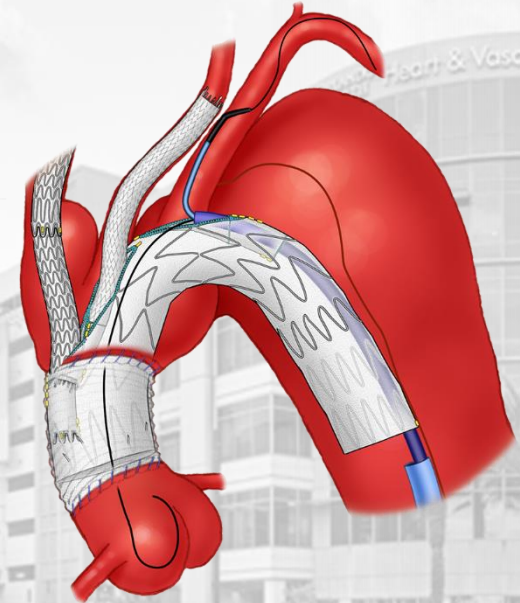


Update on a dedicated platform for the arch

Aleem K. Mirza MD

Assistant Professor of Surgery
Director of Aortic Program
Division of Vascular Surgery

Orlando Health Heart and Vascular Institute
Orlando Regional Medical Center
University of Central Florida College of Medicine



THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING

MARCH 21 & 22 2024
COPENHAGEN/MALMÖ
SCANDIC TRIANGELN, MALMÖ

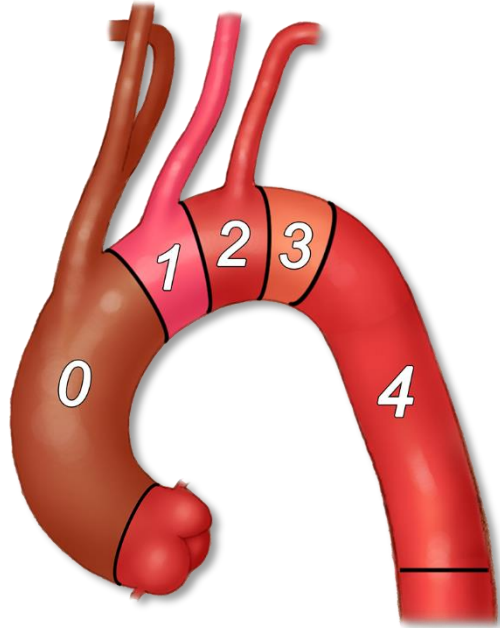
ORLANDO
HEALTH[®]
Heart & Vascular
Institute

Faculty disclosures

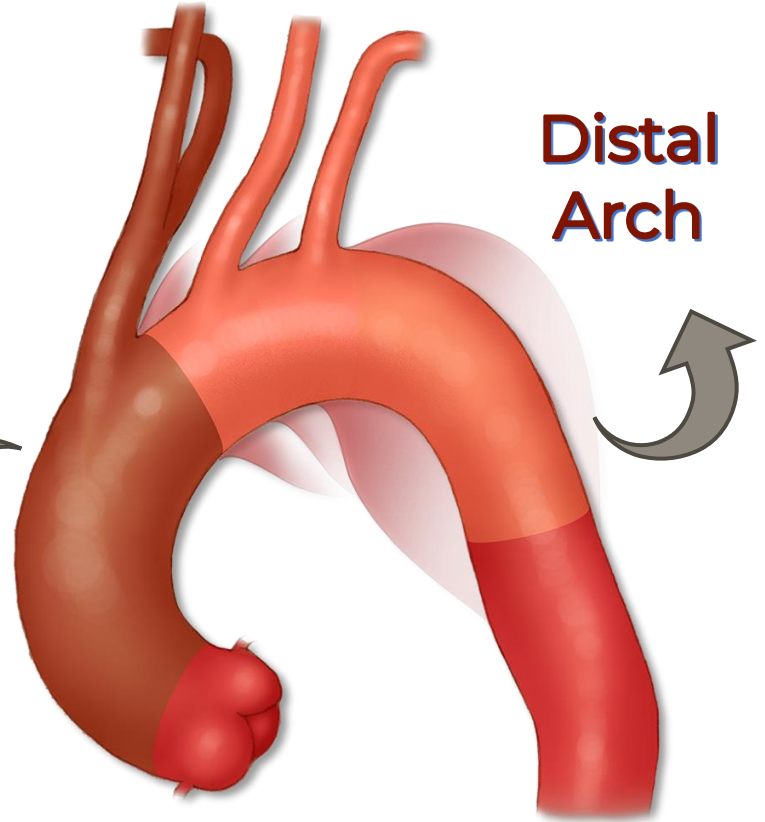
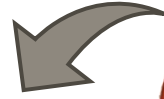
AK. Mirza

- **Consulting**
W.L. Gore, Cook Medical, Boston Scientific
- **Investigational use of devices**
- **Special thank you**
Gustavo Oderich MD

Landing zones

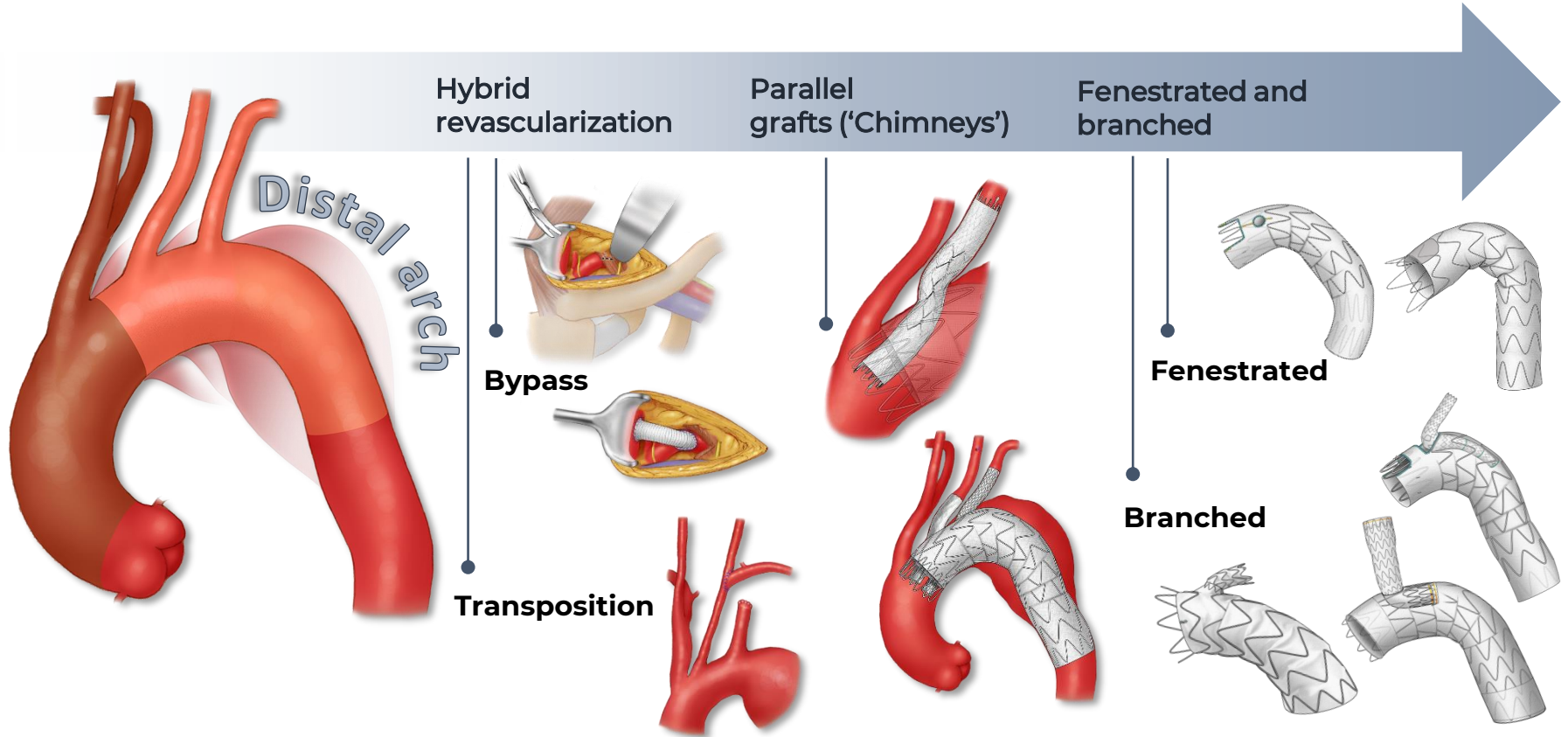


Proximal Arch

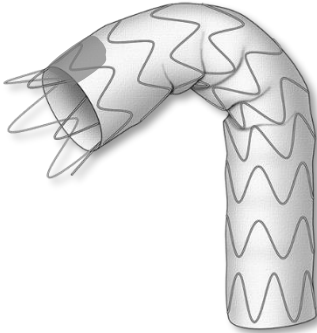
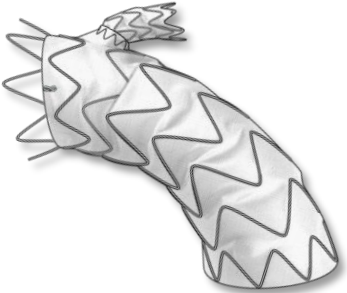
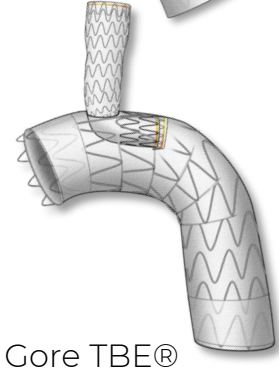


