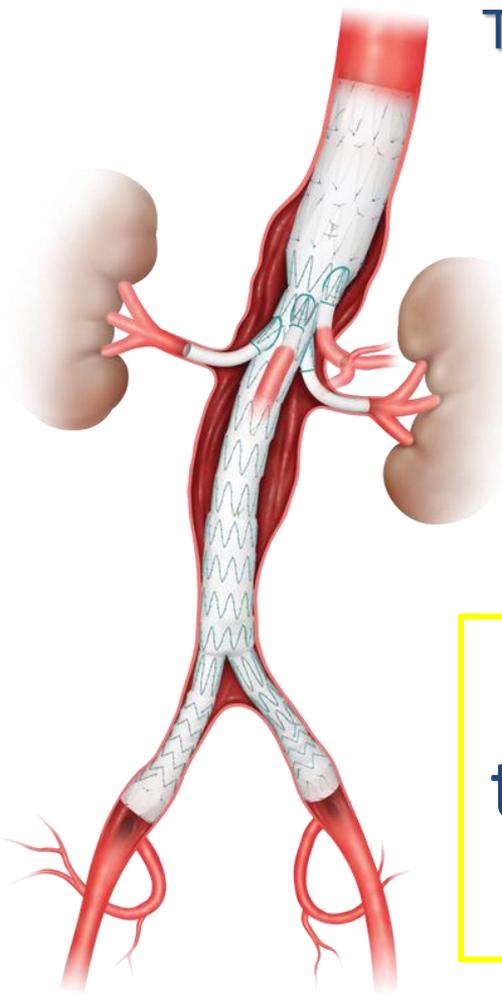


Tomasz Jakimowicz



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

Do not complicate the planning,
take an off-the-shelf since it does not
affect the success or outcome?





Disclosure



Speaker name:

TOMASZ JAKIMOWICZ

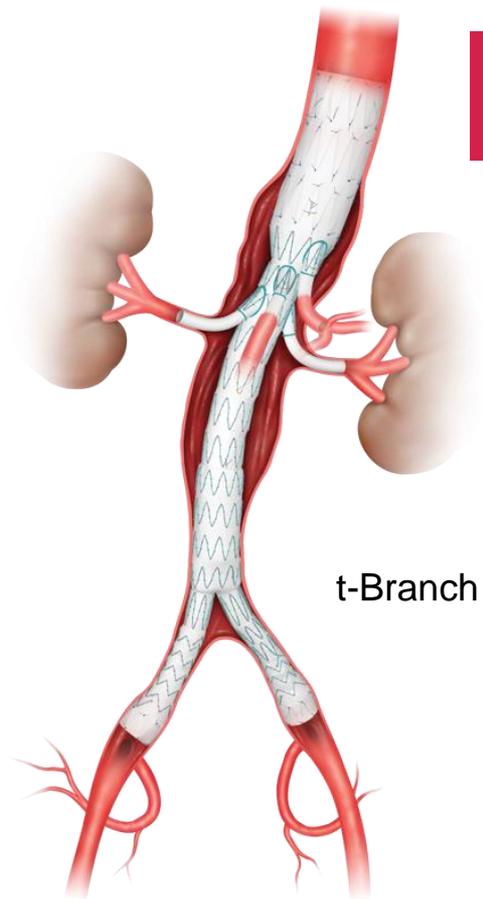
I have the following potential conflicts of interest to report:

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

- I do not have any potential conflict of interest



Off-the-shelf devices



t-Branch



ARTIVION™
Formerly CryoLife® | Jotec®

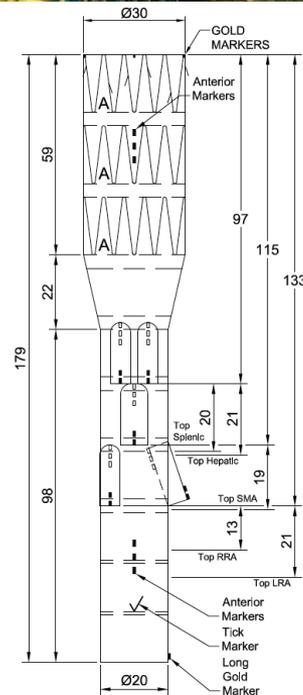
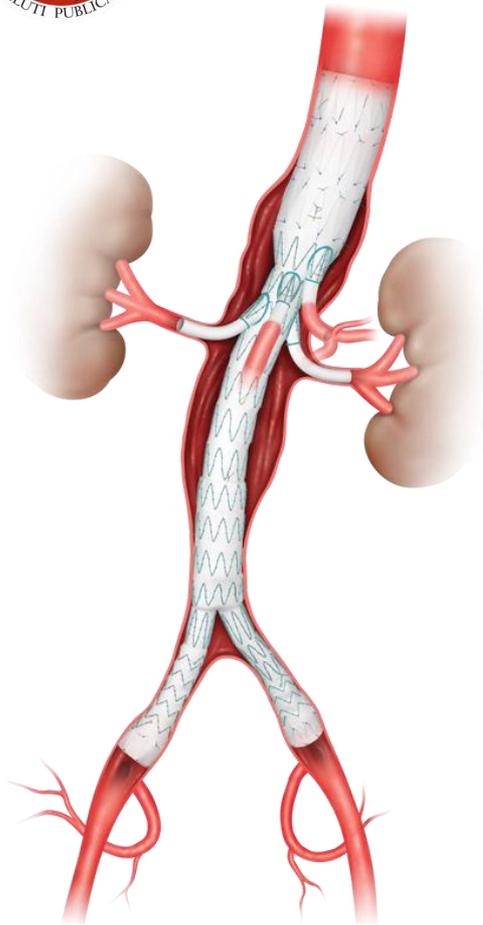


E-nside





OTS vs. CMD

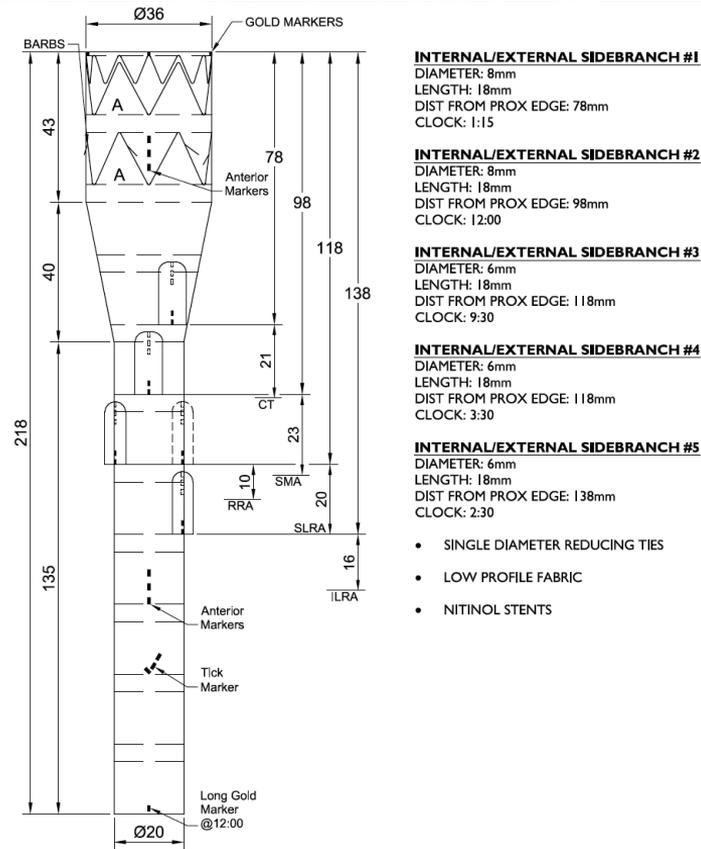


Increased risk of aneurysm rupture while waiting



Perfect CMD for patient anatomy?

