

### Real World Evaluation Of The OTS Pre-Cannulated Inner Branched Endograft (E-nside From Artivion) For Pararenal Aortic Aneurysms

#### Advantages And Limitations

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Lee H. Bouwman MD PhD  
Vascular surgeon, Zuyderland Medical Center  
Professor of Clinical Engineering, Faculty of Science and Engineering

Theodorios Bisdas MD PhD FACS  
Head, Clinic of Vascular Surgery III, Athens Medical Center  
Assoc. Professor for Vascular Surgery, University Clinic of Muenster  
Founder and COO, Vascupedia

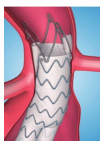
### Disclosures

- Research grant Artivion
- Research grant Abbott


### Endovascular repair of PAAAs in urgent setting



**Physician modified FEVAR**  
Gouveia E, Melo R, EJVES 2022




**CHEVAR**  
Cherfan et al, J Vasc Surg 2022



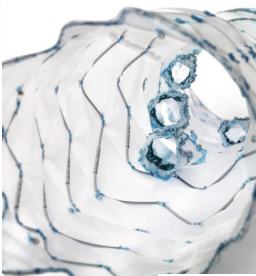
**T-branch (COOK)**  
Walker et al, J Vasc Surg 2019

### E-nside TAAA – iBEVAR (FMR 01-2021)



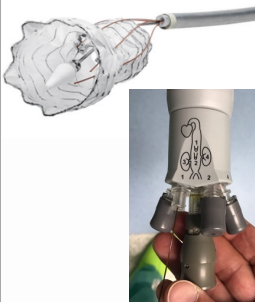
Off the shelf  
Elective, urgent and emergency

### E-nside TAAA - iBEVAR




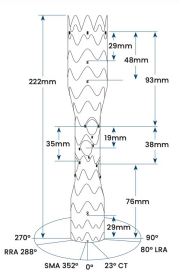
- Off the shelf
- Inner Branched EVAR iBEVAR

### E-nside TAAA - iBEVAR



- Off the shelf
- Inner Branched EVAR – iBEVAR
- Precannulated branches

• Precannulated branches  
Snare to arm or contralateral CFA

- TC/SMA branch Ø 8mm, L 19mm  
- RRA/LRA branch Ø 6mm, L 17mm

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Clinical Investigation

**Real-World Evaluation of the Off-the-Shelf Precannulated Inner-Branched Endograft for Pararenal Aortic Aneurysms**

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### Study design

Retrospective analysis of prospectively collected data (2 centers)

Consecutive patients with E-side implantation for PAAAs

PAAA defined as at least 1 renal involved and not the SMA

Study period (2021-2023)

- **Primary outcome**
  - Technical success (implantation, use of precannulation tubes, delivery of BSG\*)
- **Key secondary outcomes**
  - Aortic coverage (above CTA)
  - Positioning of branches as fenestration
  - Target vessel instability
  - Spinal cord ischemia
  - Angulation of BSG

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### Patient characteristics

Study cohort	Results
Number of patients	21
Male	20 (95%)
Mean age (mean, standard deviation), in years	71 (6)
Arterial hypertension	20 (95%)
Chronic obstructive pulmonary disease	9 (43%)
Diabetes mellitus	2 (10%)
Chronic kidney disease	6 (29%)
Carotid artery disease	8 (38%)
Statins	21 (100%)
Smoking	16 (76%)
Coronary artery disease	13 (62%)

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### Study cohort

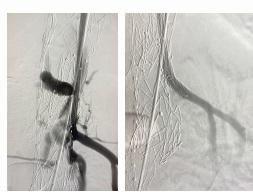
Indications

Study cohort	Results
Number of patients	21
<b>Main indications for E-side implantation</b>	
Symptomatic PAAAs	9 (43%)
Severe angulation of the proximal neck	5 (24%)
Aneurysm Ø > 80mm	4 (19%)
Coexistent aneurysm of TV's origin	1 (5%)
Patient's autonomous choice	2 (10%)
<b>Concomitant common iliac artery aneurysm</b>	5 (24%)