Distal Arch

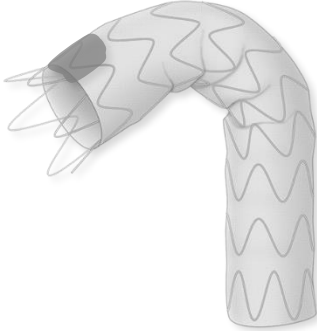
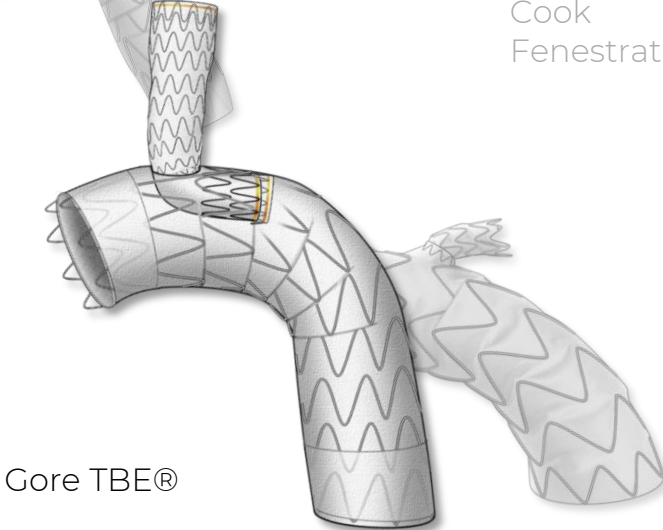
Left subclavian artery revascularization



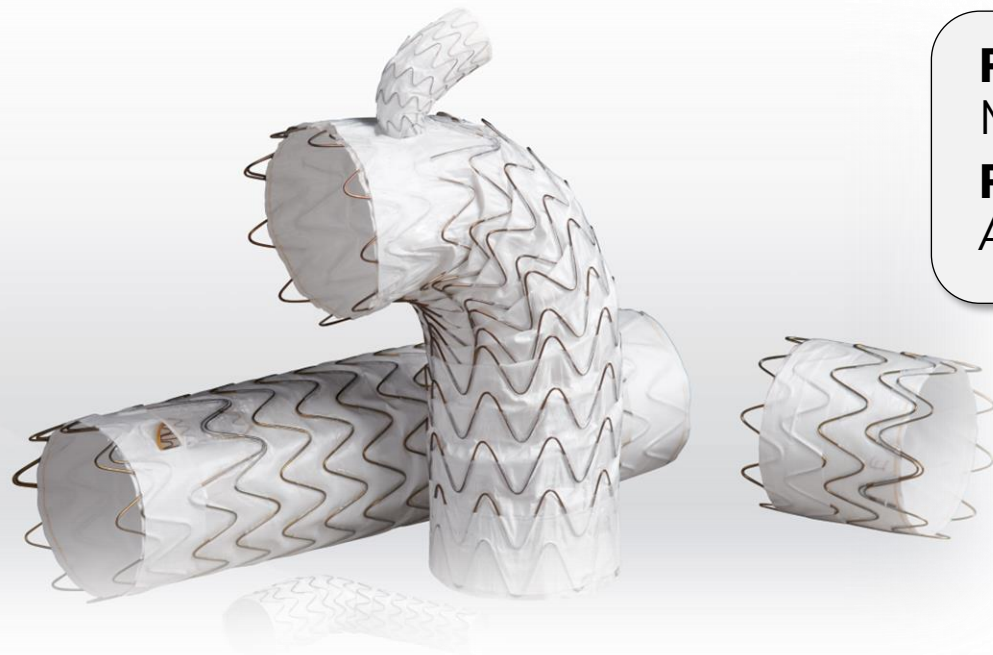
Landing zones



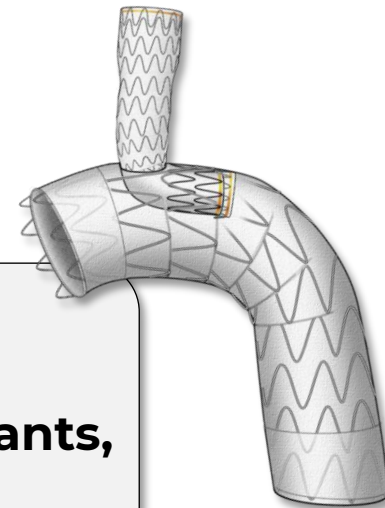
Landing zones



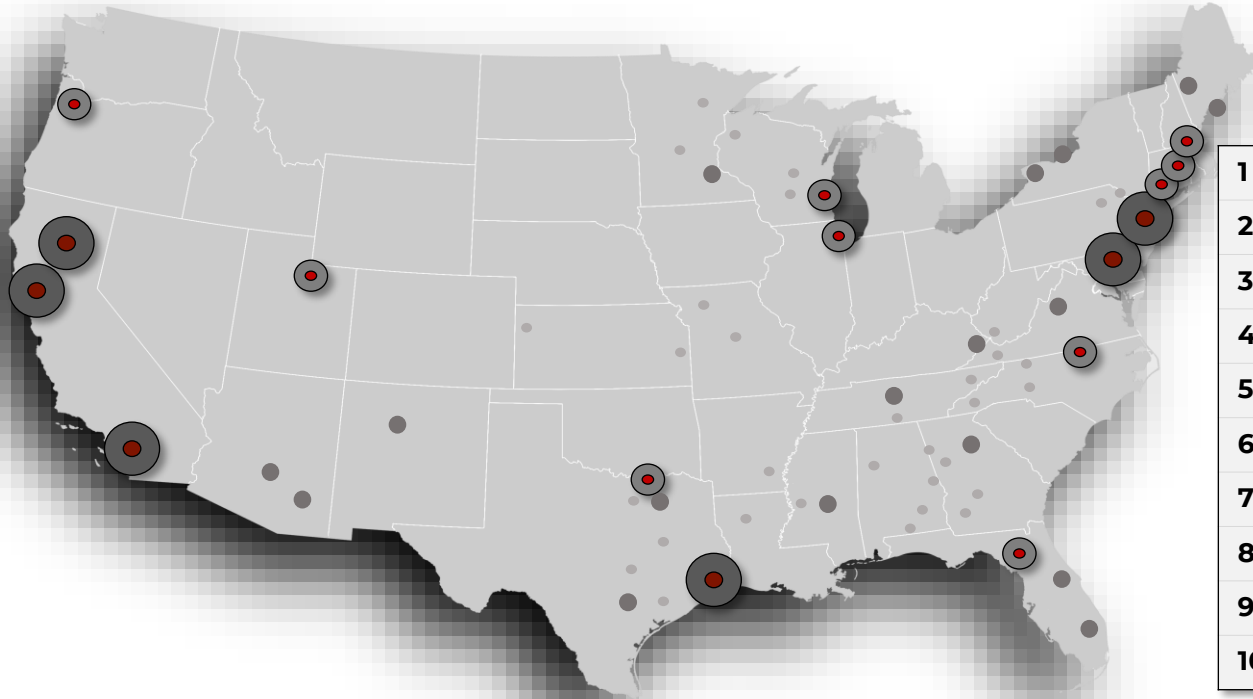
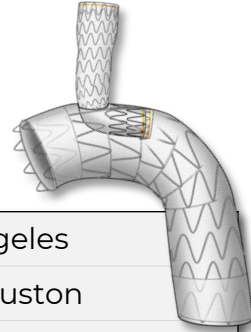
Distal arch options