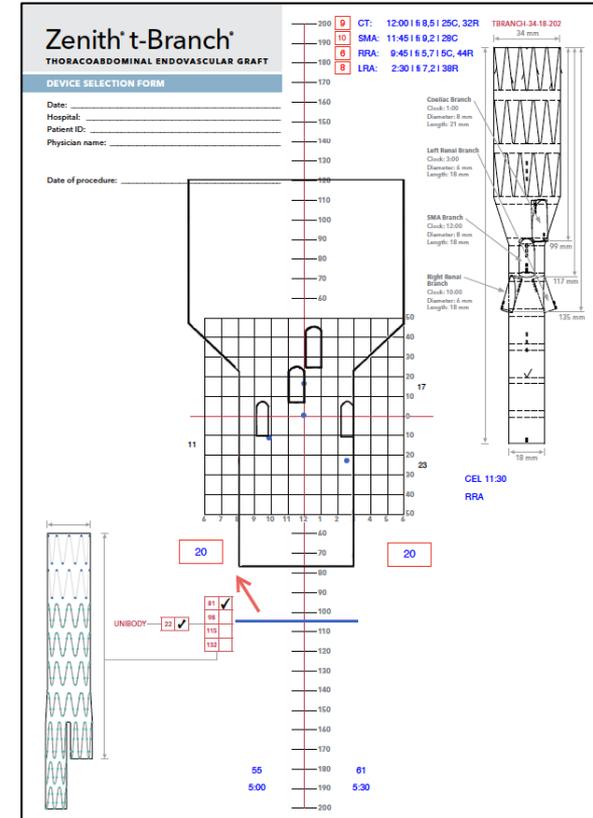
- ✓ Possibility of non-perfect positioning
- ✓ Unknown behaviour in different situation (aortic kinking)
- ✓ Difficult manufacturing
- ✓ The only one piece of specific design that exists...





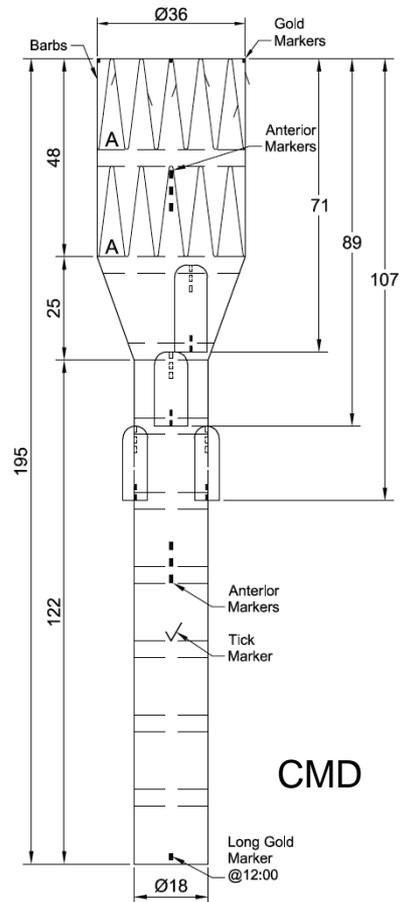
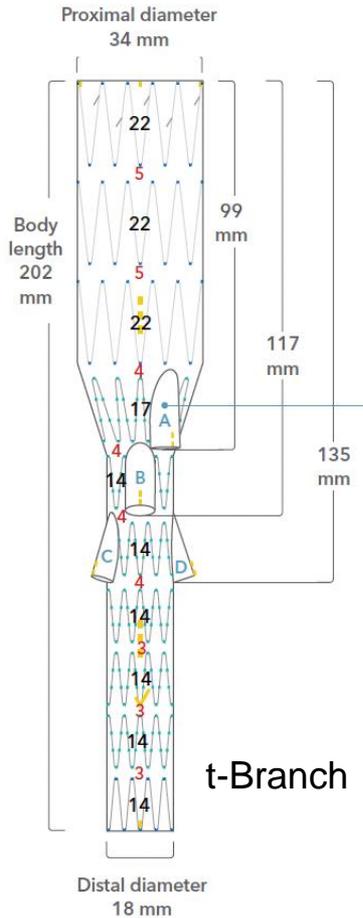
Fit the existig off-the-shelf to the patient

- ✓ 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!**





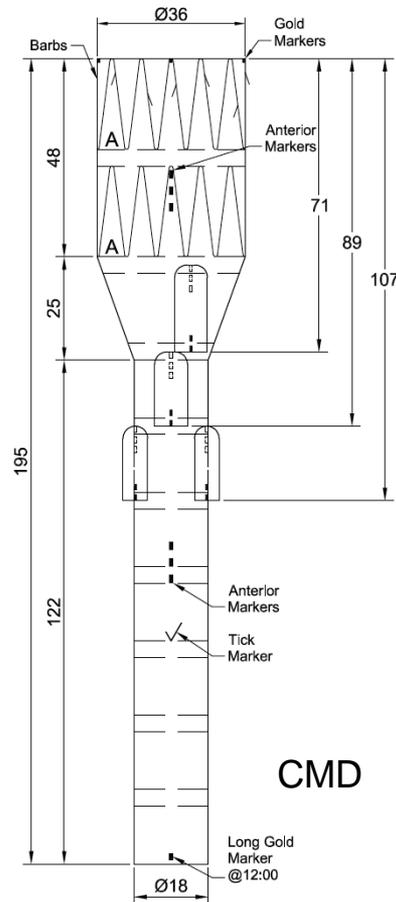
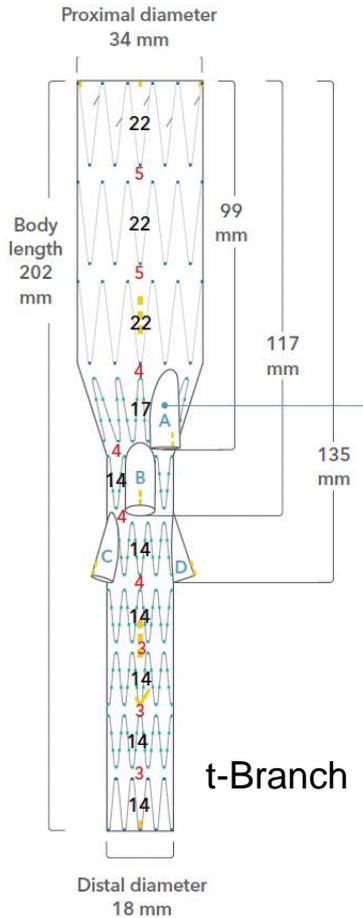
OTS vs. CMD



- ✓ number of branches
- ✓ (clock) position of the branches
- ✓ level of the branches
- ✓ pre-cannulation
- ✓ proximal/distal diameter
- ✓ proximal length
- ✓ introducer diameter



OTS vs. CMD



- ✓ number of branches
- ✓ (clock) position of the branches
- ✓ level of the branches
- ✓ pre-cannulation
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- ✓ proximal length
- ✓ introducer diameter



