THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING
MARCH 21 & 22 2024
COPENHAGEN/MALMÖ
SCANDIC TRIANGELN, MALMÖ

LOW PROFILE TEVAR DEVICES

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EVANGELISMOS GENERAL HOSPITAL OF ATHENS, GREECE

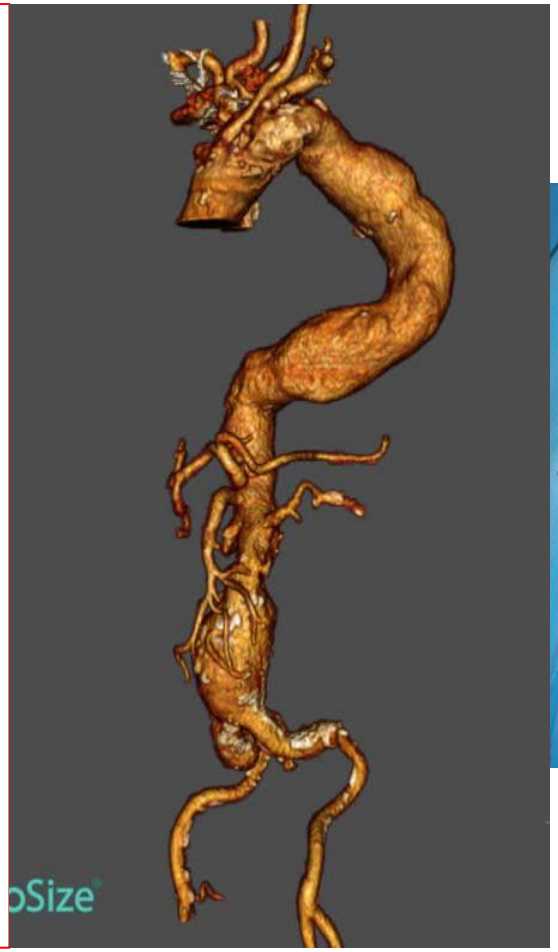
ΓΕΝΙΚΟ ΝΟΣΟΚΟΜΕΙΟ ΑΘΗΝΩΝ
Ο ΕΥΑΓΓΕΛΙΣΜΟΣ

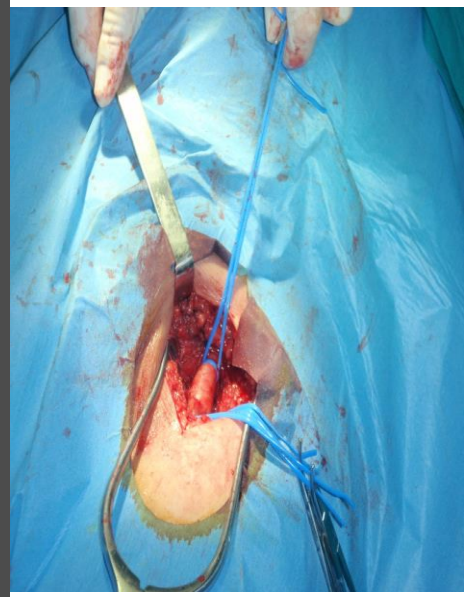
- Older generation thoracic stent grafts:

1. GORE TAG
2. MEDTRONIC CAPTIVIA
3. COOK ZENITH TX1,2
4. JOTEC E-VITA
5. BOLTON RELAY

- Had large delivery systems up to 26F OD

- Challenging or even impossible to cross heavily atherosclerotic-stenosed and/or tortuous iliac arteries
- Open femoral cut and/or limited percutaneous approach