FDA approval,
May 13, 2022
First U.S. implants,
August 2022

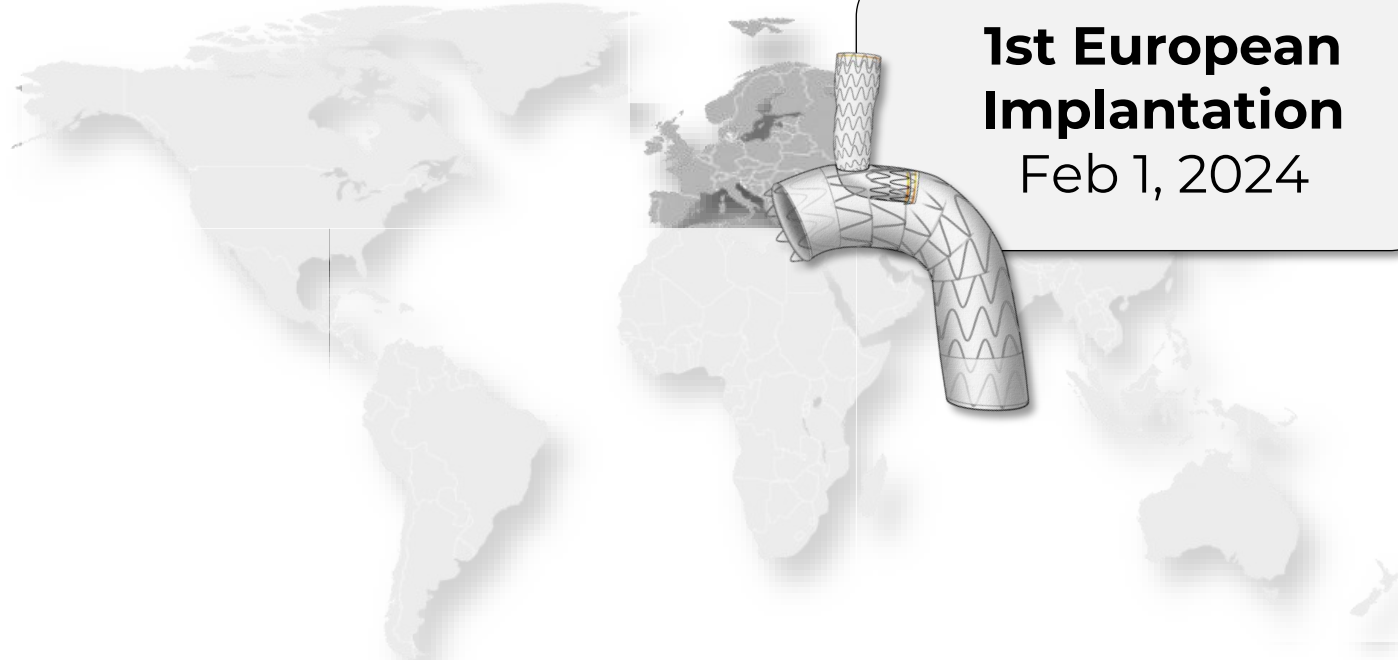


Gore® TAG® TBE case distribution in the U.S



- | | |
|----|--------------------------------|
| 1 | USC , Los Angeles |
| 2 | UTH-MH , Houston |
| 3 | Stanford , Palo Alto |
| 4 | UC Davis , Sacramento |
| 5 | U Maryland , Sacramento |
| 6 | U Penn , Philadelphia |
| 7 | Duke , Durham |
| 8 | U Colorado , Denver |
| 9 | MedStar Washington, DC |
| 10 | U Washington , St Louis |

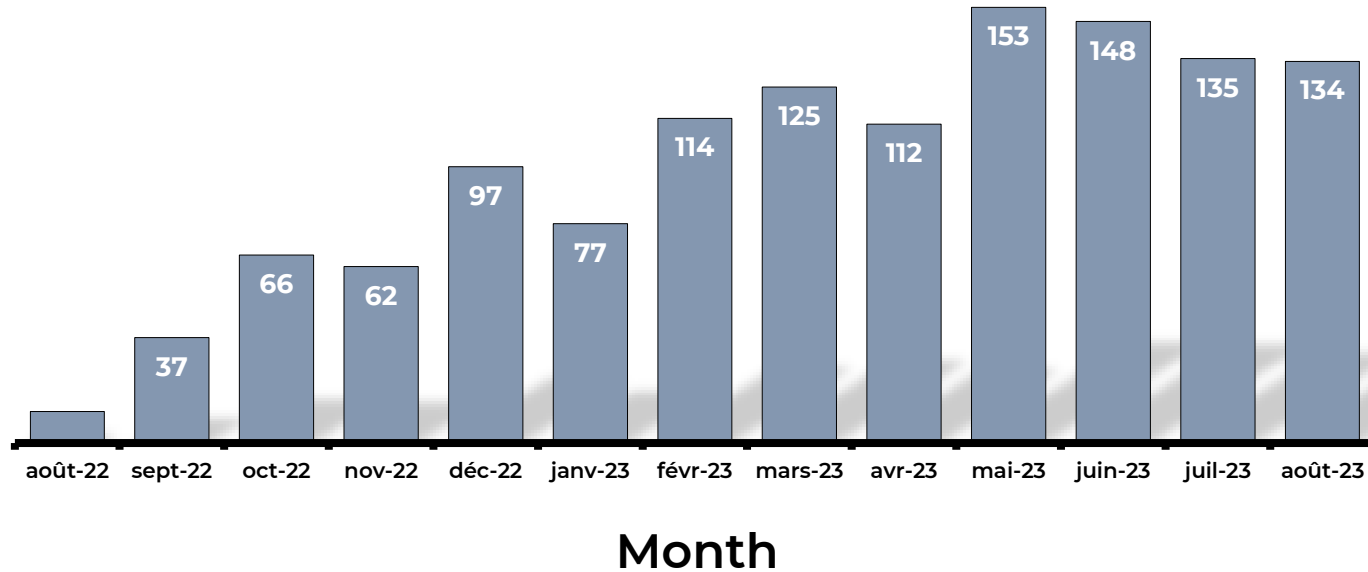
Gore® TAG® TBE First Implantation



**1st European
Implantation**
Feb 1, 2024

Gore® TAG® TBE cases per month in the U.S

1,271 patients treated in first year post-approval



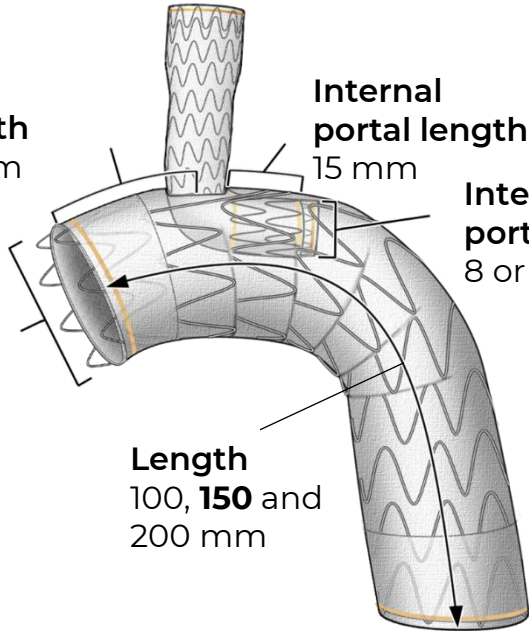
Aortic and side branch component

Aortic component

Proximal segment length
20, 25 or 40 mm

Diameter
21, 26, 30,
34, 37, 40,
and 45 mm

Length
100, **150** and
200 mm

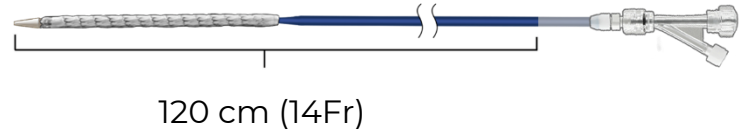
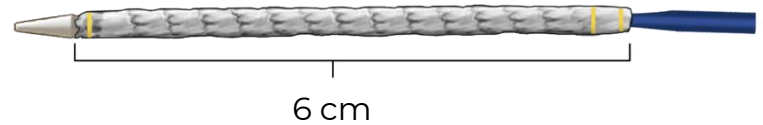
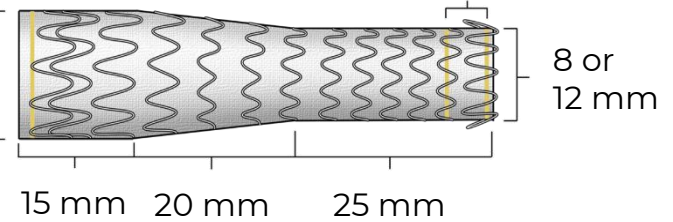