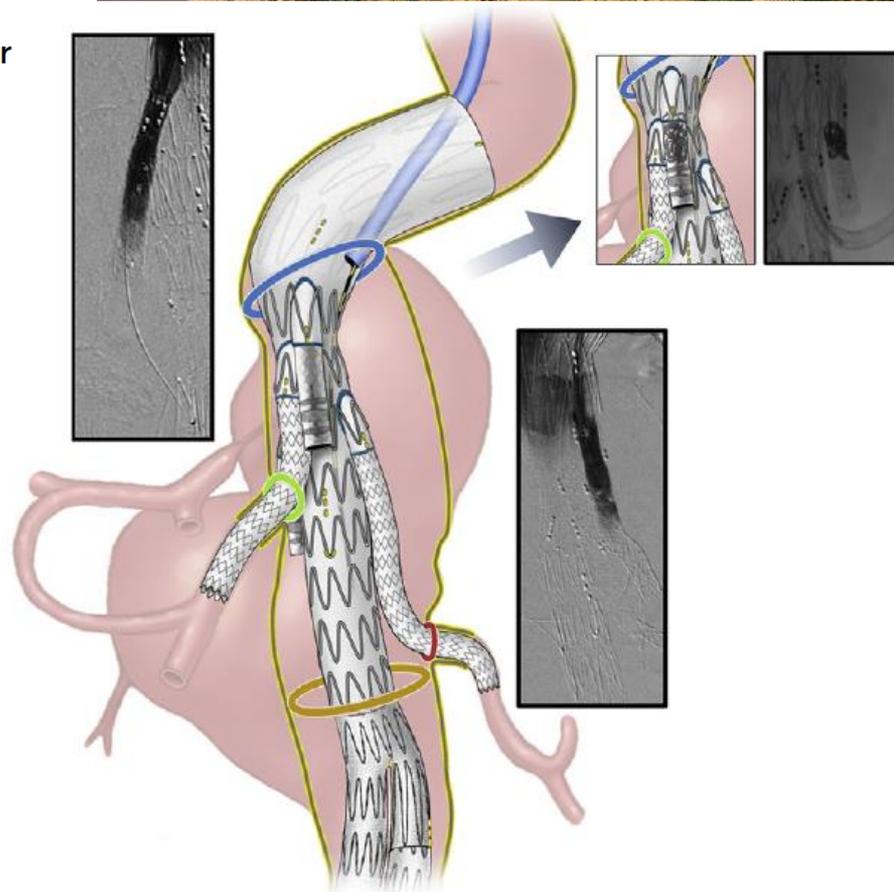
≤3 vessels – branch closure



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

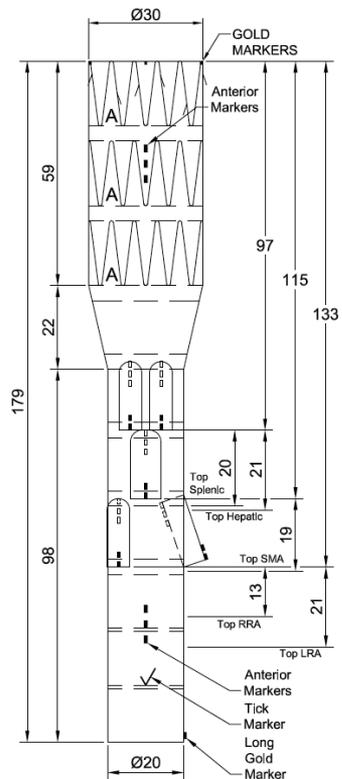
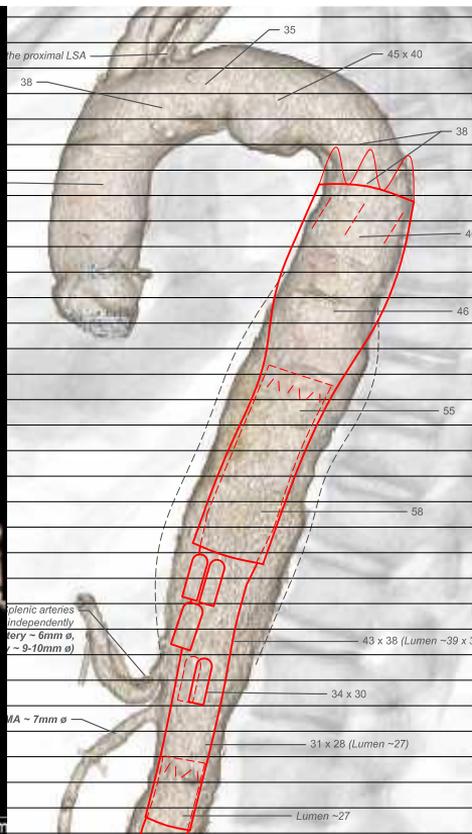
Emanuel R. Tenorio, MD, PhD,^a Gustavo S. Oderich, MD,^a Tilo Kölbel, MD, PhD,^b Mauro Gargiulo, MD,^c Carlos H. Timaran, MD,^d Luca Bertoglio, MD,^e Bijan Modarai, MD, PhD,^f Katarzyna Jama, MD,^g Ahmed Eleshra, MD,^b Guilherme B. B. Lima, MD,^a Carla Scott, MD,^d Roberto Chiesa, MD,^e and and Tomasz 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.)





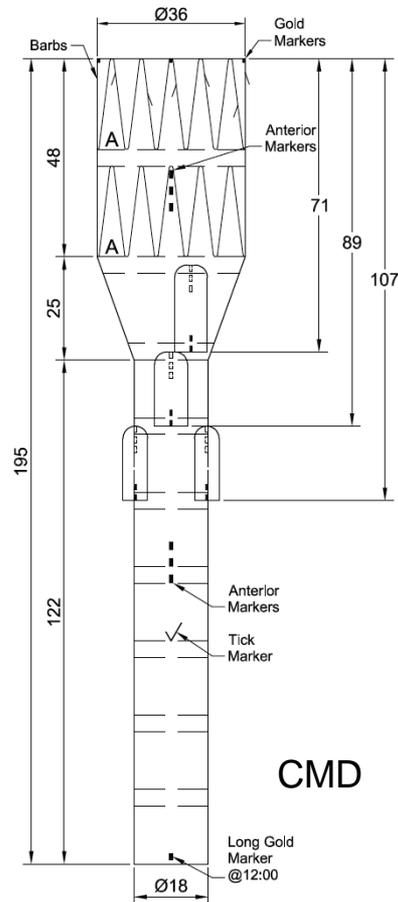
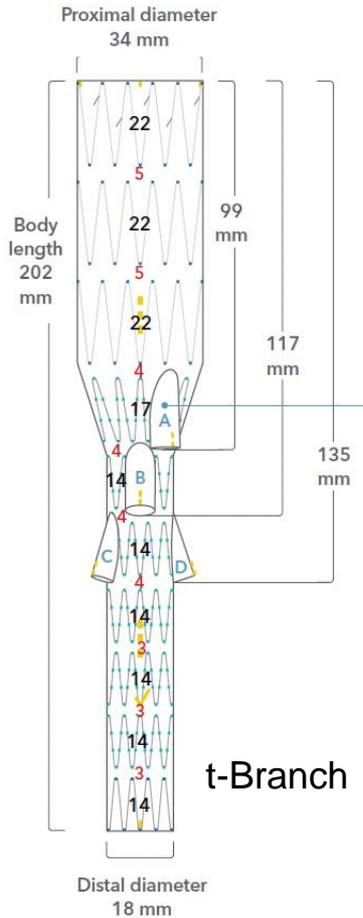
5 vessels additional branch



separate
hepatic/splenic artery
additional renal artery
could be embolized
while urgent



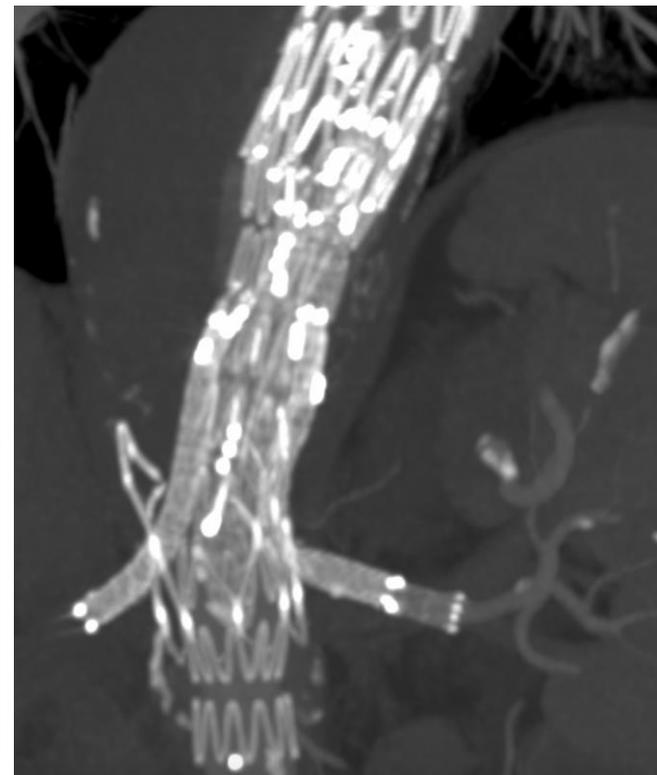
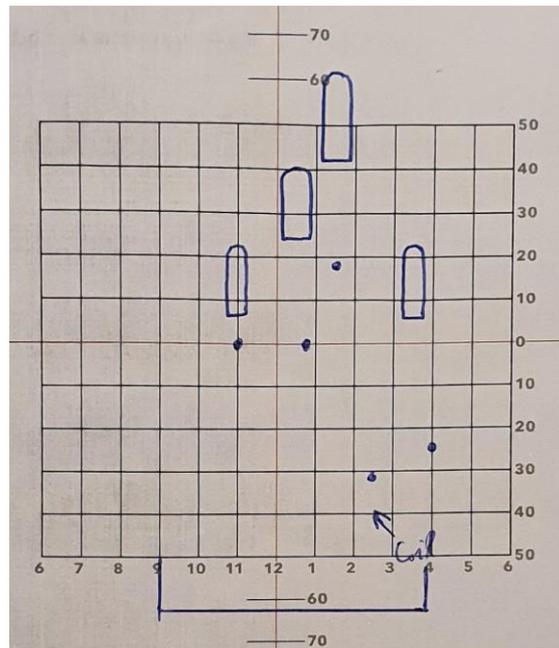
OTS vs. CMD



