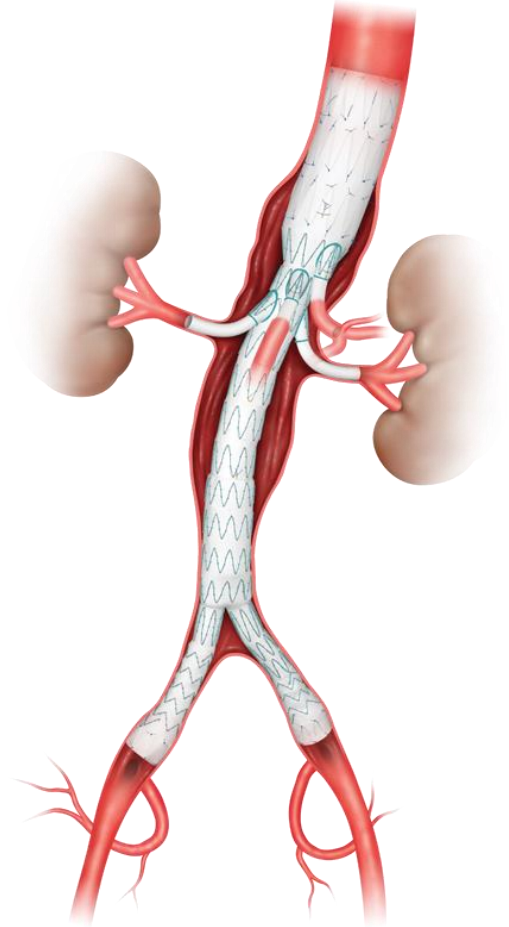
Tomasz Jakimowicz



Department of General, Vascular and Transplant Surgery
Medical University of Warsaw, Poland

Lesson from the past: off the shelf devices are always the best option?

Disclosure

Speaker name:

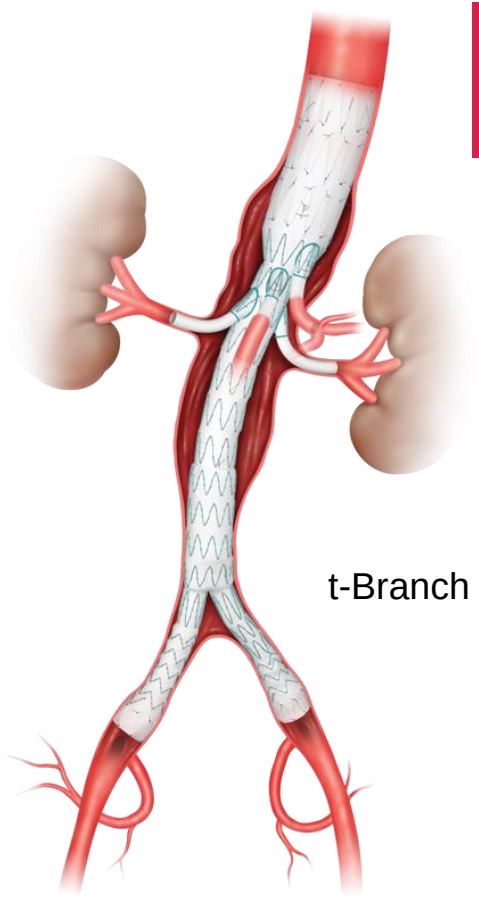
TOMASZ JAKIMOWICZ

I have the following potential conflicts of interest to report:

- ☑ **Consulting (COOK, JOTEC/Cryolife, Brail)**
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☑ **Other(s): Travel grants (COOK, JOTEC/Cryolife)**

☐ I do not have any potential conflict of interest

Off-the-shelf devices



t-Branch

E-nside

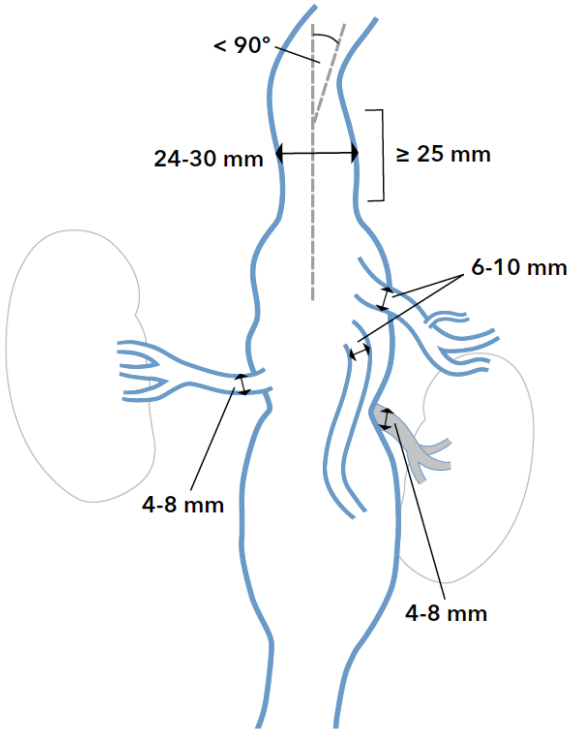
Are there any contraindications for t-branch?

Is CMD-bra better than t-branch?

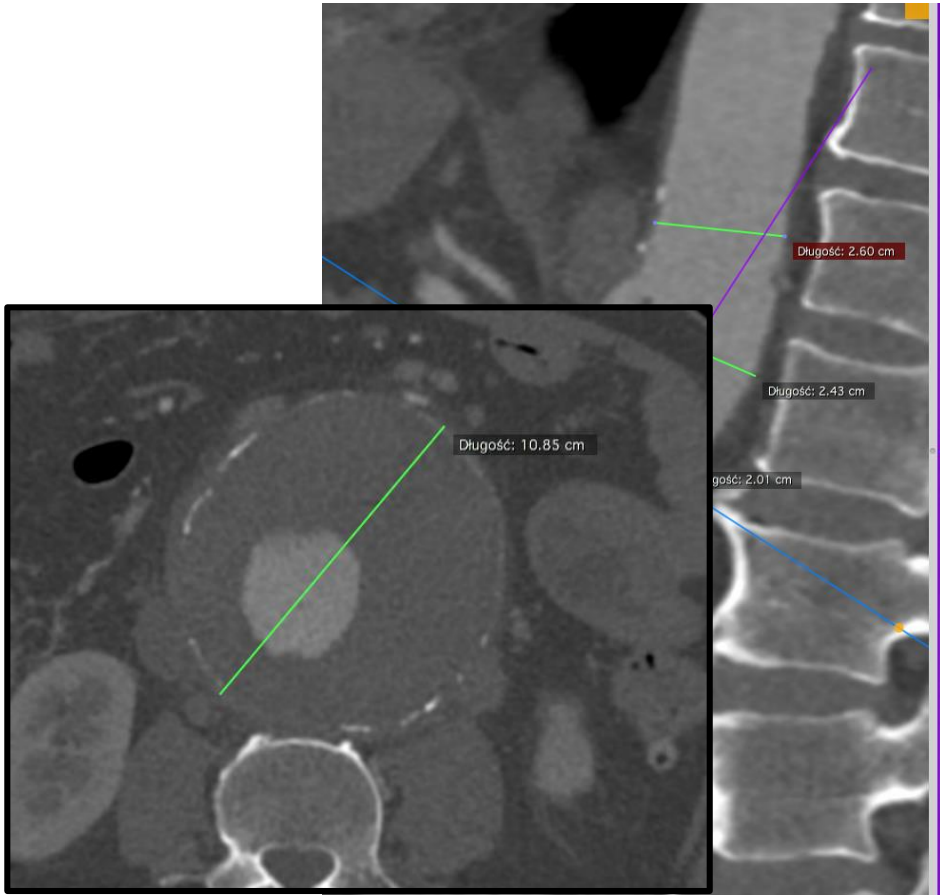

Physicia
pocket reference
Indications for use
Component ordering inform
Introduction system informa
Graft specifications
Accessory products
Zenith
ENDOVASCULAR GR
COOK
MEDICAL
zenithglobal.
≥ 25 mm
6-10 mm
4-8 mm

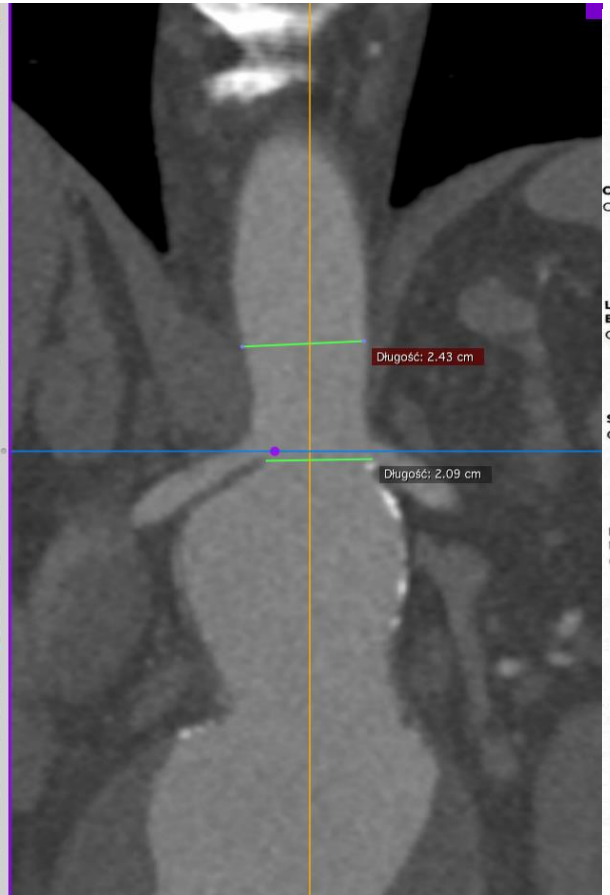
Requirements for t-Branch usage

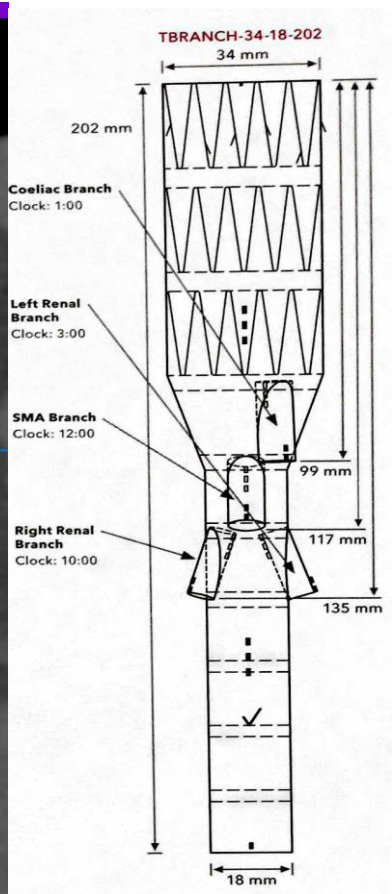
- ✓ Diameter at visceral arteries
- ✓ Angle of visceral arteries
- ✓ Number of target vessels
- ✓ Angle of thoracic aorta
- ✓ Lenght of infrarenal aorta
- ✓ Sufficient iliac vessels



