

# Cook Medical T Branch® System

*Stablished off-the-shelf Thoracoabdominal Endovascular System*

**FOR ER AND ELECTIVE CASES**



SERVIZO  
GALEGO  
de SAÚDE

Complexo Hospitalario Universitario  
de Santiago de Compostela  
Santiago de Compostela



**Nilo J  
Mosquera, MD.**

**HEAD OF DEPARTMENT  
Angiology and Vascular Surgery Department**

**Complexo Hospitalario Universitario de  
Santiago de Compostela. Spain**



## Disclosure

Speaker name:

**Nilo J Mosquera, MD.**

**I have the following potential conflicts of interest to report:**

**Consulting: Lombard Medical, Cook Medical, WL Gore, Bolton Medical, JOTEC-Cryolife, Cardinal Health.**

Employment in industry

Stockholder of a healthcare company

Owner of a healthcare company

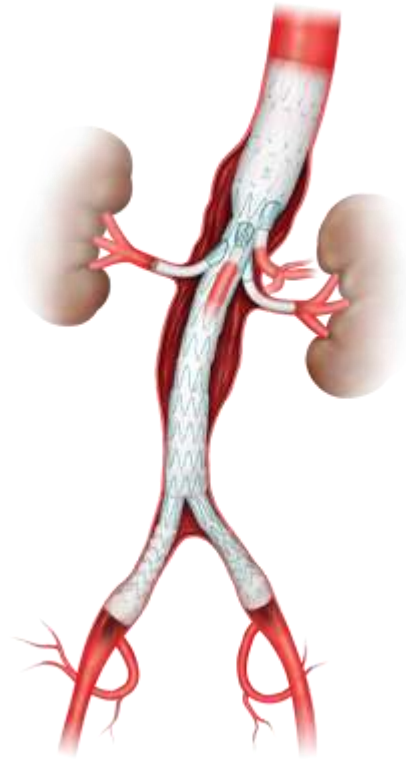
**Other(s): Spanish National Health Service Employee**

I do not have any potential conflict of interest

## Available option to deal with acute treatment

Zenith® t-Branch™ is the **first off-the-shelf complete** platform specifically designed for the treatment of patients with thoracoabdominal aneurysms.

### What about programmed cases?



J ENDOVASC THER.  
2009; 16:229-304.

• ISES ENDOVASCULAR RESEARCH COMPETITION, SECOND PLACE

### A Standardized Multi-Branched Thoracoabdominal Stent-Graft for Endovascular Aneurysm Repair

Matthew P. Sweet, MD, MS<sup>1</sup>; Jade S. Hiramoto, MD<sup>1</sup>; Ki-Hyuk Park, MD<sup>1</sup>; Linda M. Reilly, MD<sup>1</sup>; and Timothy A.M. Chuter, DM<sup>2</sup>

<sup>1</sup>Department of Surgery, Division of Vascular Surgery, University of California San Francisco, California, USA; <sup>2</sup>Department of Surgery, Division of Vascular Surgery, Daegu Catholic University School of Medicine, Daegu, Korea.

Chuter T et al  
J Endovasc Therapy 2009

Austermann M et al  
J Vasc Surgery 2014

### Custom-made versus off-the-shelf multibranch endografts for endovascular repair of thoracoabdominal aortic aneurysms

Theodosios Bisdas, MD, Konstantinos P. Donas, MD, Michel J. Bessler, MD, Giovanni Torcillo, MD, and Martin Austermann, MD, Munster, Germany

46 patients

100% tech success

Tech success and outcome comparable to CMD design

to eliminate (reduce) the need for CMD devices

**Purpose:** To assess the feasibility of endovascular thoracoabdominal aortic aneurysm (TAAA) repair using a standard off-the-shelf multi-branched stent-graft (TAAAG) using a standard off-the-shelf multi-branched stent-graft. **Methods:** The aortic anatomy of 68 patients (48 men; mean age 74 years, range 56-84) referred for endovascular repair of TAAA was measured using 3-dimensional CT scan images from computed tomographic angiography. In particular, the widest longitudinal position of the bifurcation of each iliac artery, right renal artery, and left renal artery were measured relative to the location of the superior mesenteric artery orifice. Based on prior experience, branch insertion with a standard endograft was considered feasible under the following conditions: (1) no more than 4 mm of distance between the bifurcation and the iliac artery; (2) the renal artery and SMA were 6 to 8 mm in diameter; (3) the renal artery was 4 to 8 mm in diameter; (4) at target angle (diagonal) between the bifurcation and the iliac artery; (5) the distance between each side of the bifurcation was 4 to 8 mm; and (6) the line between the bifurcation and the iliac artery was 4 to 8 mm. **Results:** Seven (10%) of 68 patients had no more than 4 mm of distance between the bifurcation and the iliac artery; 10 (15%) had 4 to 6 mm; 17 (25%) had 6 to 8 mm; 14 (20%) had 8 to 10 mm; 8 (12%) had 10 to 12 mm; 3 (4%) had 12 to 14 mm; and 5 (7%) had 14 to 16 mm. **Conclusion:** A standardized, off-the-shelf, multi-branched stent-graft is applicable in cases of TAAA that would otherwise have been treated using customized stent-graft use of a pre-made stent-graft has the potential to eliminate long manufacturing lead times and the cost of endovascular repair of TAAA.

**Objective:** This study compared early outcomes between the custom-made and the new off-the-shelf multibranch endograft (mbEVAR, t-branch Cook Medical, Bloomington, Ind) for the endovascular repair of thoracoabdominal aortic aneurysms (TAAAs).

**Methods:** Between January 2010 and January 2013, 46 consecutive patients with TAAAs underwent endovascular repair with mbEVARs. A custom-made device was used in 24 patients (group A, 52%), and the t-branch endograft was used in 22 patients (group B, 47%), with type II, 4 (17%); type III, 9 (38%); and type IV/V, 9 (38%), and type IV/V, 1 (4%). The main outcome measure was technical success, defined as successful target revascularization without occlusion of the bridging endograft or type III endoleak at the completion angiography. Secondary end points were mortality, unplanned reinterventions, branch occlusion, paraplegia, and persistent (after discharge) paraparesis.