- ✓ number of branches
- ✓ (clock) position of the branches
- ✓ level of the branches
- ✓ pre-cannulation
- ✓ proximal/distal diameter
- ✓ proximal length
- ✓ introducer diameter



unsuitable clock position =
longer distance
to target vessels



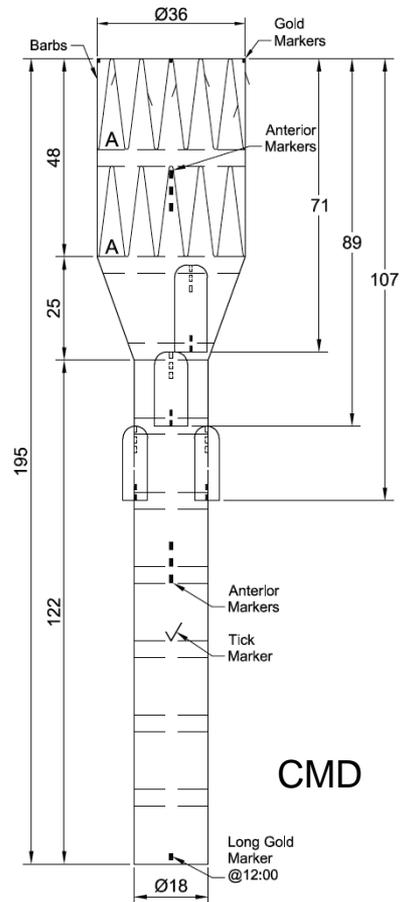
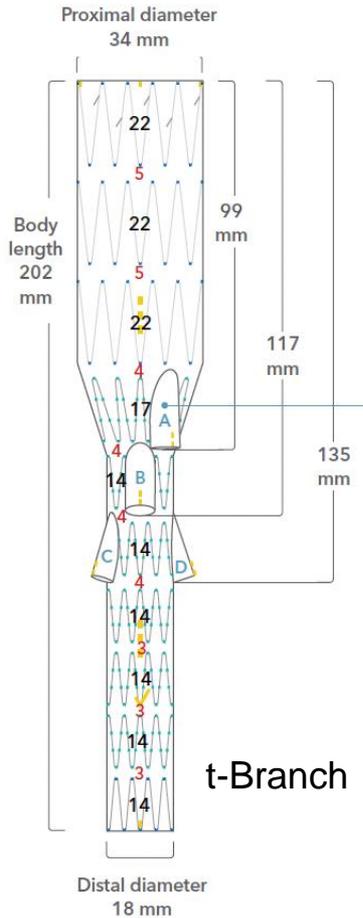


branched device malrotation





OTS vs. CMD

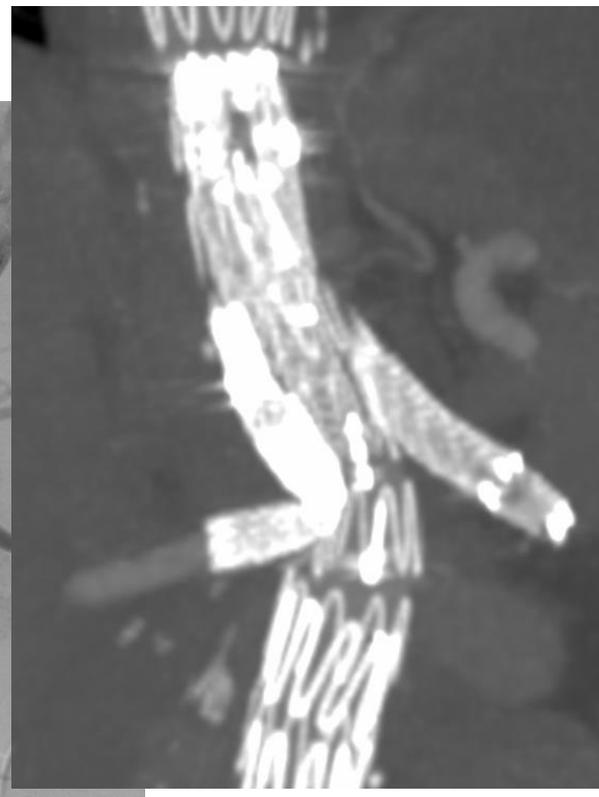
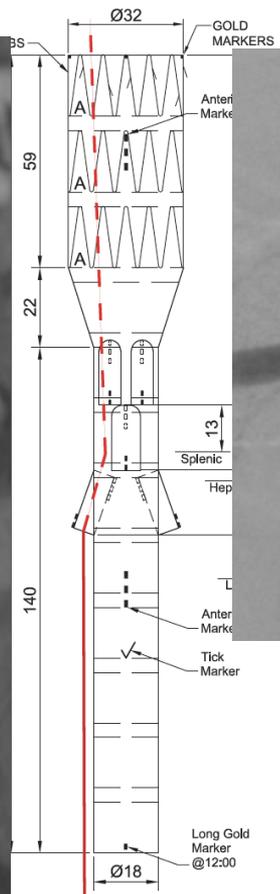


- ✓ number of branches
- ✓ (clock) position of the branches
- ✓ level of the branches
- ✓ pre-cannulation
- ✓ proximal/distal diameter
- ✓ proximal length
- ✓ introducer diameter



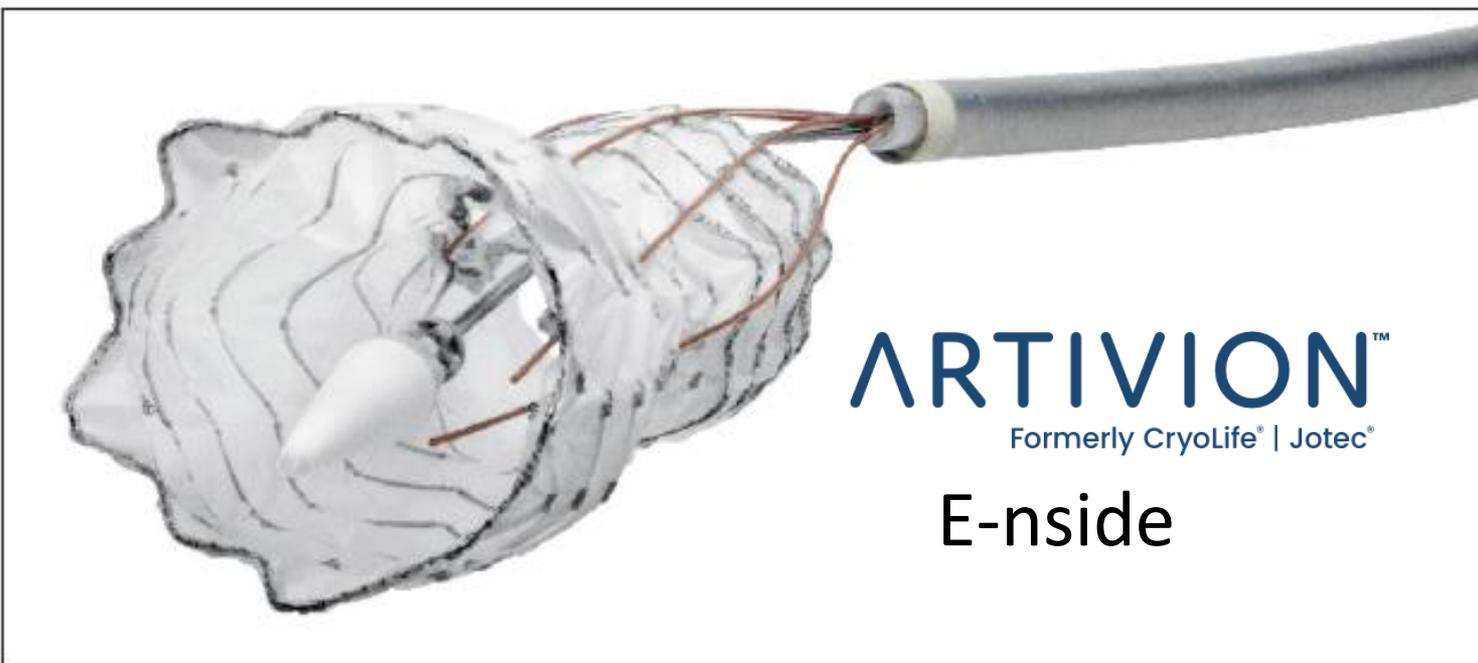


Preloaded catheter (5 bra)