Narrow aorta at renals

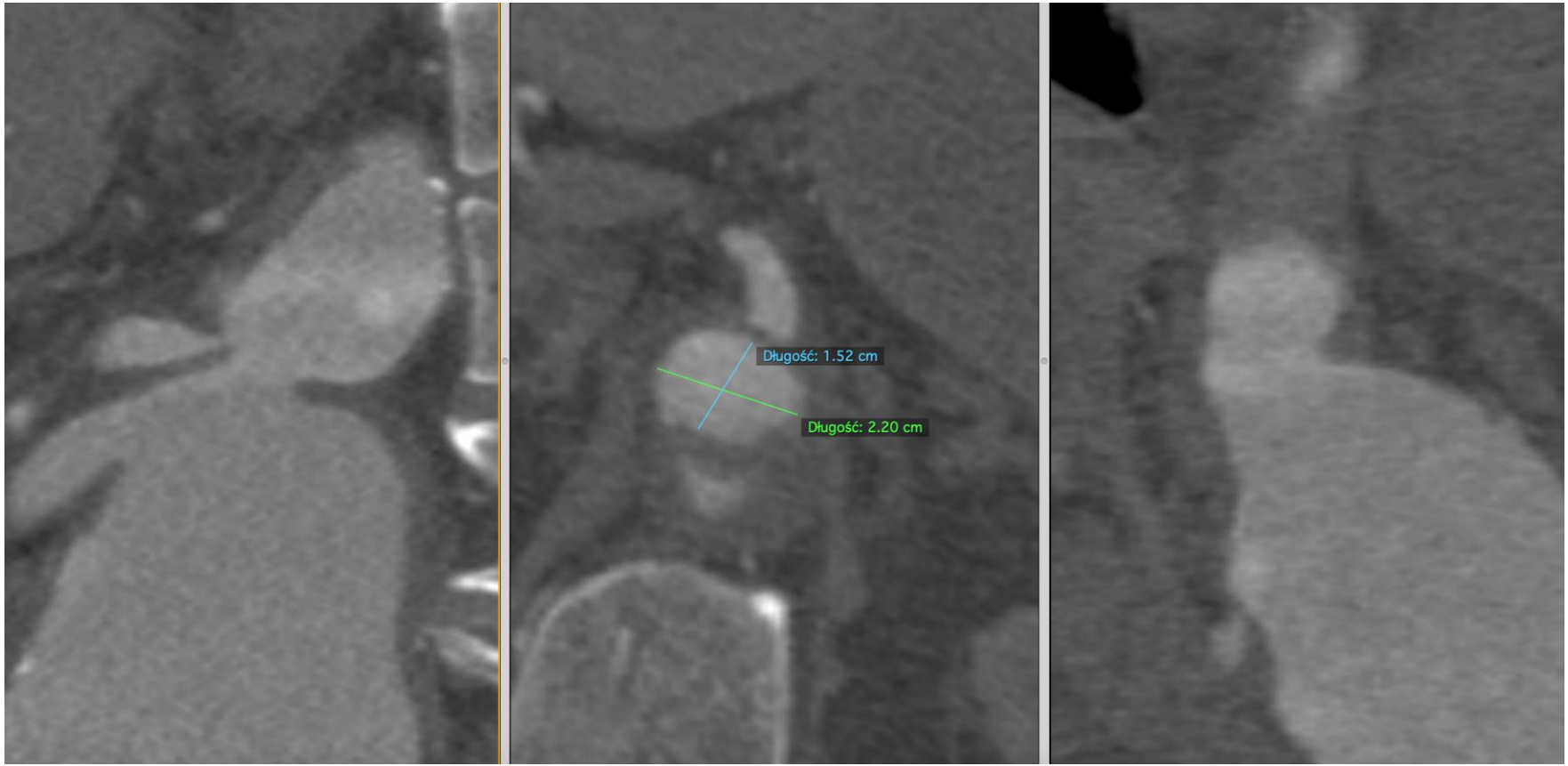




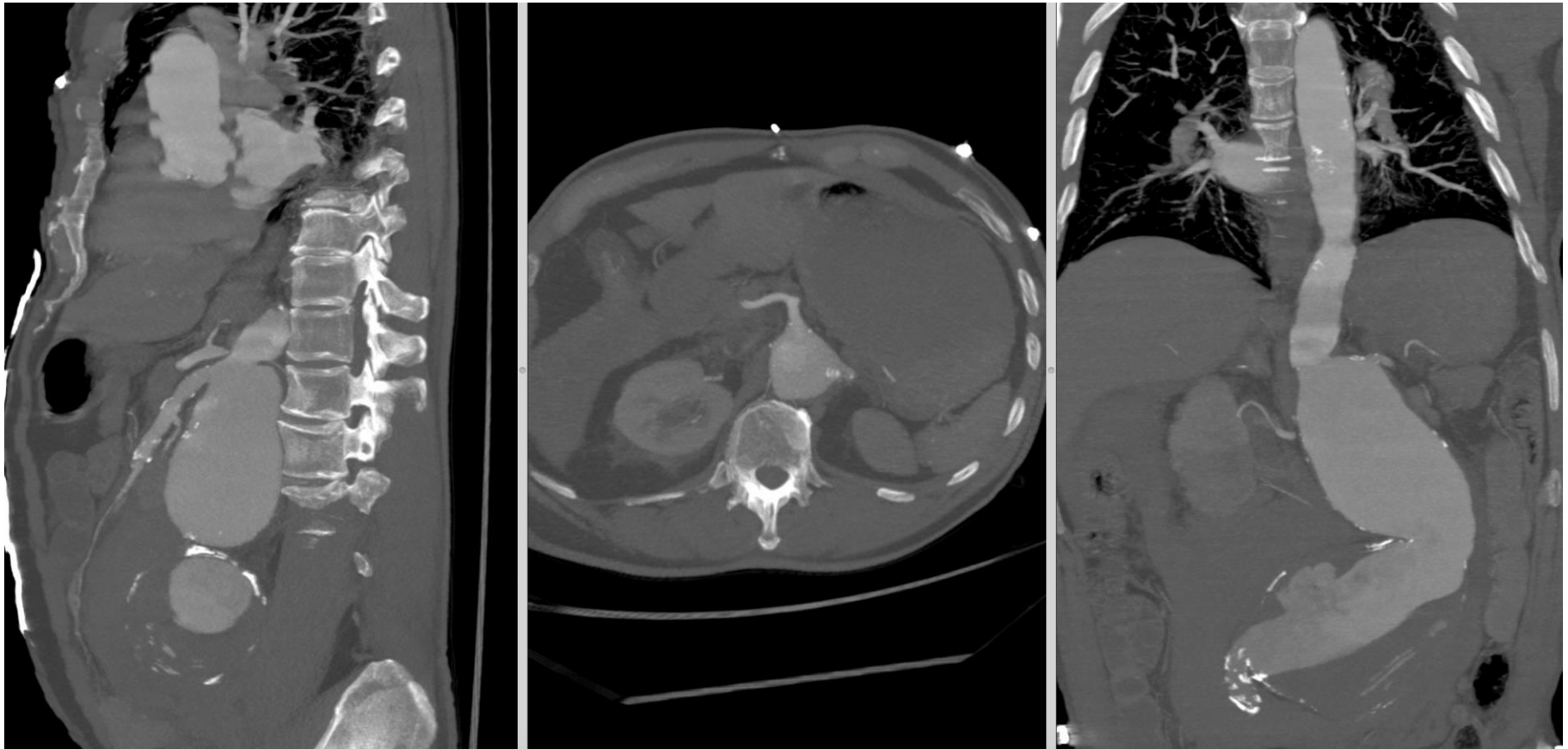


Final result

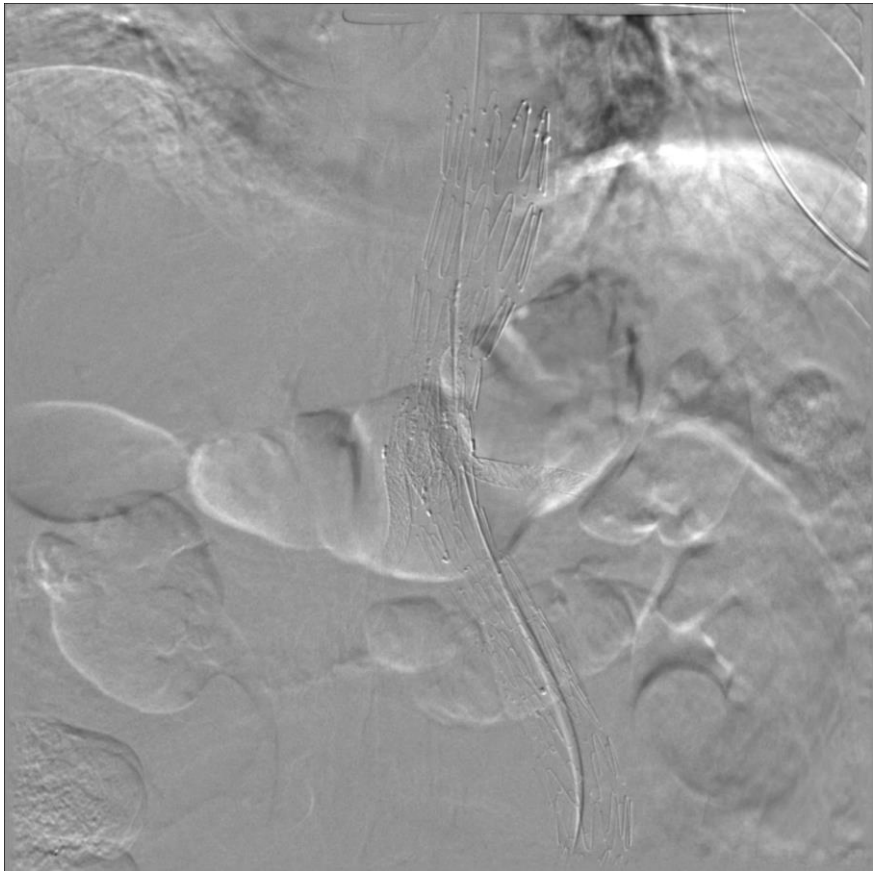
Narrow aorta at CT/SMA



Narrow aorta at CT/SMA

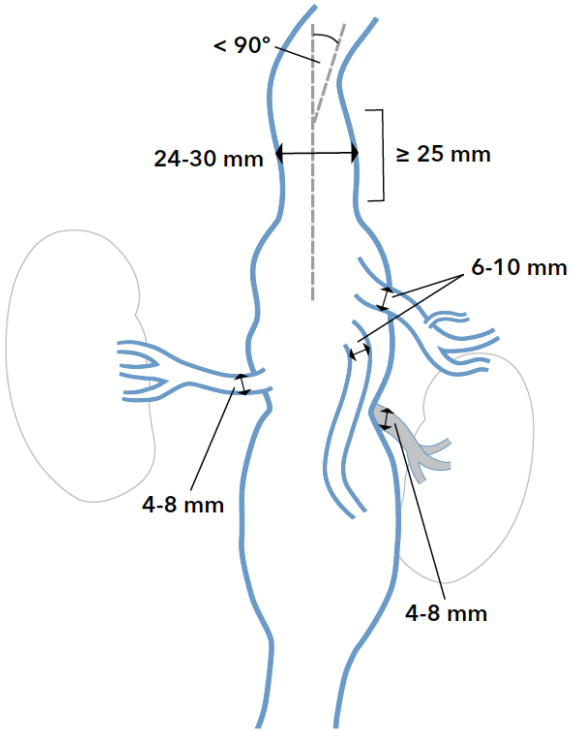


Final result

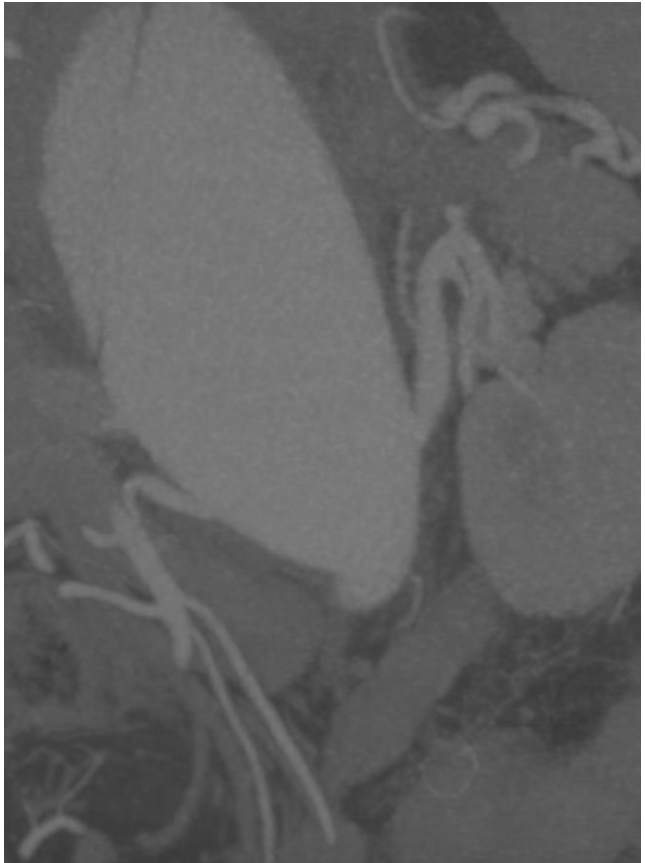


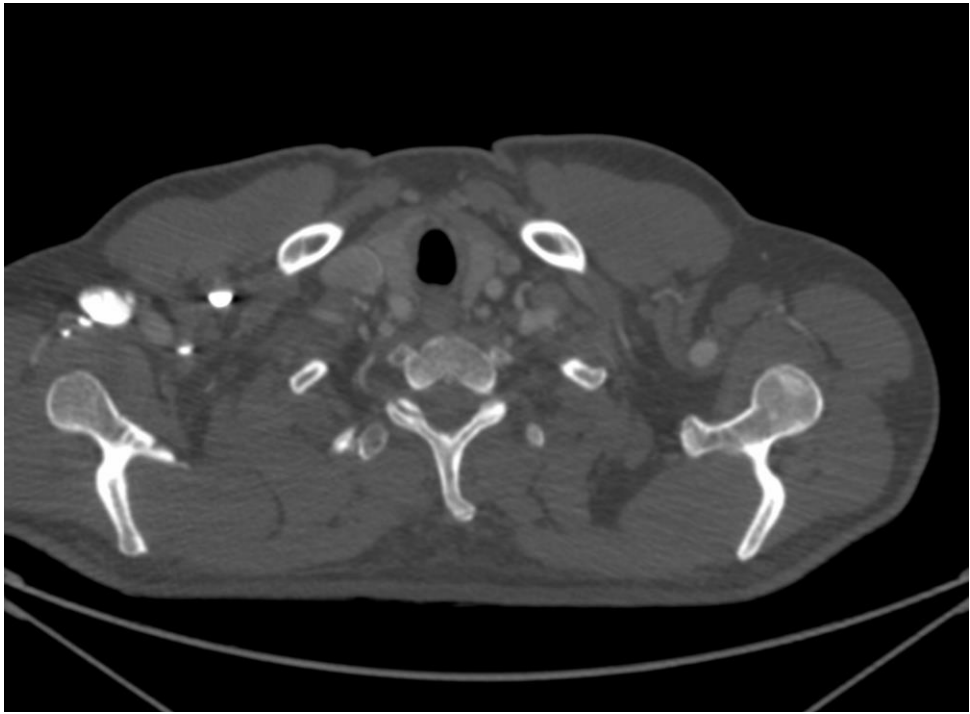
Requirements for t-Branch usage

- ✓ Diameter at visceral arteries
- ✓ Angle of visceral arteries
- ✓ Number of target vessels
- ✓ Angle of thoracic aorta
- ✓ Lenght of infrarenal aorta
- ✓ Sufficient iliac vessels