Internal portal length
15 mm

Internal portal diameter
8 or 12 mm

Side Branch component

Diameter
8, 10, 12,
15, 17 and
20 mm

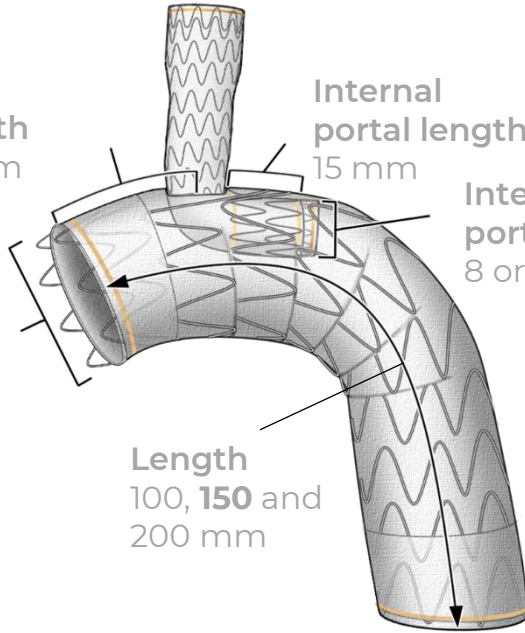


Aortic and side branch component

Aortic component

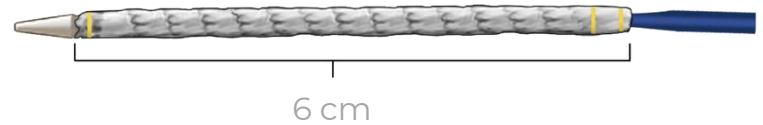
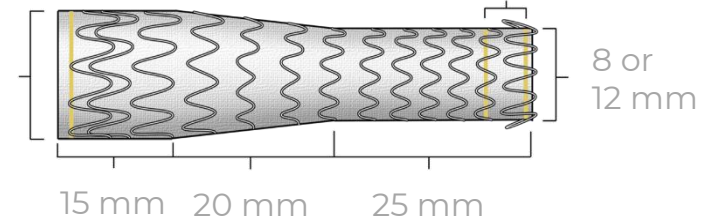
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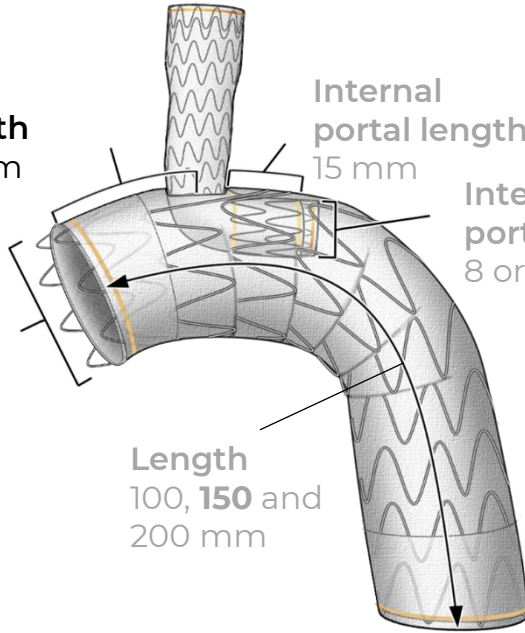


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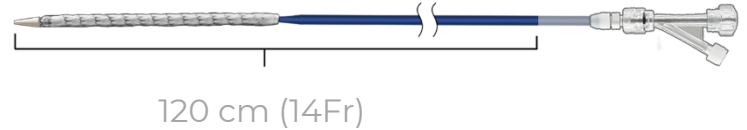
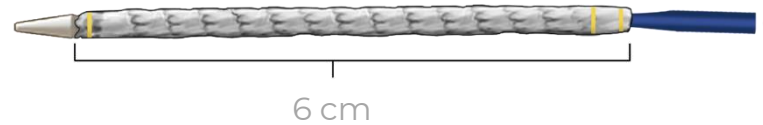
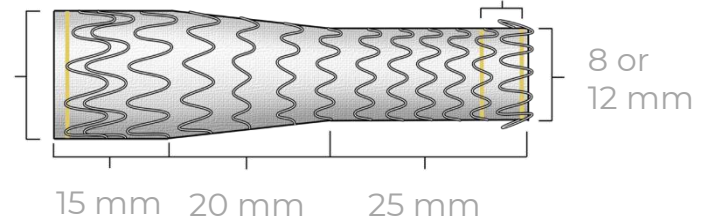
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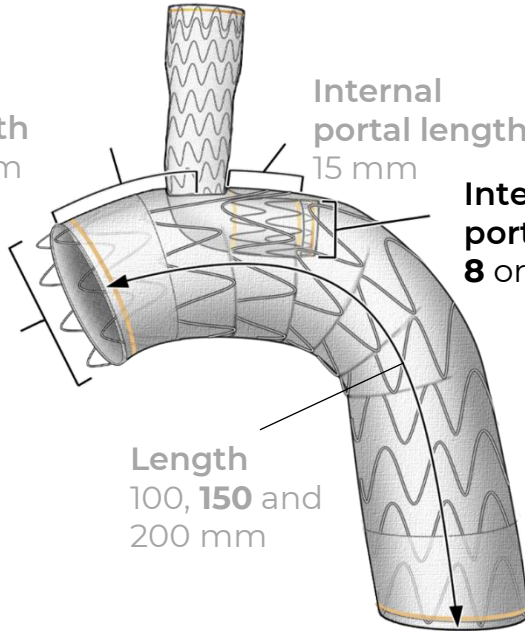


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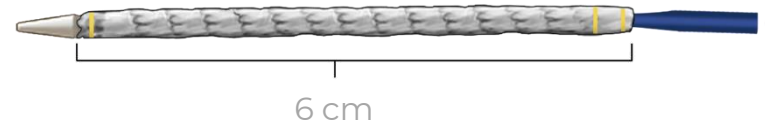
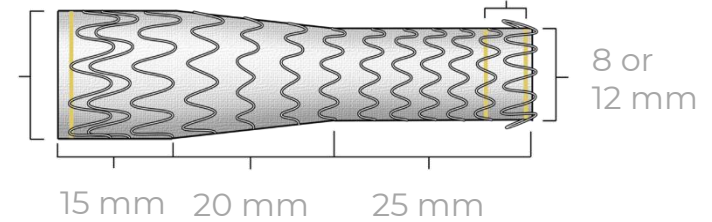
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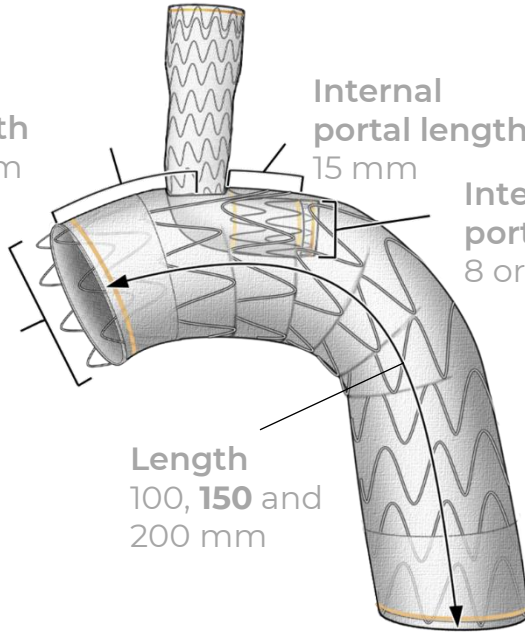


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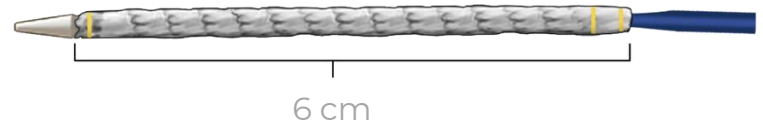
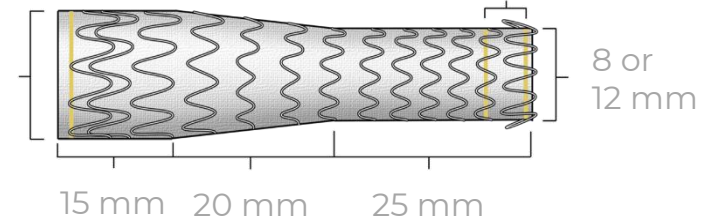
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Anatomical criteria (Zone 2)

