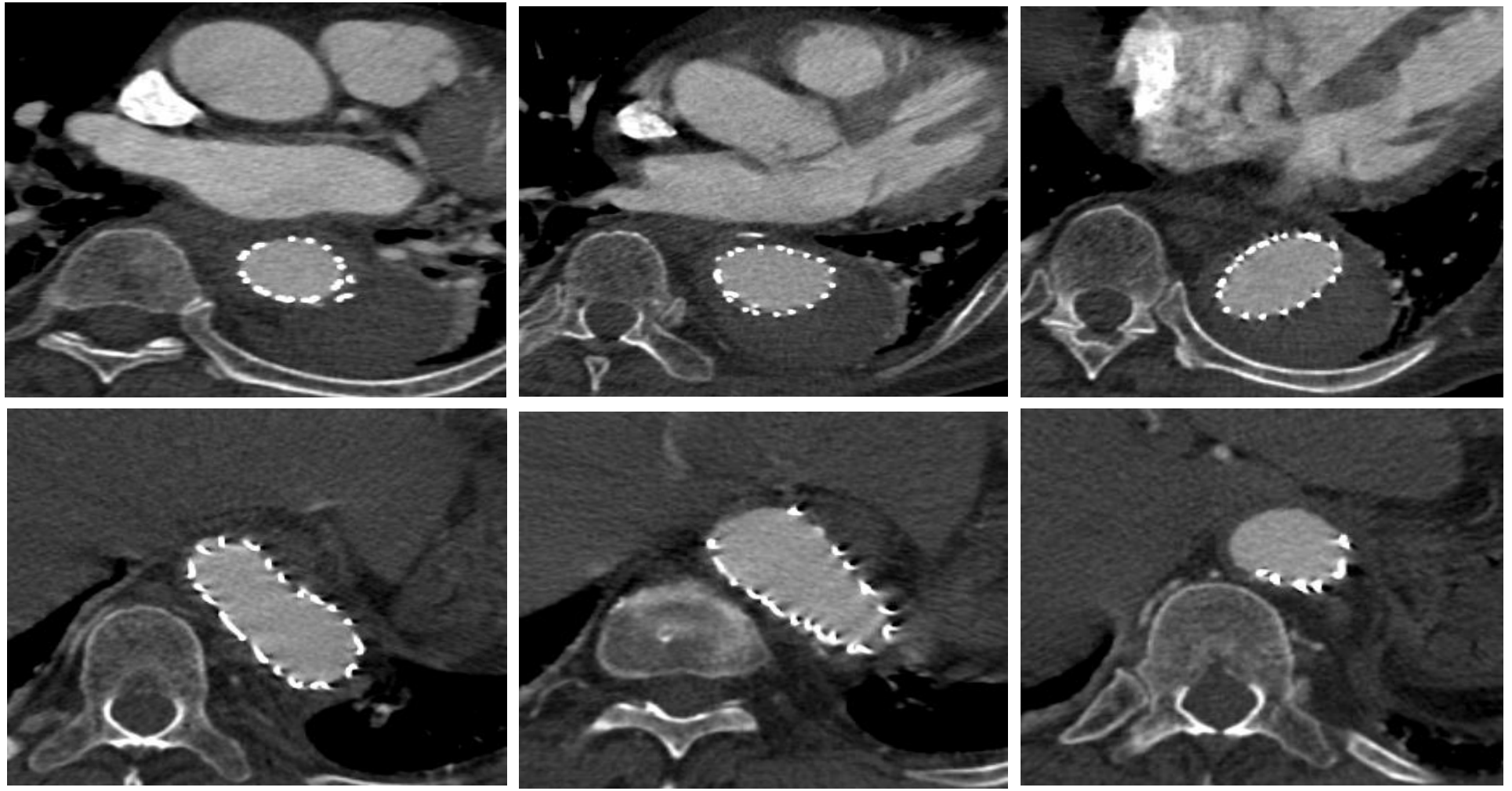












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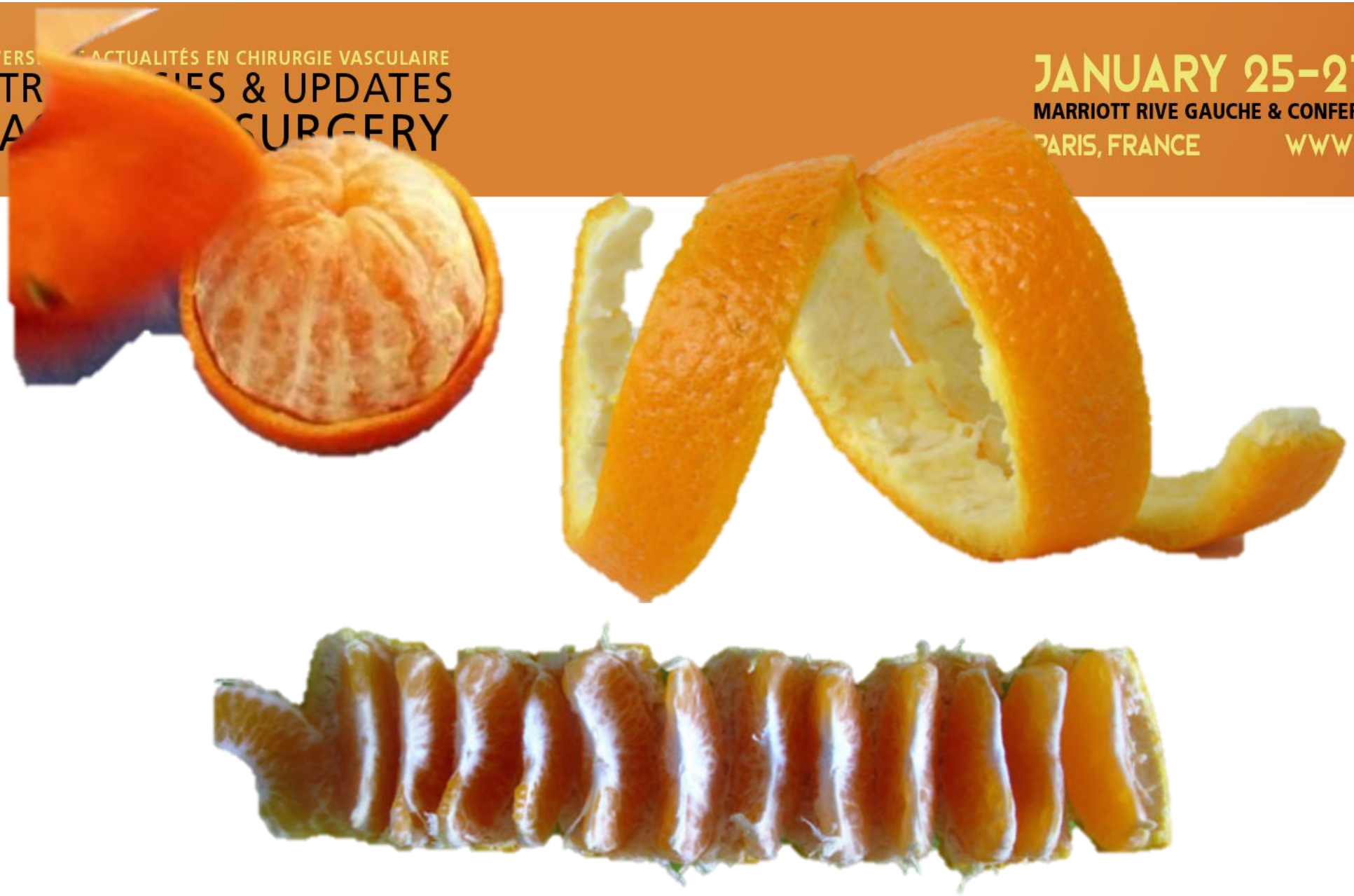
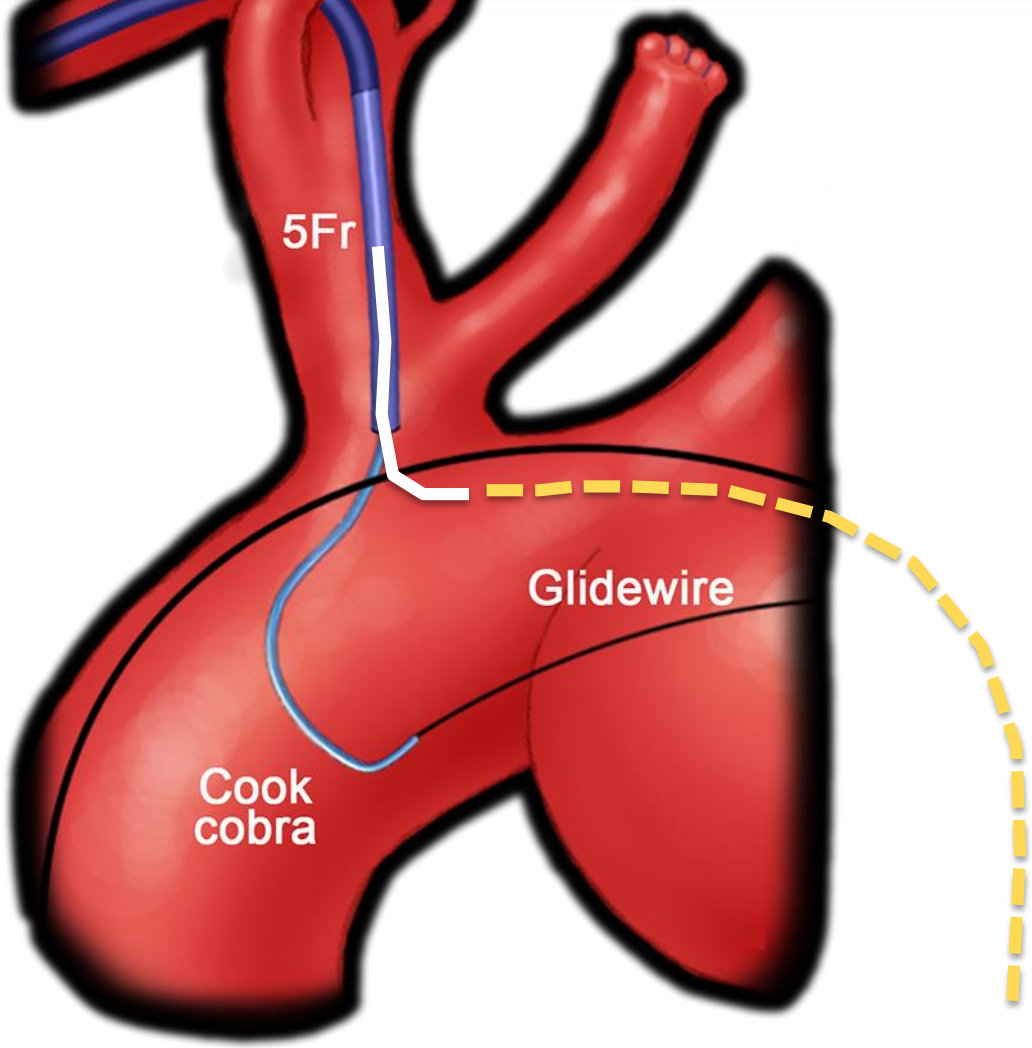