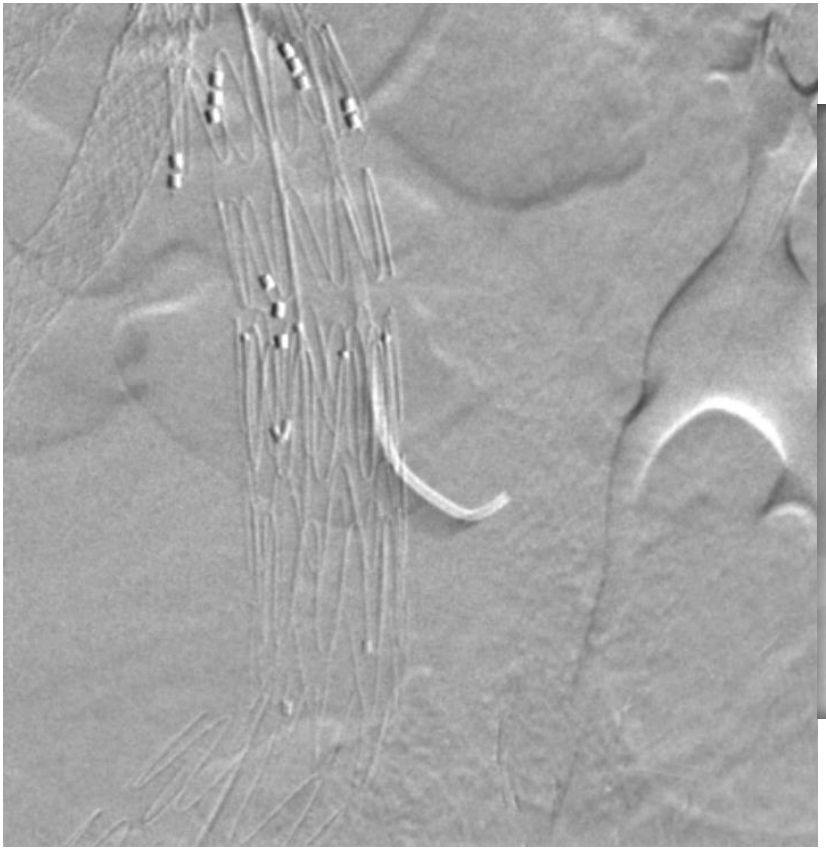


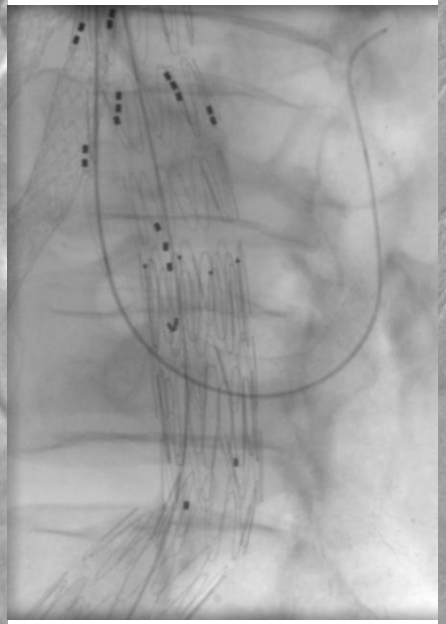
Steep angle of renal arteries

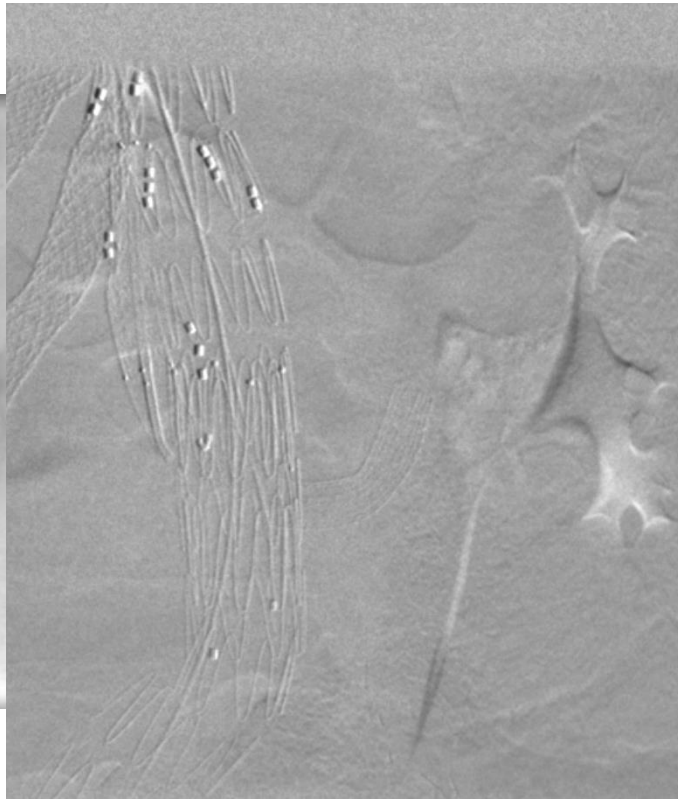




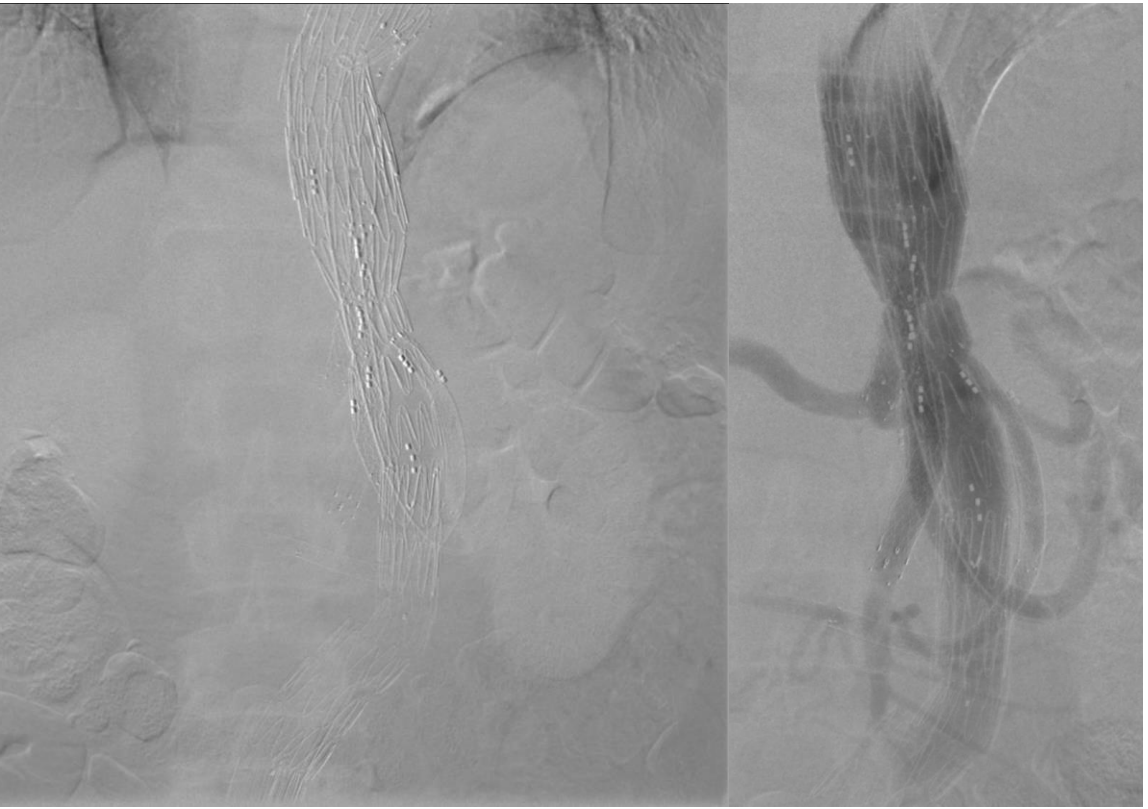
Steep angle of renal arteries

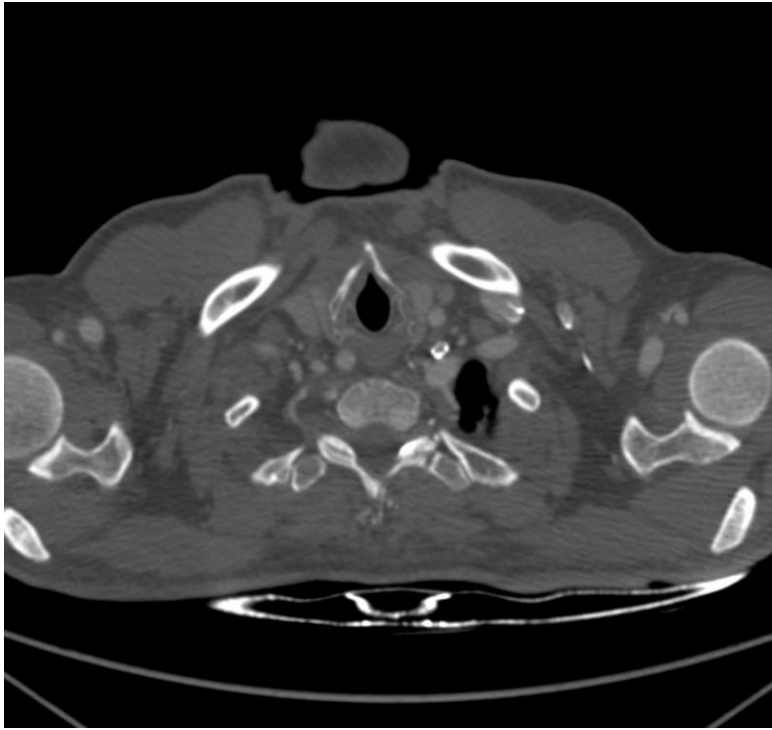




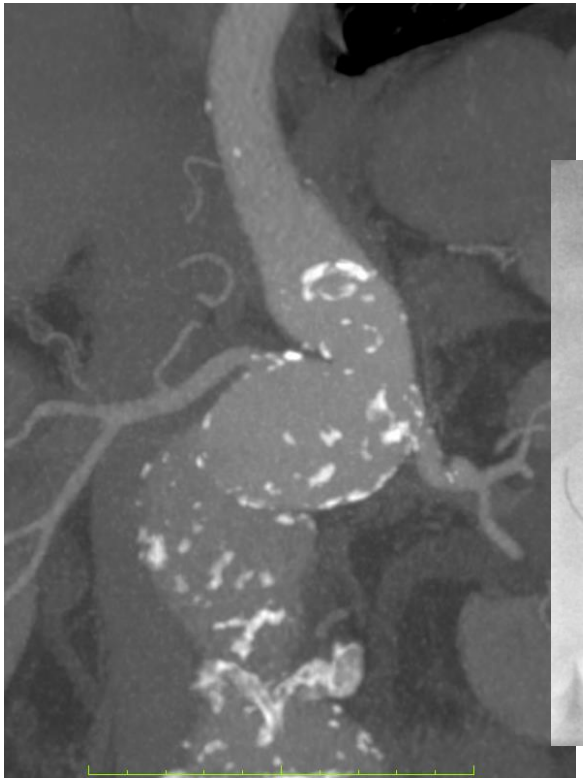


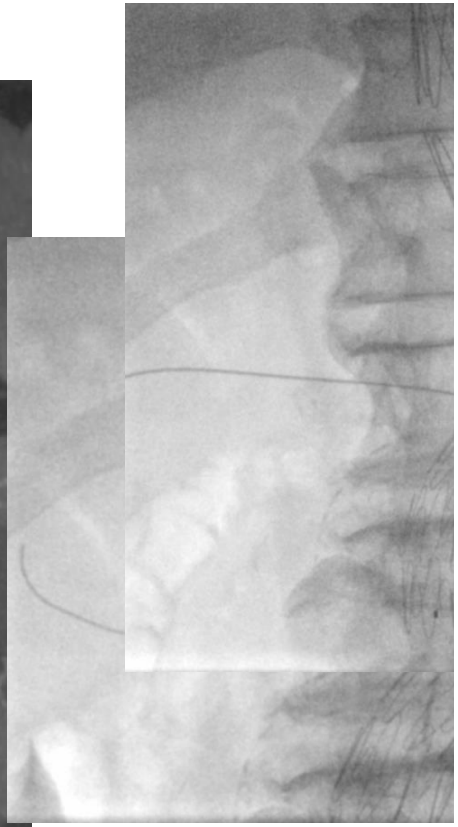
Steep angle of renal arteries

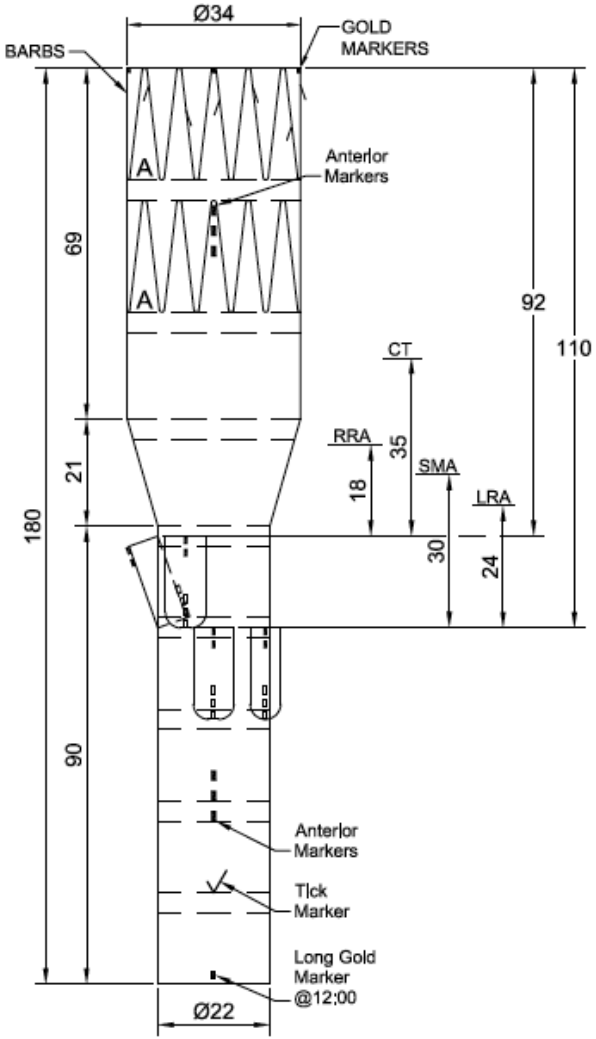


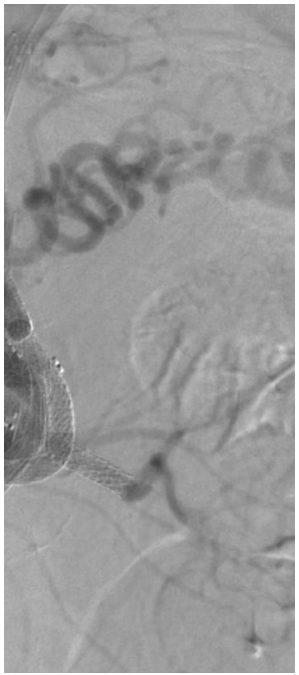


Unfavorable angle of renal arteries



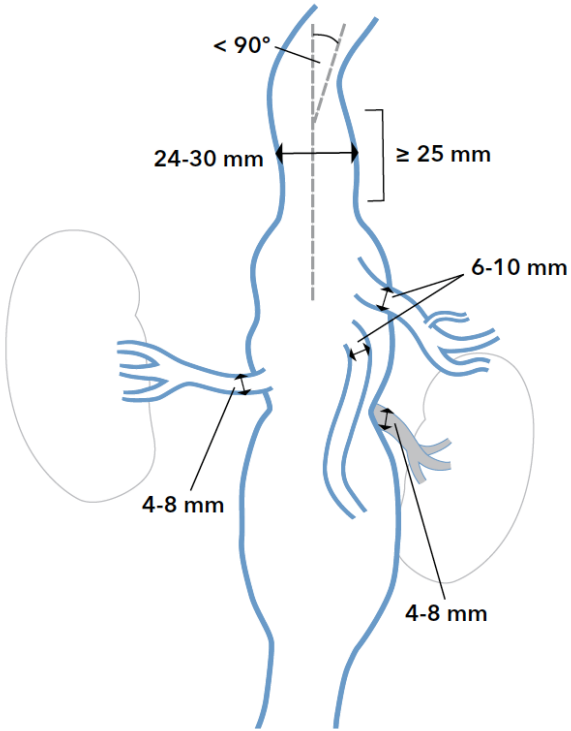






Requirements for t-Branch usage

- ✓ Diameter at visceral arteries
- ✓ Angle of visceral arteries
- ✓ Number of target vessels
- ✓ Angle of thoracic aorta
- ✓ Lenght of infrarenal aorta
- ✓ Sufficient iliac vessels

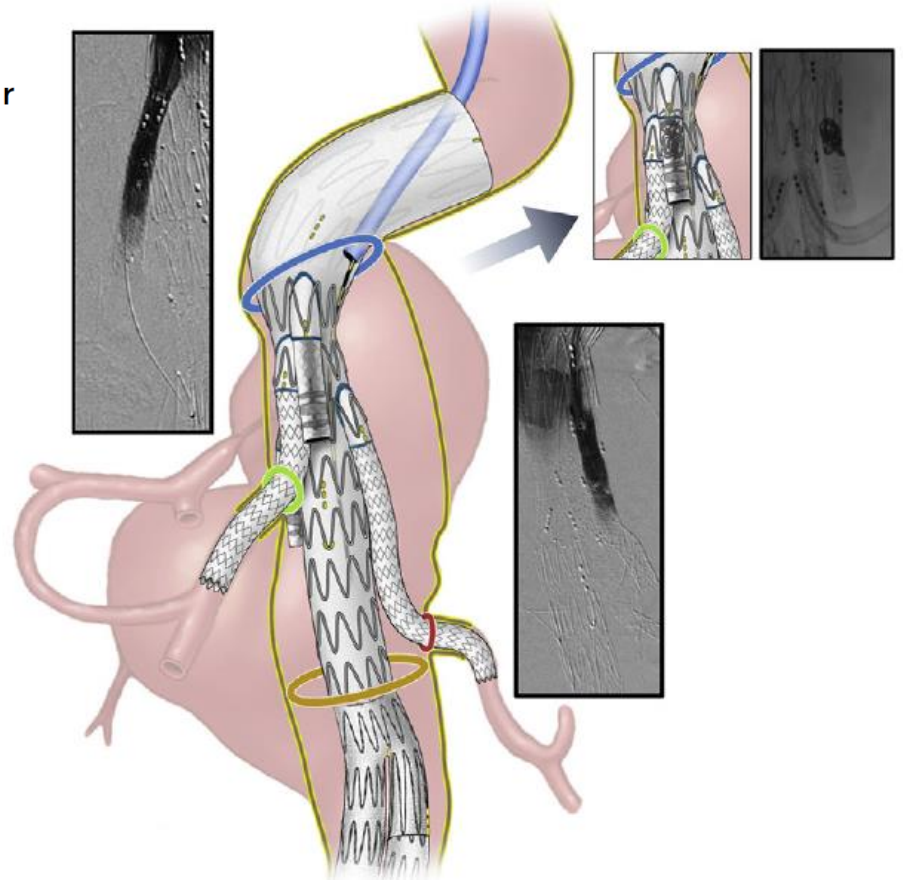


3 vessels – branch closure

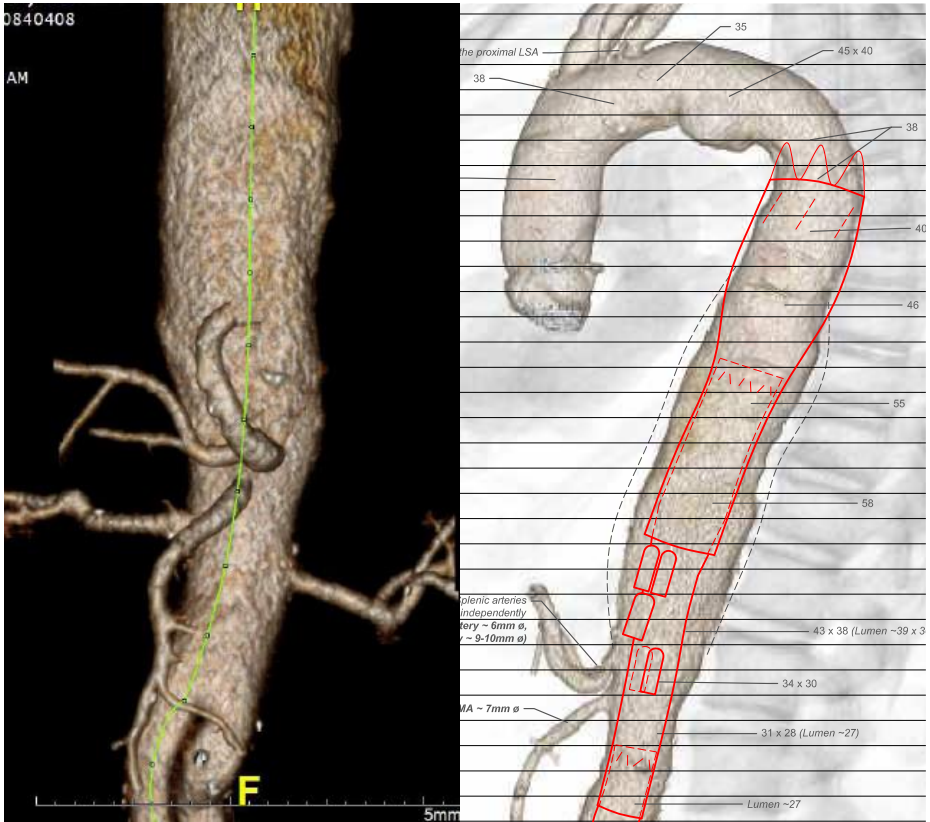