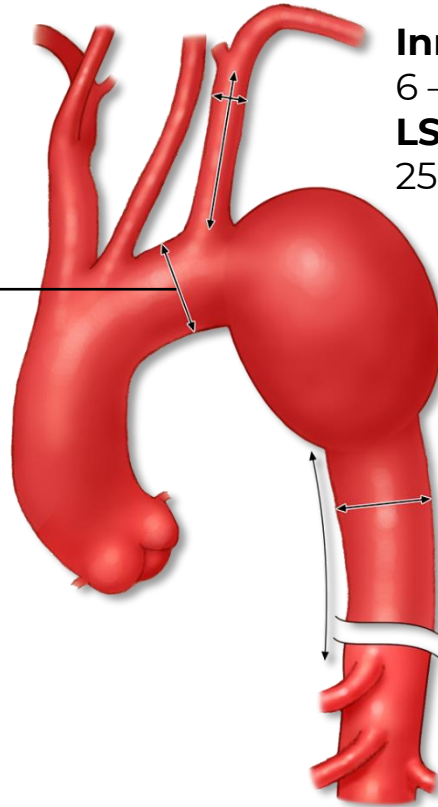
Instructions for use

Inner Aortic Diameter

16 – 42 mm

Landing zone

≥ 20 mm length of non-aneurysmal aorta with no dissection, thrombus or calcium



Inner LSA Diameter

6 – 18 mm

LSA length

25 – 30 mm

Proximal Segment Length

8 mm portal: ≥20-25 mm

12 mm portal: ≥40 mm

Proximal Covered Length

8 mm portal: ≥15-20 mm

12 mm portal: ≥33-36 mm

Surgical grafts

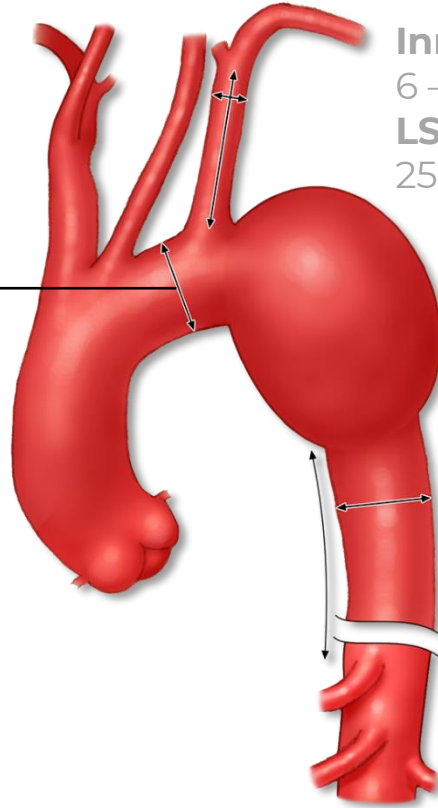
≥ 20 mm to distal anastomosis

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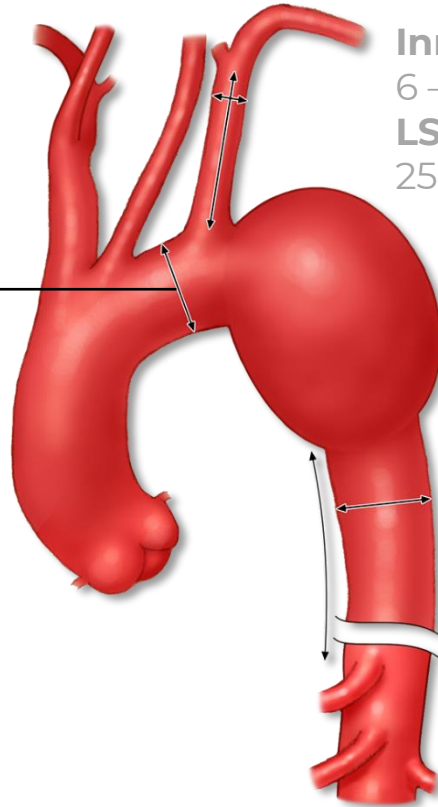
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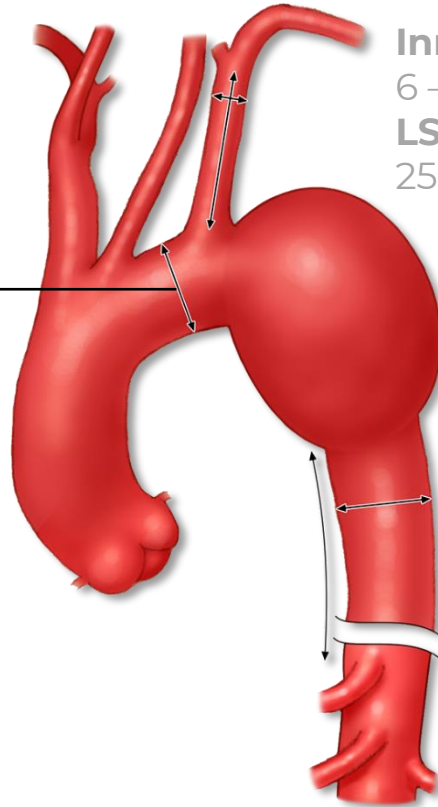
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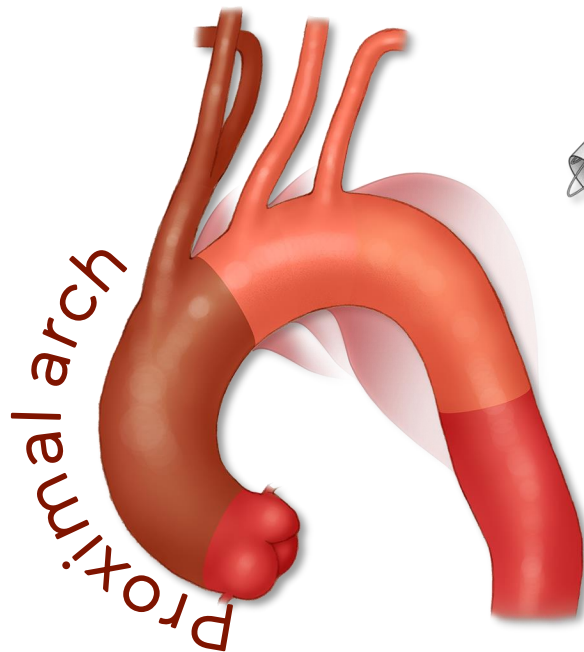
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≥ 20 mm to distal anastomosis

Midterm Outcomes of Endovascular Repair of Aortic Arch Aneurysms with the Gore Thoracic Branch Endoprosthesis

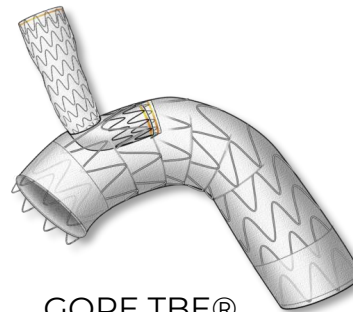
Nathan L. Liang ^{a,*}, Michael D. Dake ^b, Michael P. Fischbein ^c, Joseph E. Bavaria ^d, Nimesh D. Desai ^d, Gustavo S. Oderich ^e, Michael J. Singh ^a, Mark Fillinger ^f, Bjoern D. Suckow ^f, Jon S. Matsumura ^g, Himanshu J. Patel ^h, Michel S. Makaroun ^a

- 40 patients (31 Zone 2, 9 Zone 0)
- Mean follow up, **3.8 years**
- No device migration, fracture, aortic rupture
- Freedom from **reintervention, 97%** at 3-years
- **Primary patency, 95%** at 3-years
- 3 >30-days cerebrovascular events (2 unrelated)
- Patient survival, 84% at 3-years

Proximal arch options



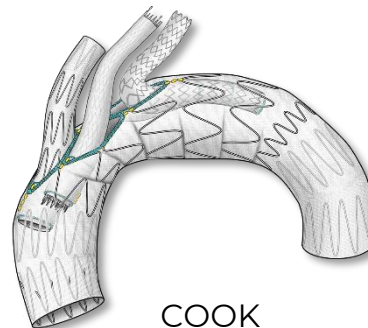
INOUE



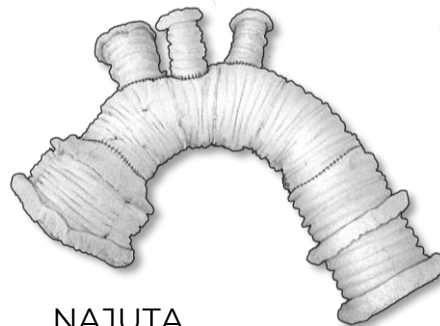
GORE TBE®



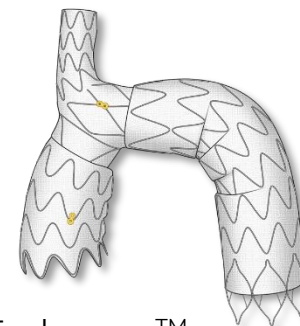
BOLTON®
Arch Branch



COOK
a-Branch®



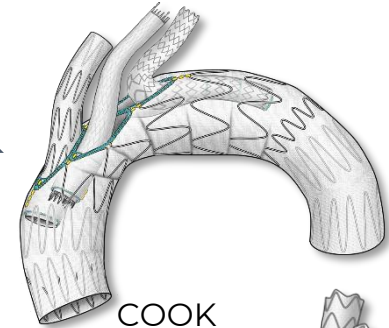
NAJUTA



Nexus Endospin™

Double and triple branch devices

- No cervical debranching
- Antegrade or retrograde branches
- Total percutaneous technique
.....
- More arch manipulation
- Less forgiving to ascending aortic graft kinks
- Wound complications with cervical incisions