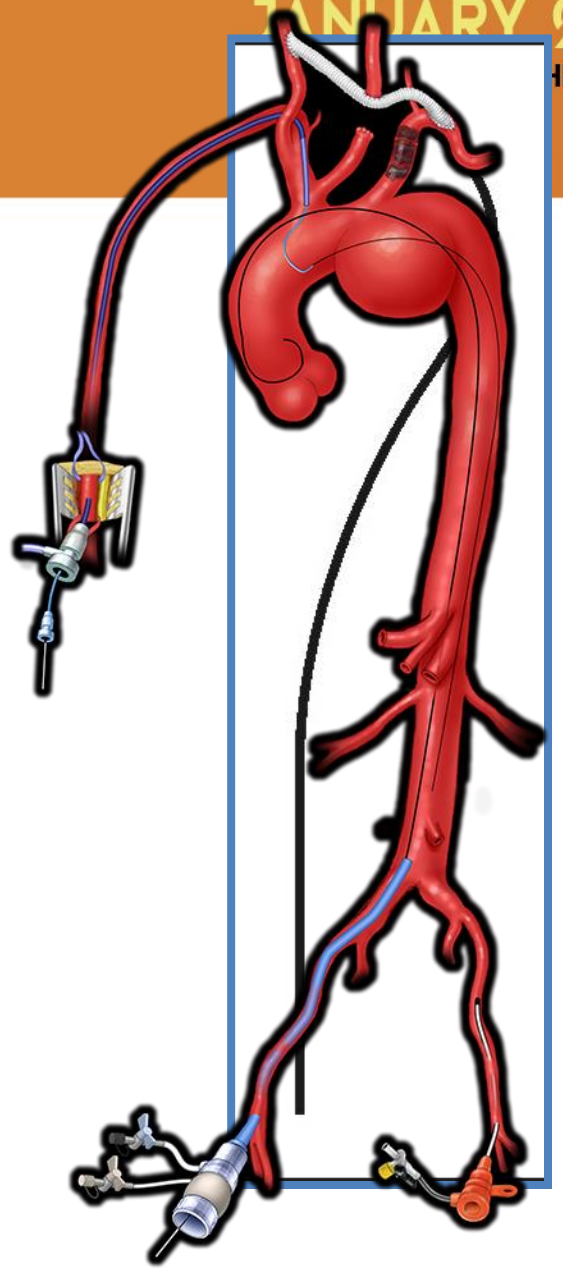
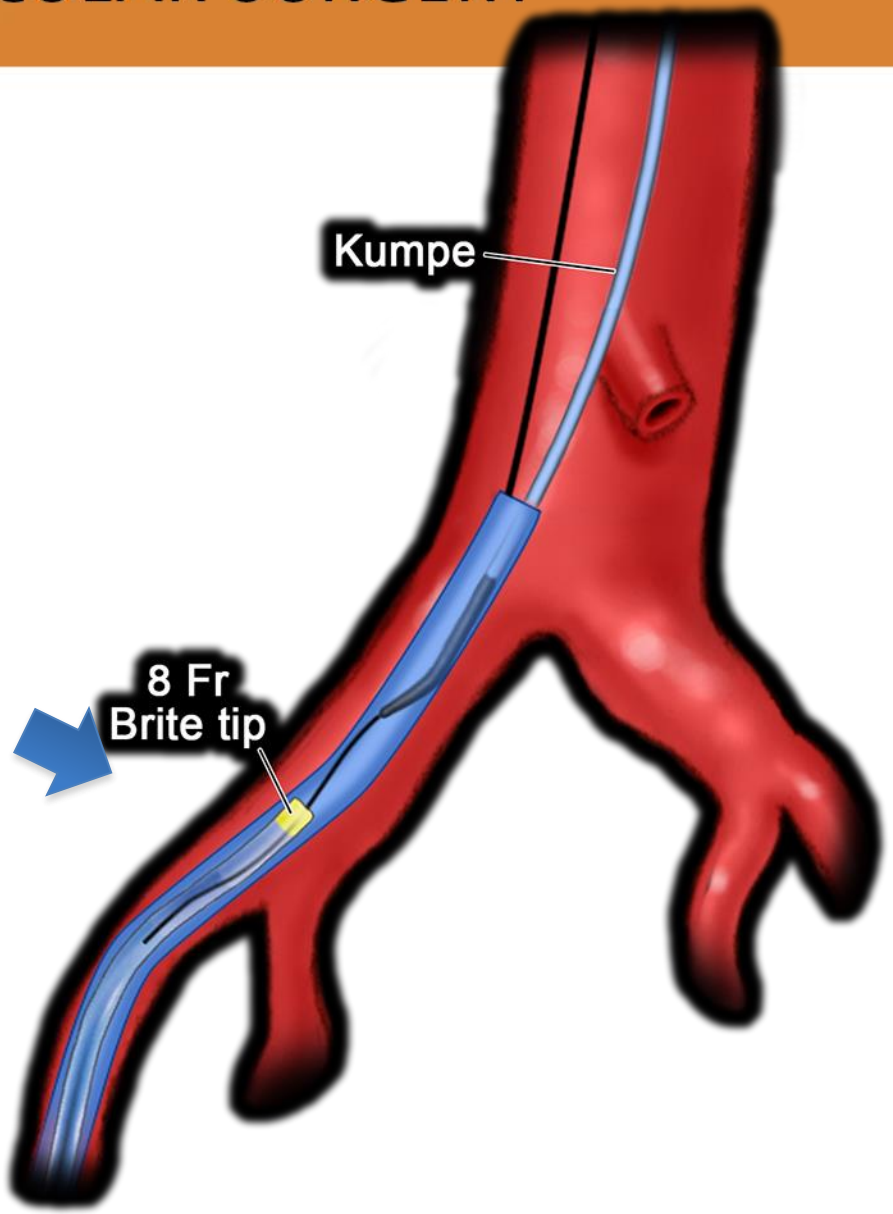
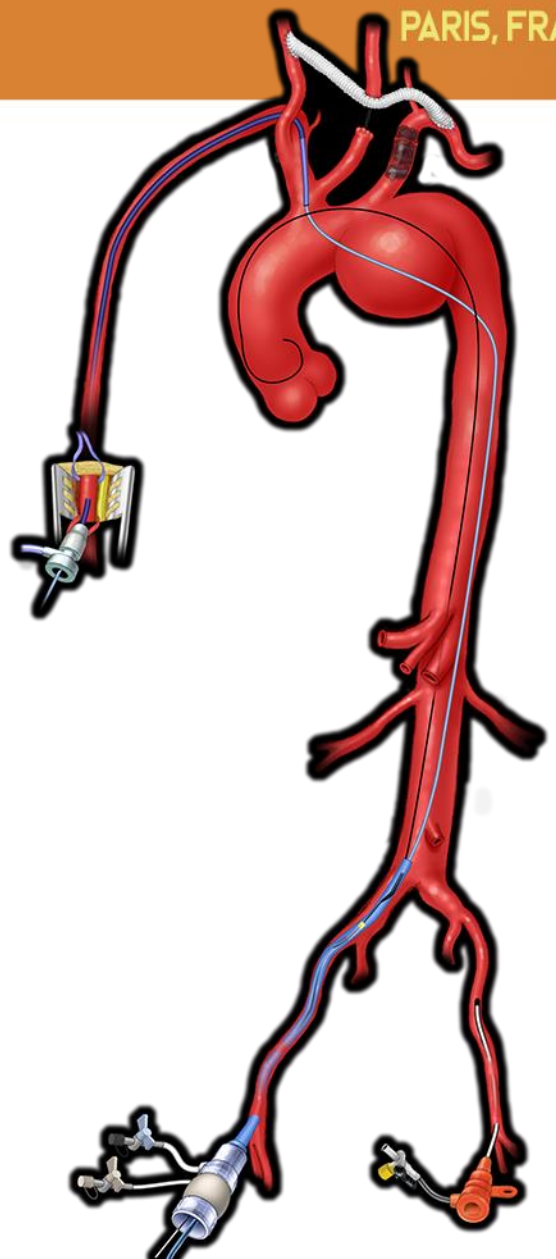
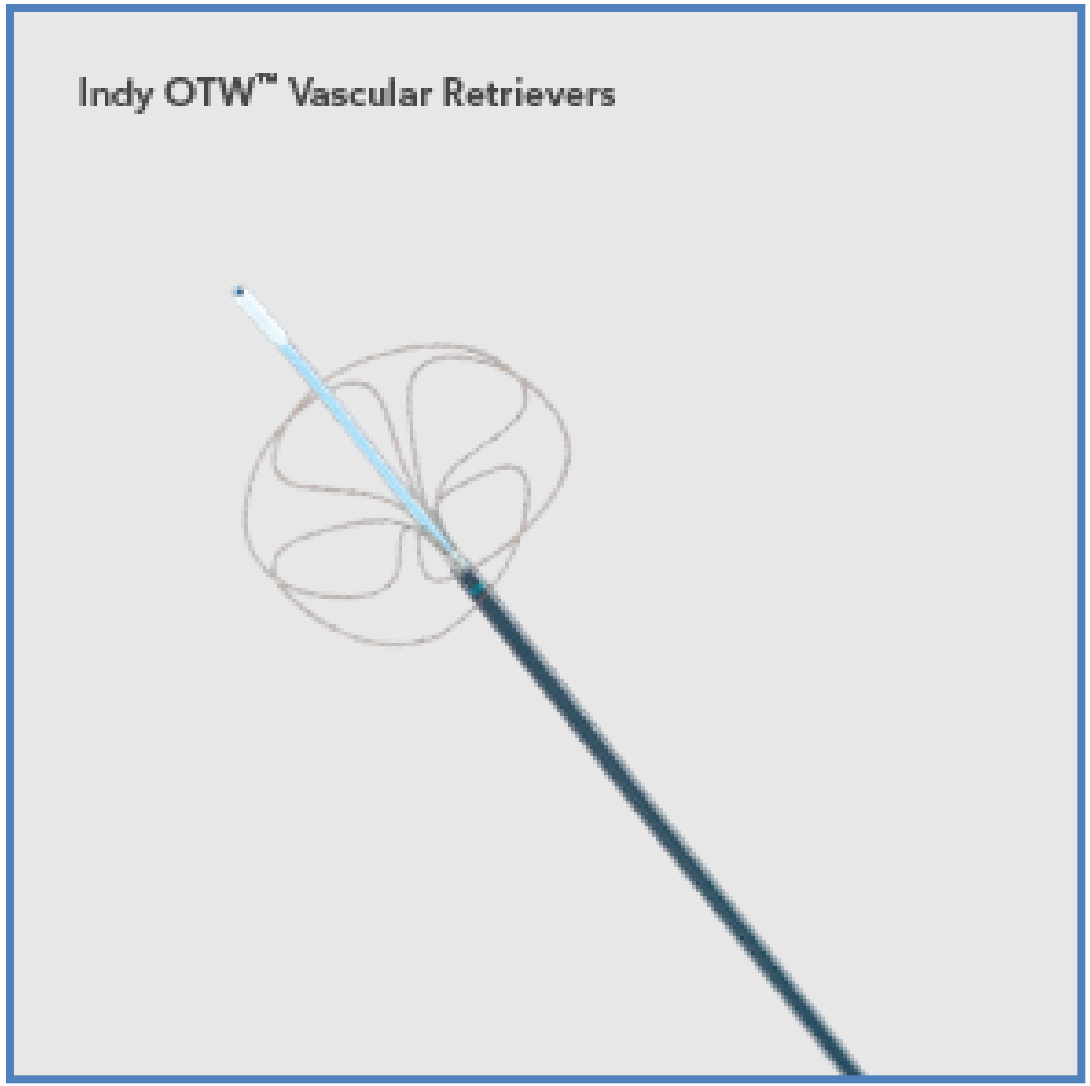