**Results:** Technical success was 100% in group A (mean follow-up, 13 ± 11 months) and 94% in group B (mean follow-up, 6 ± 3 months) ( $P = .04$ ). There was only one procedure-related death caused by cerebral bleeding ( $P = .51$ ). Survival rates at 6 months were 71% in group A (mean follow-up, 6 ± 3 months) and 70% in group B (mean follow-up, 6 ± 3 months). The freedom from reintervention rate at 6 months was 100% in group A (mean follow-up, 11.5 months) and 99% in group B (mean follow-up, 6 ± 3 months). No branch occlusions were observed in either group. The reason for a branch occlusion occurred in three patients in group B (in all cases the bridging endograft occluded the renal artery). In two patients, the possible reason for branch occlusion was a thrombotic disorder, whereas in one patient, the reason remains unknown. Paraplegia was observed in one patient in each group (group A: 4% group B: 5%) and persistent paraparesis in two patients in group A (8%) and in one patient (5%) in group B ( $P = .51$ ) and persistent paraparesis in two patients in group A (8%) and in one patient (5%) in group B ( $P = .51$ ) and persistent paraparesis in two patients in group A (8%) and in one patient (5%) in group B ( $P = .51$ ). **Conclusion:** The t-branch device, with the unique advantage of direct implantation without any delay for manufacturing showed 100% technical success and comparable clinical outcomes to the traditional custom-made mbEVARs. Further long-term evaluation remains mandatory. [J Vasc Surg 2014;60:1186-95.]

ARTICLE IN PRESS

Systematic review and meta-analysis of published studies on endovascular repair of thoracoabdominal aortic aneurysms with the t-Branch off-the-shelf multibranched endograft

Nikolaos Konstantinou, MD,<sup>1</sup> Constantine N. Antonopoulos, MD,<sup>2\*</sup> Thomas Jakkou, MD,<sup>3</sup> Ramin Banafsche, MD,<sup>4</sup> Tilo Kolbel, MD, PhD,<sup>5</sup> Beatrice Ficardi, MD,<sup>6</sup> and Nikolaos Tsimparis, MD, PhD,<sup>7</sup> Munich and Hamburg, Germany, and Athens, Greece

ABSTRACT

**Background:** Endovascular treatment of thoracoabdominal aortic aneurysms is becoming increasingly popular in clinical practice, mainly because of its reduced perioperative mortality and morbidity. However, the custom-made stent graft platform that companies offer requires detailed preoperative planning and production time that can take up to 12 weeks. This may delay surgery in elective patients and is not an option for urgent or emergent cases. To surpass this limitation, the t-Branch (Cook Medical, Bloomington, Ind) was launched in 2012 in Europe as the first off-the-shelf standardized multibranched endograft for the endovascular treatment of thoracoabdominal aneurysms. Our aim was to systematically evaluate all published experience with this commercially available off-the-shelf thoracoabdominal stent graft.

**Methods:** We performed a systematic inquiry of the medical databases to identify all published studies that reported on the outcomes of patients treated with the t-Branch stent graft and then conducted a qualitative synthesis and meta-analysis of the results. The main end points studied were technical success, mortality, major stroke, spinal cord ischemia, primary branch patency, and renal insufficiency during the first 30 days along with midterm mortality and reintervention rate. We estimated pooled proportions and 95% confidence intervals (CI).

**Results:** We identified seven retrospective studies published between 2014 and 2018, with a total of 197 patients. Mean age: 72.5 ± 7 years; 70% male. Among 165 patients, 45% were symptomatic and 19% were treated for a ruptured aortic aneurysm. In 197 patients, pooled technical success was 92.5% (95% CI, 83.9%-98.7%), and in 126 of the cases, an early endoleak was detected (65% CI, 0.95%-84.0%). The rate of spinal cord ischemia was 12.2% (95% CI, 4.7%-25.2%), observed in 4% of the patients (95% CI, 0.8%-13.6%). Acute renal failure was 12.1% (95% CI, 0.9%-25.0%), whereas primary branch patency was calculated at 59.2% (95% CI, 36.7%-79.2%), major stroke was 1.5% (95% CI, 0.1%-5.4%), and pooled reintervention rate was 6.3% (95% CI, 2.44%-12.8%) and pooled mortality rate was 5.7% (95% CI, 1.70%-10.4%).

**Conclusions:** This pooled analysis indicated good technical success rate after t-Branch endograft implantation, with acceptable mortality and neurologic complications despite a high rate of urgent procedures. Thoracoabdominal endovascular repair with the t-Branch endograft is a feasible and safe therapeutic option for elective and urgent patients. (J Vasc Surg 2020 ■ 1-10.)

Systematic performance review

Thoracoabdominal off the shelf repair with Tbranch is feasible and safe....  
for elective and Urgent cases

Tsimparis N, Kolbel T et al  
J Vasc Surgery in press

# Standardized configuration simplifies device selection

## SMA Branch

**Diameter:** 8 mm  
**Length:** 18 mm  
**Distance from proximal end of graft to distal end of branch:** 117 mm  
**Clock:** 12:00