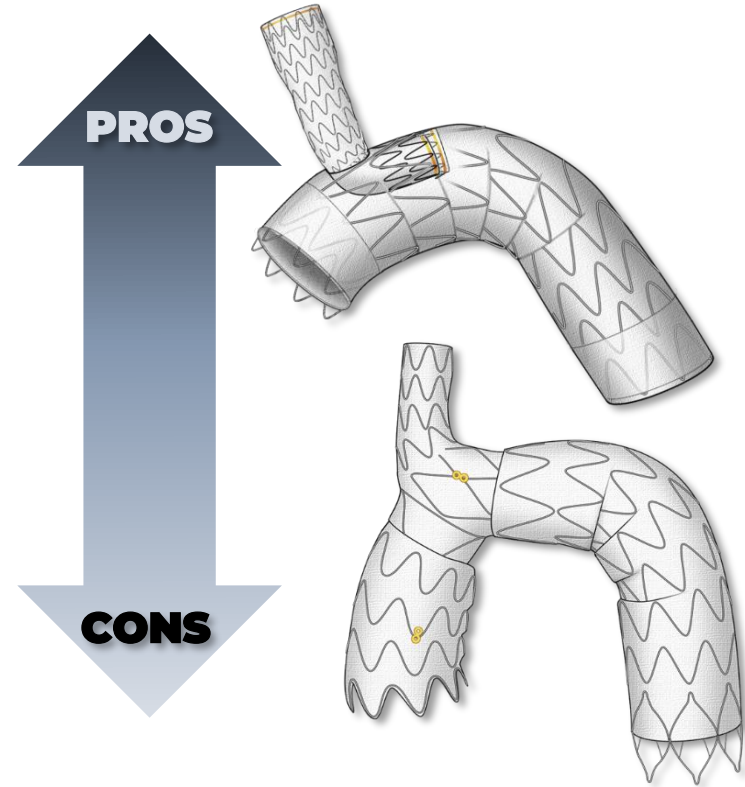
COOK
a-Branch®



BOLTON®
Arch Branch

Single branch devices

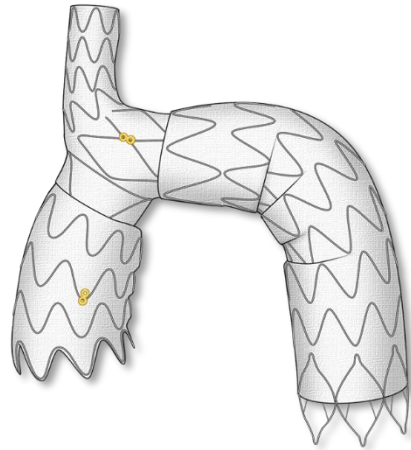
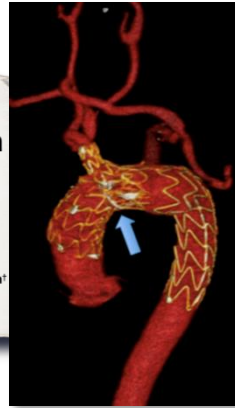
- Less arch manipulations
- Potential for single branch cerebral protection
- High flow
-
- **Cervical debranching**
- Patency based on single vessel
- Retrograde configuration (Gore)
- Component separation (Nexus)



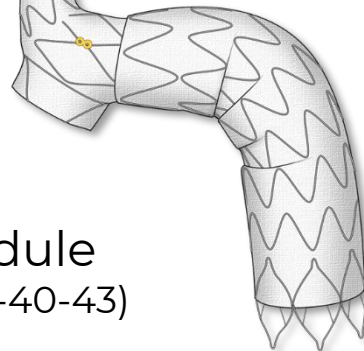
Nexus™ Endospan arch device

Three-year follow-up of aortic arch endovascular stent grafting with the Nexus device: results from a prospective multicentre study

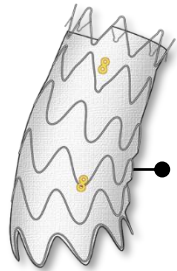
Augusto D'Onofrio ^{a*}, Mario Lachat ^b, Nicola Mangialardi ^c, Michele Antonello ^a, Hubert Schelzig ^d, Lyubov Chaykovska ^b, Andrew Hill ^e, Andrew Holden ^e, Thomas Lindsay ^f, Kong Ten Tan ^f, Matteo Orrico ^c, Sonia Ronchey ^g, Gabby Elbaz Greener ^h, Paul Hayes ⁱ, Giulia Lorenzoni ^a, Gino Gerosa ^{a†} and David Planer ^{h††}



1st Module
(IA Br \varnothing 14-17-20)



2nd Module
(Asc \varnothing 36-40-43)

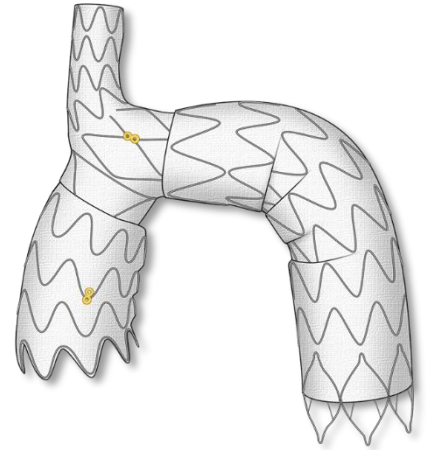


- 28 patients (72±6 years-old)
- 100% technical success
- 30-day mortality, 7%
- Stroke, 3.6% (disabling)
- No component separation between arch modules

TRIOMPHE IDE


(Investigational Device Exemption)

- Presented at annual STS meeting, Jan 2024
- 30-day data for first 22 patients
- 30 centers in the United States
- Chronic dissection 13, aneurysm 8 , PAU 1
- Mean age 68 ± 9 years
- 30-day mortality 9.1%
- No disabling stroke



Nexus™ Endospan arch device

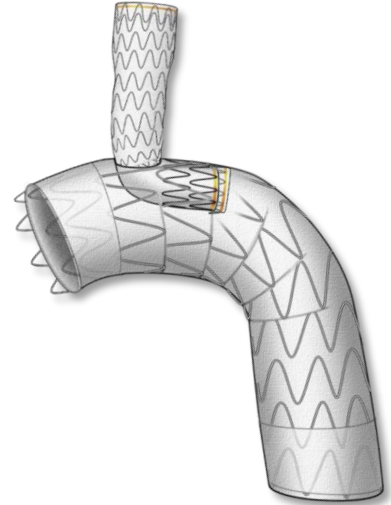
Nexus™ Duo

- Custom-made vs. Off-the shelf
- Integrated innominate Br.
- **Retrograde preloaded** LCCA or LSA Br. 
- Allows a total transfemoral approach for delivery of all components
- Experience with first 10 patients at LINC 2023



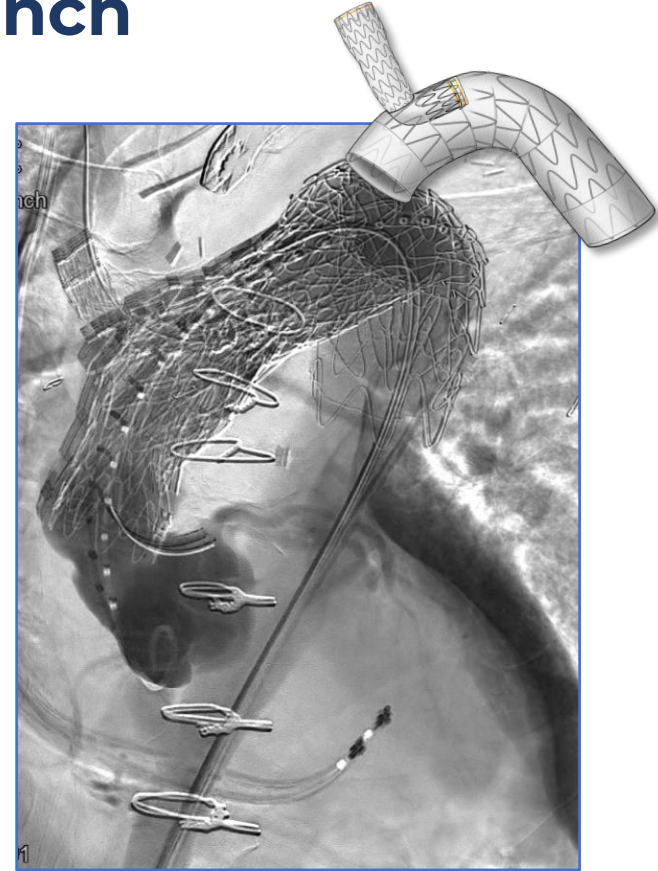
Zone 0 Gore® TAG® Thoracic Branch Endoprosthesis (TBE)

- Not currently FDA-approved
- Performed with cervical debranching
- 12mm portal device provides up to 4cm of proximal coverage
- ARISE II Pivotal study
 - Gore® Ascending Stent Graft with TBE
 - Isolated lesions, chronic residual type A dissections
 - First patient enrolled in December 2023



Zone 0 Gore® TAG® Thoracic Branch Endoprosthesis (TBE)