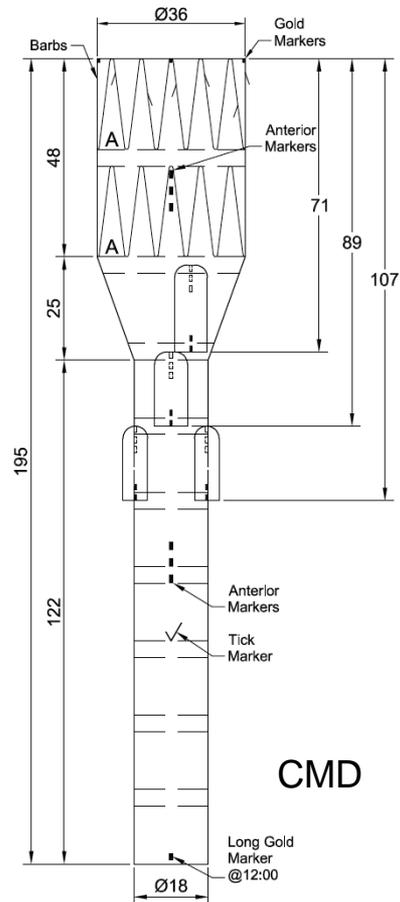
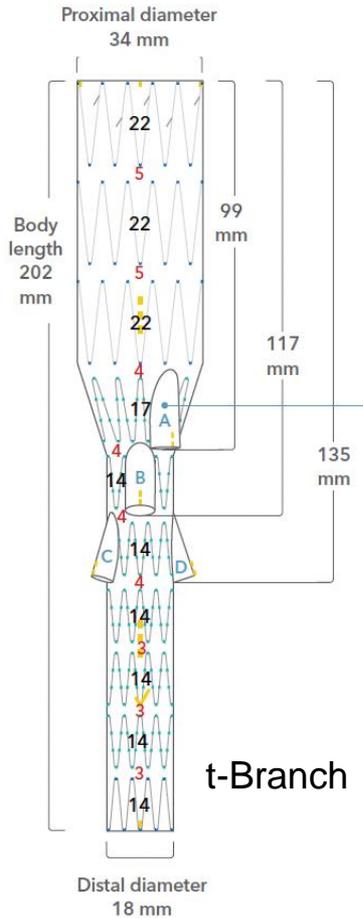


Pre-cannulated OTS



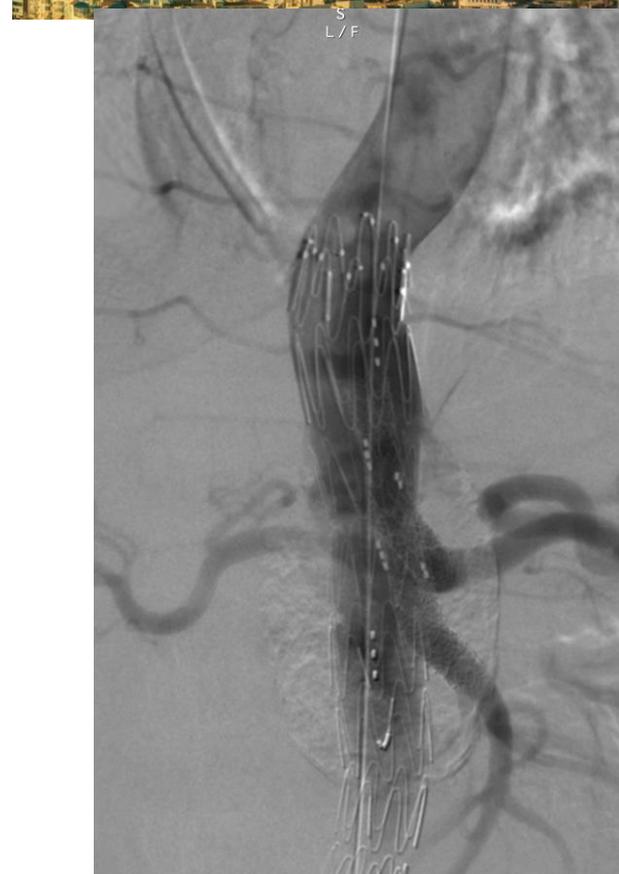
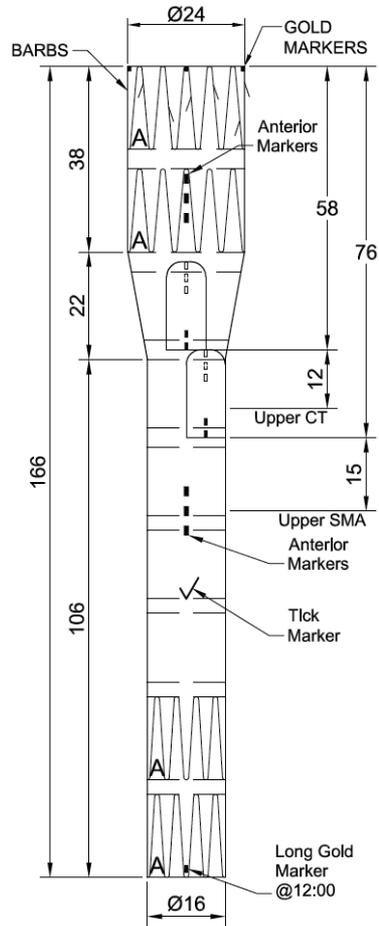
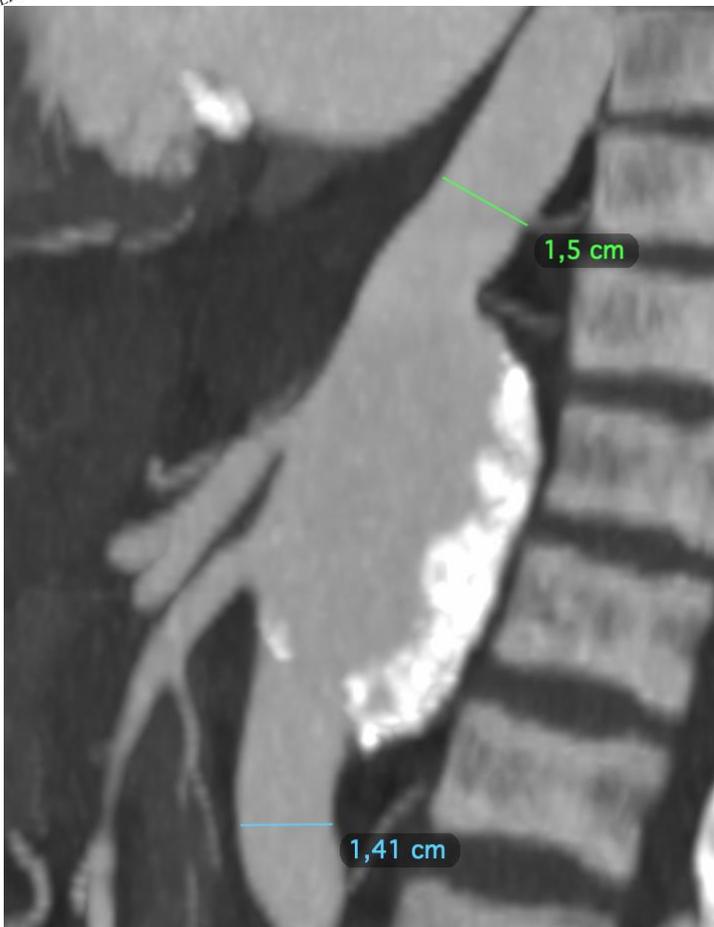


OTS vs. CMD



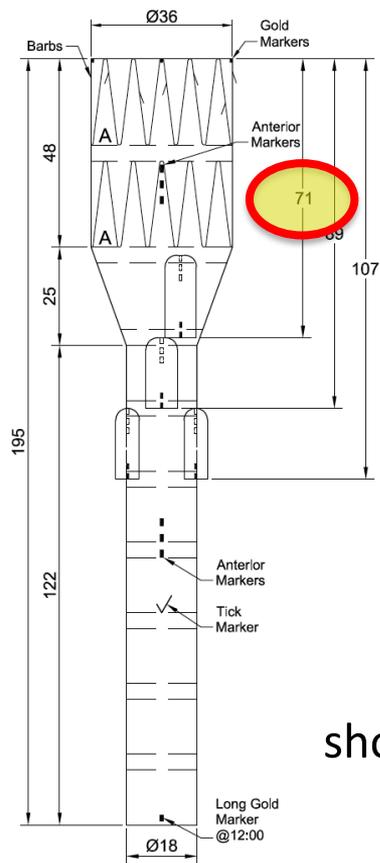
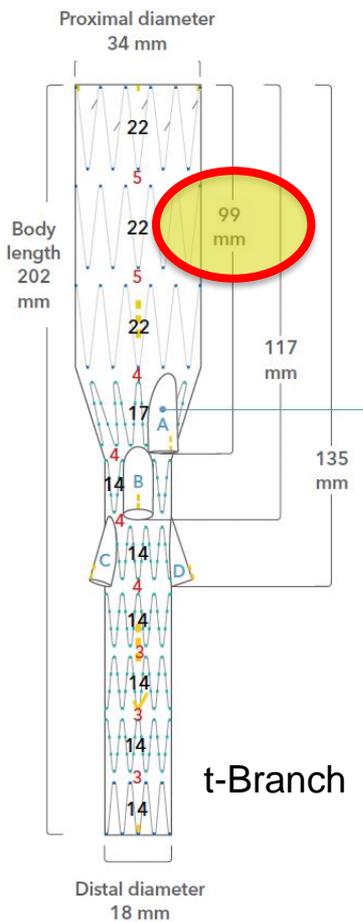
- ✓ number of branches
- ✓ (clock) position of the branches
- ✓ level of the branches
- ✓ pre-cannulation
- ✓ proximal/distal diameter
- ✓ proximal length
- ✓ introducer diameter