Outcomes of off-the-shelf multi-branched stent grafts with intentional occlusion of directional branches using endovascular plugs during endovascular repair of complex aortic aneurysms

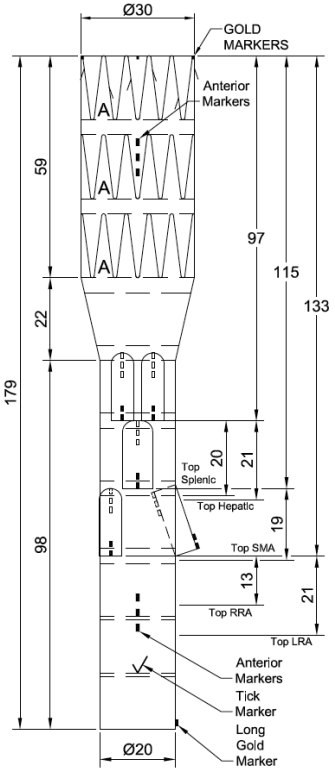
Emanuel R. Tenorio, MD, PhD,[a] Gustavo S. Oderich, MD,[a] Tilo Kölbel, MD, PhD,[b] Mauro Gargiulo, MD,[c] Carlos H. Timaran, MD,[d] Luca Bertoglio, MD,[e] Bijan Modarai, MD, PhD,[f] Katarzyna Jama, MD,[g] Ahmed Eleshra, MD,[b] Guilherme B. B. Lima, MD,[a] Carla Scott, MD,[d] Roberto Chiesa, MD,[e] *and and* Tomasz Jakimowicz, MD,[g] on behalf of the Trans-Atlantic Aortic Research Consortium, *Houston, Tex; Hamburg, Germany; Bologna, Italy; Dallas, Tex; Milano, Italy; London, United Kingdom; and Warszawa, Poland*

(J Vasc Surg 2021;■:1-9.)



5 vessels additional branch





Urgent procedure?

Coil embolization

Requirements for t-Branch usage

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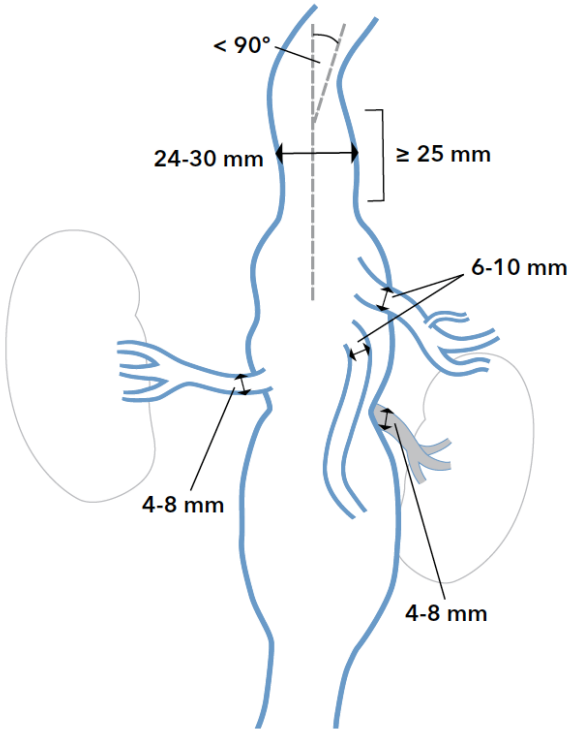
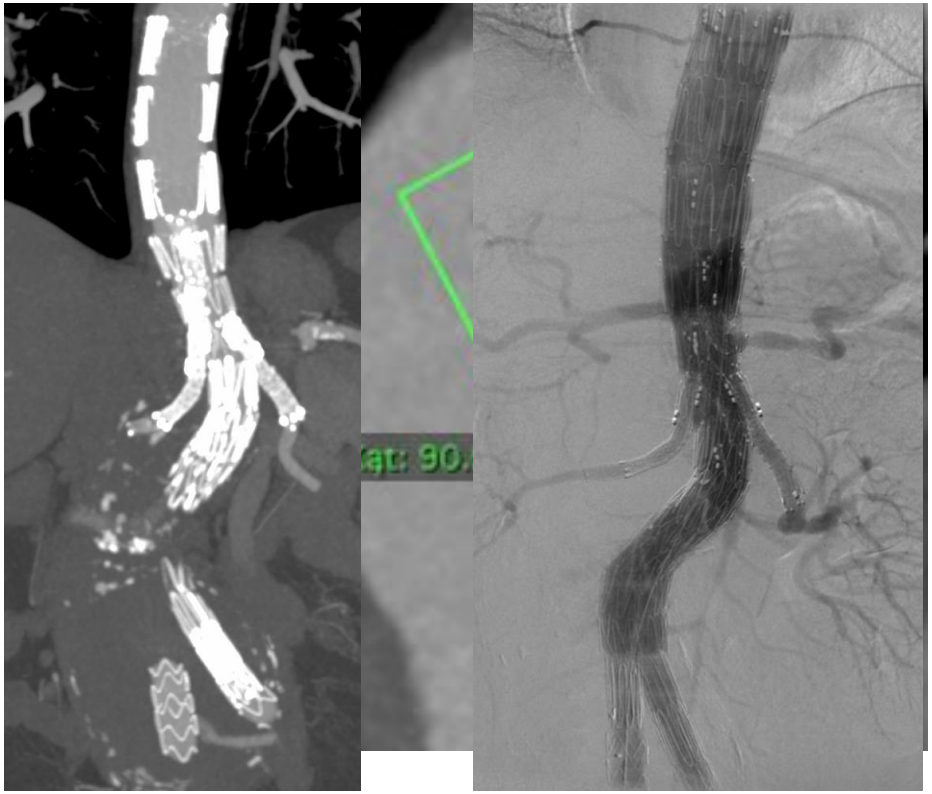