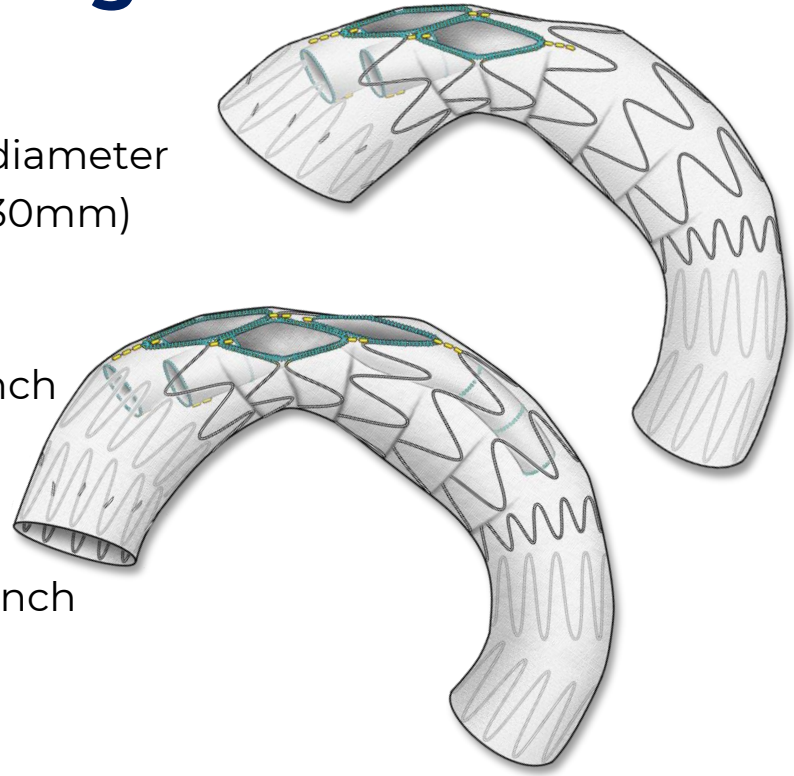
- 75 M with **prior ascending repair** for acute type A dissection
 - zone 3 TEVAR
- **Enlarging anastomotic pseudoaneurysm** and dilatation of the arch
- Nonoperative candidate
 - Zone 0 TBE
 - Proximal and distal extensions with Gore cTAG



Courtesy of Steve Maximus, UC Davis

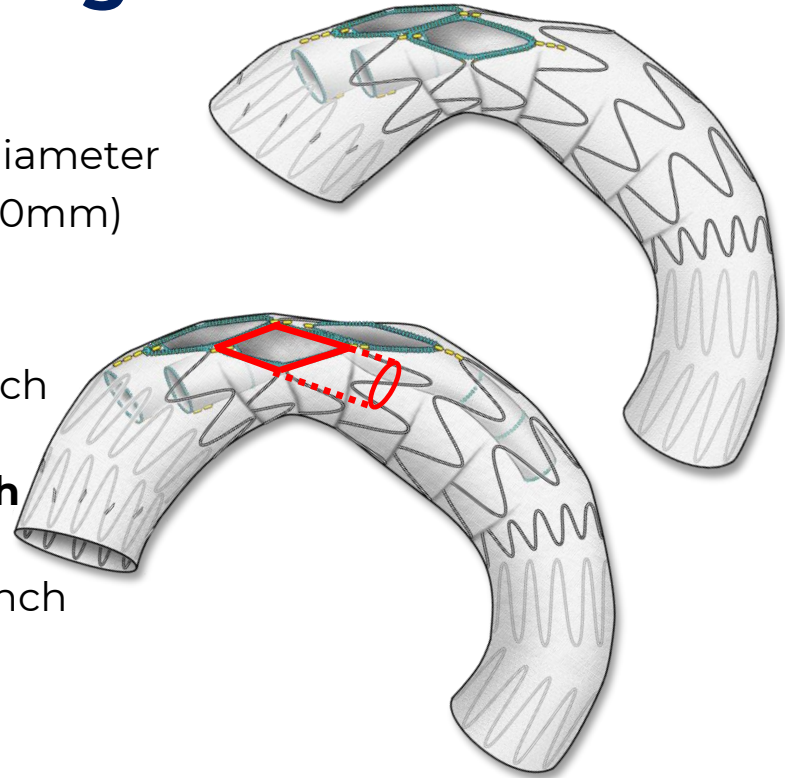
Cook arch branch stent-graft

- Stent-graft design parameters
 - 34 to 46mm proximal and distal diameter
 - Tapered mid-segment (26, 28 or 30mm)
 - Low-profile fabric
 - 1 or 2 proximal sealing stents
 - Innominate inner antegrade branch
12 x 21 mm (12:30)
 - L carotid inner antegrade branch
8 x 21 mm (11:30)
 - L subclavian inner retrograde branch
10 x 21 mm (12:30)
 - Preloaded catheter
 - 22-24 Fr delivery system



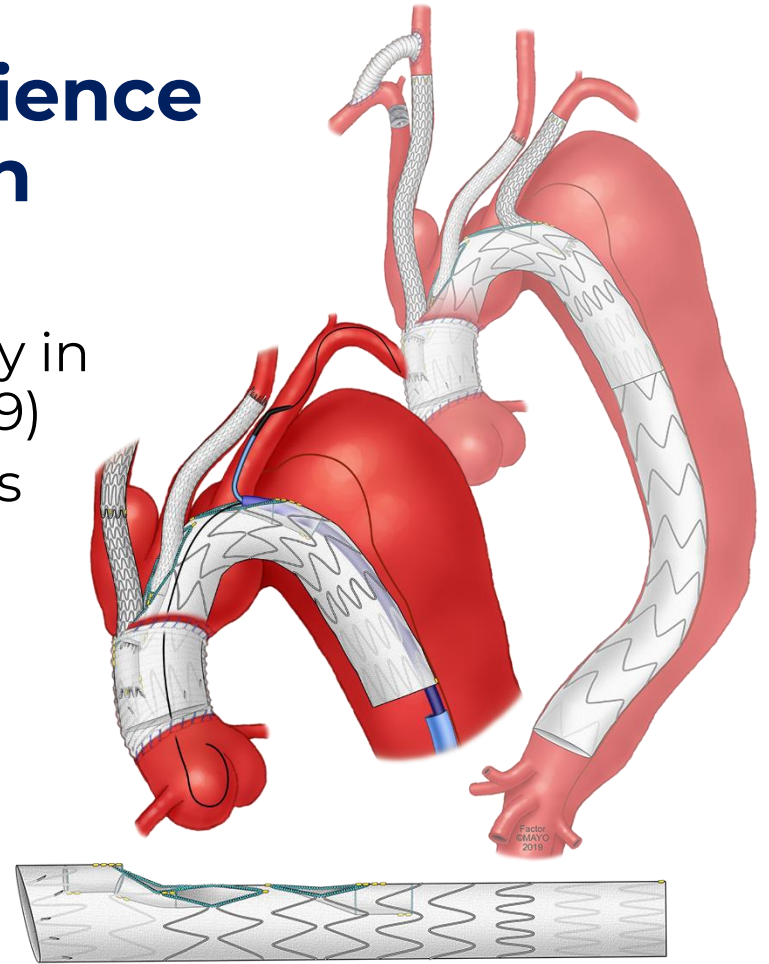
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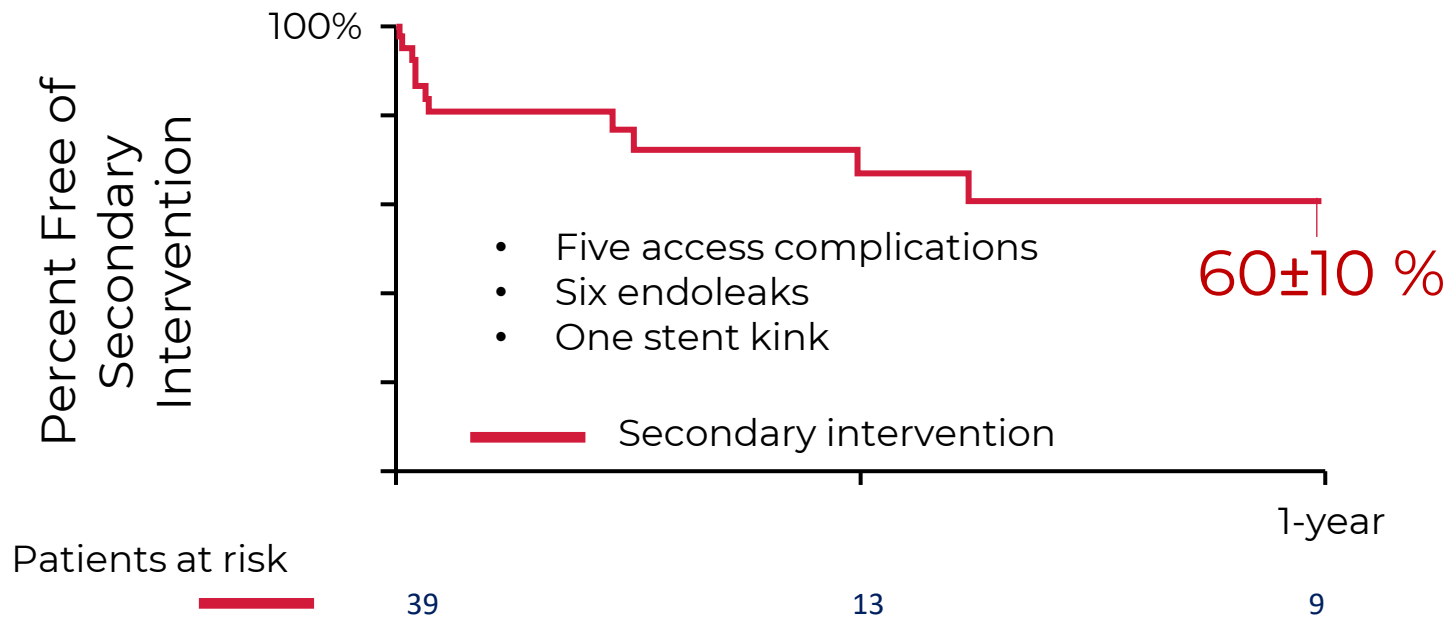