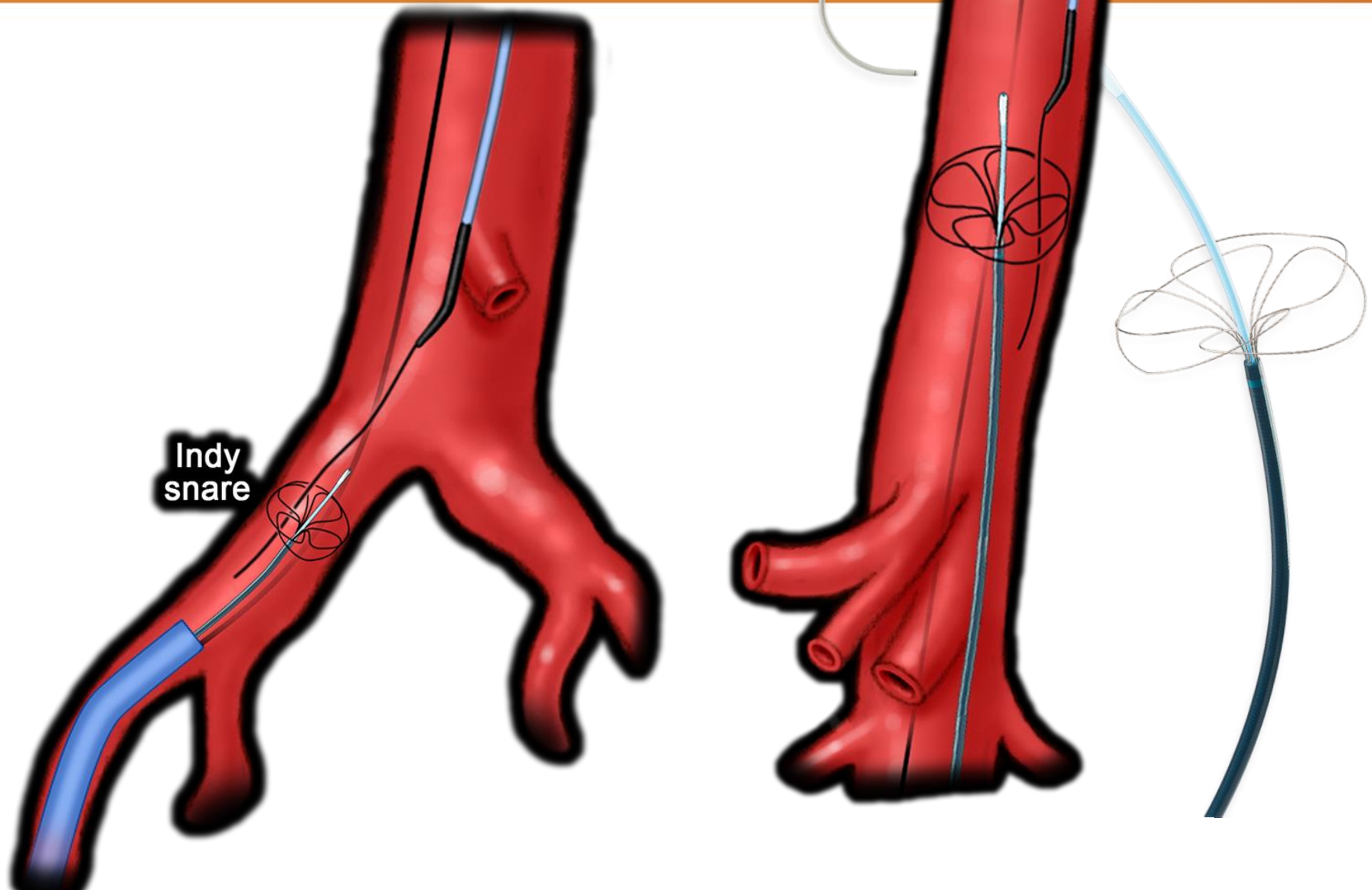

5Fr
Glidewire
Cook
cobra

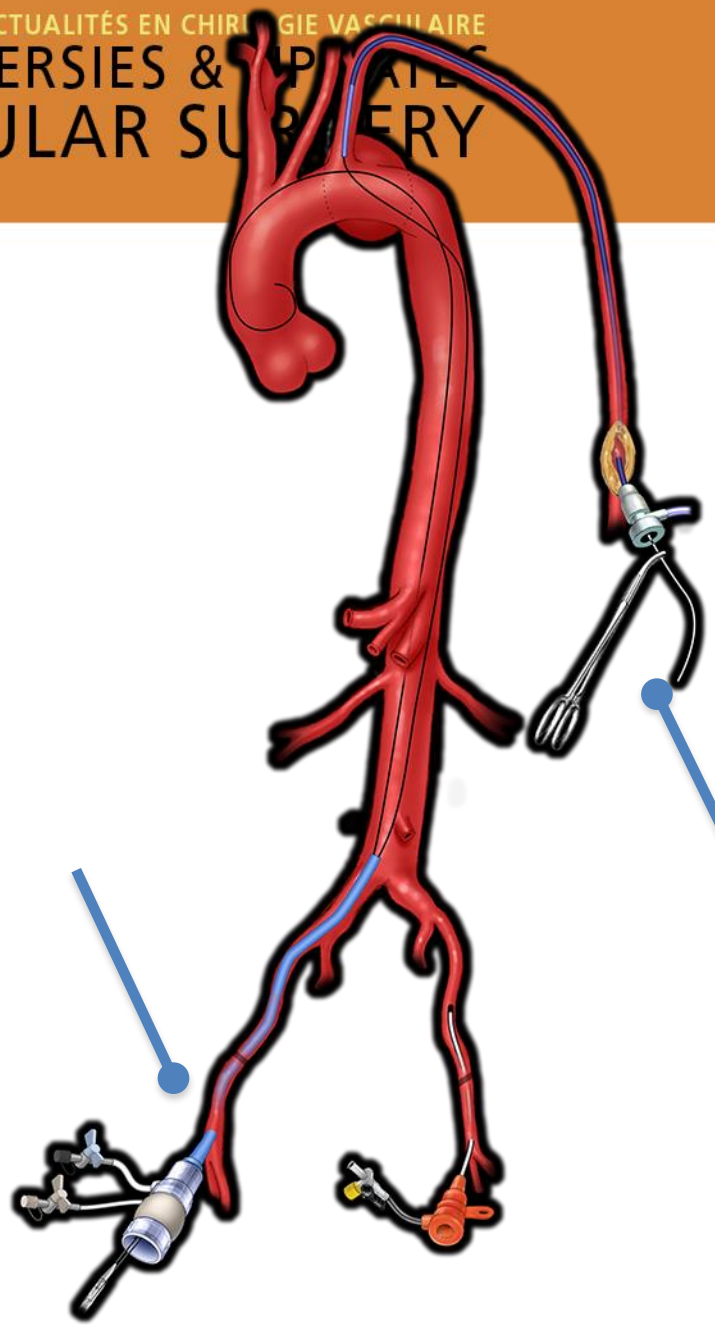


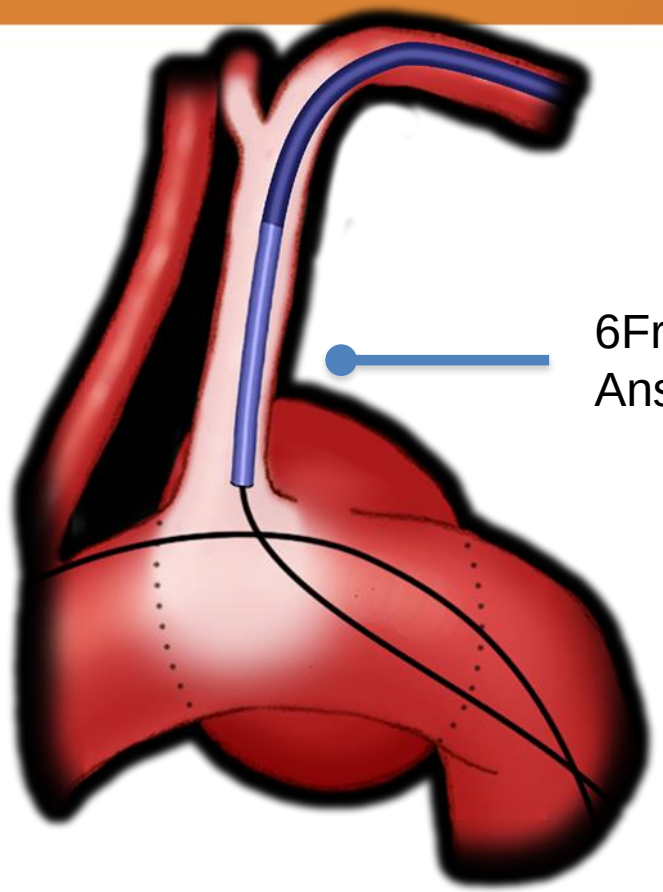

Kumpe
8 Fr
Brite tip




Indy OTW™ Vascular Retrievers

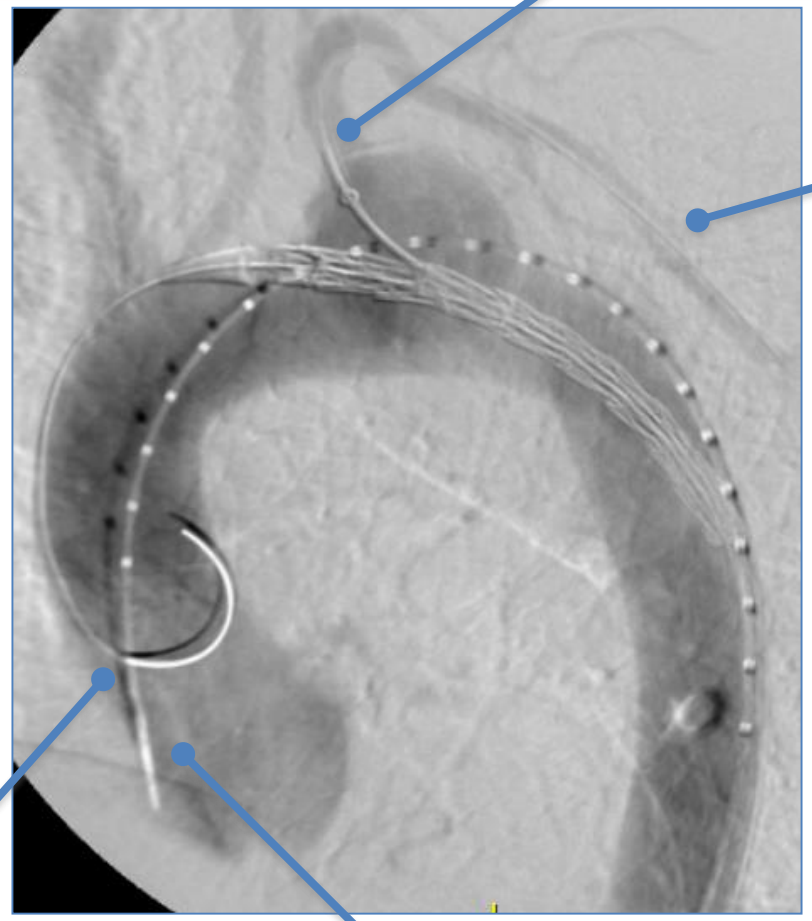

Indy
snare



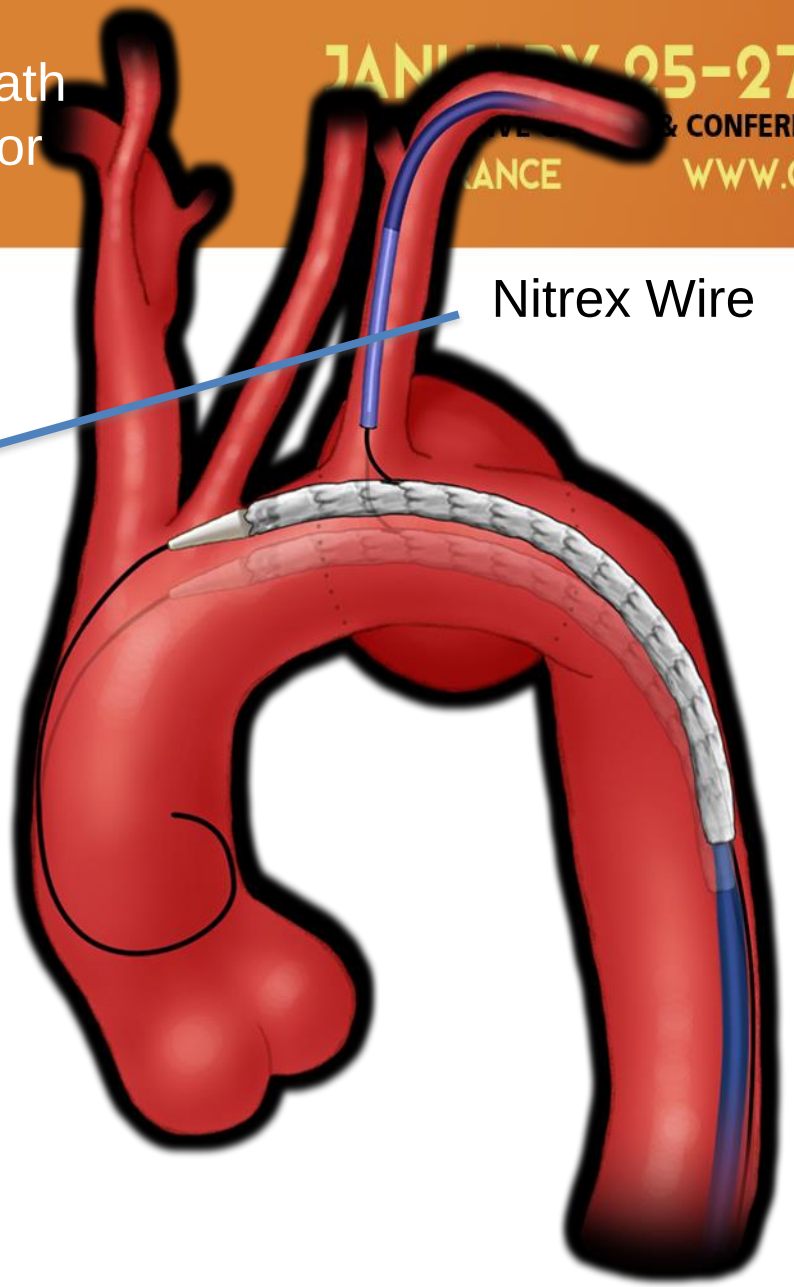


6Fr HiFlex
Ansel II