Narrow aorta

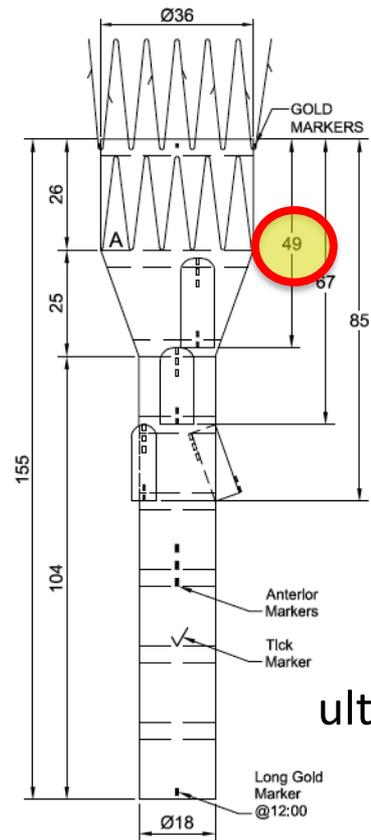




proximal length



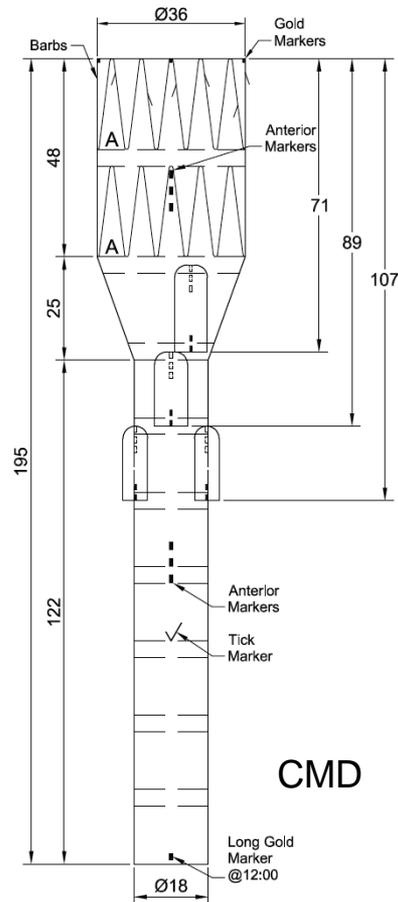
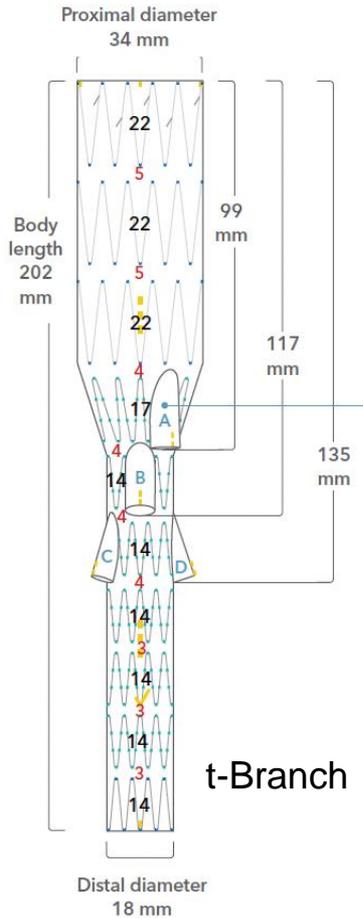
short branch



ultrashort branch



OTS vs. CMD



- ✓ number of branches
- ✓ (clock) position of the branches
- ✓ level of the branches
- ✓ pre-cannulation
- ✓ proximal/distal diameter
- ✓ proximal length
- ✓ introducer diameter



Narrow / calcified iliac vessels – iliac conduit



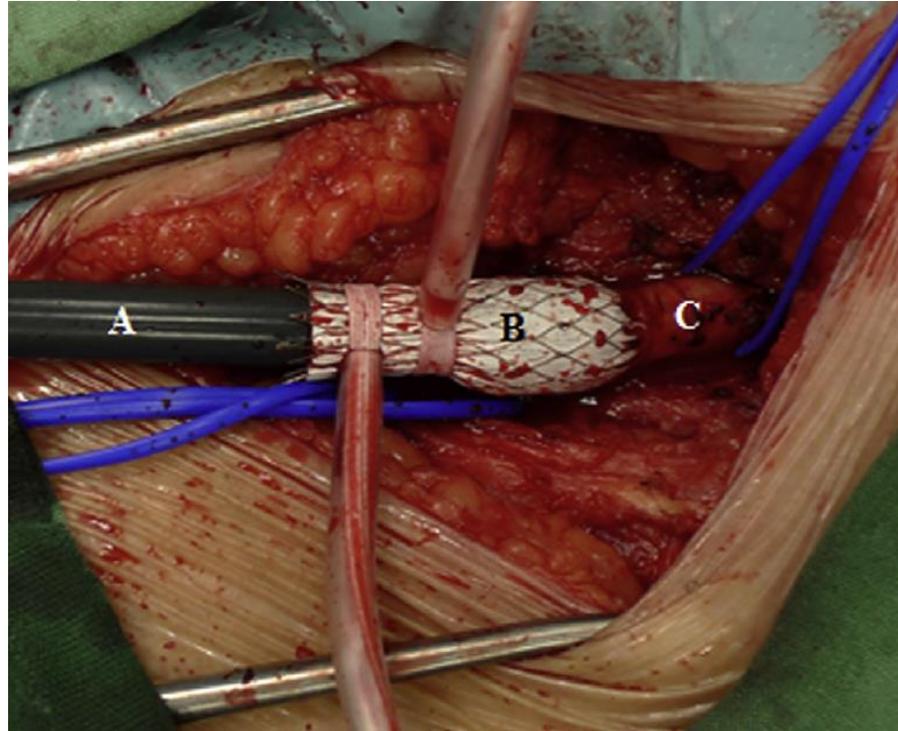
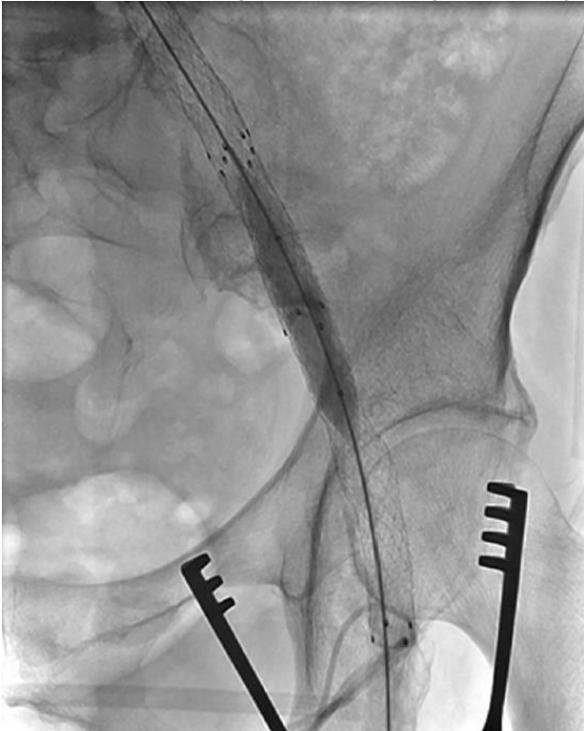
Narrow iliac vessels – endoconduit



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. Ascitutto ^{a,*}, M. Aronici ^{a,b,c}, T. Resch ^a, B. Sonesson ^a, T. Kristmundsson ^a, N.V. Dias ^a