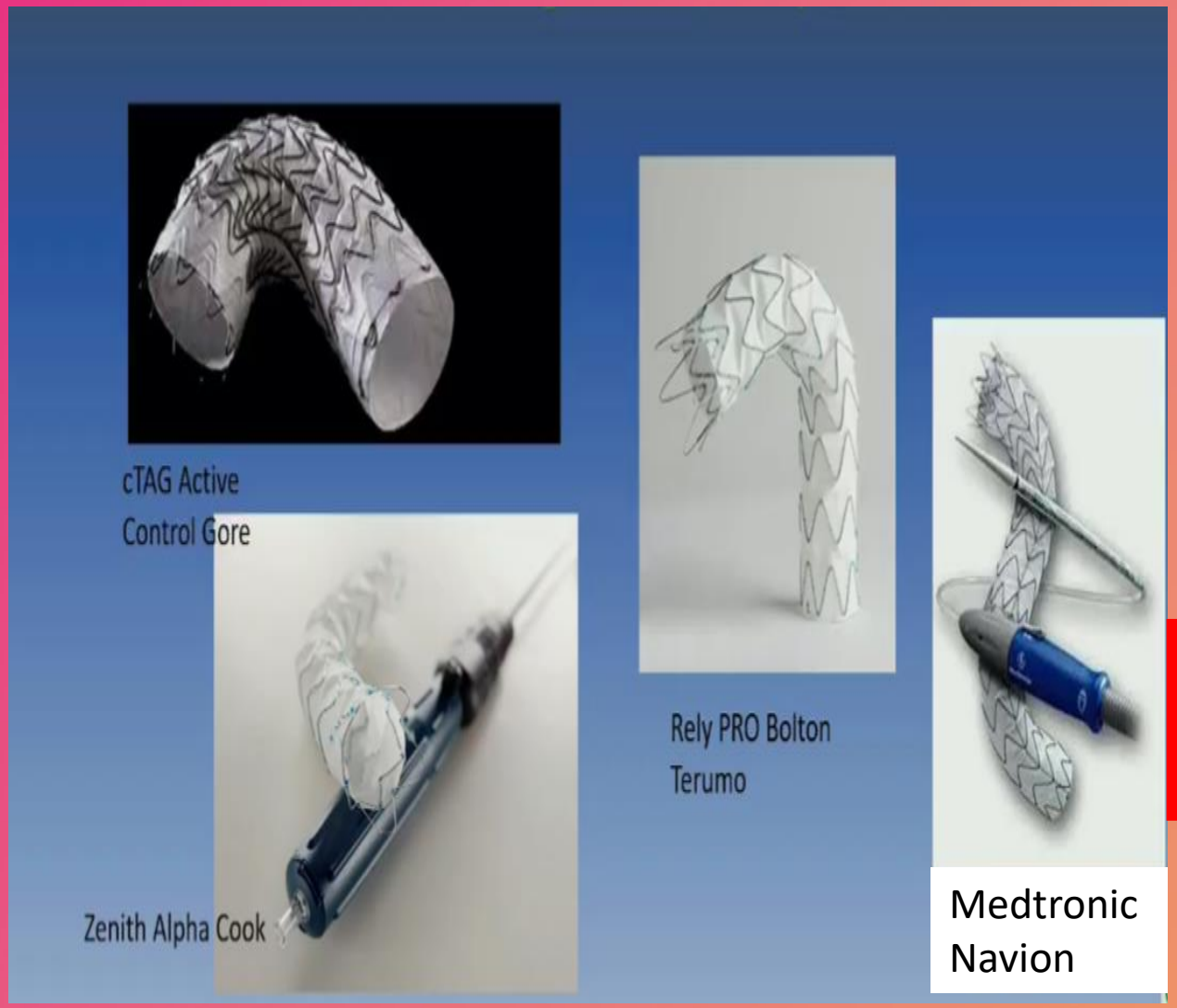
MARCH 21 & 22 2024

COPENHAGEN/MALMÖ

SCANDIC TRIANGELN, MALMÖ

Older stent graft generations	Newer lower profile stent graft generations
Access related Complications: • Artery rupture, perforation, dissection, post op stenosis, A-V fistulas, Haematoma • Aortic dissection • Distal embolization	**Percutaneous Access** • less pain, less scar, less complications

New lower profile stent graft generations



Observational Study > Vascular. 2022 Dec;30(6):1069-1079.
doi: 10.1177/17085381211051486. Epub 2021 Dec 31.

Endoleak outcomes with different stent-graft generations in a 25-years thoracic endovascular aortic repair experience

Stefano Gennai [1], Nicola Leone [1], Luigi A Maria Bartolotti [1], Tea Covic [1], Antonio Lauricella [1], Francesco Andreoli [1], Giuseppe Saitta [1], Roberto Silingardi [1]

Results: A total of 509 TEVAR were included with a 44.3 ± 42.5 months mean follow-up.