## Celiac Branch

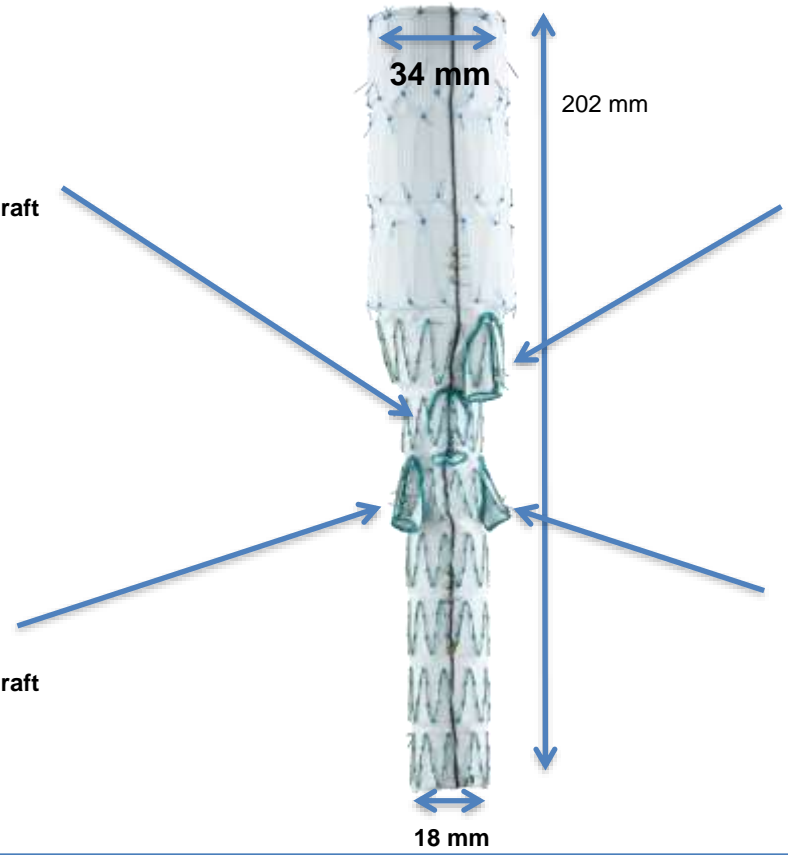
**Diameter:** 8 mm  
**Length:** 21 mm  
**Distance from proximal end of graft to distal end of branch:** 99 mm  
**Clock:** 1:00

## Right Renal Branch

**Diameter:** 6 mm  
**Length:** 18 mm  
**Distance from proximal end of graft to distal end of branch:** 135 mm  
**Clock:** 10:00

## Left Renal Branch

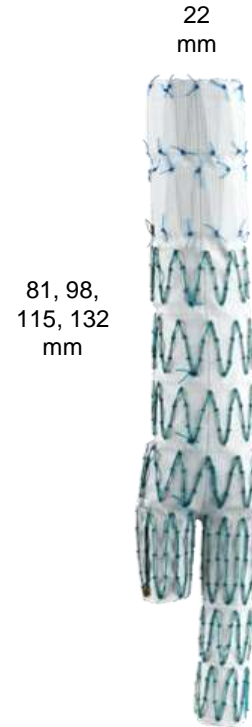
**Diameter:** 6 mm  
**Length:** 18 mm  
**Distance from proximal end of graft to distal end of branch:** 135 mm  
**Clock:** 3:00



# Universal Distal Body:

## Unique Dedicated design to combine with Tbranch

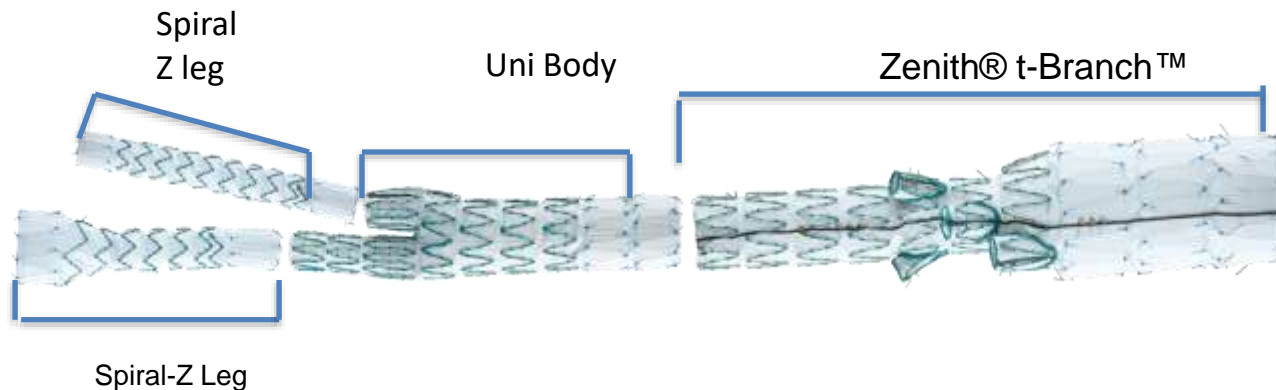
- Four sizes:
  - UNIBODY 22-81
  - UNIBODY 22-98
  - UNIBODY 22-115
  - UNIBODY 22-132\*\*
- Proximal diameter: 22 mm
- Lengths: 81 mm, 98 mm, 115 mm, 132 mm





## Off-the-shelf capability related to **versatility**

More than a simple graft : A complete off-the-shelf solution for immediate treatment of thoracoabdominal aneurysms.





# The durability of the Zenith devices

Choose a device with superior endoleak and migration resistance

ARC Technology™ is the name for Zenith's unrivaled systemic migration resistance:

**A**ctive fixation,

**R**adial force and

**C**olumnar strength...working in unison.

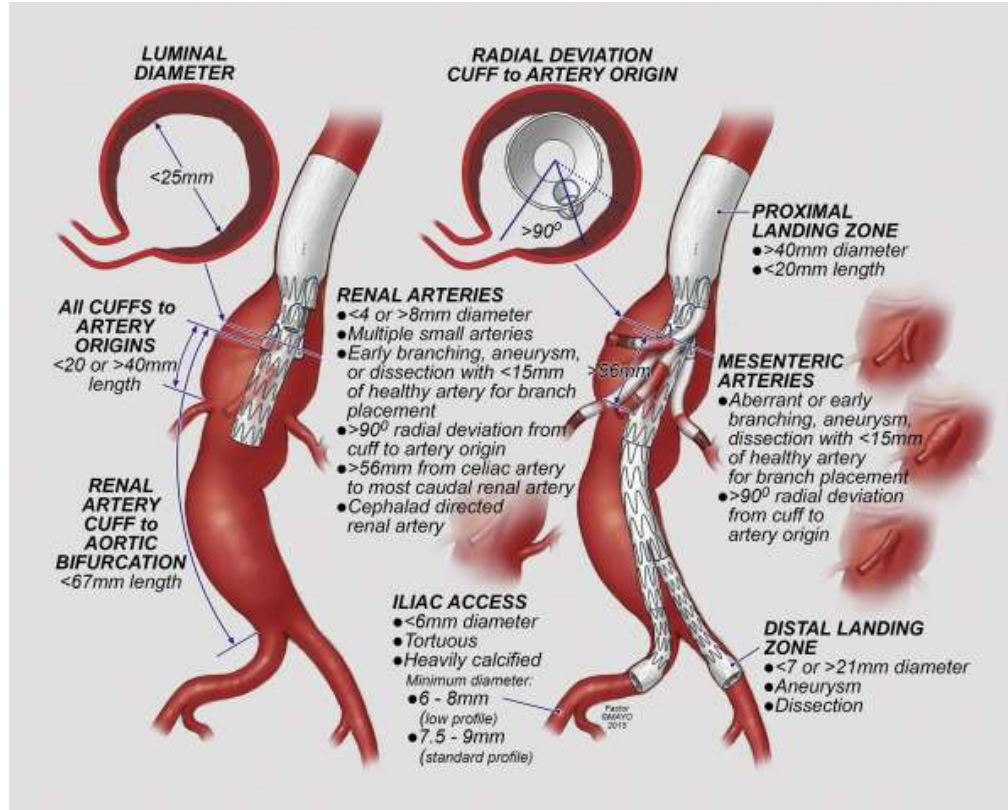
- Only Zenith from Cook Medical has ARC Technology
- Stents from branches placed in the viscerals locks graft in place



# Expand applicability in ER and elective patients: Tips and Tricks for T-Branch

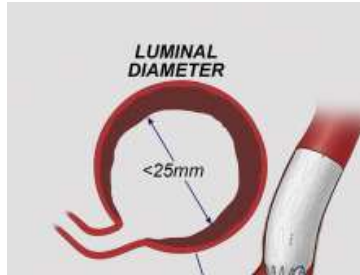
1. Sizing and Planning: tips to plan procedure and overcome limitations
2. Deployment sequence: My personal approach.
3. Stage your T branch

## Sizing and Planning: tips to plan procedure and overcome limitations

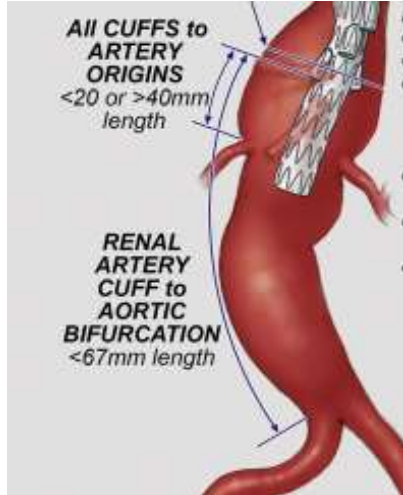


## Sizing and Planning: tips to plan procedure and overcome limitations

Really important issue: investigate IVD at visceral segment and take care of IVD related to branches.



Not important issues: play with landing and bridge stent lengths



## Sizing and Planning: tips to plan procedure and overcome limitations

### RENAL ARTERIES

- <4 or >8mm diameter
- Multiple small arteries
- Early branching, aneurysm, or dissection with <15mm of healthy artery for branch placement
- >90° radial deviation from cuff to artery origin
- >56mm from celiac artery to most caudal renal artery
- Cephalad directed renal artery

Important issue: compromise sealing and patency.  
(>8 mm renal not really a problem)

Small polar renal consider sacrifice

Not important issues: play with landing, bridge stent lengths and use more flexible bridge stents or relining

## Sizing and Planning: tips to plan procedure and overcome limitations



Critical issue, not a limitation: never doubt  
in going hybrid!!!

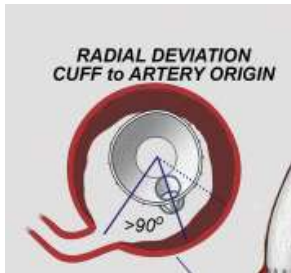


Not important issues: go hybrid again or  
just use more Cook grafts: ZBIS is your tool

## Sizing and Planning: tips to plan procedure and overcome limitations



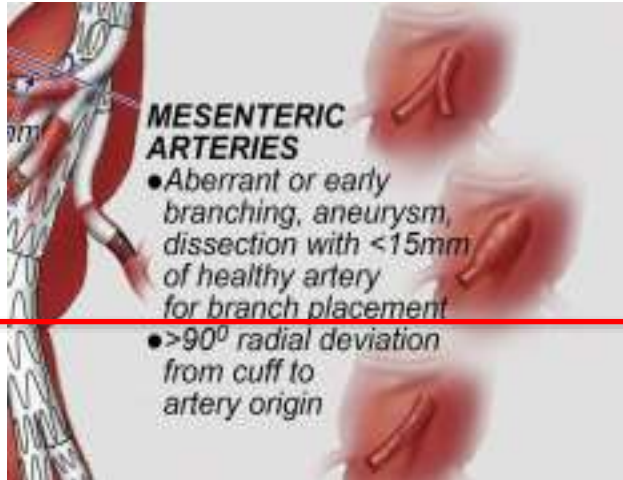
Not a limitation: go higher or tune your landing with thoracic component!!!