Straight aorta



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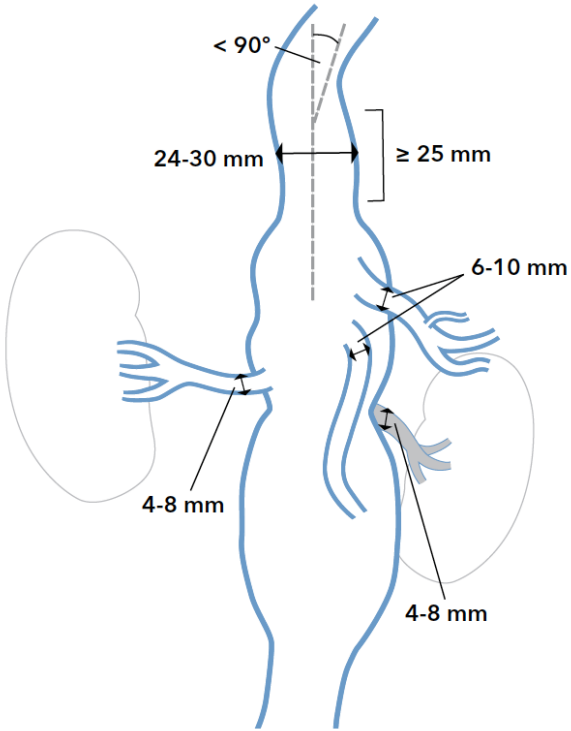
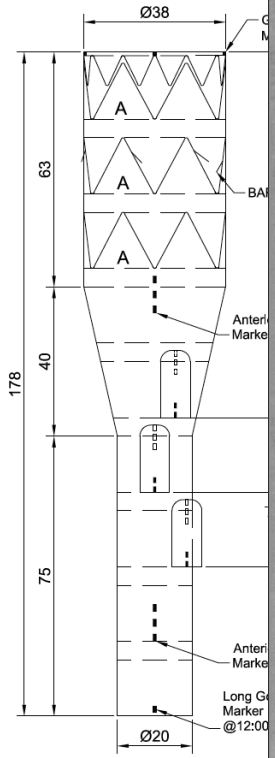
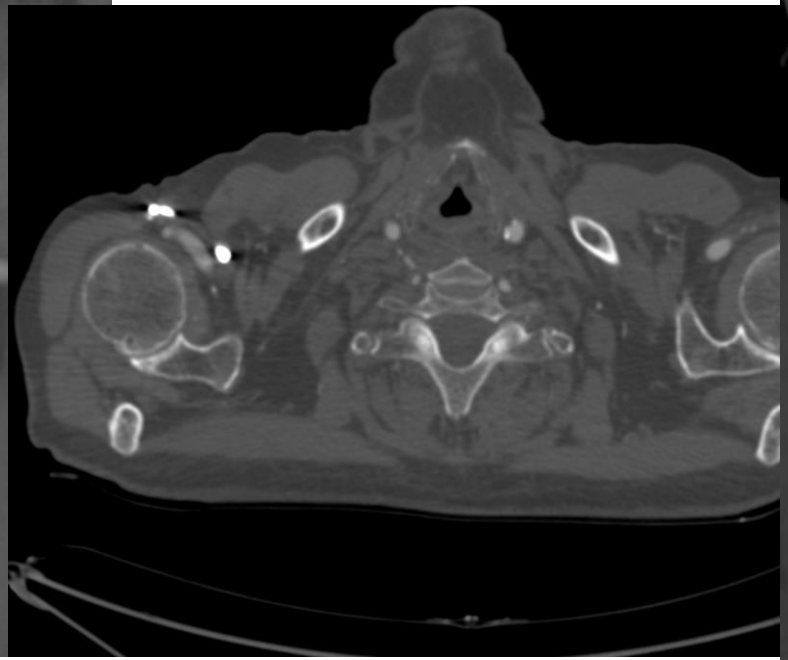
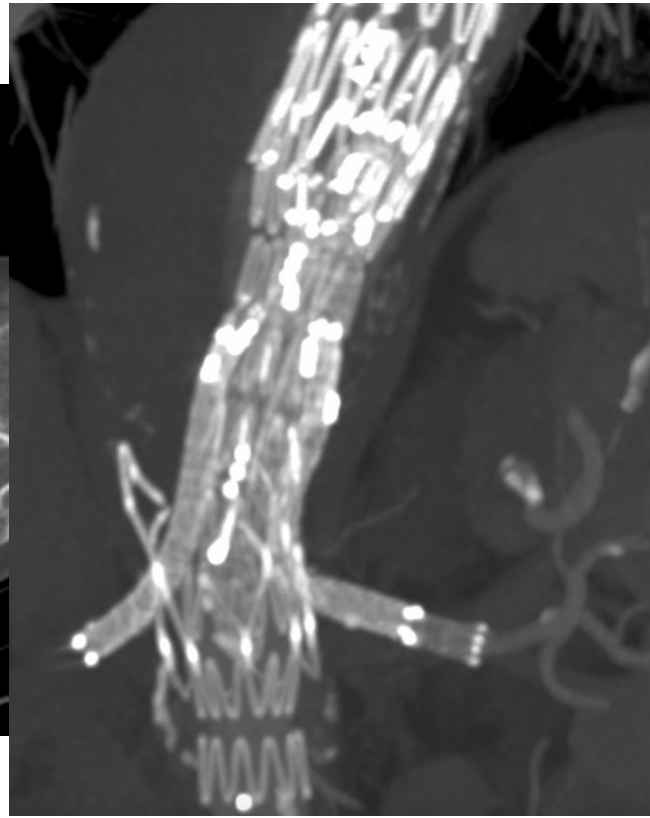


short distance to bifurcation
CMD with short bifurcation



short distance to bifurcation = long distance to target vessels





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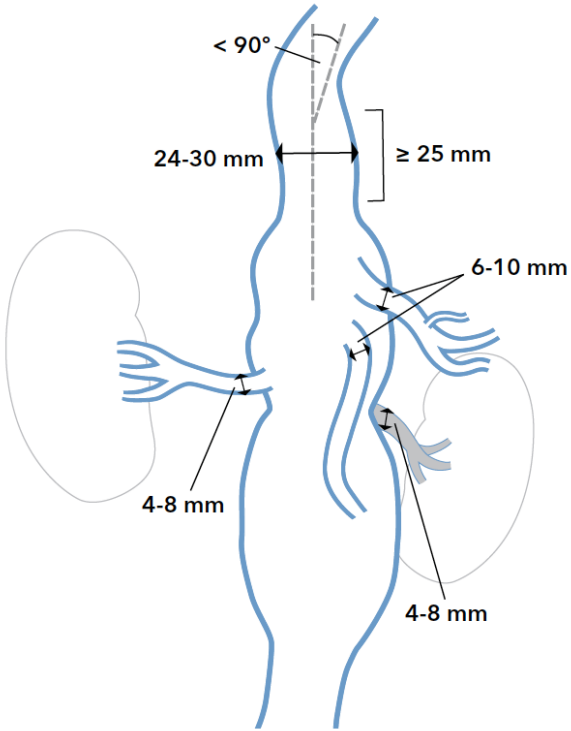


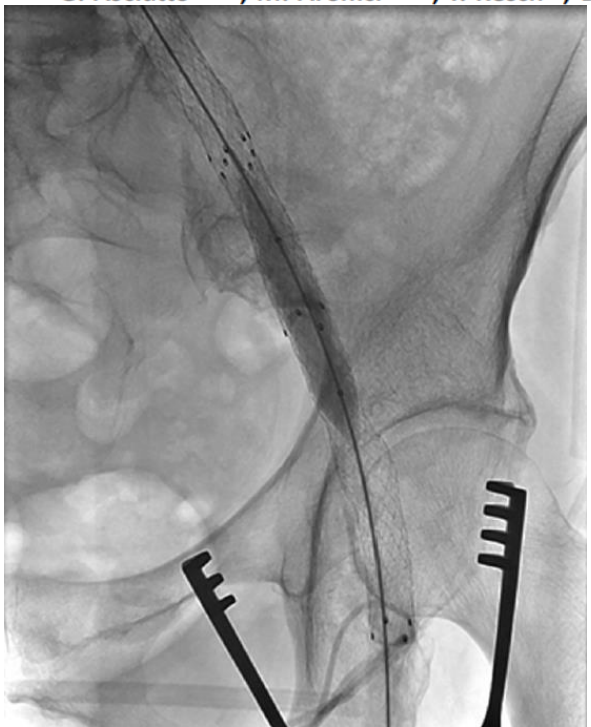
Narrow / calcified iliac vessels – iliac conduit

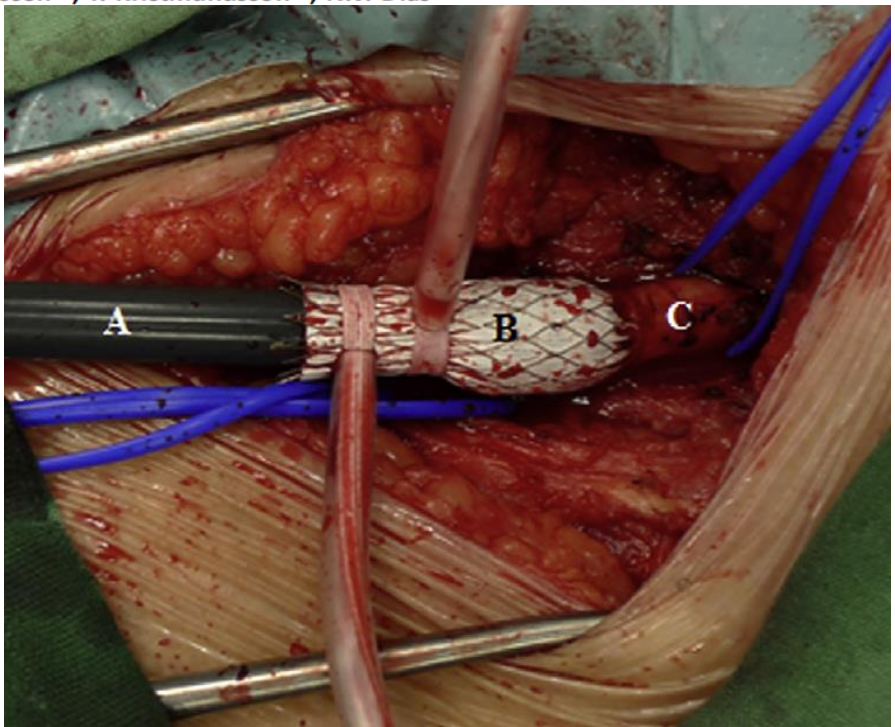
Narrow iliac vessels – endoconduit

Endoconduits with "Pave and Crack" Technique Avoid Open Ilio-femoral Conduits with Sustainable Mid-term Results

Eur J Vasc Endovasc Surg (2017) 54, 472–479

G. Asciutto [a,*,c], M. Aronici [a,b,c], T. Resch [a], B. Sonesson [a], T. Kristmundsson [a], N.V. Dias [a]



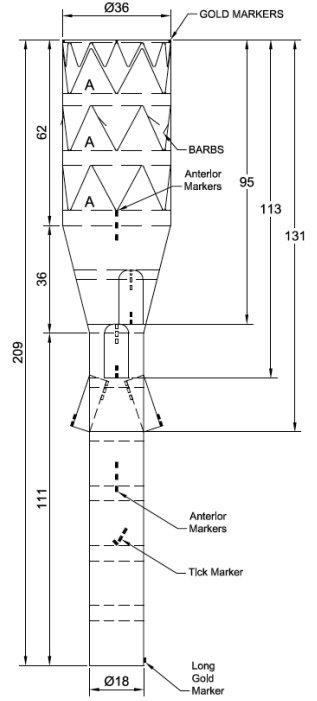


Narrow iliac vessels – low profile (nitinol) ”t-branch”

REA34244_v2 | **NON STANDARD DEVICE REQUEST - PROPRIETARY COOK MEDICAL** | **VERSION 1**

Device: BRANCH-DESCENDING-THORACOABDOMINAL-DEVICE
Component: THORACO-ABDOMINAL-SIDE-BRANCH

PAGE 2 of 3



INTERNAL/EXTERNAL SIDEBRANCH #1
DIAMETER: 8mm
LENGTH: 18mm
DIST FROM PROX EDGE: 95mm
CLOCK: 1:00

INTERNAL/EXTERNAL SIDEBRANCH #2
DIAMETER: 8mm
LENGTH: 18mm
DIST FROM PROX EDGE: 113mm
CLOCK: 12:00

INTERNAL/EXTERNAL SIDEBRANCH #3
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 131mm
CLOCK: 9:30

INTERNAL/EXTERNAL SIDEBRANCH #4
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 131mm
CLOCK: 2:30

- SINGLE DIAMETER REDUCING TIES
- UAT TIP
- NITINOL CANNULA
- LOW PROFILE FABRIC
- NITINOL STENTS

Plus:

ZTA-PT-38-34-217

Please note the following: 1. By signing this graft plan you are confirming that the patient has consented to the provision of their personal information to Cook Medical. The patient understands that in order to plan and manufacture the requested device, Cook Medical may share his/her personal information with other Cook Group companies in the United States, Australia, Denmark, United Kingdom and Ireland and has consented to his/her personal information being so shared. 2. You are confirming that all clinically important features (eg. fenestration size / orientation, gold marker placement, sealing stents) are included in this graft design prior to your approval. 3. Unsigned plans or alterations may lead to a delay in the supply of this device. Please sign and date each page. If you wish to alter any part of this plan please initial and date each change.