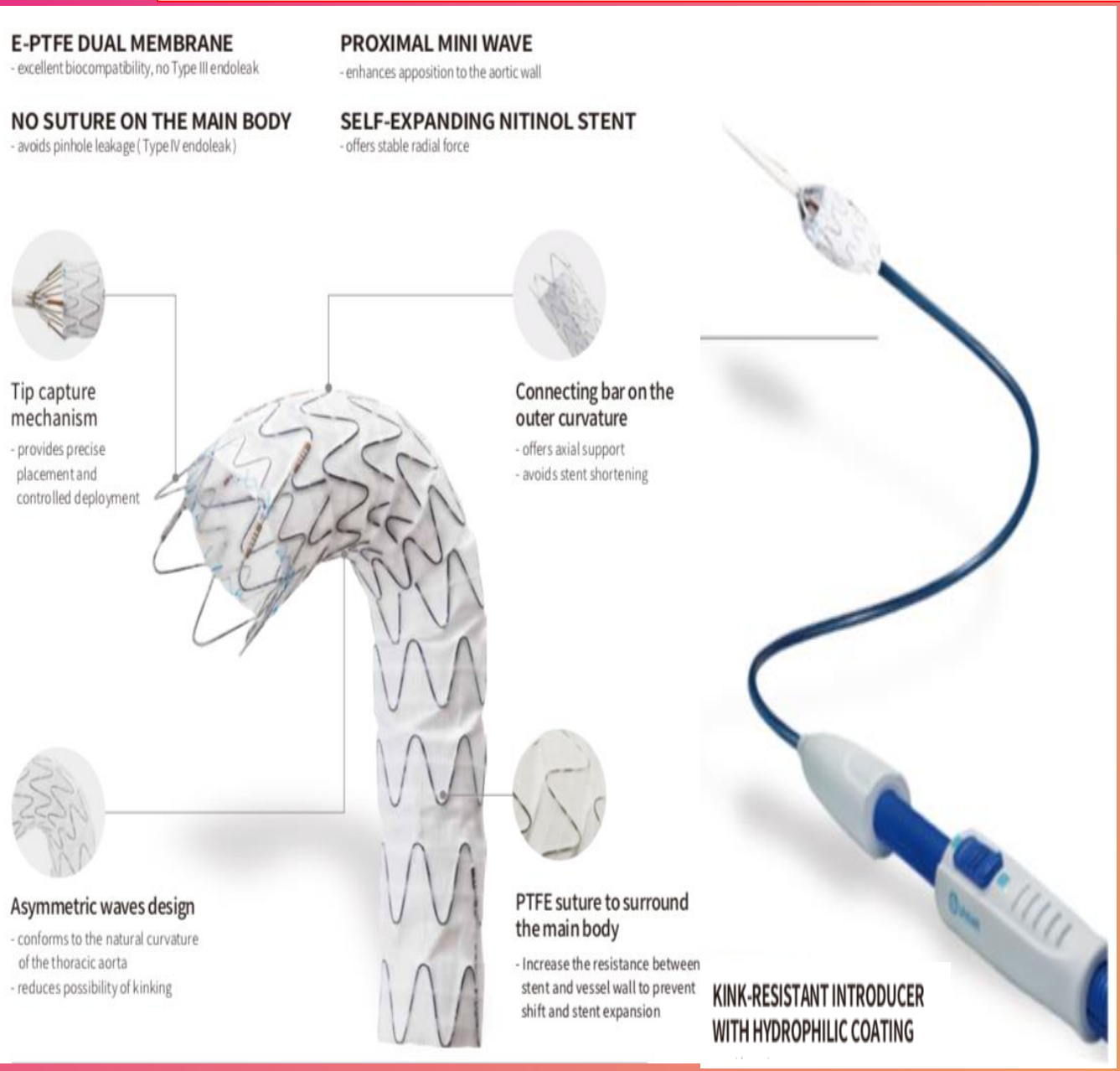
Conclusion: Endoleak occurred in a non-negligible percentage of TEVAR patients. A significant reduction of endoleak incidence over evolving stent-grafts generations was registered. Newer stent-graft generations demonstrated better long-term endoleak. Data about long-term outcomes require ongoing updates to prove both the reliability and the durability of newer stent-graft generations.

COOK- Zenith Alpha™ Thoracic Endovascular Graft : 18-22F

- Non-aneurysmal aortic segments (fixation sites) proximal and distal with a length of at least 20 mm, and with a diameter measured outer-wall-to-outer-wall of no greater than 42 mm and no less than 20 mm

- Tight woven polyester and nitinol stents
- 24-46mm diameter, straight or tapered
- Prox and/or distal bare rounded metal stents
- 18-22F
- Custom made program available

LIFETECH SCIENTIFIC - NEW ANKURA™ THORACIC STENT GRAFT : 20-22F



- Straight grafts: 20-46mm diameter
  40-200mm length
- Tapered grafts: 4,6, and 8 mm diameter difference,
  160-180-200mm length
- <u>LOWER PROFILE 20-22 Fr Outer Diameter</u>
  (instead of 21-24Fr the older generation)

ELSEVIER

Journal of Vascular Surgery
Volume 69, Issue 4, April 2019, Pages 996-1002.e3

Clinical research study
Thoracic aortic disease

Repair of descending thoracic aortic aneurysms with Ankura Thoracic Stent Graft

Theodoros Kratimenos MD, MSc [a], Constantine N. Antonopoulos MD, MSc, PhD, FEBVS [b], Dimitrios Tomais MD, MSc [a], Panagiotis Dedeilias MD, MSc, PhD, FETCS [b], Vasileios Patris MD, MSc [b], Ilias Samiotis MD, MSc [b], John Kokotsakis MD, MSc, PhD, FETCS [b], Dimosthenis Farsaris MD [a], Michalis Argiriou MD, MSc, PhD, FETCS [b]