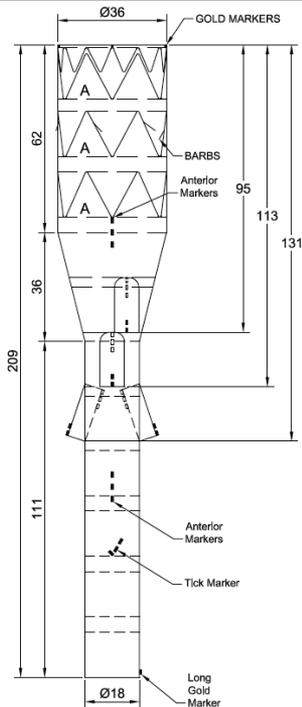


Narrow iliac vessels – low profile (nitinol) "t- branch"



RE434244_v0 NON STANDARD DEVICE REQUEST - PROPRIETARY COOK MEDICAL VERSION 1

Device: BRANCH-DESCENDING-THORACOABDOMINAL-DEVICE PAGE 2 of 3
Component: THORACO-ABDOMINAL-SIDE-BRANCH



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

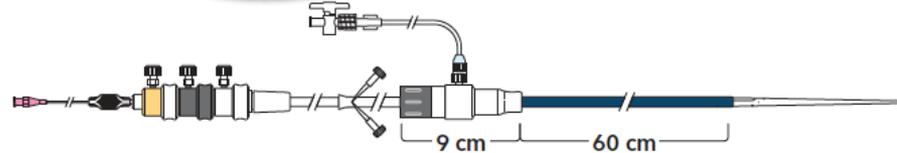
Date: 23-Nov-16

Not to scale

All Dimensions shown are in mm

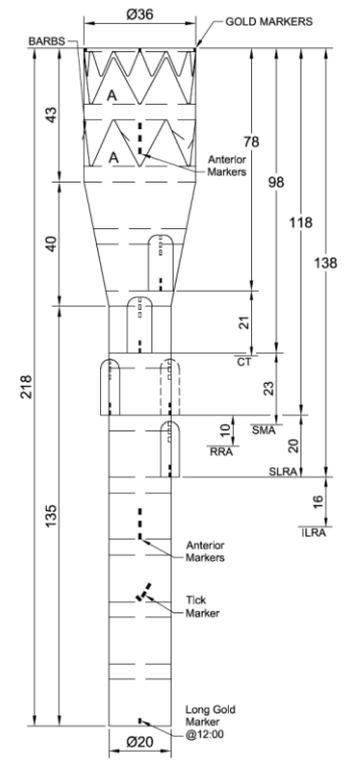
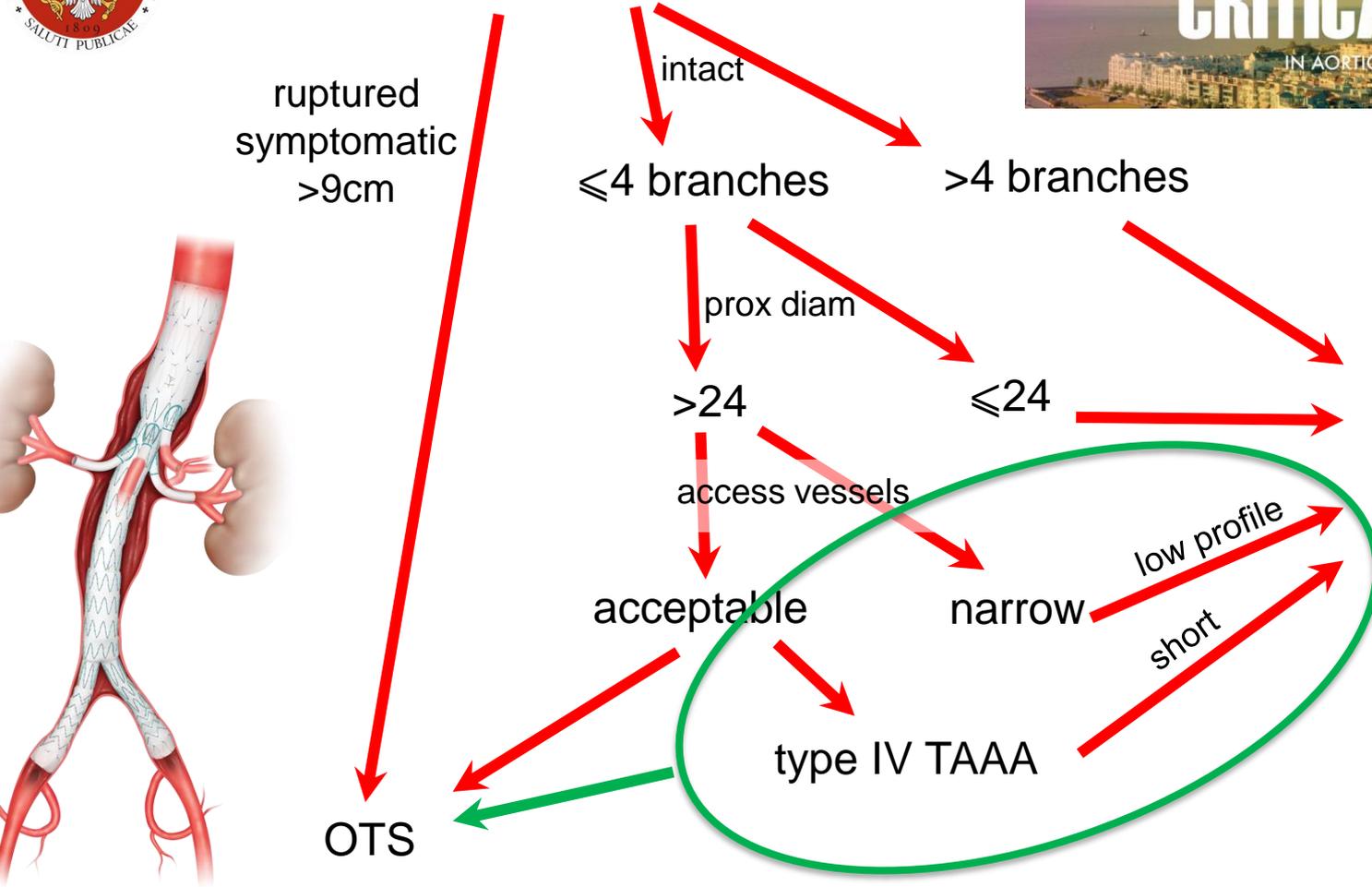
H&L-B One-Shot™ Introduction System for t-Branch graft