Sheath Size:	18FR FLEXOR	Patient ID:	GUTOWSKI E No.:
O.D.:	7.1mm	Doctor:	Prof. Jakimowicz
Sheath Length:	75cm	Hospital:	Clinical Hospital, Warsaw, Poland
UK-CW	Drawn - SC	Date: 23-Nov-16	
Not to scale	All Dimensions shown are in mm	Drs Signature:	Date:

Sheath Size: 18FR FLEXOR

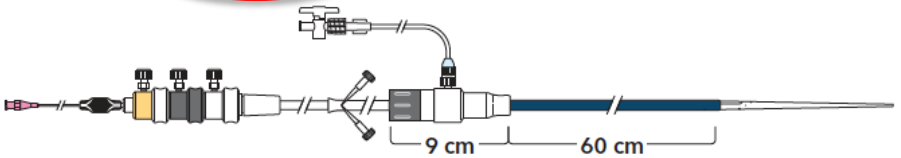
O.D.: 7.1mm

Sheath Length: 75cm

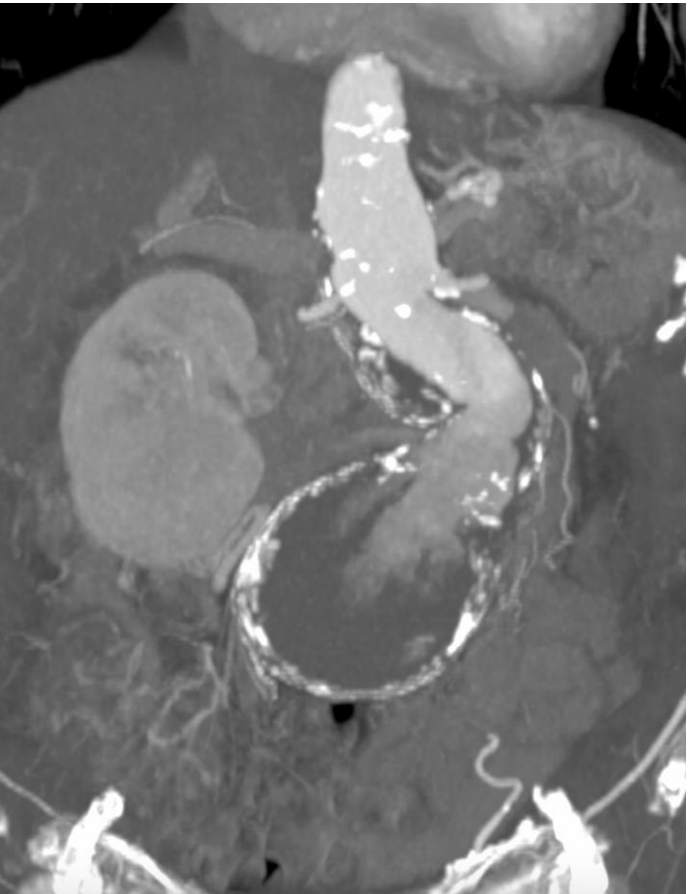
UK-CW	Drawn - SC	Date: 23-Nov-16
Not to scale	All Dimensions shown are in mm	

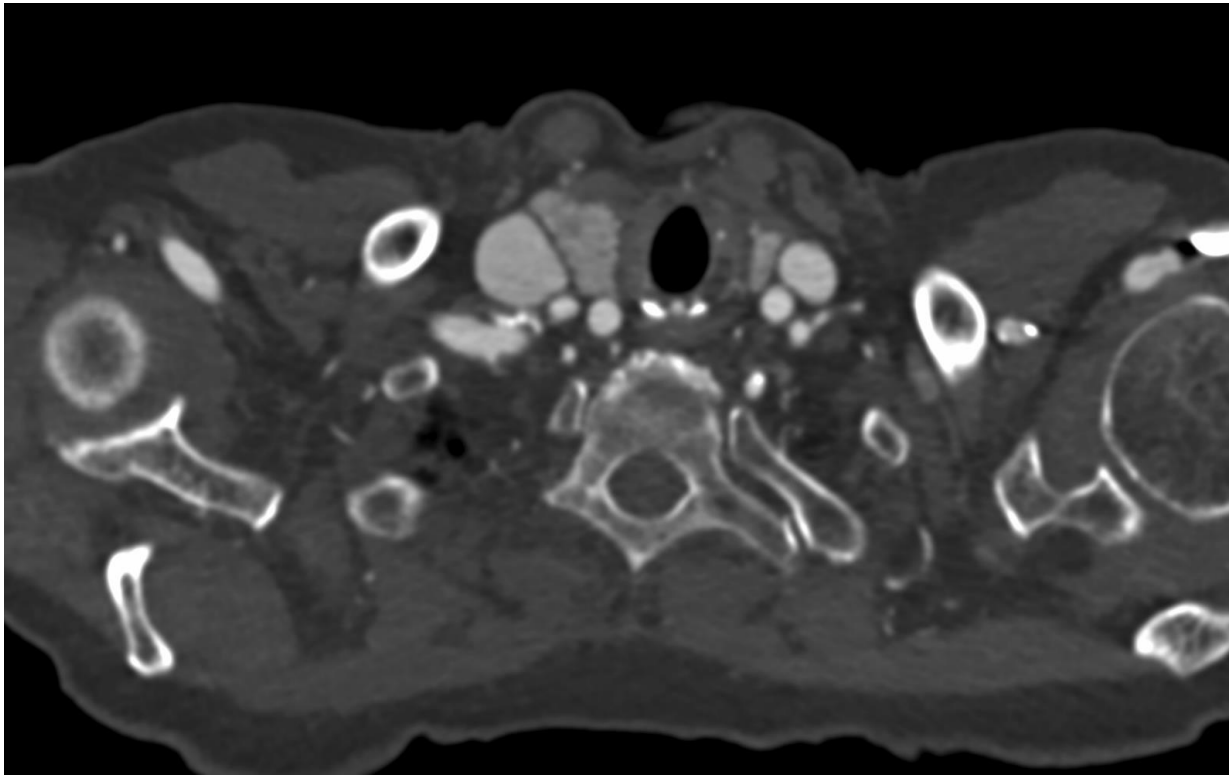
H&L-B One-Shot™ Introduction System for t-Branch graft

22 Fr (7.3 mm) ID/8.5 mm OD

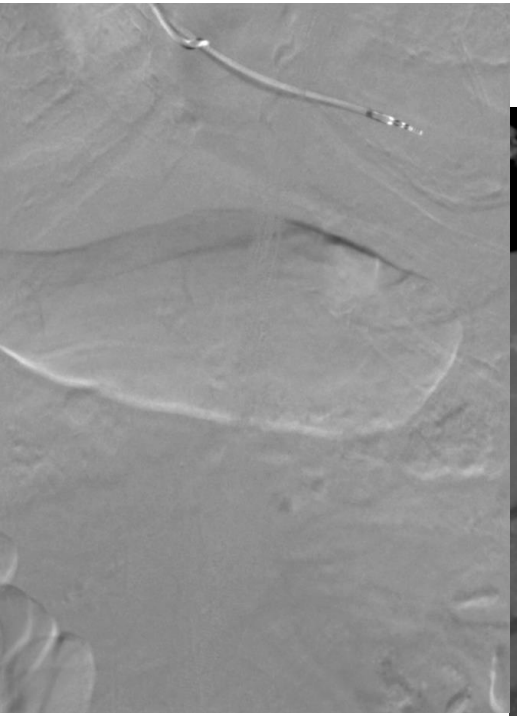


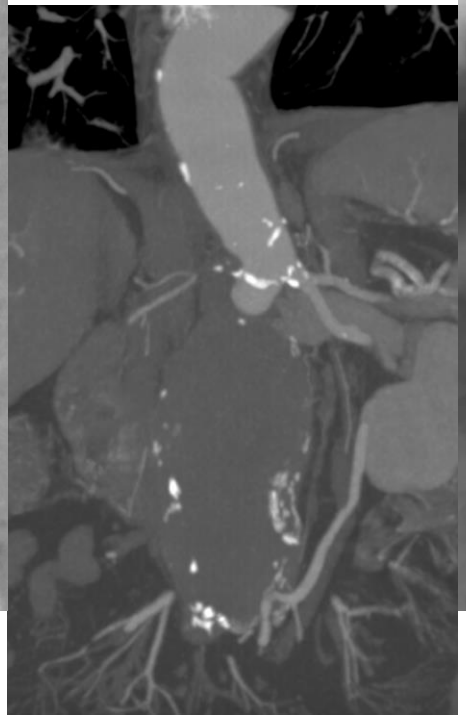
Occluded aorta – (absolute?) contraindication





Occluded aorta

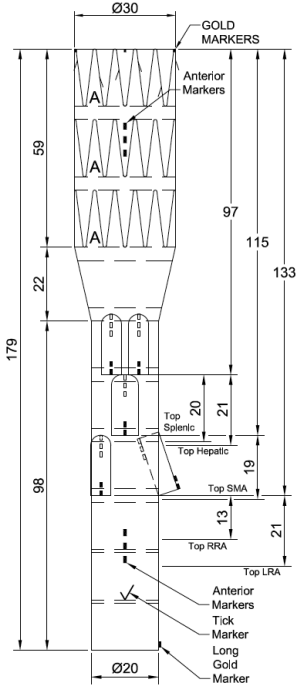


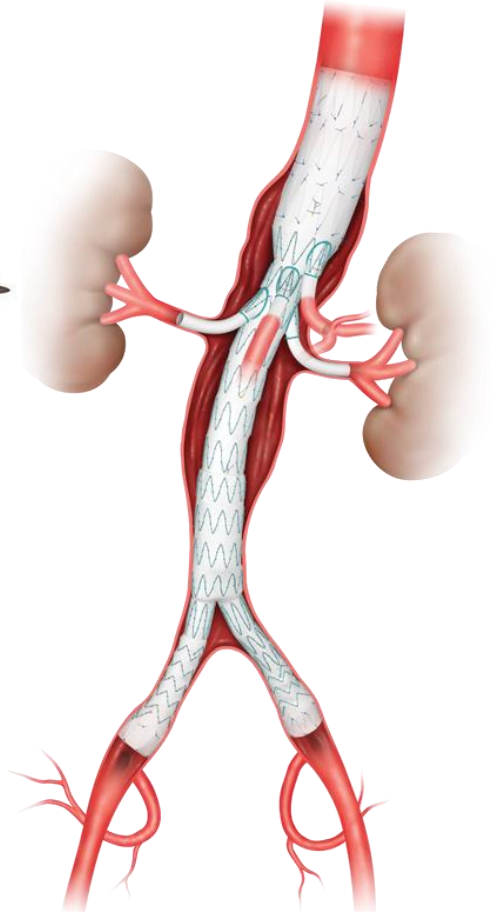


~~Are there any contraindications for t-branch?~~

Is CMD-bra better than t-branch???

CMD vs t-Branch

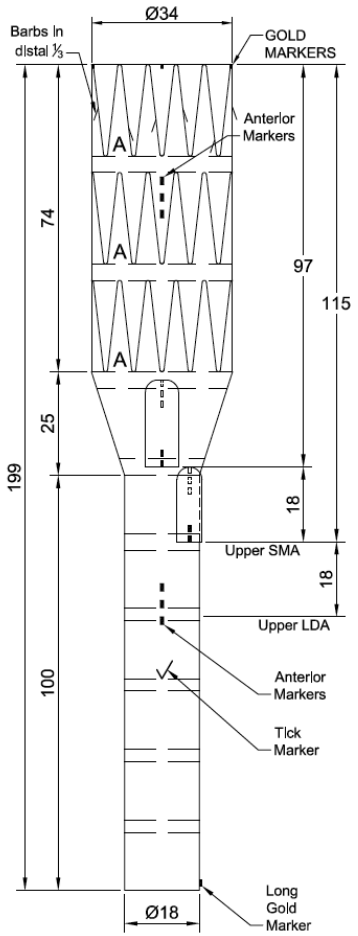




Increased risk of aneurysm rupture while waiting

Produce the perfect CMD for patient anatomy?

- ✓ **Possibility of non-perfect positioning**
- ✓ Unknown behaviour in different situation
- ✓ Difficult manufacturing
- ✓ The only one piece of specific design that exists…



INTERNAL/EXTERNAL SIDEBRANCH #1
DIAMETER: 8mm
LENGTH: 21mm
DIST FROM PROX EDGE: 97mm
CLOCK: 12:00

INTERNAL/EXTERNAL SIDEBRANCH #2
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 115mm
CLOCK: 2:15

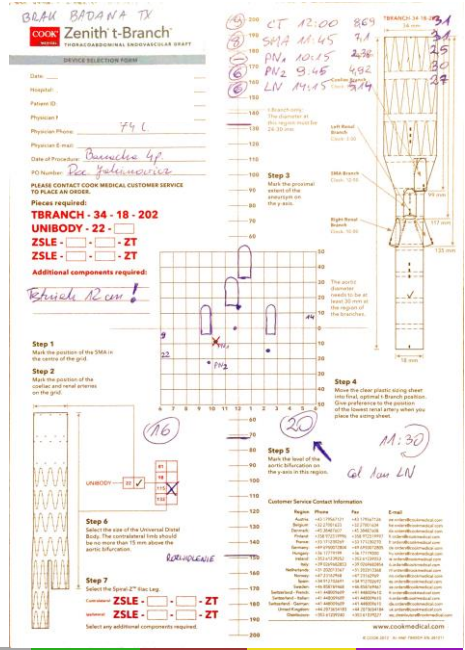
- SINGLE DIAMETER REDUCING TIES
- UAT TIP
- NITINOL CANNULA

Plus:

ZTA-PT-36-32-161

Fit the existig off-the-shelf to the patient

- ✓ Unfavourable angle could be compromised by longer distance from the branch to target vessel
- ✓ Easier to manufacture (should be cheaper...)
- ✓ Well known stent-graft behaviour and design (markers!)
- ✓ Easier for surgeon – less room for the mistakes…
- ✓ Clear planning-chart
- ✓ **Standard implantation!**



Is endovascular treatment better than open repair for TAAA?