6Fr Ansel Sheath
Hyperflex dilator

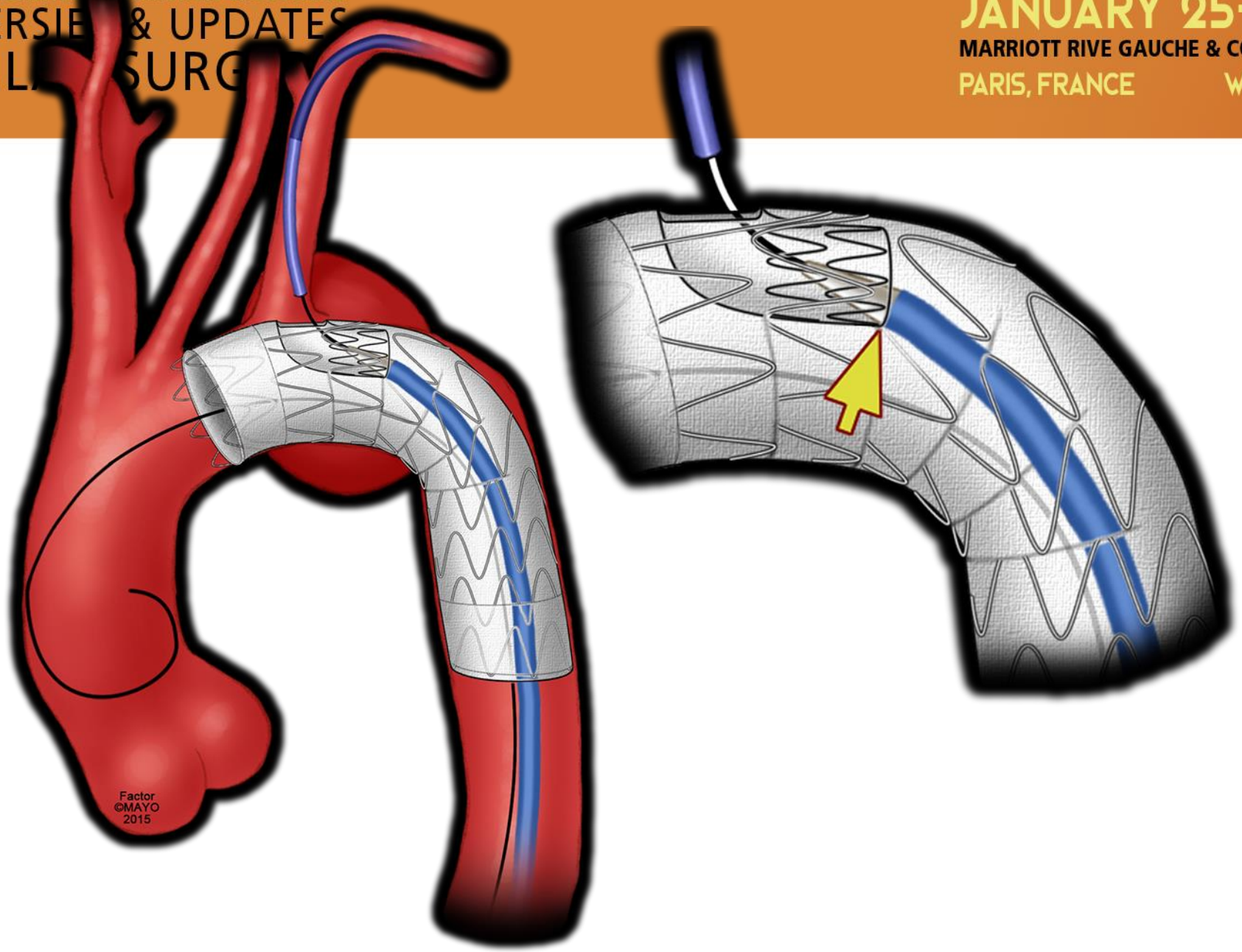


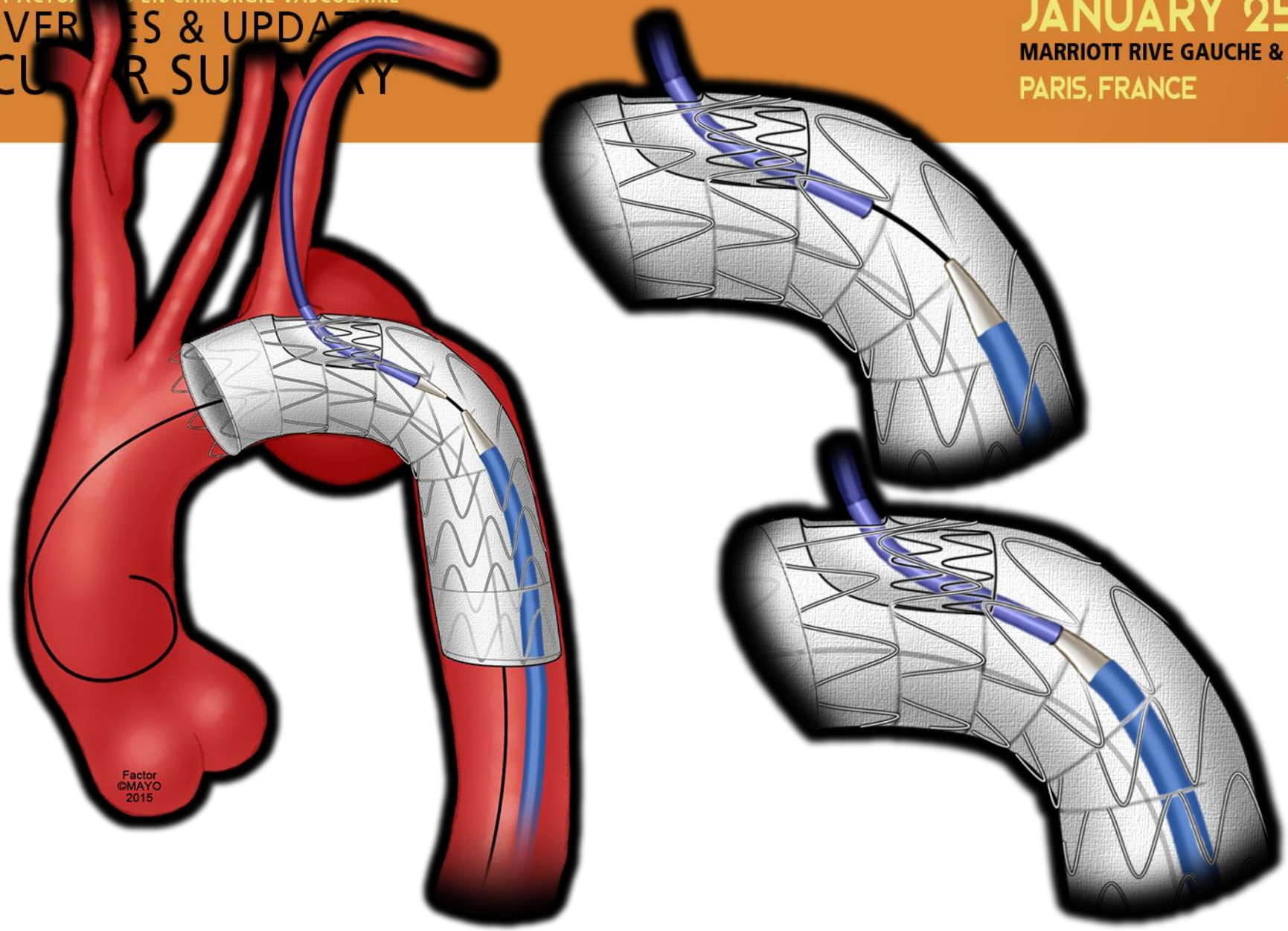
Nitrex Wire



Lunderquist Wire

Flush catheter


Factor
©MAYO
2015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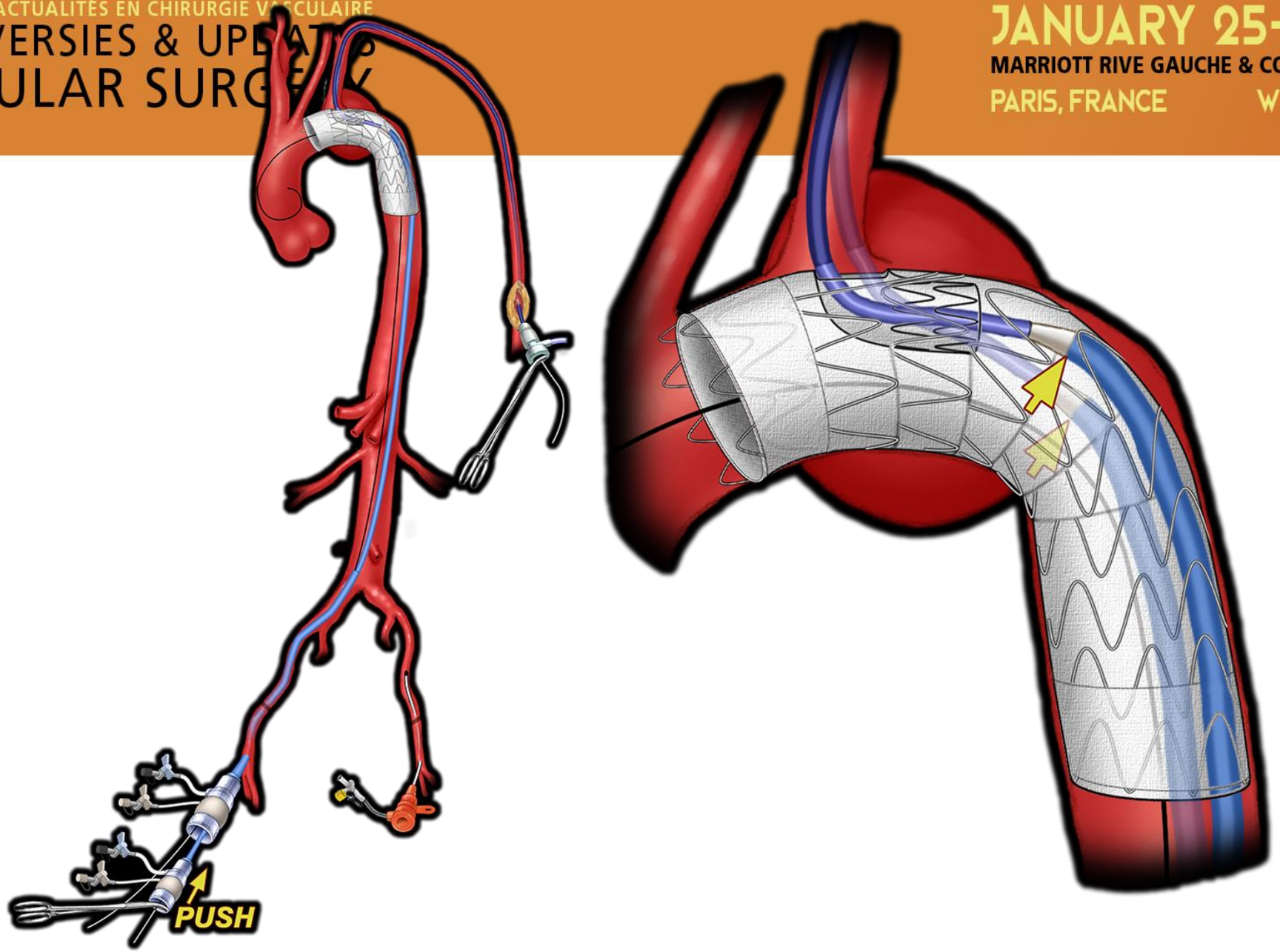
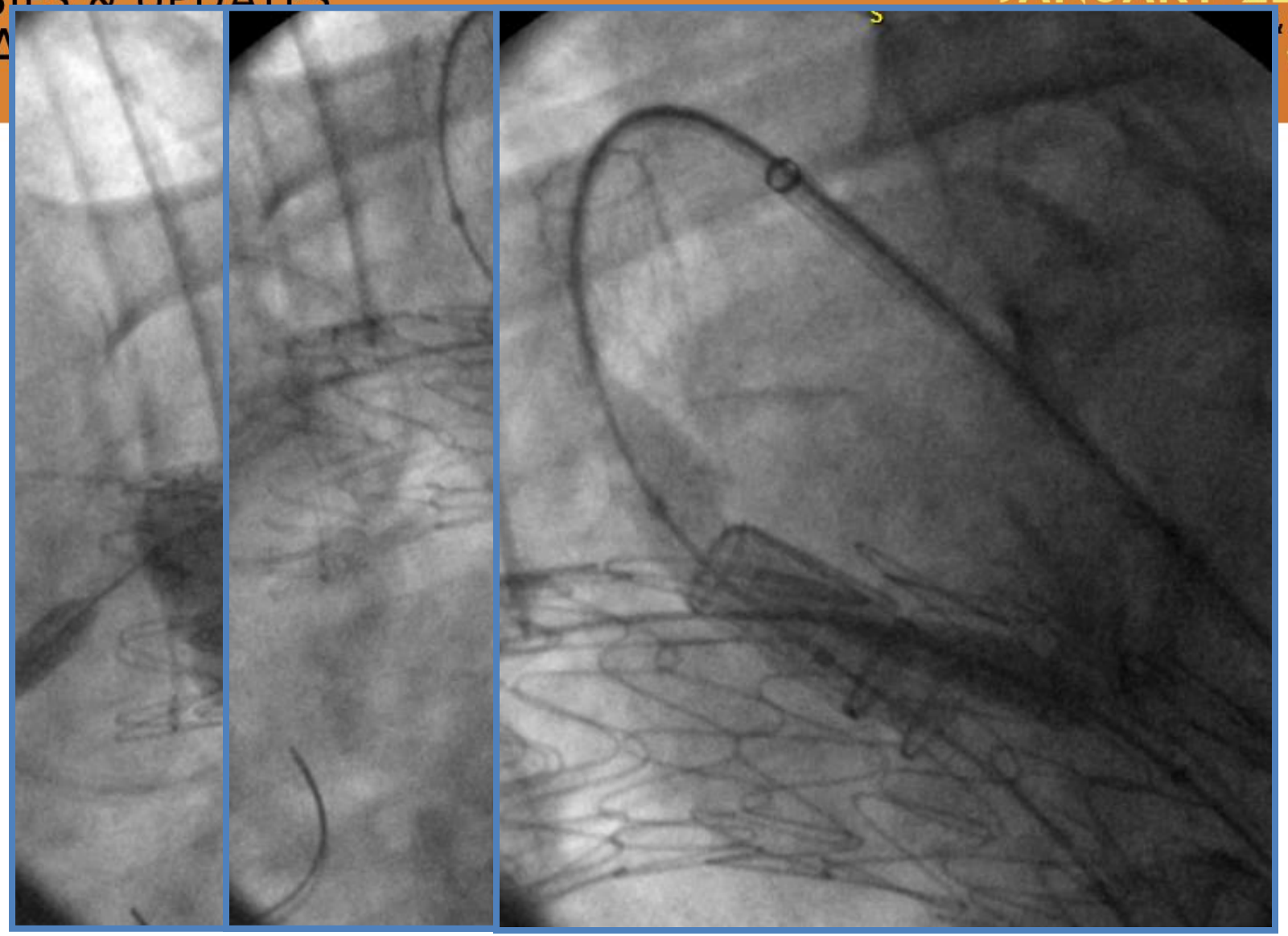