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### Intraoperative details

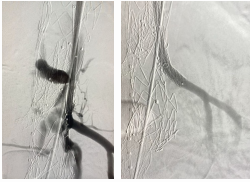
Target vessel and type of covered stent	N (%)
<b>Common iliac trunk</b>	<b>29 (100)</b>
ViVax (W.L. Gore)	13 (45)
BeGraft plus (Bentley)	9 (31)
BeGraft (Bentley)	4 (14)
iCover (Vascular)	2 (7)
Adrena V12 (Atrium)	1 (3)
<b>Superior mesenteric artery</b>	<b>31 (100)</b>
ViVax (W.L. Gore)	16 (52)
BeGraft plus (Bentley)	6 (19)
BeGraft (Bentley)	5 (16)
iCover (Vascular)	3 (10)
Adrena V12 (Atrium)	1 (3)
<b>Right renal artery</b>	<b>27 (100)</b>
ViVax (W.L. Gore)	18 (67)
BeGraft plus (Bentley)	4 (15)
iCover (Vascular)	2 (7)
BeGraft (Bentley)	2 (7)
ViVax (W.L. Gore)	1 (4)
<b>Left renal artery</b>	<b>25 (100)</b>
ViVax (W.L. Gore)	16 (64)
BeGraft plus (Bentley)	3 (12)
iCover (Vascular)	3 (12)
BeGraft (Bentley)	2 (8)
ViVax (W.L. Gore)	1 (4)






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### Intraoperative details

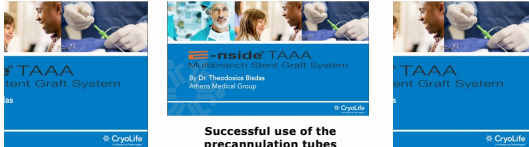
Intraoperative parameters	Results
Number of BSGs	112
Median number of BSG / TV (IQR)	
CTA	1.5 (1-2)
SM	1.5 (1-2)
RRA	1 (1-2)
LRA	1 (1-2)



### Technical success




# 95%



**Introduction of the 24F device**

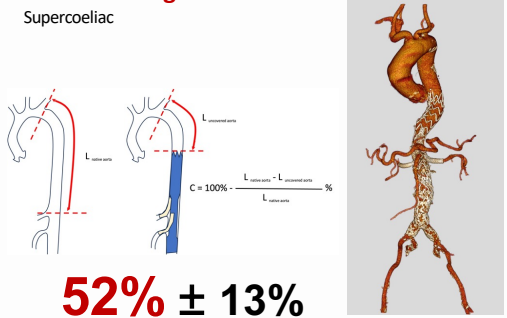
**Successful use of the precannulation tubes**

**Successful delivery and implantation of the BSG**



### Aortic coverage

Supercoeliac



$C = 100\% - \frac{L_{\text{coverage}} - L_{\text{supercoeliac}}}{L_{\text{coverage}}} \times 100\%$

# 52% ± 13%

### Target vessel instability (TVI)


Mean follow-up: 14 ± 7 months

**TVI:**




- Branch occlusion @ 30 days\* (n=1)

Reintervention-free survival at 1 year: **95%**

Freedom from TVI at 1 year: **95%**



\*clopidogrel resistance

### Spinal cord ischemia

**Paraplegia**




# 5%

(n=1)

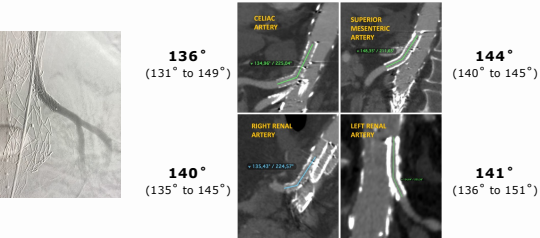
**At 6 months**




Muscle function grade from **grade 0** to **grade 3**

Sensory grade from **grade 0** to **grade 1**

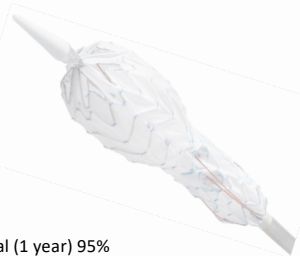
### Median angle of branches



## Conclusions

- The **E-nside stent-graft** is a feasible and safe off-the-shelf solution for urgent PAAAs
- Technical success 95%
- Very low rate of TVI (< 1%)
- Reintervention rate survival (1 year) 95%



## Considerations

- Follow-up studies required
- Comparative studies with other off the shelf devices required
- Improvements in device are warranted
  - A truncated version to reduce the risk of SCI
  - Lower profile (24Fr)