Not a limitation: design your deployment to minimize or just buy some more room, go higher again



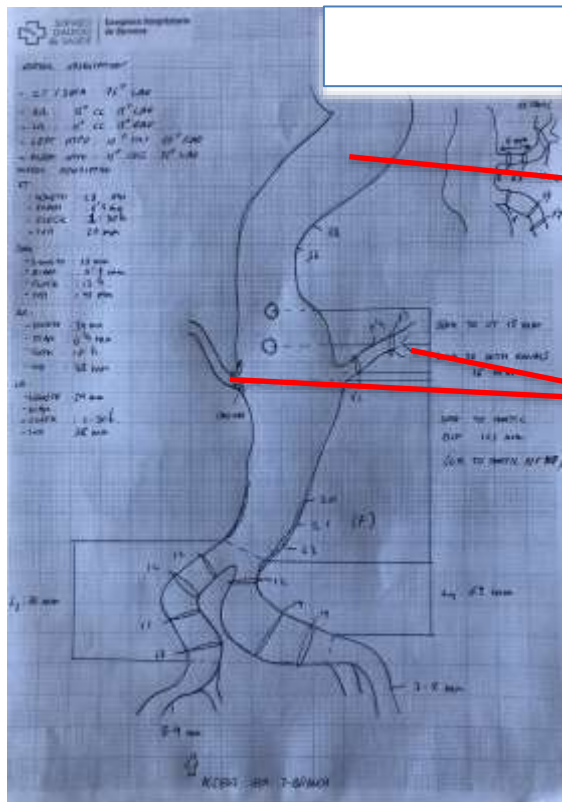
## Sizing and Planning: tips to plan procedure and overcome limitations



Important limitation: consider hybrid approaches

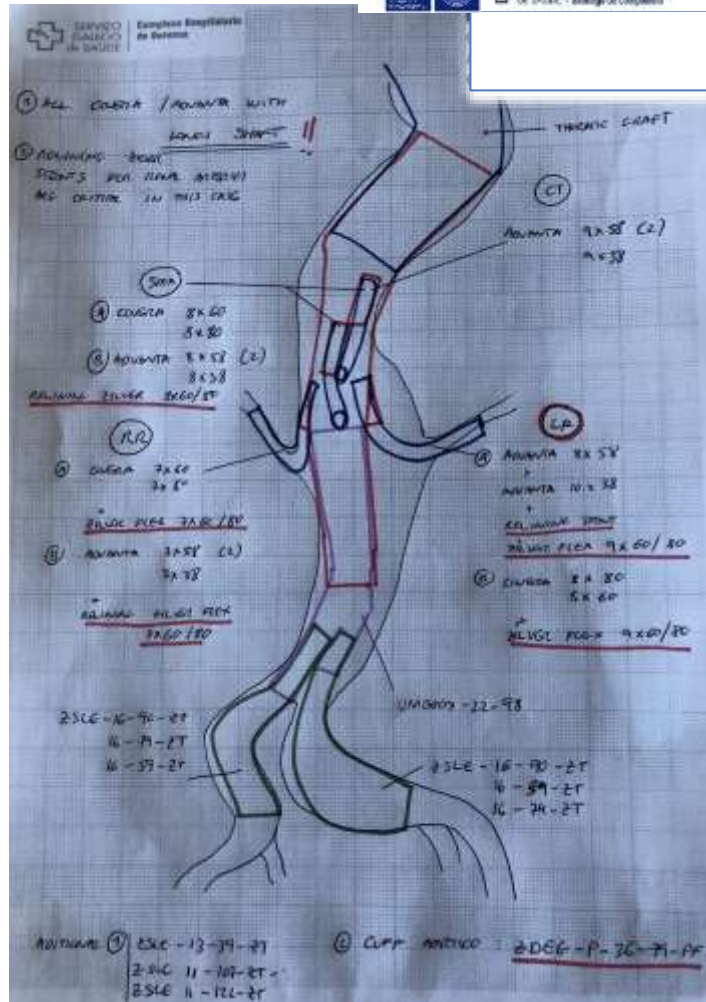
Not a limitation: use more flexible bridge stents and higher deployment

# Sizing and Planning Tips:

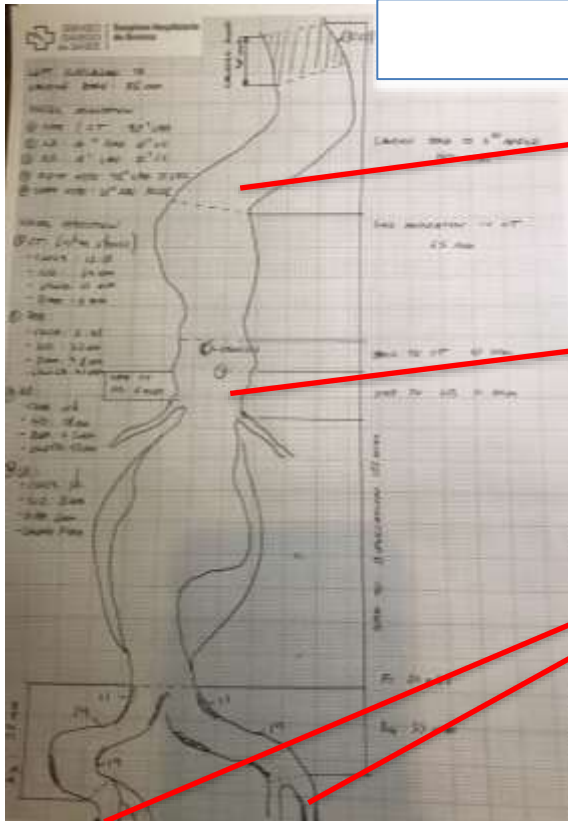


1. Not suitable for 34 mm

2. Upcranial direction for renals



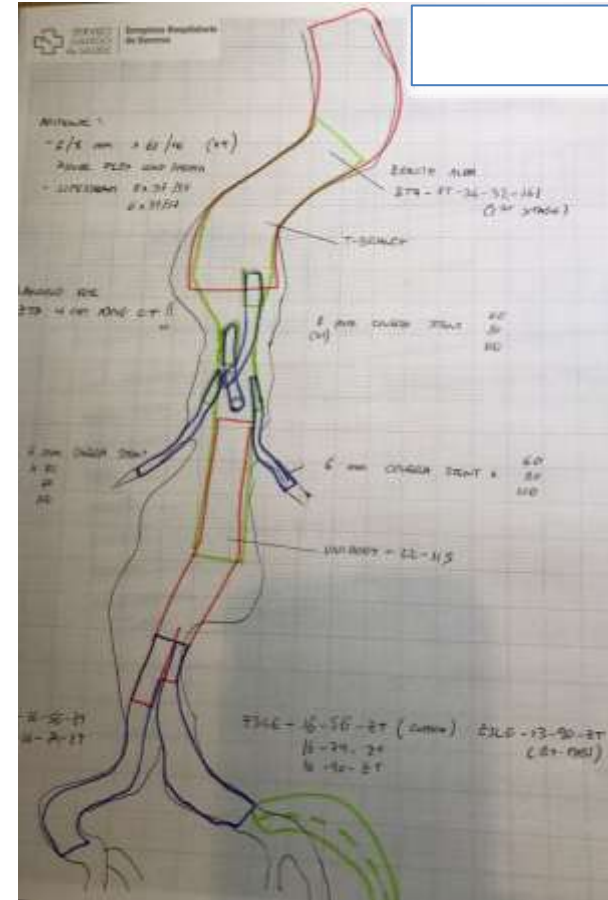
## Sizing and Planning Tips:



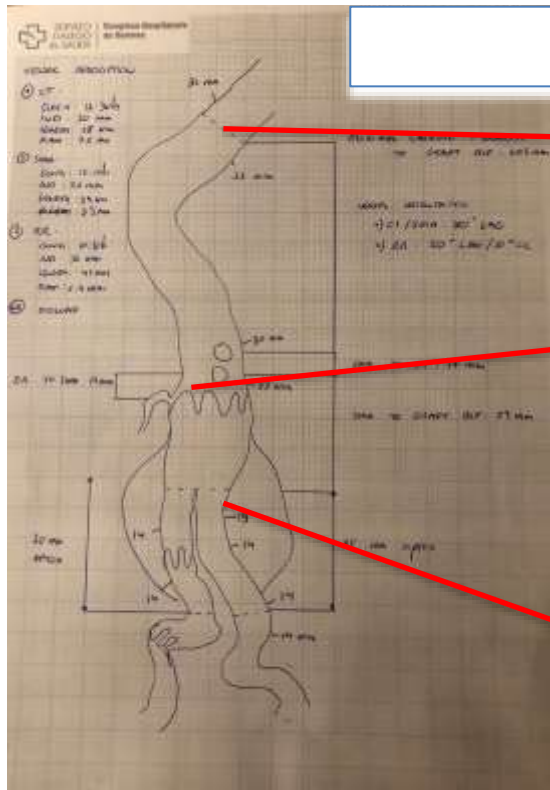
1. Not suitable for 34 mm

2. SMA and renals close (6 mm)

2. Small calcified access



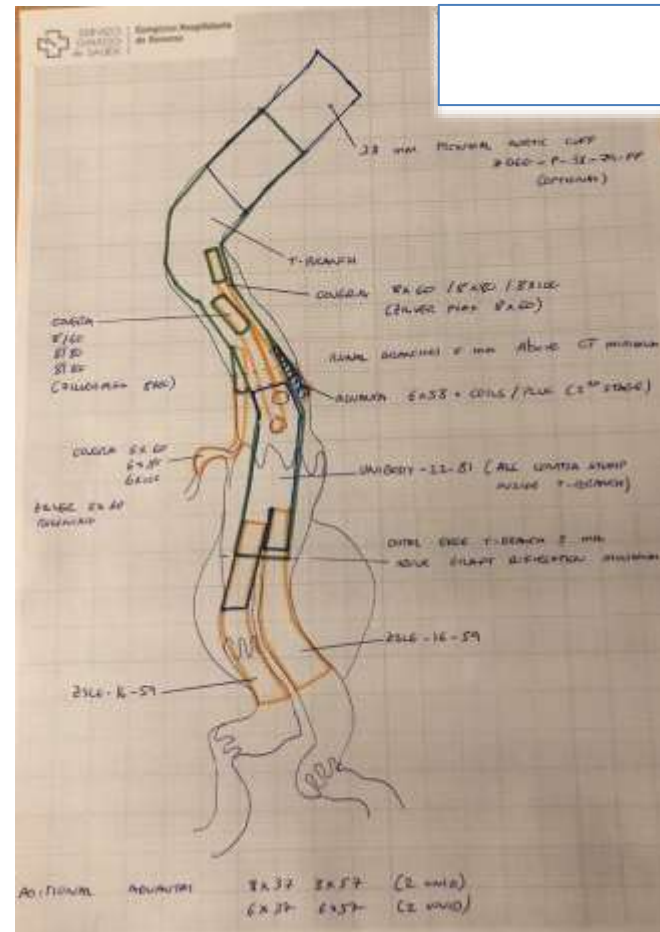
## Sizing and Planning Tips:



1. Not suitable for 34 mm

2. Just 1 renal patent

3. Small distance renal to neobifurcation (graft)

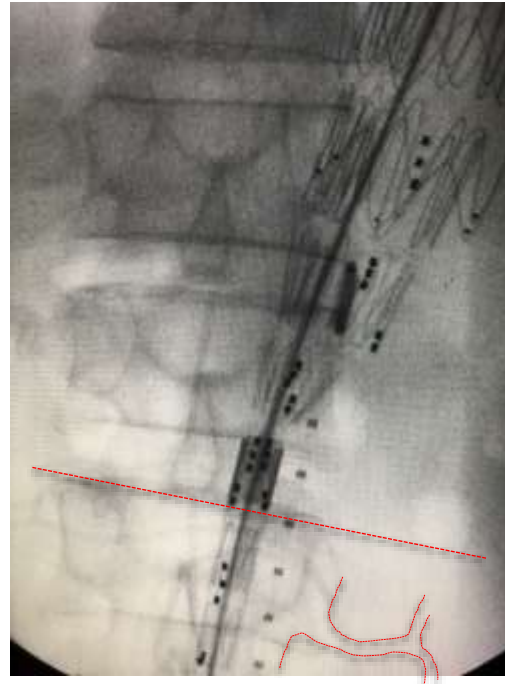


## Implantation sequence: our sequence

Run with graft in place 5<sup>o</sup>  
CC



Renal branches 2 cm above  
center reference renal



Unibody in place: deploy



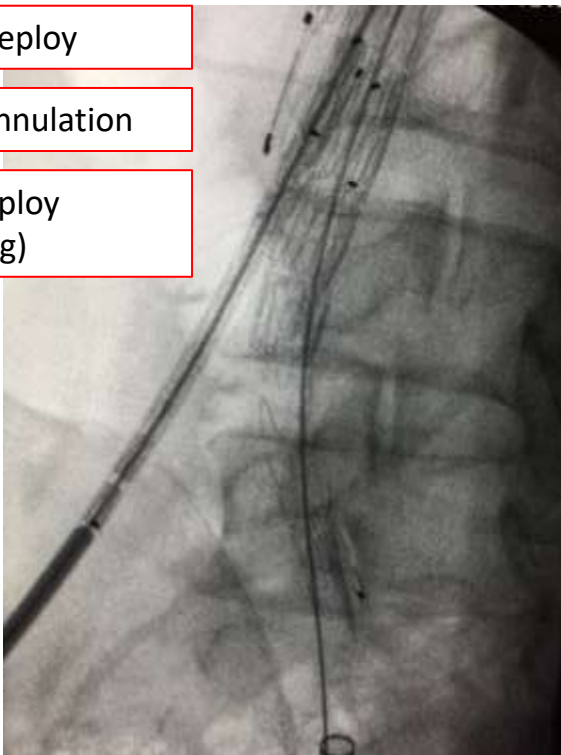


## Implantation sequence: our sequence

Ipsilateral ZISL deploy

Contralateral cannulation

Contralateral deploy  
(optional; staging)