PUSH




S
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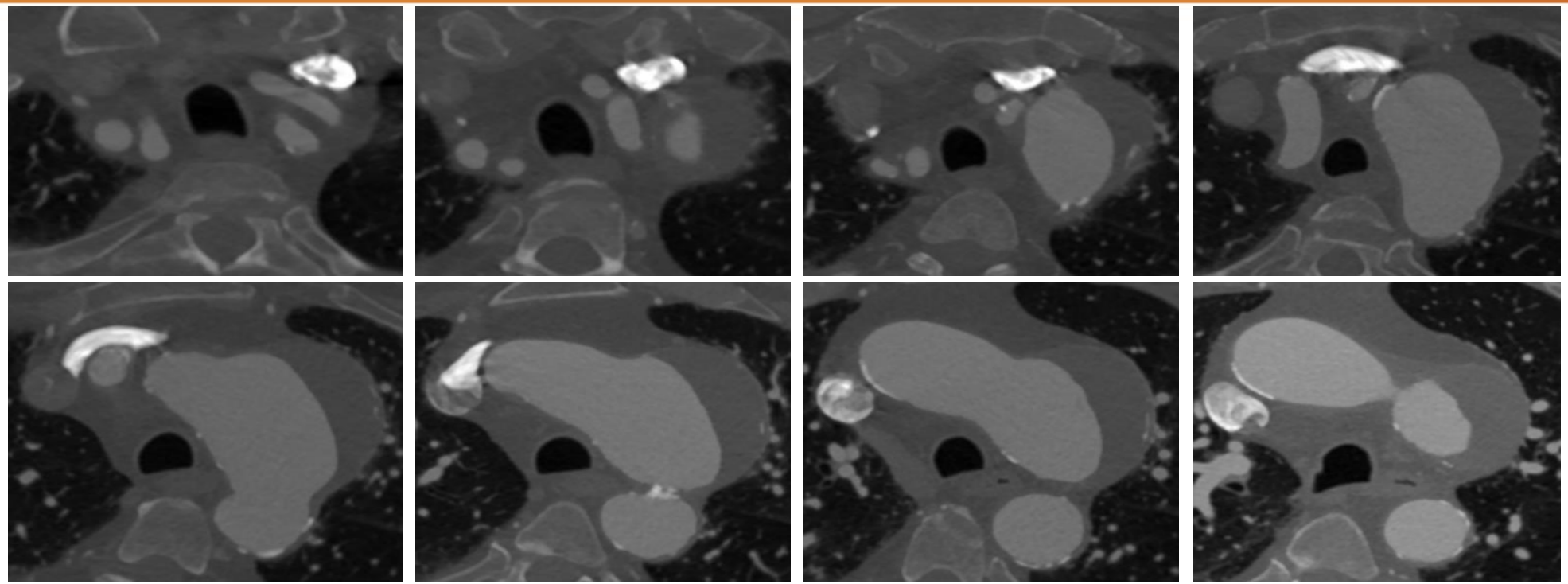
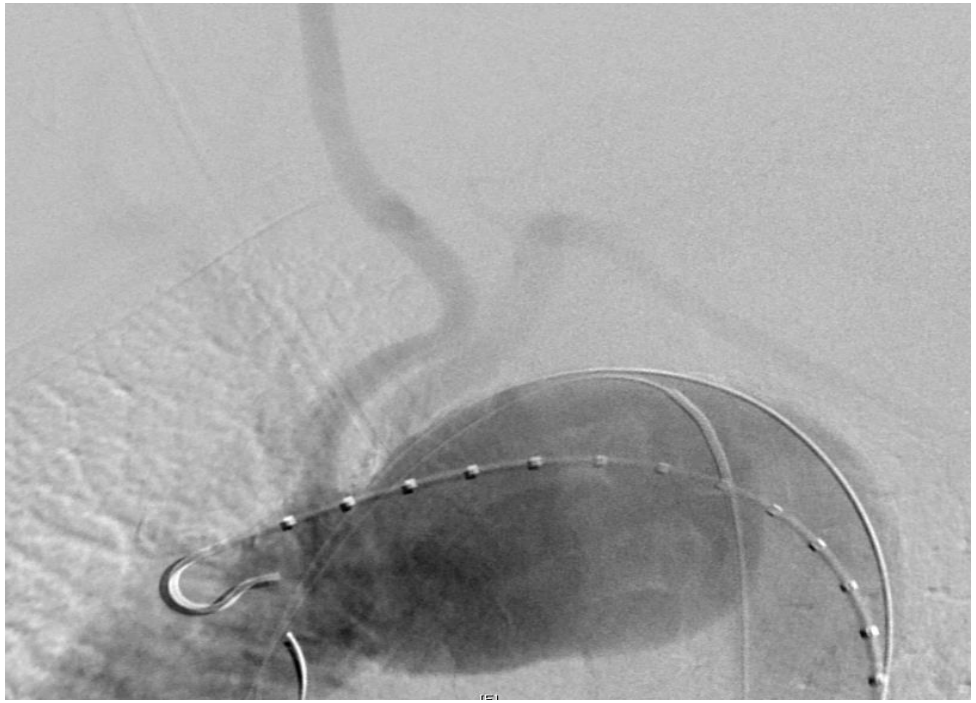
STEPS TO DEVICE ORIENTATION

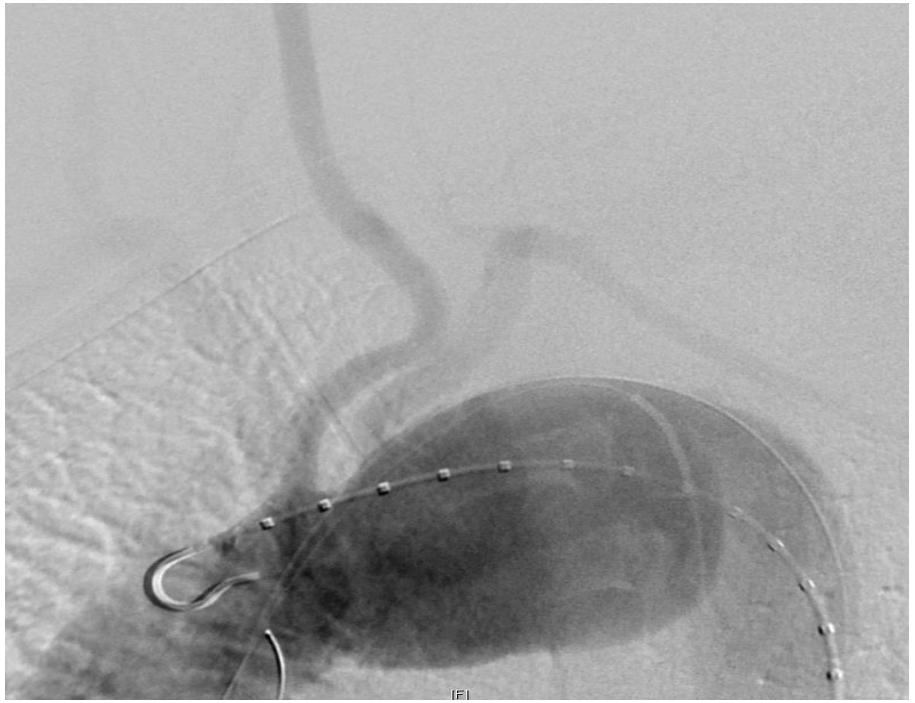
- Avoid wrapping during introduction of the side wire
- Preferential use of a support system for the side branch wire (brachial-femoral access)
  - Support brachial femoral wire by sheath/catheter
- More response closer to the femoral artery
  Iliacs > Infrarenal > Descending > Arch
- Orientation STARTS in the iliacs/infra-renal aorta, and is perfected during advancement to the descending thoracic aorta
- Movement of rotation in a single direction with advancement/withdrawal of the device, with side-wire support by sheath and catheter

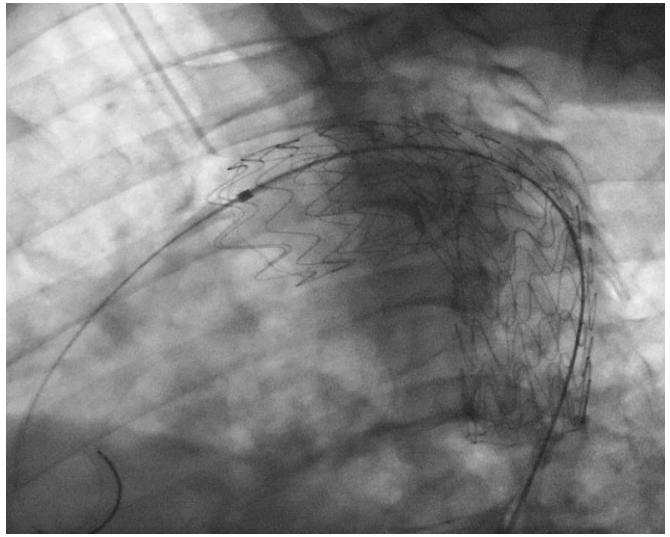
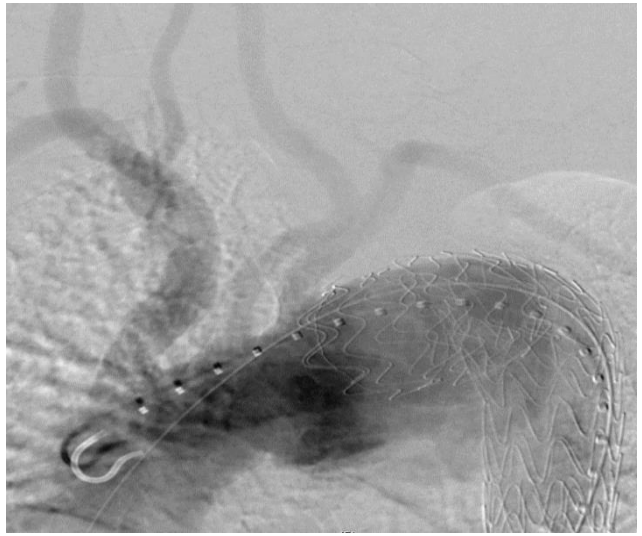
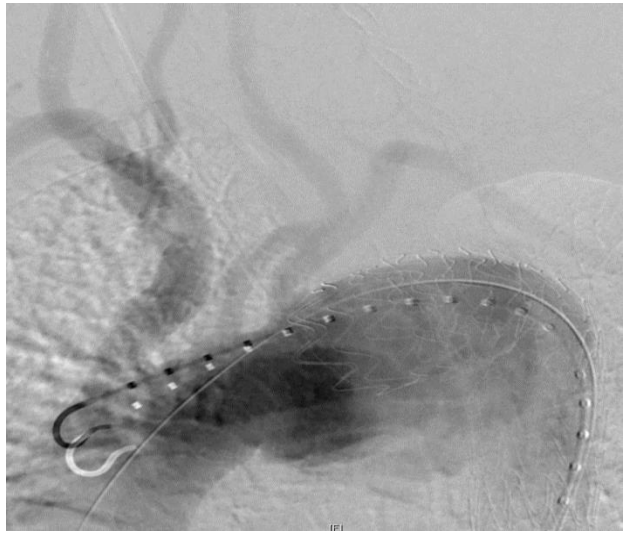
Zone 1

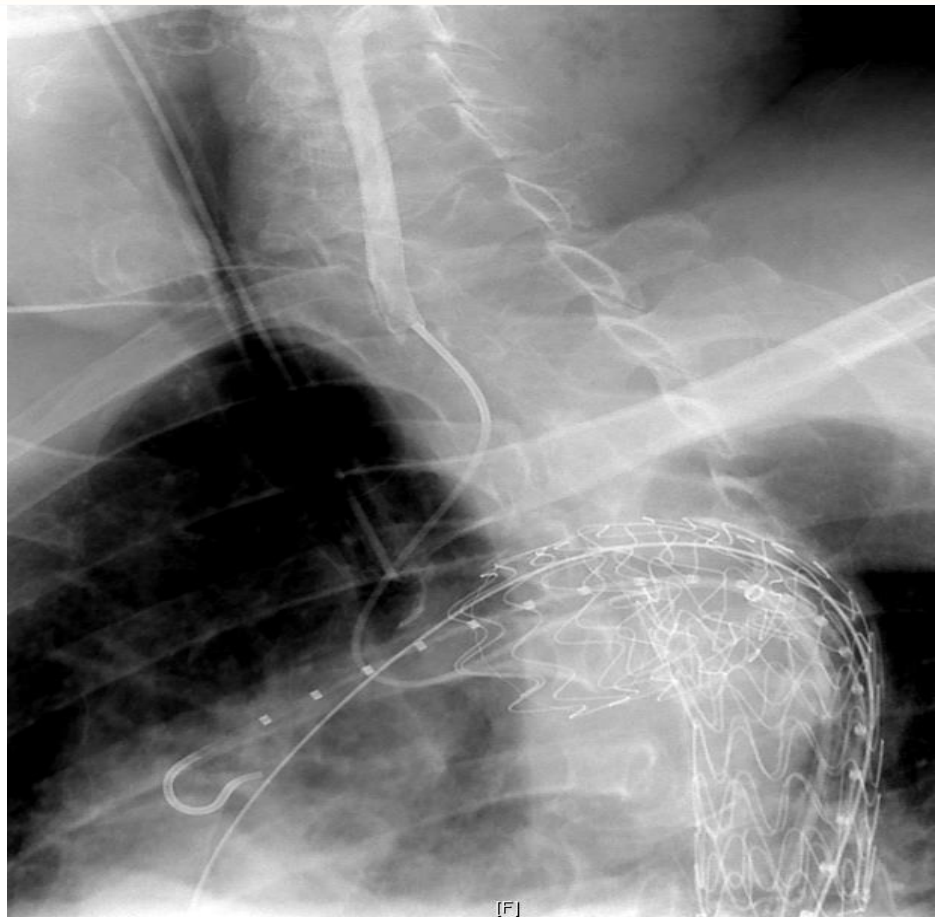


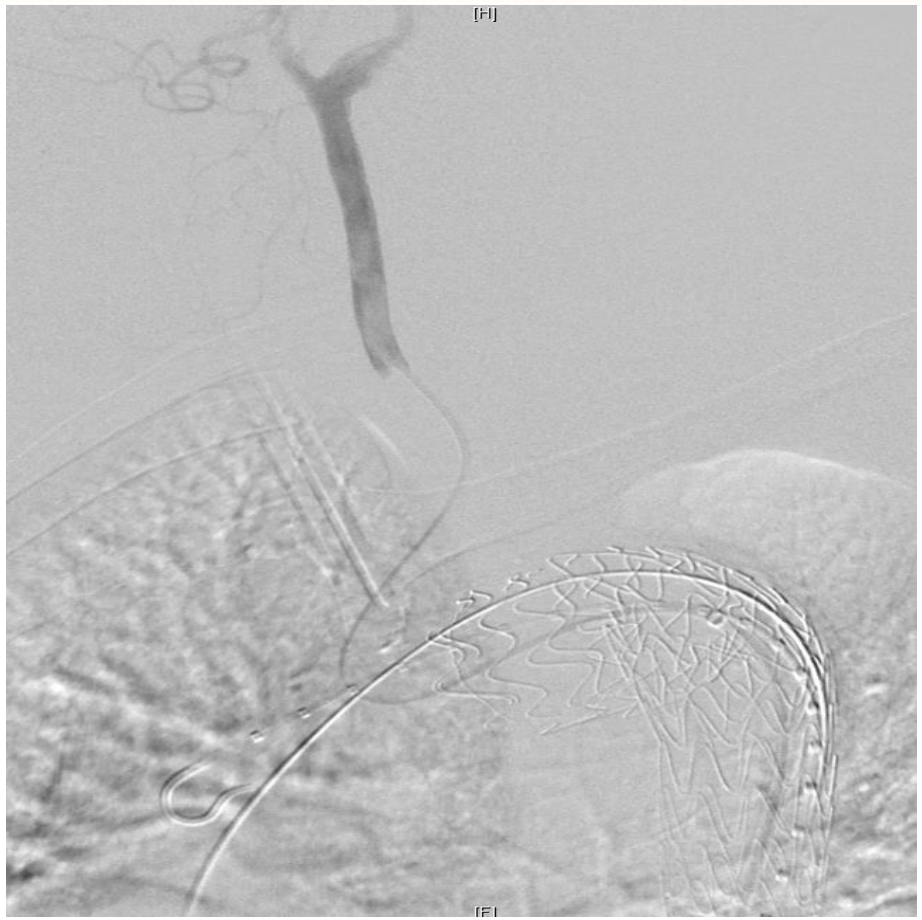
76-year-old man with significant history of ETOH and cigarette use and aneurysm that involves the left subclavian artery