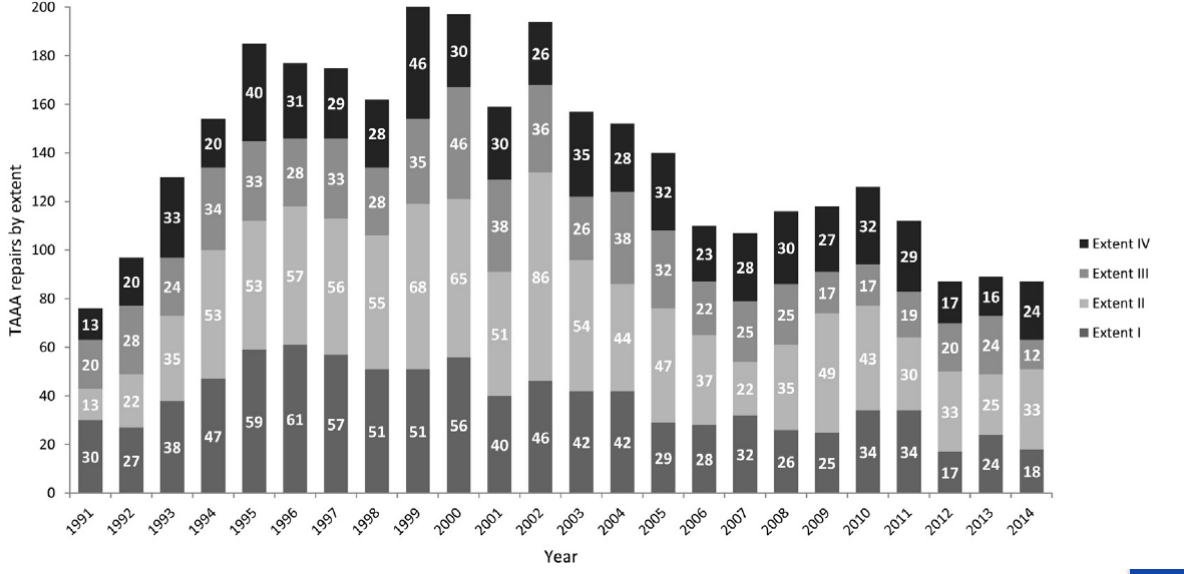
What to do with „healthy” 60-years old TAAA patient???

Open vs endovascular TAAA repair

Outcomes of 3309 thoracoabdominal aortic aneurysm repairs

Joseph S. Coselli, MD,[a,d,e] Scott A. LeMaire, MD,[a,b,c,d,e] Ourania Preventza, MD,[a,d,e]
Kim I. de la Cruz, MD,[a,d,e] Denton A. Cooley, MD,[d] Matt D. Price, MS,[a,d] Alan P. Stolz, MEd,[a,d]
Susan Y. Green, MPH,[a,d] Courtney N. Arredondo, MSPH,[b] and Todd K. Rosengart, MD[a,c,d,e]

J Thorac Cardiovasc Surg 2016;151:1323-38



Open vs endovascular TAAA repair

Outcomes of 3309 thoracoabdominal aortic aneurysm repairs

Joseph S. Coselli, MD,[a,d,e] Scott A. LeMaire, MD,[a,b,c,d,e] Ourania Preventza, MD,[a,d,e]
Kim I. de la Cruz, MD,[a,d,e] Denton A. Cooley, MD,[d] Matt D. Price, MS,[a,d] Alan P. Stolz, MEd,[a,d]
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J Thorac Cardiovasc Surg 2016;151:1323-38

TABLE 4. Results of consecutive elective cases (n = 2586)

Variable	All n = 2586	Extent I n = 700	Extent II n = 866	Extent III n = 504	Extent IV n = 516	*P* value
Adverse event	329 (12.7)	63 (9.0)	154 (17.8)	73 (14.5)	39 (7.6)	<.001
Operative mortality	161 (6.2)	32 (4.6)	72 (8.3)	41 (8.1)	16 (3.1)	<.001
Permanent paraplegia*	66 (2.6)	8 (1.1)	37 (4.3)	18 (3.6)	3 (0.6)	<.001
Permanent paraparesis*	57 (2.2)	14 (2.0)	25 (2.9)	10 (2.0)	8 (1.6)	.4
Permanent renal failure necessitating dialysis*	132 (5.1)	17 (2.4)	64 (7.4)	28 (5.6)	23 (4.5)	<.001
Permanent stroke*	60 (2.3)	17 (2.4)	31 (3.6)	5 (1.0)	7 (1.4)	.007
Survival with life-altering complication†	168 (6.5)	31 (4.4)	82 (9.5)	32 (6.3)	23 (4.5)	<.001

Values are n (%). Outcomes of interest (paraplegia, paraparesis, renal failure necessitating dialysis, and stroke) are permanent complications present at discharge or present in those patients with early death. *Excludes 5 patients who died during the operation. †Discharge with permanent paraplegia, paraparesis, renal failure, or stroke in 2425 early survivors of elective repair.

Open vs endovascular TAAA repair

Thirty-day mortality statistics underestimate the risk of repair of thoracoabdominal aortic aneurysms: A statewide experience

J Vasc Surg 2006;43:217-23

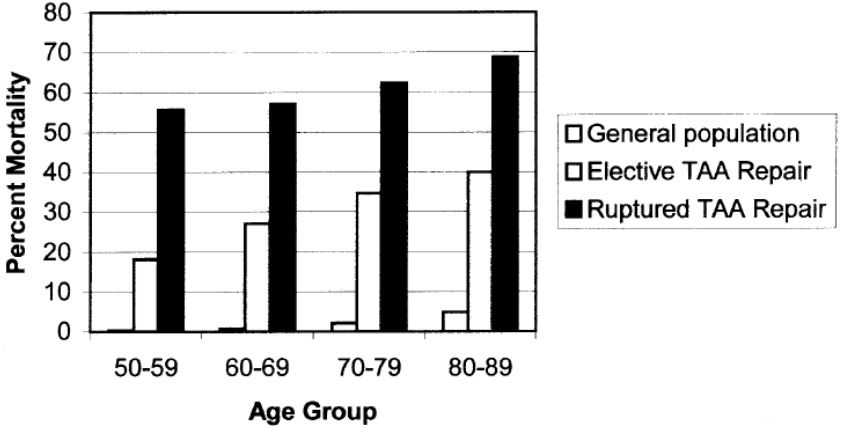


Fig. This graph illustrates 1-year mortality for treatment of elective and ruptured thoracoabdominal aortic aneurysms *(TAA)*. The results are stratified into groups by increasing decade of life. Comparison is also provided with age-matched white males. These data are from the National Vital Statistics report.

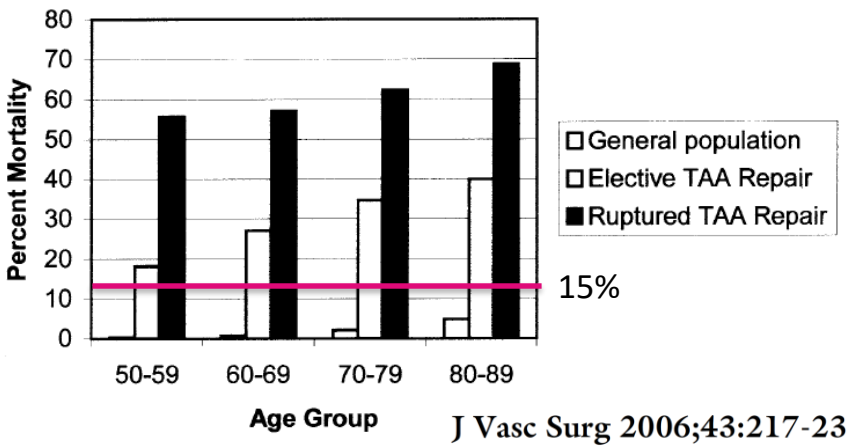
Mortality rates stratified by age (%) for
odominal aneurysm repair

	Overall	*50-59 years*	*60-69 years*	*70-79 years*	*80-89 years*
(n)	797	77	273	392	55
%)	19.2	10.4	17.2	21.2	27.3
(%)	11.7	7.8	9.9	13.5	12.7
(%)	30.9	18.2	27.1	34.7	40.0
(n)	213	9	63	109	32
%)	48.4	33.3	47.6	50.5	46.9
(%)	13.1	22.3	9.5	11.9	21.9
(%)	61.5	55.6	57.1	62.4	68.8

Open vs endovascular TAAA repair

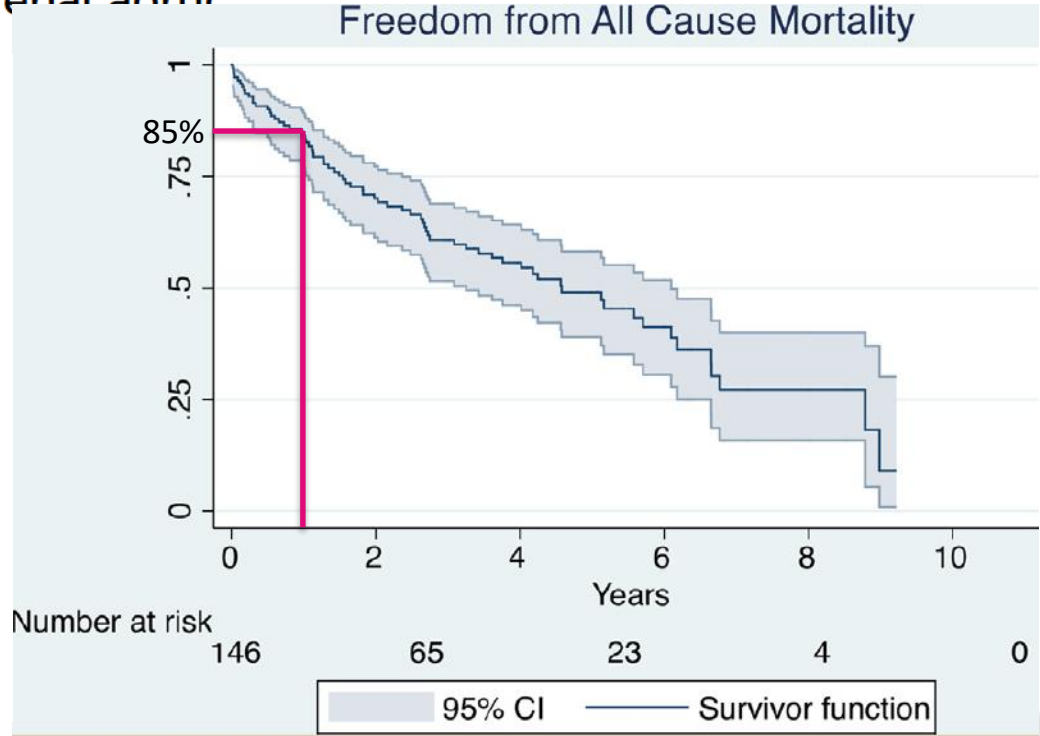
Long-term durability of multibranched endovascular repair of thoracoabdominal and pararenal aortic

J Vasc Surg 2019;69:341-7



J Vasc Surg 2006;43:217-23

Fig. This graph illustrates 1-year mortality for treatment of elective and ruptured thoracoabdominal aortic aneurysms *(TAA)*. The results are stratified into groups by increasing decade of life. Comparison is also provided with age-matched white males. These data are from the National Vital Statistics report.