Multicenter global experience with 3-vessel arch branch device

- Multicenter global feasibility study in eight academic centers (2016-2019)
- 3-vessel inner branch arch devices with retrograde LSA branch
- 39 patients (mean age, 70)
- In-hospital mortality, 5%
- Stroke, 5%
- Technical success, 100%
- No LSA branch occlusions



Freedom from secondary intervention





JACC: CASE REPORTS

Total Transfemoral Percutaneous Endovascular Aortic Arch Repair Using 3-Vessel Inner Branch Stent-Graft

Emanuel R. Tenorio, MD PhD, Thanila A. Macedo, MD, Laura Ocasio, MD, Marina Dias Neto, MD PhD, Guilherme B. Barbosa Lima, MD, Aidin Baghbani-Oskouei MD, Anthony L. Estrera, MD, Abhijeet Dhoble, MD, Shaofeng Zhou, MD, Gustavo S. Oderich, MD

Early Outcomes on Triple-Branch Arch Device With Retrograde Left Common Carotid Branch: A Case Series

[Petroula Nana, MD, PhD](#) , [Thomas Le Houérou, MD](#), [...], and [Stéphan Haulon, MD, PhD](#)   [View all authors and affiliations](#)

[OnlineFirst](#) | <https://doi.org/10.1177/15266028231195758>

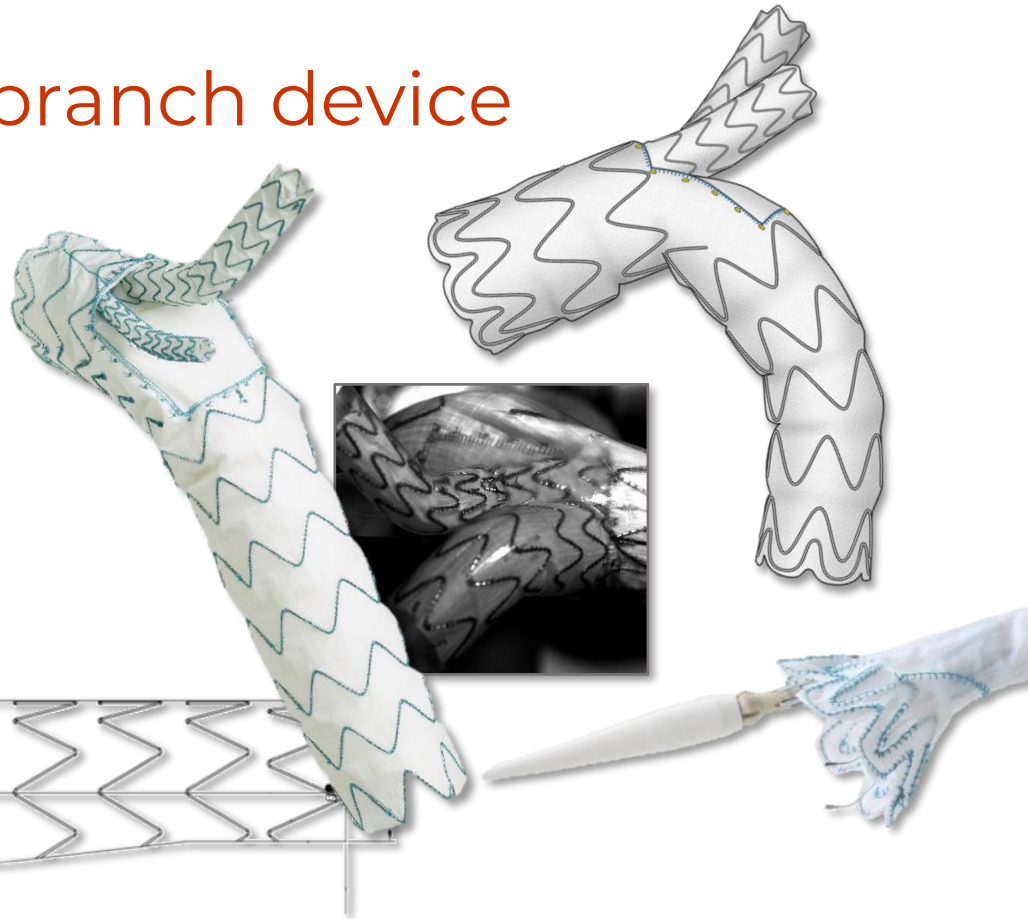
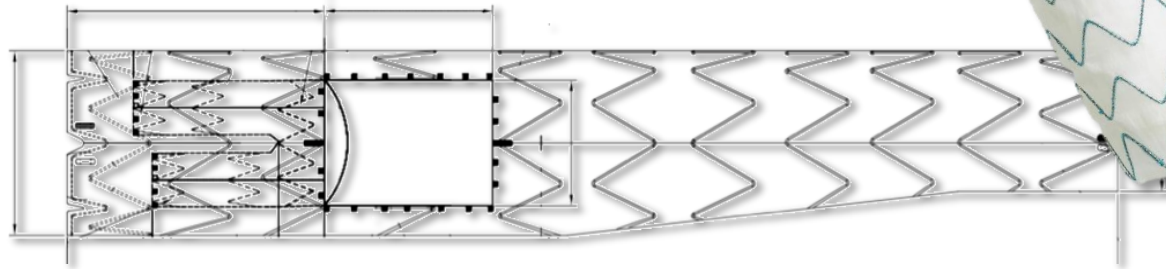


- 8 elective patients (87.5% male, 72.3 years old)
- 5 patients had prior open repair for type A dissection
- Percutaneous femoral & axillary access in all but 3
 - Three patients with right common carotid cutdown
- Technical success 100%
- **Femoral access** for **LCCA** bridging stent in all patients
- No death or **cerebrovascular** event at 30 days

Terumo Aortic arch branch device

- Prox diameter: 32-48mm
- Dist diameter: 22-48mm
- Branch diameter: 12mm

Prox length Tunnel length
45-60mm 50mm

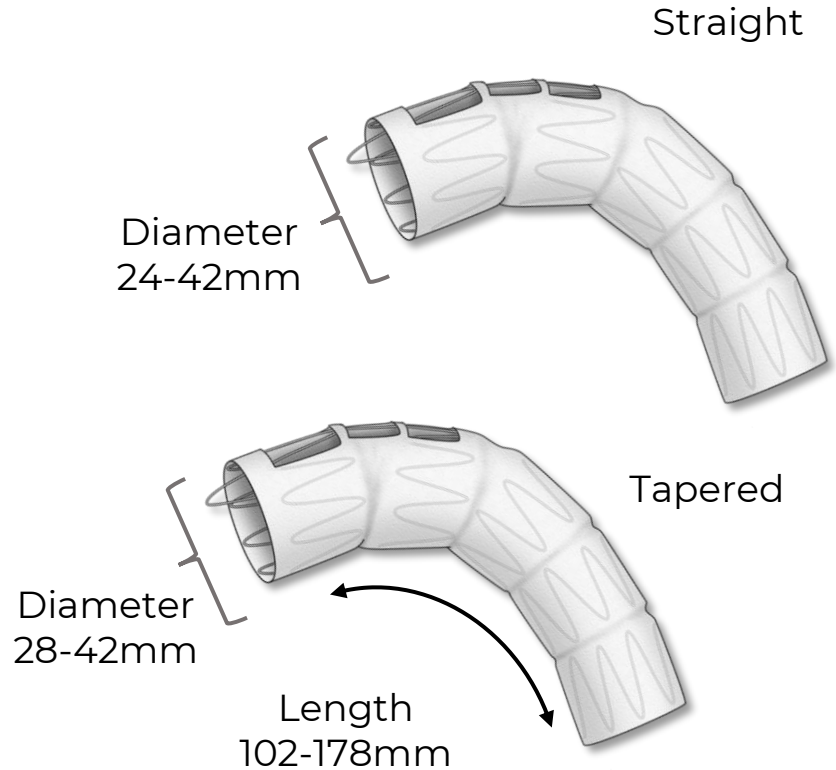


Terumo Aortic arch branch device



Najuta thoracic stent graft

- Semicustom-made **fenestrated** stent-graft
- Approved for use in Japan in 2013
- CE marked in Europe in 2017
- Deployed over a right brachial-femoral wire
- Used in particular for pathology of lesser curve



Conclusions

- There is increasing experience with dedicated platforms for endovascular repair of arch pathology
- Zone 2 repair has increased rapidly in the US since commercial availability of a thoracic branch, in all settings
- Single branch platforms provide an off-the-shelf option for total arch repair when coupled with cervical debranching
- Double or triple branch devices can avoid the risks with cervical debranching, but carry the risk of access site issues
- Retrograde branch configuration in double/triple branch devices may be a natural evolution to facilitate efficient transfemoral bridging stent delivery

Thank You!



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