Balloonning and closure



Percutaneous seath downsizing

TBRANCH:  
22F sheath



Unibody: 20F  
Sheath

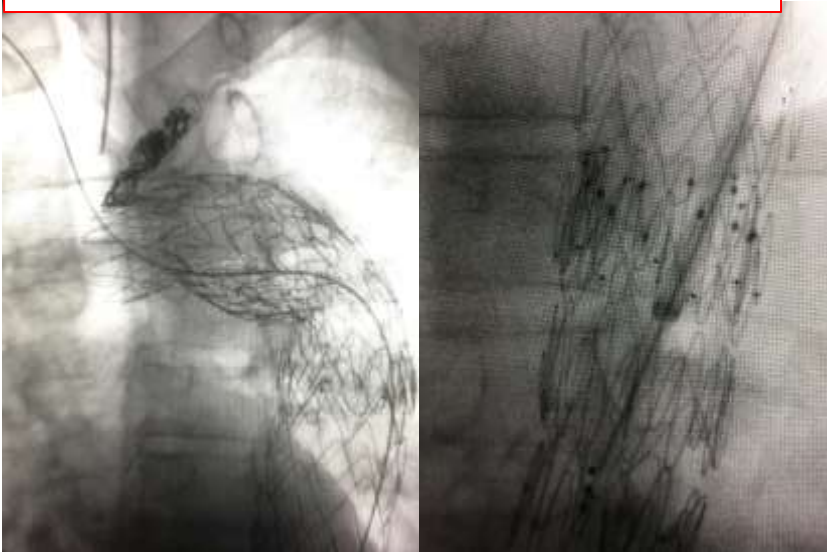


Limb extensión  
Balloon&closure : 18F  
Sheath

## Implantation sequence: our sequence

### Sequential Branch Cannulation and deployment for brigde stent

12F sheath access from axilar approach to stabilize



8F 70 cm Flexor sheath  
coaxial for vessel  
cannulation

Always start with  
SMA

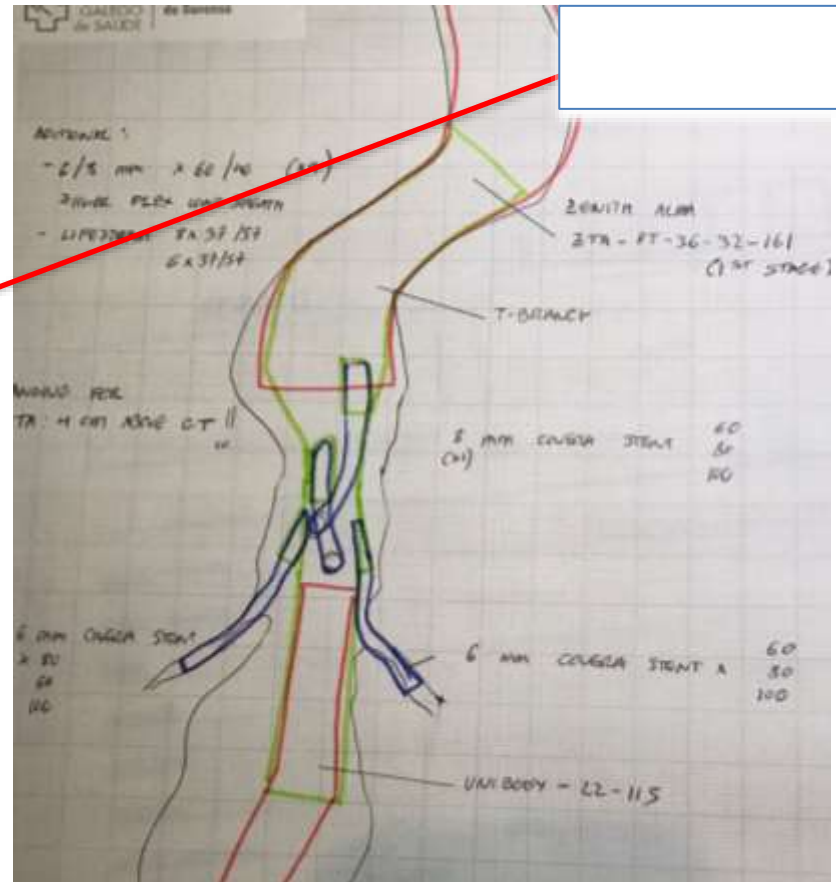




# STAGE your TBRANCH!!!

Prevent spinal cord ischemia with 2 or 3 Stages

If additional thoracic component is needed do this as first approach

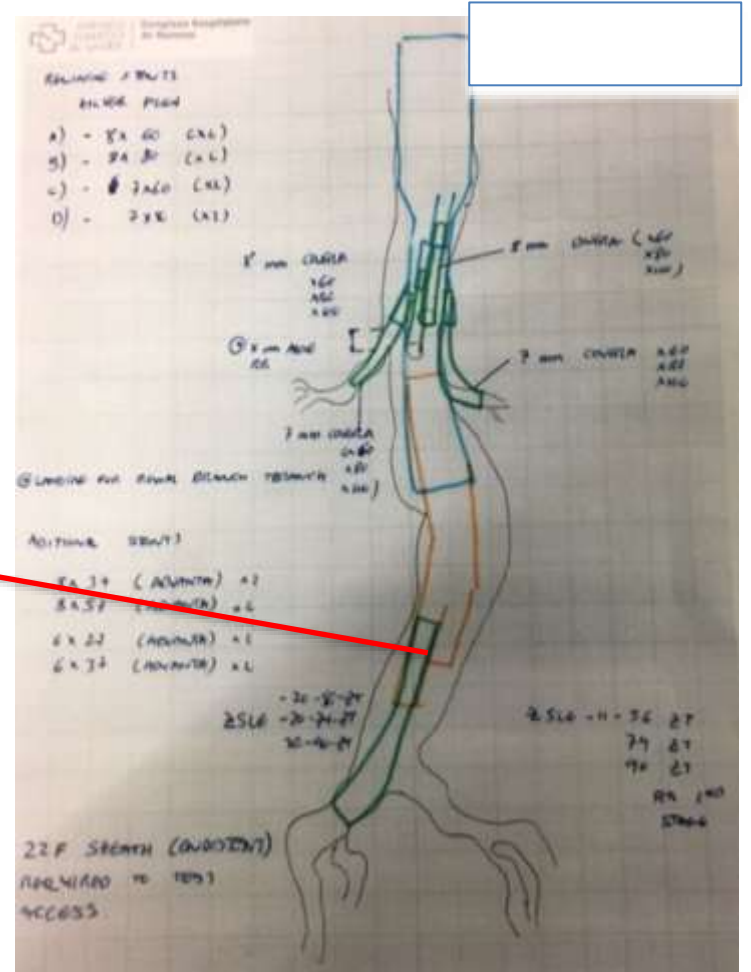


# STAGE your TBRANCH!!!

Prevent spinal cord ischemia with 2 or 3 Stages

If additional thoracic component is needed do this as first approach

If the treatment is Tbranch alone then leave contralateral for second stage



## STAGE your TBRANCH!!!

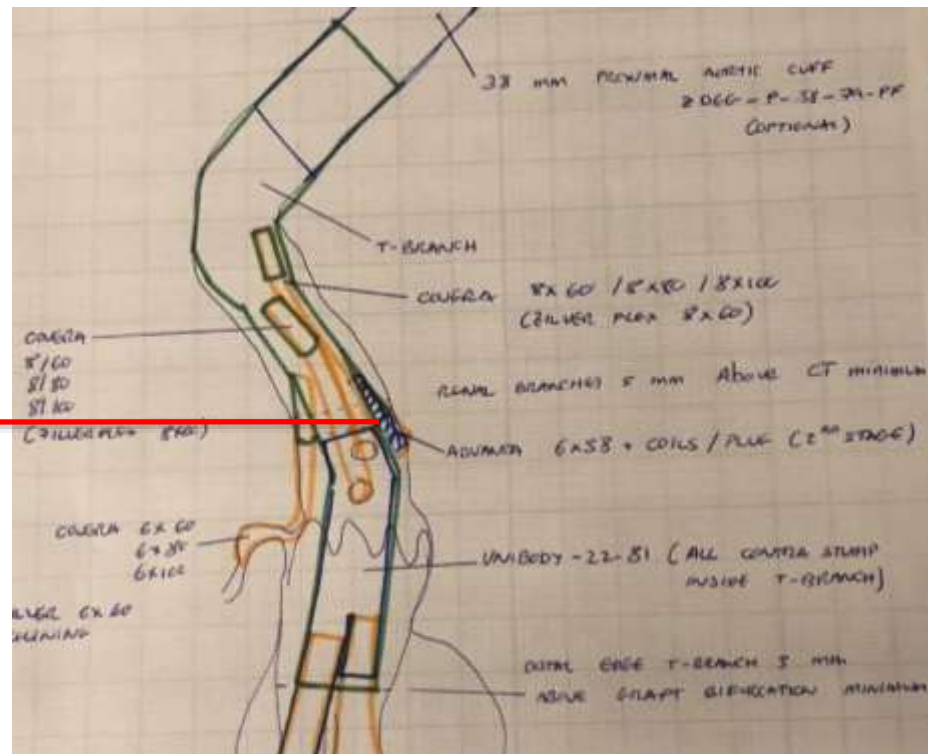
Prevent spinal cord ischemia with 2 or 3 Stages

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If the treatment is Tbranch alone  
then leave contralateral for second  
stage

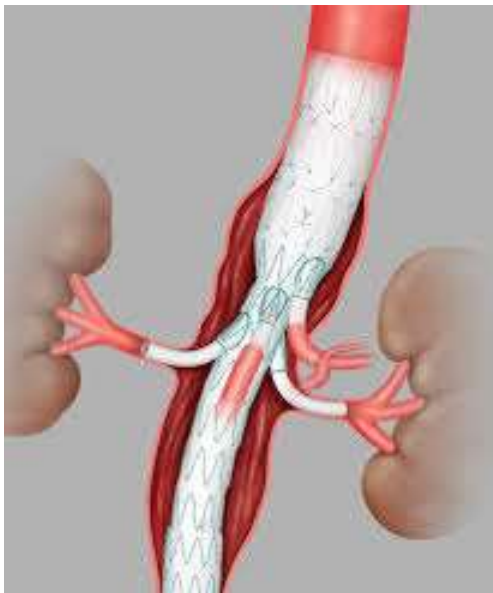
Sometimes you can plan a  
perfusion branch...

If possible use evoked potentials



# No conclusions: 1 comment

...more than a “simple” thoracoabdominal device



A Real proven and safe Multi-tool System  
(with some T&T) for thoracoabdominal  
repair in ER and elective cases