22 Fr (7.3 mm) ID/8.5 mm OD





TAAA – endograft choice



CMD



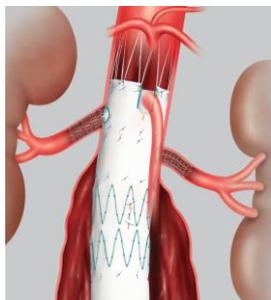
Own experience





1183 complex aortic surgery

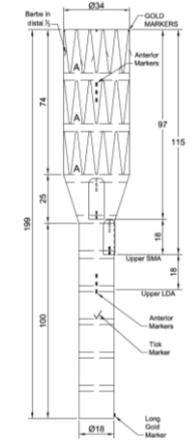
od 17.10.2014 do 17.03.2024



67
jAAA

67
fenestr

- 1138 Cook
- 41 Jotec
- 3 Brail
- 1 Bolton

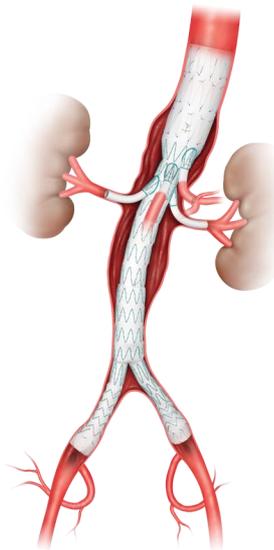


1027 TAAA

59
CMD

968
OTS

89 aortic arch

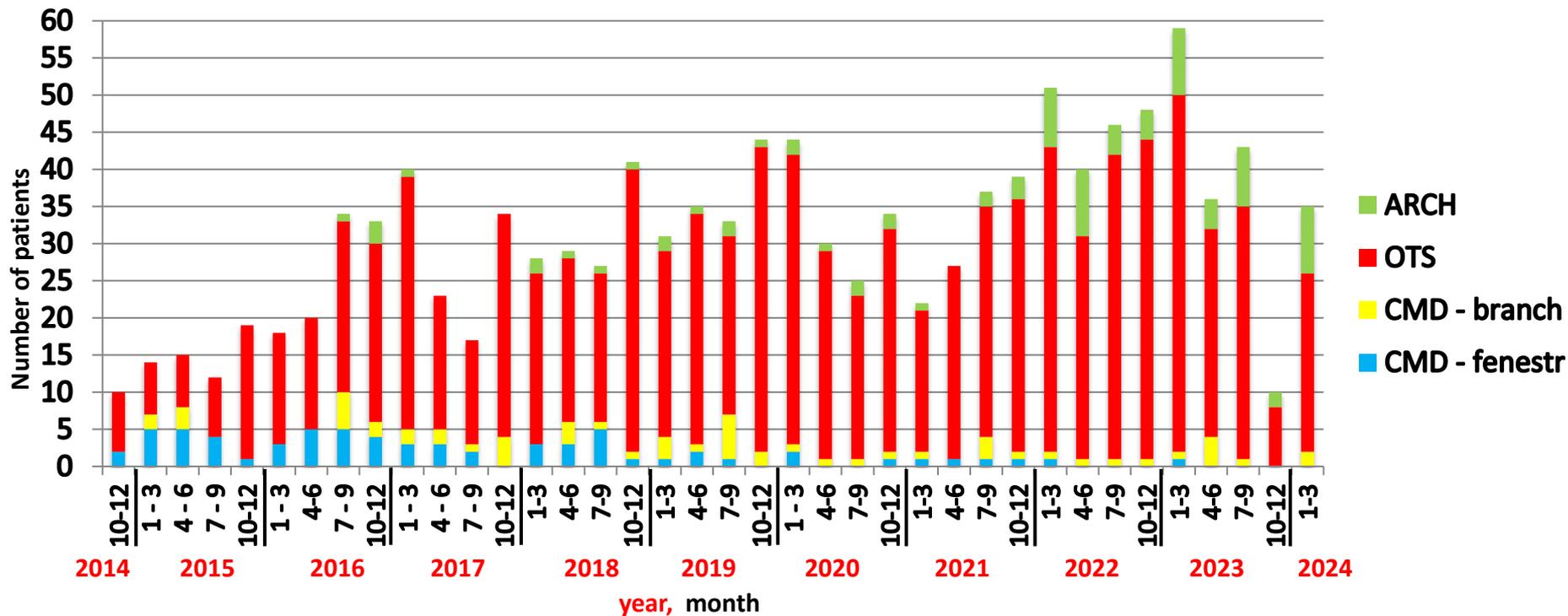




1183

complex aortic surgery

from 17.10.2014 to 17.03.2024





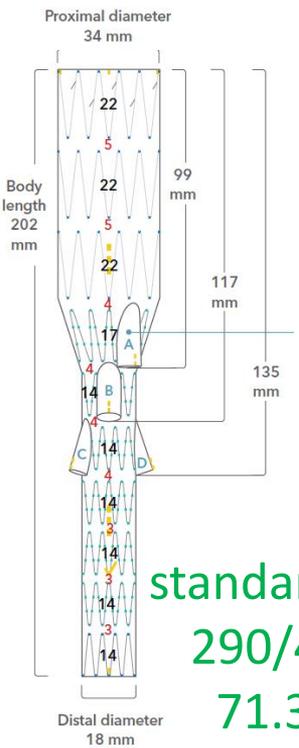
Material



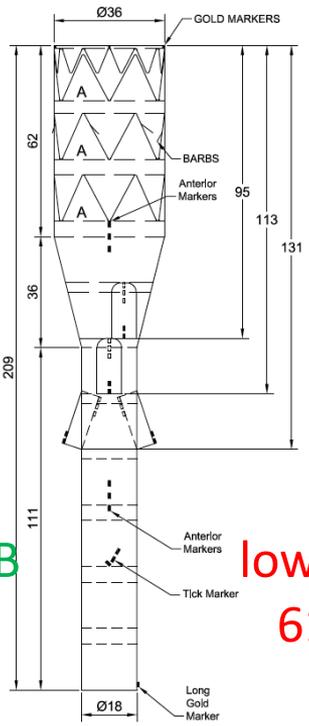
- ✓ 424 consecutive patients with TAAA treated by bEVAR during last 27 months (01.01.2021 – 17.03.2024)
- ✓ Mean age 73,6
- ✓ 335 male and 89 female (21% female)
- ✓ 100% bEVAR; **CMD – 17 (4.2%), OTS 407 (95.8%)**
- ✓ 114 urgent indications (ruptured, symptomatic or >90mm),
310 elective



OTS variations



standard t-B
290/407
71.3%

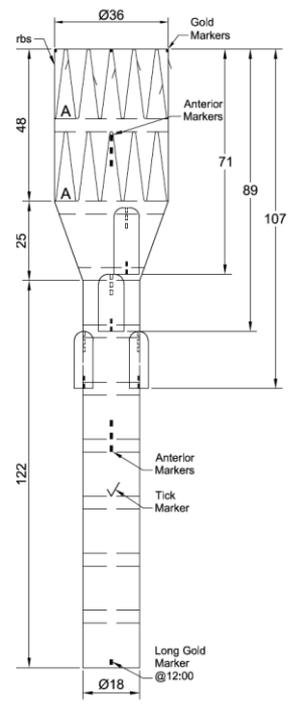


low profile
61/407
15%

- 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
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CLOCK: 9:30
- INTERNAL/EXTERNAL SIDEBRANCH #4**
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 131mm
CLOCK: 2:30

Plus:
ZTA-PT-38-34-217

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

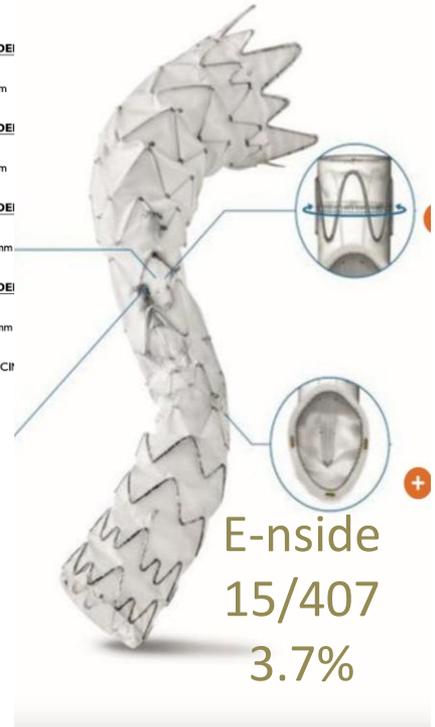


short
41/407
10%

- INTERNAL/EXTERNAL SIDE:**
DIAMETER: 8mm
LENGTH: 21mm
DIST FROM PROX EDGE: 71mm
CLOCK: 1:00
- INTERNAL/EXTERNAL SIDE:**
DIAMETER: 8mm
LENGTH: 18mm
DIST FROM PROX EDGE: 89mm
CLOCK: 12:00
- INTERNAL/EXTERNAL SIDE:**
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 107mm
CLOCK: 2:30
- INTERNAL/EXTERNAL SIDE:**
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 107mm
CLOCK: 9:30

Plus:
UNIBODY-22-132
Ipsilateral Leg Extension
ZSLE-20-74-ZT
Contralateral Leg Extension
ZSLE-20-74-ZT

- SINGLE DIAMETER REDUCI



E-nside
15/407
3.7%



Results of last 424 bEVARs

- ✓ 30-day mortality 19/424 (4.5%)
 - ✓ 5/310 elective (1.6%)
 - ✓ 14/114 urgent (12.3%)
- ✓ Paraplegia 7/424 (1.6%) – (in 5 cases lethal)
 - ✓ 2/310 elective (0.6%) – unknown reason
 - ✓ 5/114 urgent (4.4%) – 5 with intraoperative technical problems, 5 died
- ✓ Dialysis 2/405 (0.5%)
- ✓ Good clinical outcome (hospital discharge without paraplegia or dialysis)
 - ✓ 401/424 (94.6%) overall
 - ✓ 302/310 (97.4%) elective





Summary



- ✓ OTS devices can be effectively used in almost every TAAA patient especially in urgent situations
- ✓ CMD branch is not superior to OTS except of:
 - ✓ >4 branches needed
 - ✓ small proximal aorta diameter
- ✓ there is possibility of similar to t-Branch CMD production on low-profile platform or its „short version”
- ✓ both of them should be also available off-the-shelf

Tomasz Jakimowicz

THANK YOU
FOR YOUR
ATTENTION!!!



Do not complicate the planning, take an off-the-shelf ~~since~~ it does not affect the success or outcome