Department of General, Vascular and Transplant Surgery

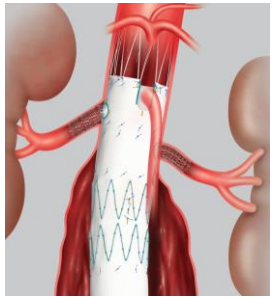
Medical University of Warsaw, Poland

Own experience

Department of General,
Vascular and Transplant Surgery
Medical University of Warsaw, Poland

904 complex aortic surgey

from 11.06.2010 to 26.11.2021



862 Cook

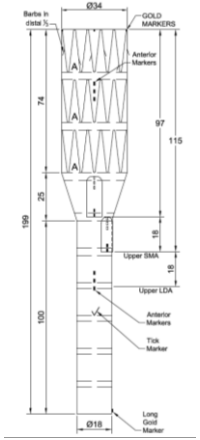
38 Jotec

3 Brail

1 Bolton

112 jAAA

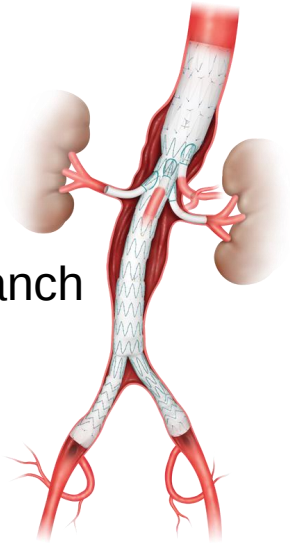
112 fenestr



764 TAAA

74 CMD

690 t-Branch

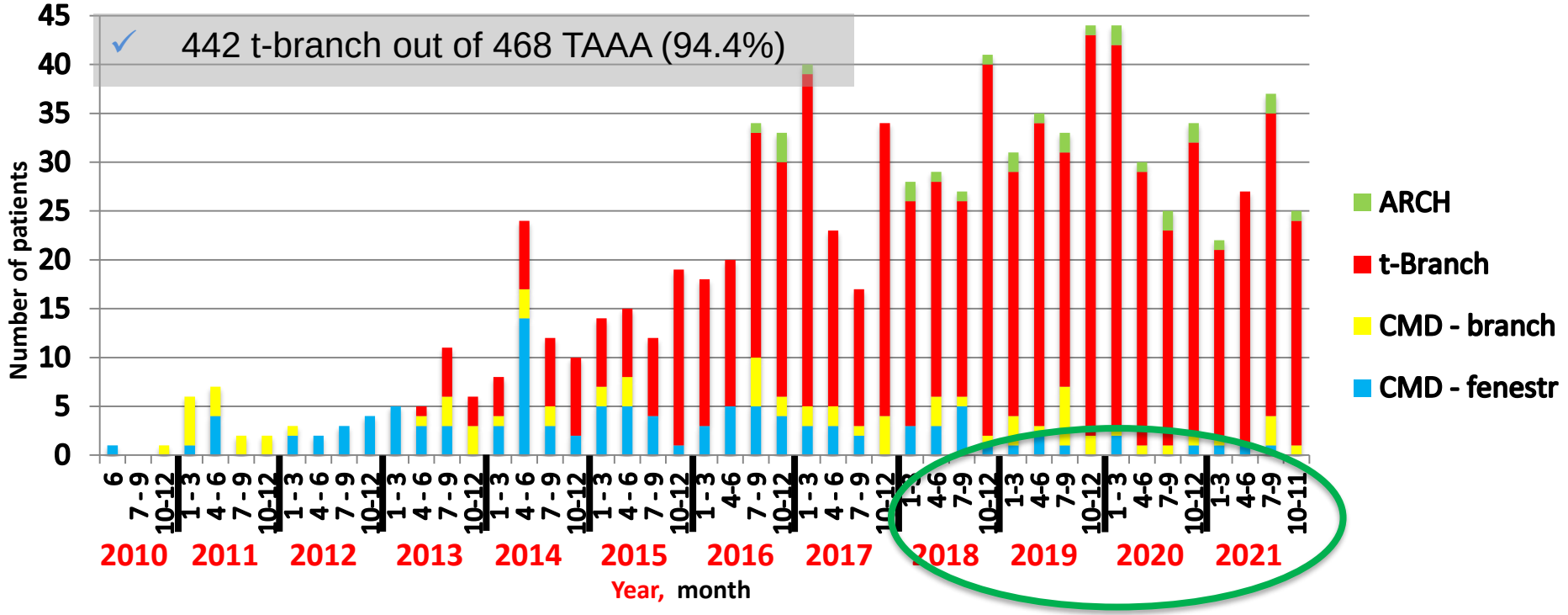


28 aortic arch

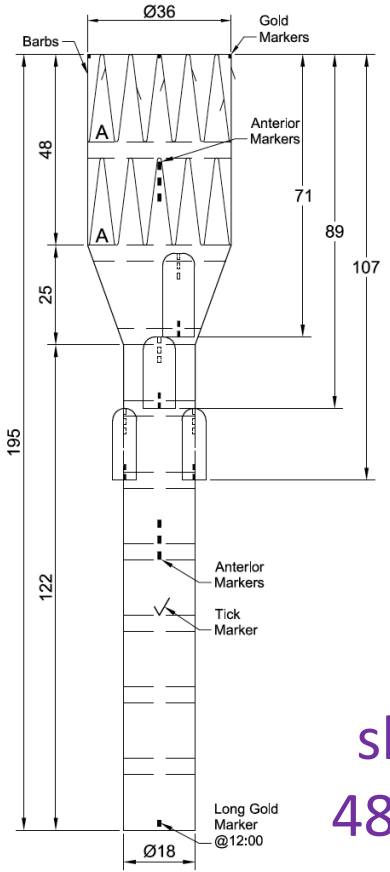
Department of General,
Vascular and Transplant Surgery
Medical University of Warsaw, Poland

904 complex aortic surgey

from 11.06.2010 to 26.11.2021



t-Branch variations



short
48/442

INTERNAL/EXTERNAL SIDEBRANCH #1
DIAMETER: 8mm
LENGTH: 21mm
DIST FROM PROX EDGE: 71mm
CLOCK: 1:00

INTERNAL/EXTERNAL SIDEBRANCH #2
DIAMETER: 8mm
LENGTH: 18mm
DIST FROM PROX EDGE: 89mm
CLOCK: 12:00

INTERNAL/EXTERNAL SIDEBRA
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDG
CLOCK: 2:30

INTERNAL/EX
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX
CLOCK: 9:30

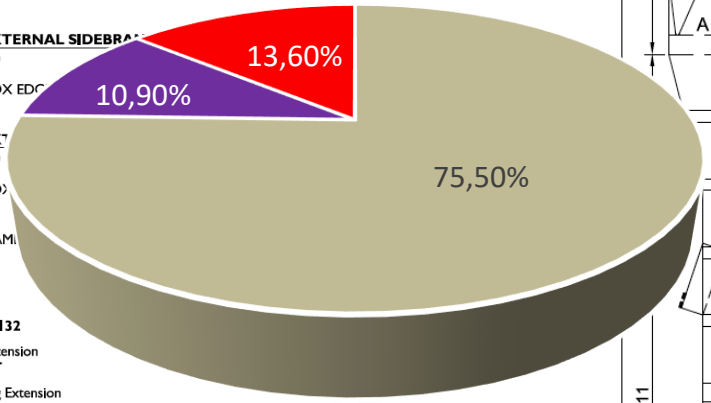
- SINGLE DIAM

Plus:

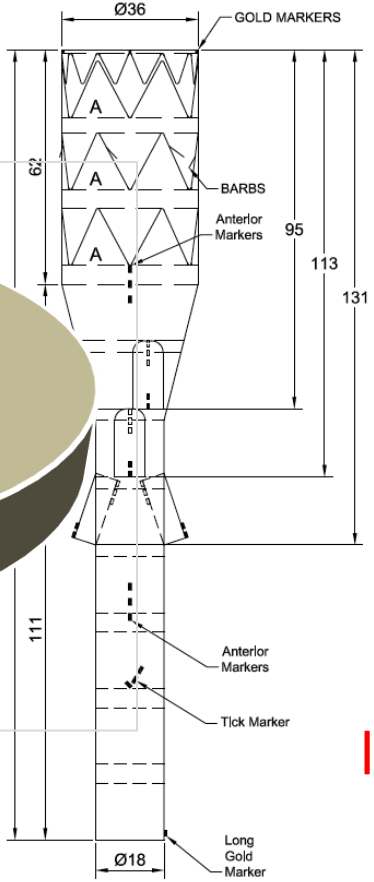
UNIBODY-22-132

Ipsilateral Leg Extension
ZSLE-20-74-ZT

Contralateral Leg Extension
ZSLE-20-74-ZT



standard t-B
334/442



INTERNAL/EXTERNAL SIDEBRANCH #1
DIAMETER: 8mm
LENGTH: 18mm
DIST FROM PROX EDGE: 95mm
CLOCK: 1:00

INTERNAL/EXTERNAL SIDEBRANCH #2
DIAMETER: 8mm
LENGTH: 18mm
DIST FROM PROX EDGE: 113mm
CLOCK: 12:00

INTERNAL/EXTERNAL SIDEBRANCH #3
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 131mm
CLOCK: 9:30

INTERNAL/EXTERNAL SIDEBRANCH #4
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 131mm
CLOCK: 2:30

- SINGLE DIAMETER REDUCING TIES
- UAT TIP
- NITINOL CANNULA
- LOW PROFILE FABRIC
- NITINOL STENTS

Plus:

ZTA-PT-38-34-217

low profile
60/442

Early outcomes of the t-Branch off-the-shelf multi-branched stent graft in 542 patients for elective and urgent aortic pathologies – a retrospective observational study

(J Vasc Surg 2021;■:1-8.)

Tilo Kölbel, MD,[a] Konstantinos Spanos, MD,[a,b] Katarzyna Jama, MD,[c] Christian-Alexander Behrendt, MD,[a] Giuseppe Panuccio, MD,[a] Ahmed Eleshra, MD,[a] Fiona Rohlffs, MD,[a] *and* Tomasz Jakimowicz, MD,[c] *Hamburg, Germany; Larissa, Greece; and Warsaw, Poland*

Table V. Technical success and morbidity

	Total patients (N = 542)	Early survival (n = 475)	Early mortality (n = 67)	*P* value
Technical success	526/542 (97)	464 (97.6)	62 (92)	.01
Technical failure	16	11	5	
Preoperative spinal drainage	72 (13)	62 (13)	10 (15)	[a]
Postoperative spinal drainage	22 (4)	11 (2)	11 (16)	[a]
No spinal drainage	448 (83)	402 (85)	46 (69)	[a]
Early any complication				.000
SIRS/sepsis	14 (2.6)	5 (1.1)	9 (13.4)	.000
MI	10 (1.8)	5 (1)	5 (7.5)	.000
Respiratory complication	12 (2.2)	6 (1.2)	6 (9)	.000
Stroke	14 (2.5)	5 (1)	9 (13.4)	.000
SCI	57 (10.5)			
Immediate temporary	28 (5.2)	20 (4.2)	8 (12)	.000
Immediate full	8 (1.5)	4 (0.8)	4 (6)	.000
Delayed temporary	7 (1.3)	7 (1.5)	0	
Delayed full	14 (2.6)	4 (0.8)	10 (15.2)	.000
No renal impairment	449 (83)	417 (88)	32 (48)	.000
Renal impairment	72 (13)	50 (10.5)	22 (33)	.000
Temporary dialysis	15 (3)	6 (1)	9 (13)	.000
Permanent dialysis	6 (1)	2 (0.5)	4 (6)	.000

THE 24TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING

Early outcomes of the t-Branch off-the-shelf multi-branched stent graft in 542 patients for elective and urgent aortic pathologies – a retrospective observational study

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Table I. The clinical presentation and category of the patients' aneurysms

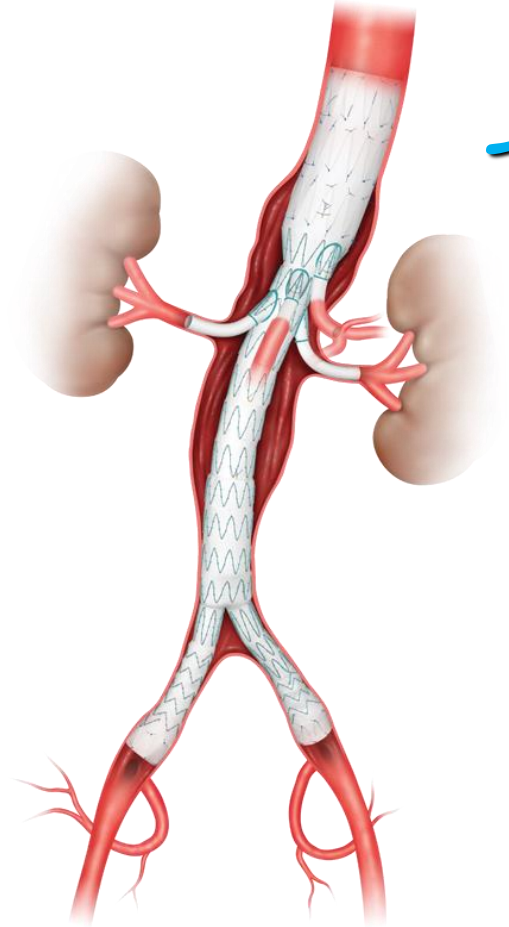
	Total patients (N = 542)	Early survival (n = 475)	Early mortality (n = 67)
Status			
Asymptomatic	339	310 (91.4)	29 (8.5)
Contained rupture	46	32 (70)	14 (30)
Symptomatic	157	133 (84.7)	24 (15)
Urgent	203	165 (82)	38 (18)
Early	154	131 (85)	23 (15)
Late	388	344 (88.6)	44 (11.3)
Largest diameter, mm	7.5 ± 2.5	7.4 ± 2.2	8.9 ± 3.5
Infra-renal AAA	14	13 (93)	1 (7)
Juxta-renal AAA	22	20 (91)	2 (9)
Supra-renal AAA	19	18 (94.7)	1 (5.3)
TAAA	487	424 (87)	63 (13)
Type I	31	27 (87)	4 (13)
Type II	73	58 (79.5)	15 (21.5)
Type III	118	102 (86.4)	16 (13.5)
Type IV	233	208 (89)	25 (11)
Type V	32	29 (91)	3 (9)

AAA, Abdominal aortic aneurysm; *TAAA*, thoraco-abdominal aortic aneurysm.
Values are expressed as the mean ± standard deviation or the number (percent).

Summary

- ✓ t-Branch can be effectivelly used in almost every TAAA patient especially in urgent situations
- ✓ CMD branch is not superior to t-Branch except:
  - ✓ >4 branches necesity
  - ✓ need of up-branch placement
- ✓ there is possibility of CMD similar to t-Branch production on low-profile platform or „short version”
- ✓ both of them should be also aviable off-the-shelf

Tomasz Jakimowicz



THANK YOU FOR YOUR ATTENTION!!!

Lesson from the past:
off the shelf devices
are ~~always~~ the best option?

YES!