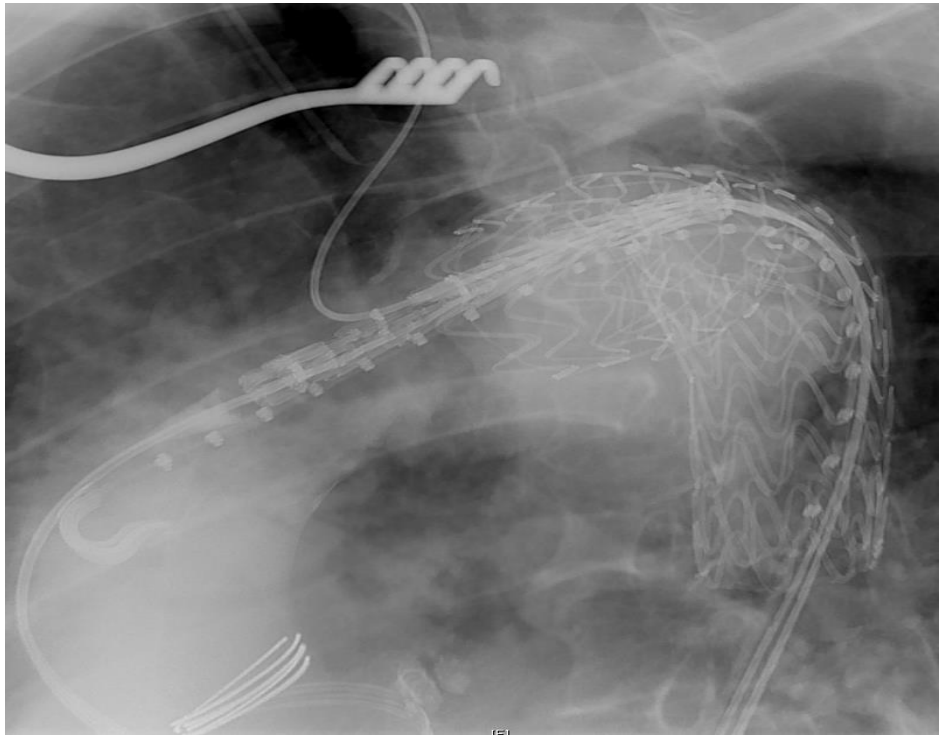


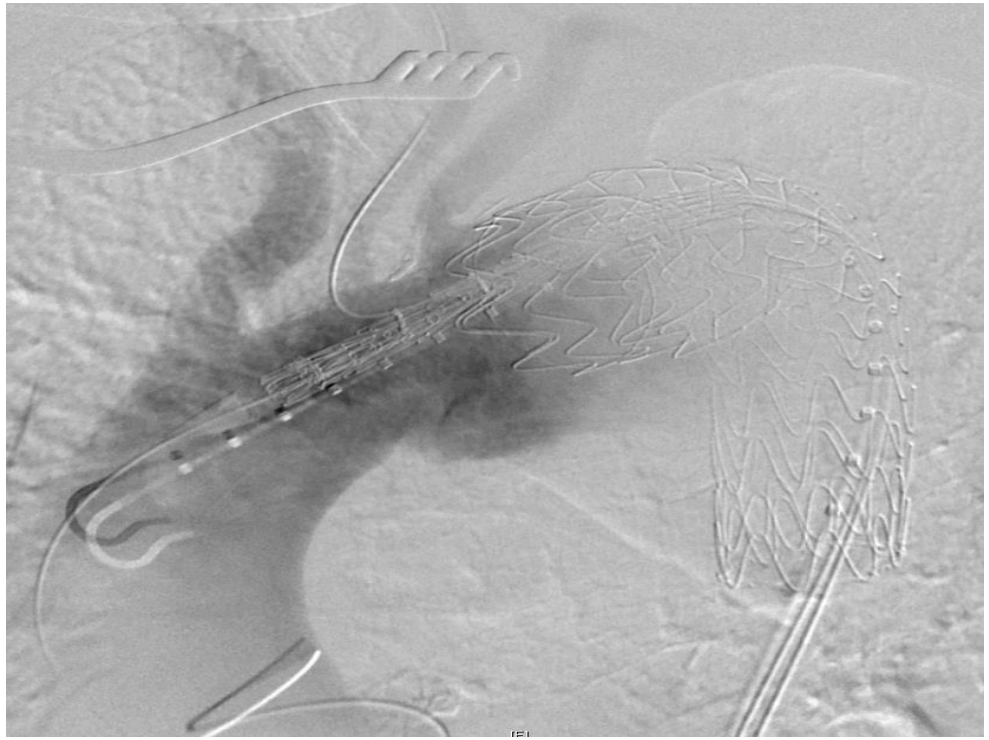


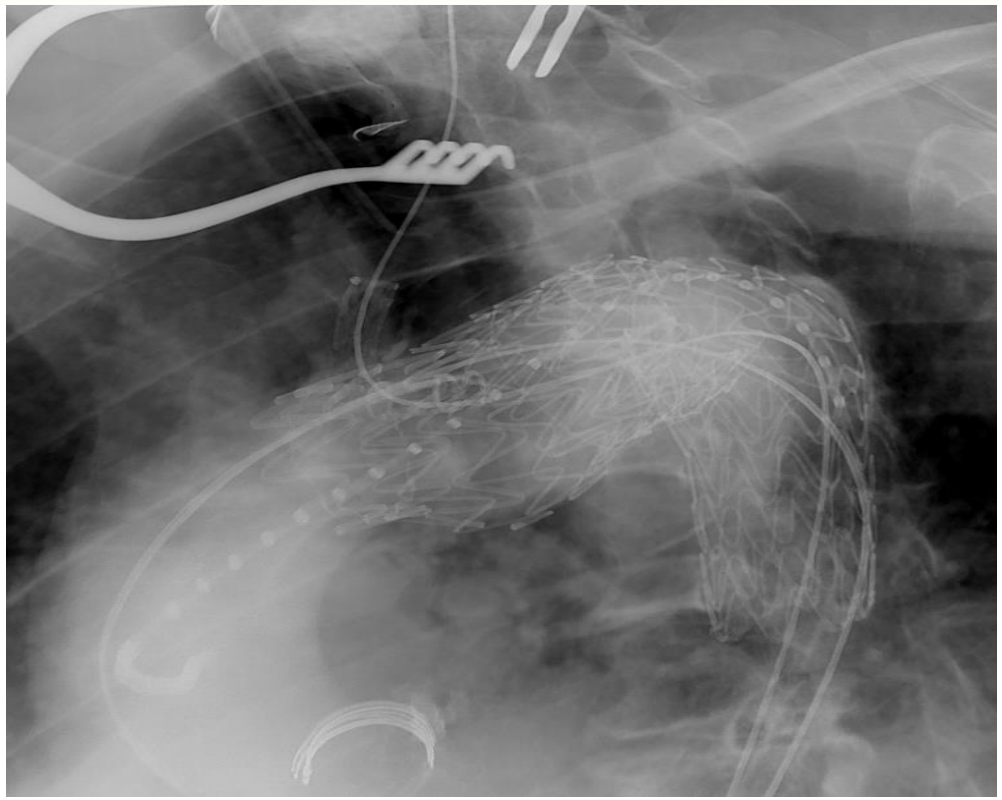




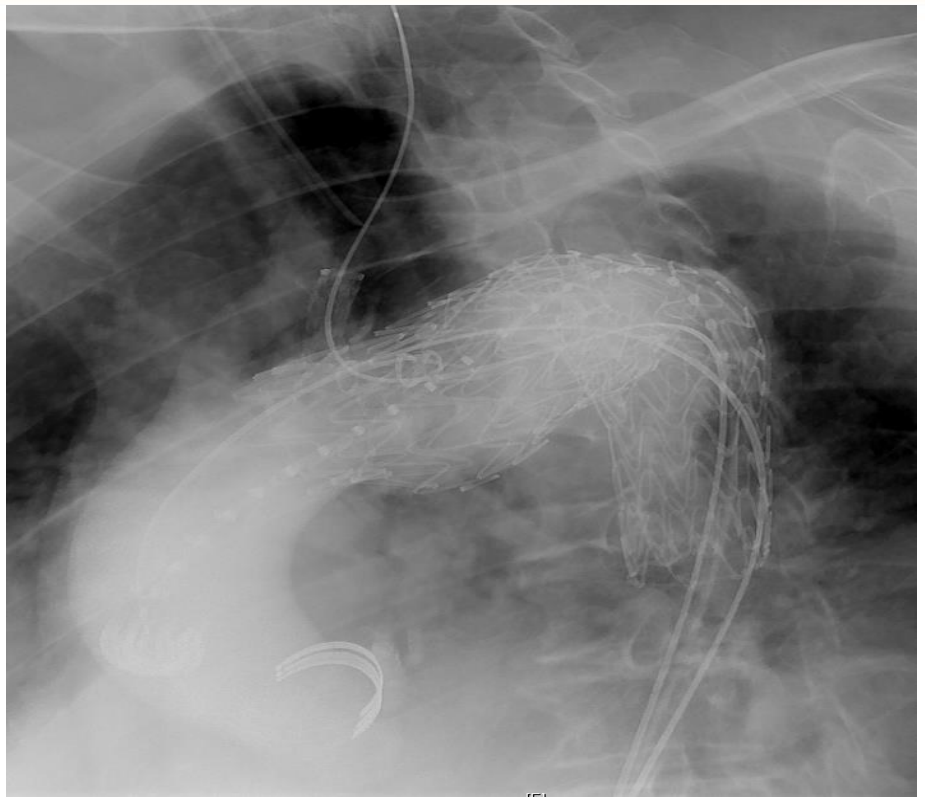


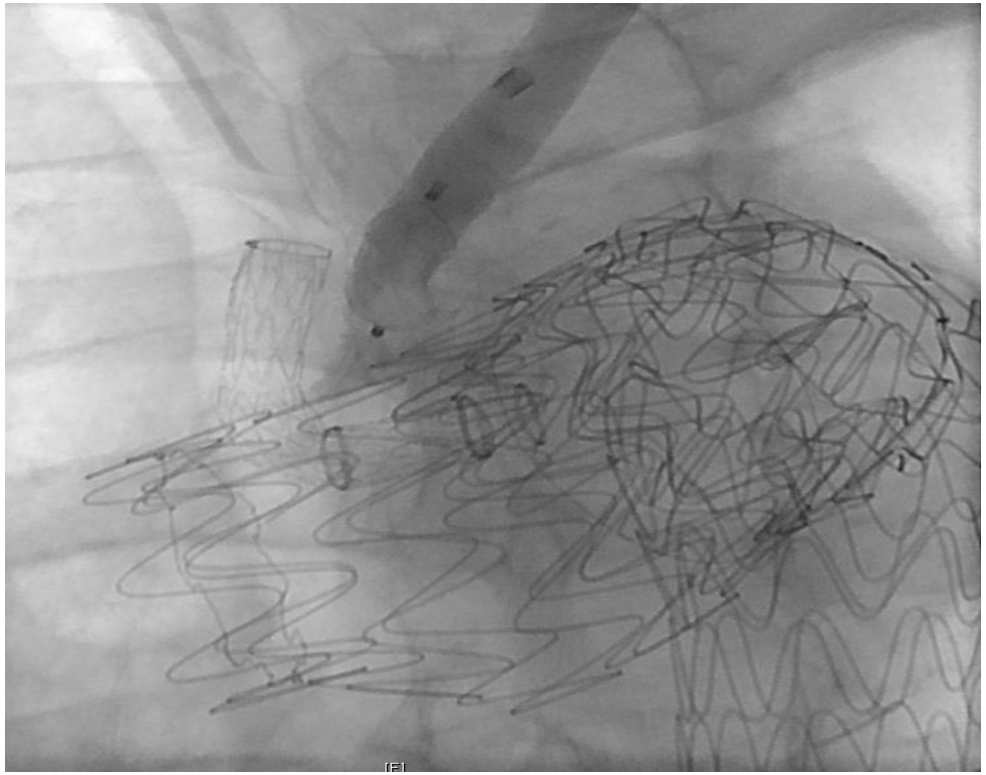


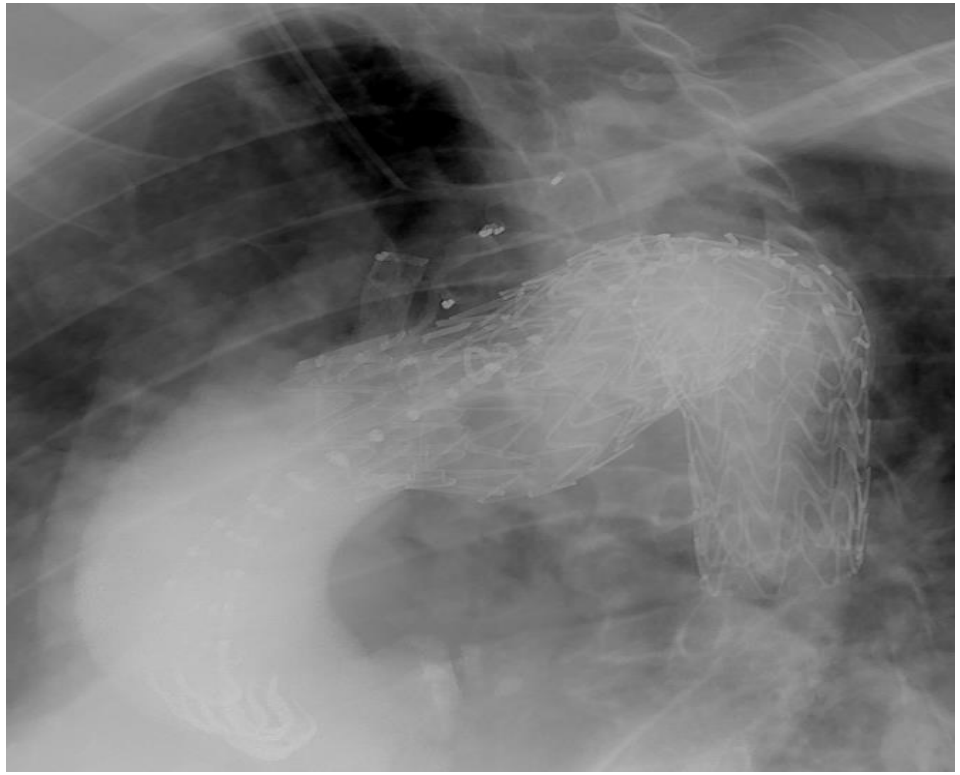


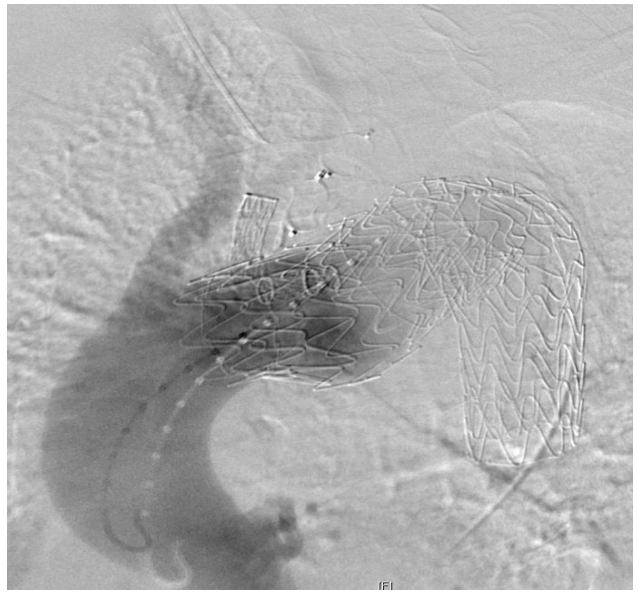


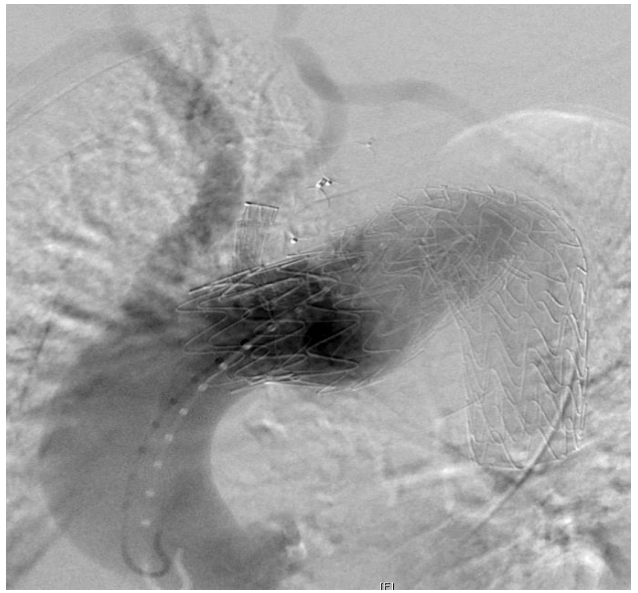


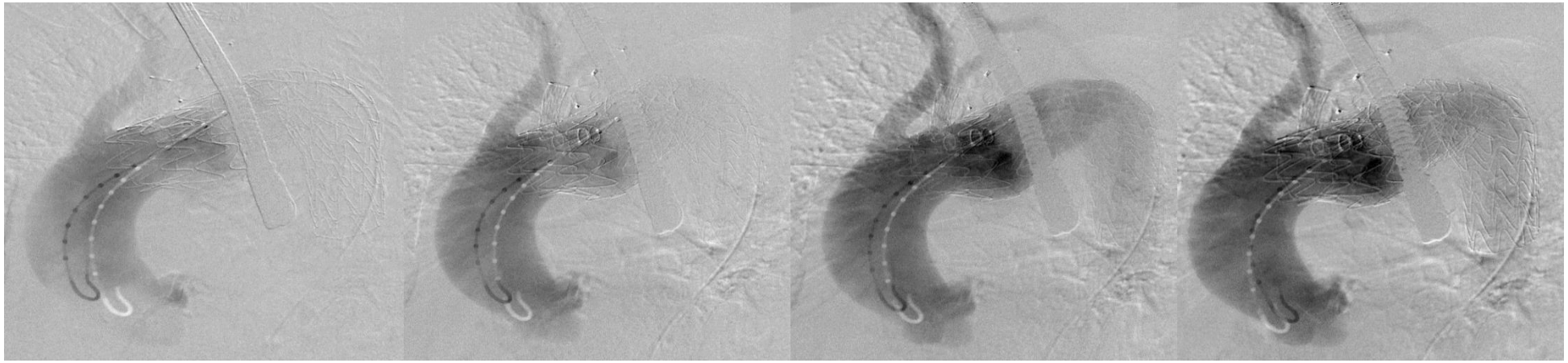


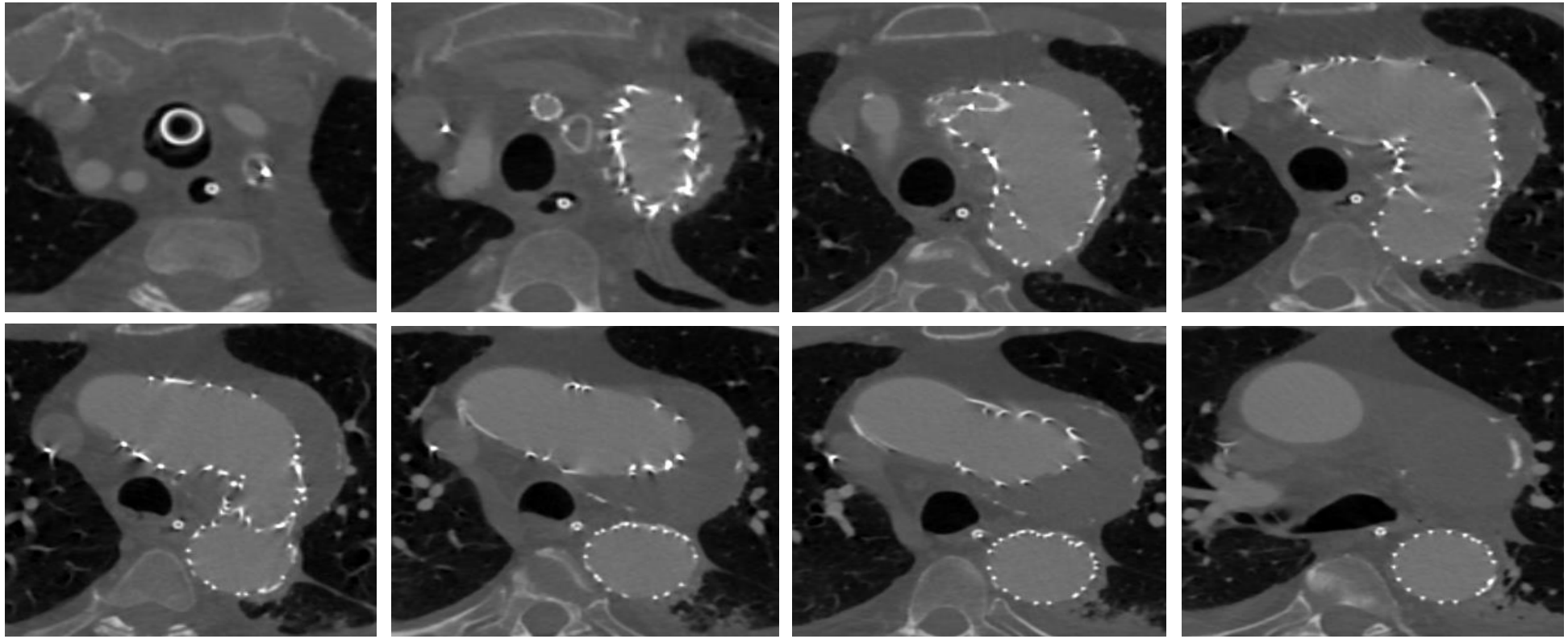


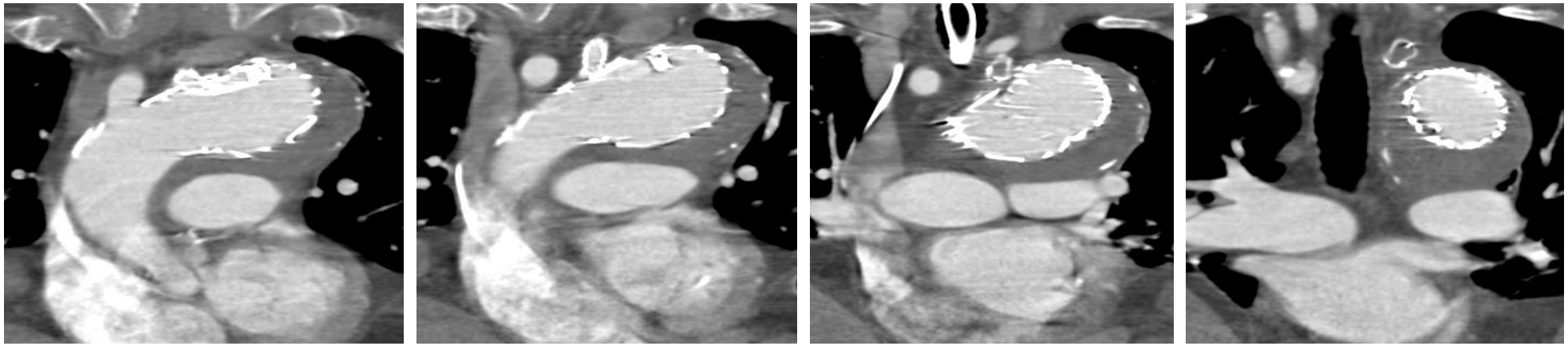












TBE Device Clinical Trials Overview Enrollment Complete

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 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

Primary and Secondary Endpoints

	Zone 2	Zone 0/1
Number of Enrolled Subjects	31	9
Primary Endpoints (procedural)		
Successful Access	100%	100%
Successful Deployment	100%	100%
Side Branch Primary Patency	100%	100%
Side Branch Primary Patency*	100%	100%
No Device-Related Endoleaks	96.6%	100%

* Will not meet primary patency if either the Core Lab assesses as not patent or if there is a reintervention to maintain patency/flow in the Side Branch reported anytime during the 1 month window.

The one device related endoleak was a type III endoleak identified between the side branch and aortic components at 1 month.

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 – Core Lab

- 1 loss of Side Branch Patency in Zone 2 at 6 months

Zone 2				
	1 Month	6 Months	12 Months	24 Months
Number of Evaluable Patients	29	19	17	6
Side Branch Patent	29	18	16	6

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

Zone 2 Device Events – Core Lab

Zone 2				
	1 Month	6 Months	12 Months	24 Months
Number of Evaluable Patients	31	27	19	6
Device Migration ≥10 mm	0/28	0/23	017	0/6
Wire Fracture	0/25	0/18	0/15	0/6
Type Ia	0/29	0/23	0/17	0/6
Type Ib	0/29	0/23	0/17	0/6
Type II	2/29	4/23	2/17	0/6
Type III	1/29	0/23	0/17	0/6

- 4 Type II endoleaks
- 1 Type III endoleak at 1 month
- No reported aneurysm enlargement for patients with endoleaks

Zone 0/1 Device Events – Core Lab

Zone 0/1			
	1 Month	6 Months	12 Months
Number of Evaluable Patients	9	6	4
Device Migration ≥10 mm	0/9	0/6	0/4
Wire Fracture	0/1	0/2	0/2
Extrusion/Erosion	0/9	0/6	0/4
Type Ia	0/7	0/6	0/4
Type Ib	0/7	0/6	0/4
Type II	0/7	0/6	1/4
Type III	0/7	0/6	0/4

- 1 Type II Endoleak at 12 months
- No reported aneurysm enlargement

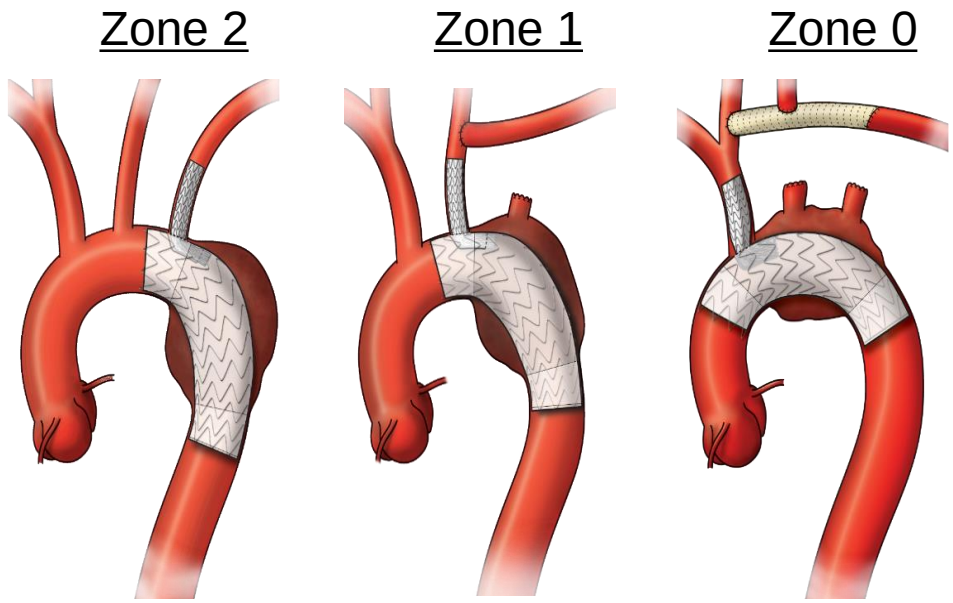
Zone 0-2 All Cause Mortality

- Reported Deaths Zones 0-2

Cause of Death	Study Day	Site reported relationship
Zone 2 subjects	**Day**	**Relation to device/procedure**
Ascending aneurysm (Aortic rupture)	113	Unknown
Arrhythmia	363	Unknown
Cardiac failure	374	Unrelated to the device and procedures
Chronic Obstructive Pulmonary Disease	402	Unrelated to the device and procedures
Zone 0/1 subjects		
Hypoxic-ishaemic encephalopathy	182	Unrelated to the device and procedures
Acute respiratory failure	265	Unrelated to the device and procedures

Summary of Preliminary Results

- 100% Technical success for Zones 0-2
- 100% Survival at 1 month for Zones 0-2
- Peri-Procedural Stroke
  - 3.3% (1/31) Zone 2
  - 22.2% (2/9) Zone 0/1
- Side Branch Patency
  - 3.3% (1/31) Zone 2 loss of patency
  - No loss of patency in Zone 0



Risks of Stroke from Branched Endografts in the Arch

- *Risk estimates between relatively low 3.3% (Zone 2) to very high 22.2% (Zones 0/1) – compares to 7.4% (non-branched TEVAR in proximal DTAA)*
- *Groups with increased risk by extension from literature for non-branched grafts: elderly; prior stroke (especially high – up to 28%); high-grade arch atheroma; mobile atheroma*
- *Acute outcome after stroke p TEVAR: dismal – mortality 33% to 57% (with rupture)*
- *One year survival after stroke p TEVAR: bleak – one-half the survival of those with no stroke*

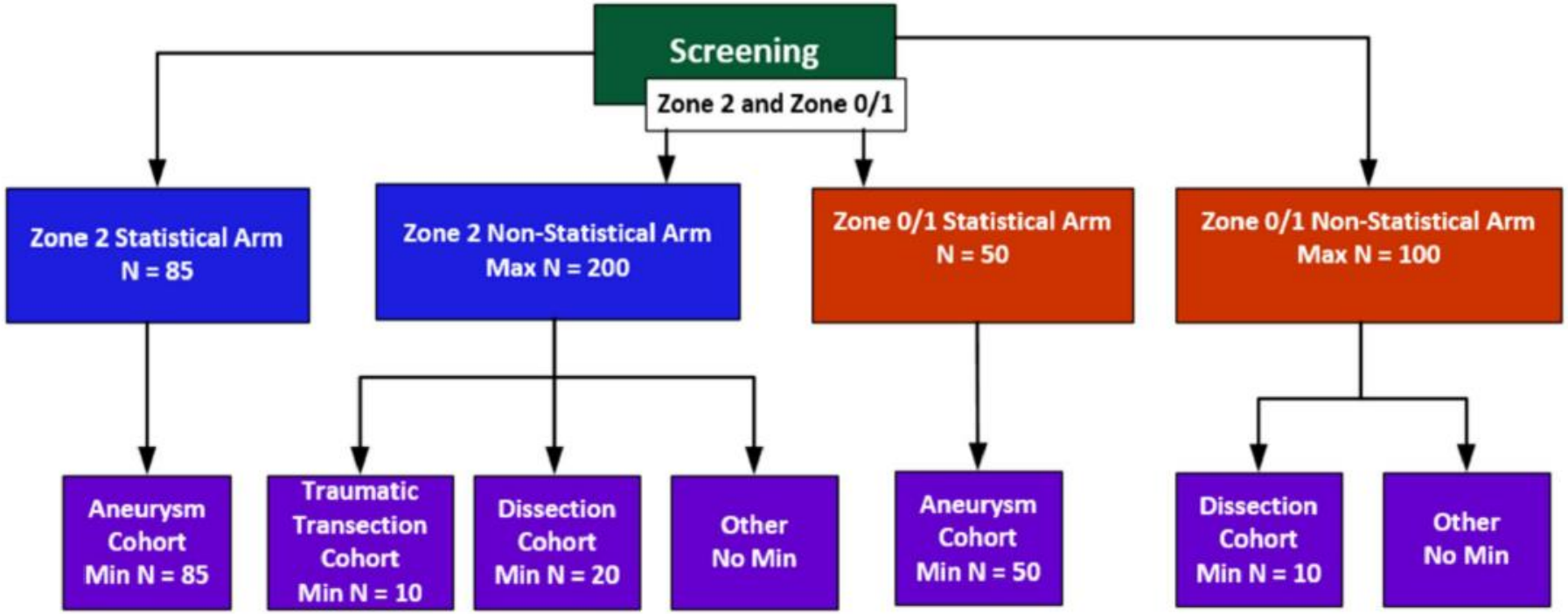
Pivotal Trial

- **Patients:**
  - Aortic arch aneurysms requiring placement of the proximal extent of the aortic stent graft in Zone 0, 1 or 2
  - First Implant completed September 19, 2016

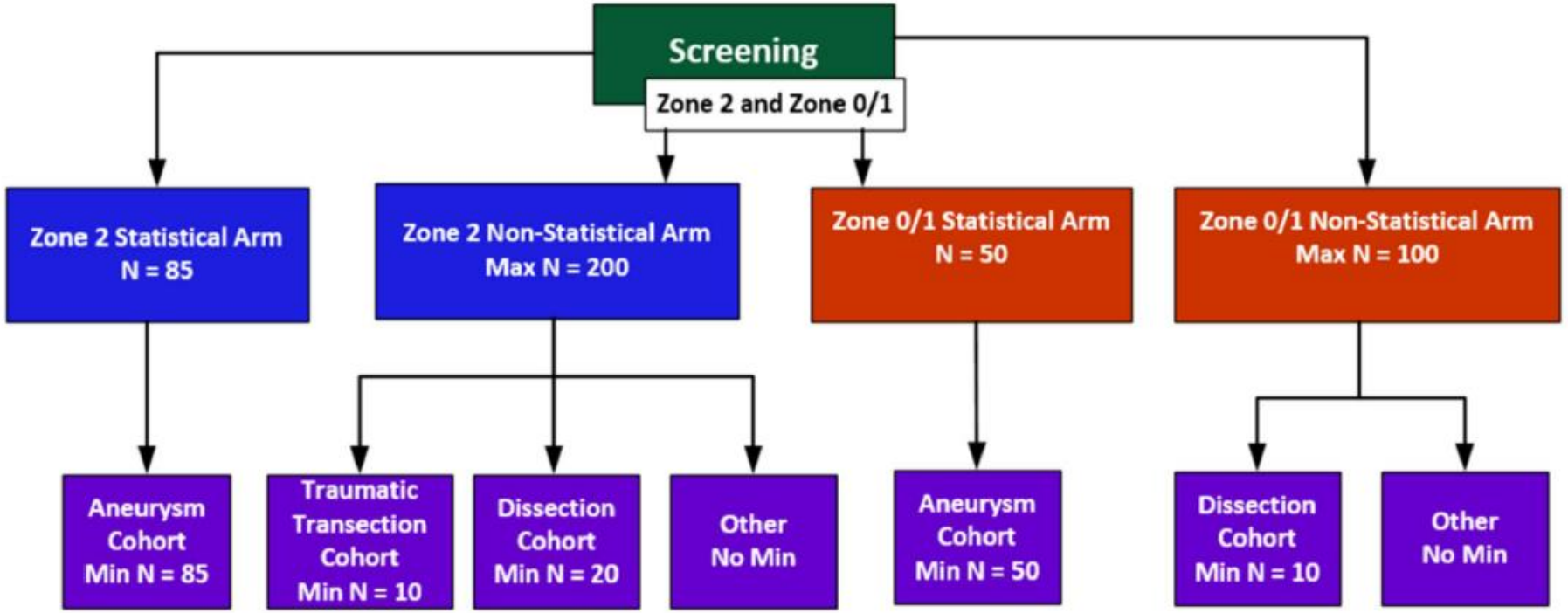
- **National Co-PIs:**
  - Himanshu Patel, MD
  - Michael Dake, MD

- Up to 40 sites
- Minimum 175 patients, Maximum 435 patients
- 5 year follow-up

Pivotal Clinical Trial Design

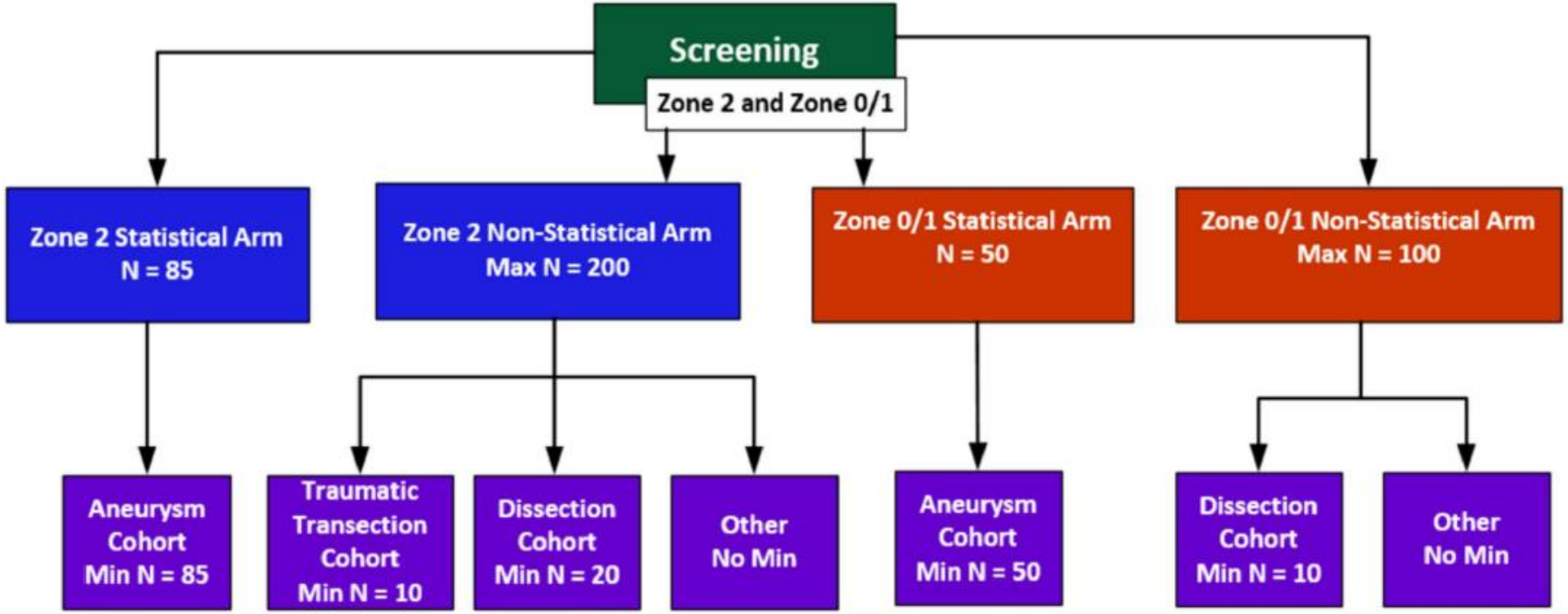


Pivotal Clinical Trial Design



Currently: n=53 n=0 n=58 n=5 n=11 n=2 n=1

Pivotal Clinical Trial Design



Overall stroke: 6.9%		Zone 2 = 6.0%				Zone 0 = 14.2%	
Stroke:	7.5%	n/a	3.4%	20%	14%	0%	0%
Early (3.8%): n=3		n/a	0%	0%	n=2	0%	0%
Late (3.1%): n=1(406)		n/a	n=2(76,196)	n=1(65)	0%	0%	0%