TERUMO AORTIC - RELAY PRO 19-22F, RELAY PRO NBS: 19-23F

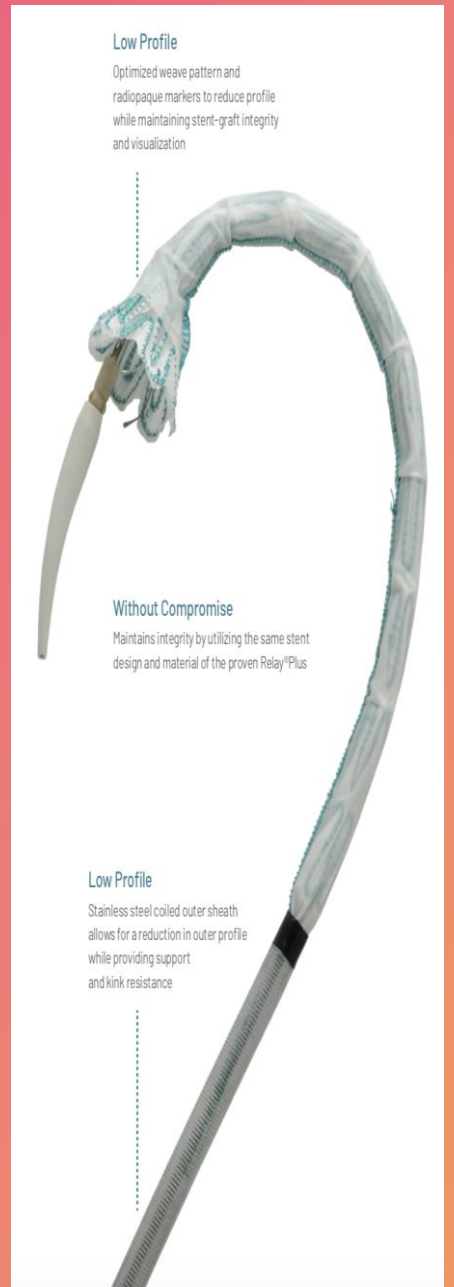
Graft material is a tight woven polyester

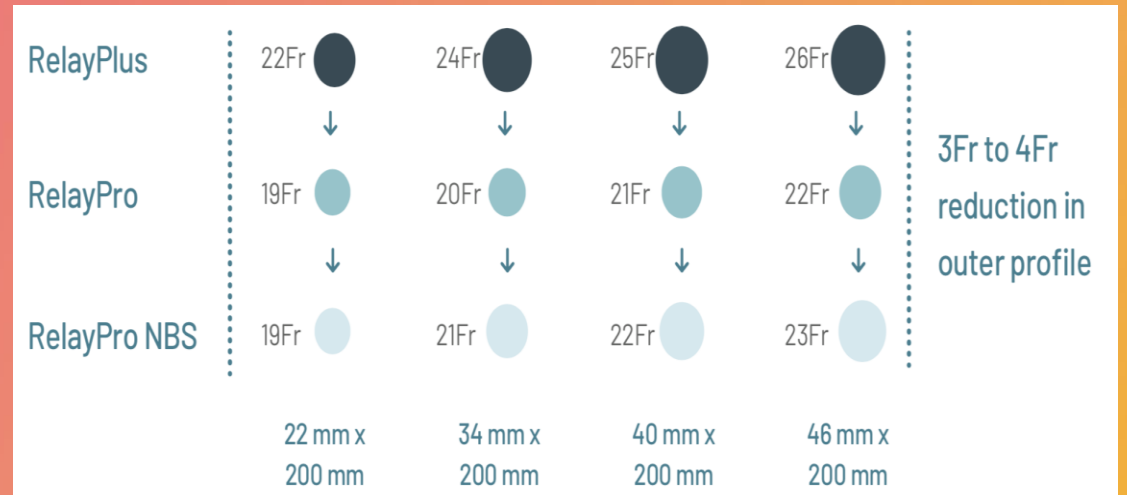
Relay®Pro offers a low profile system without compromising performance. The platform utilizes the same stent design, materials, and foundational Dual Sheath Technology of the proven Relay®Plus.

The Relay®Pro represents a next generation of the Relay stent-graft family that has over 15 years of experience, over 20,000 patients implanted and robust clinical data. The Relay®Pro device has been studied in a prospective, multicenter, non-blinded, non-randomized, international clinical study* of 110 subjects and showed: [1]

- 1.8% Stroke at 30 days
- No Mortality at 30 days
- 1.2% Type Ia and 1.2% Type Ib Endoleaks at 12 months
- No Migrations at 12 months
- No Fractures at 12 months
- No Conversion to open surgery at 12 months
- No Aneurysm ruptures at 12 months

* Clinical study data based on patients treated only for aneurysms and PAUs in the descending thoracic aorta.
[1] All data comes from the Relay®Pro Aneurysm IDE study: www.accessdata.fda.gov/cdrh_docs/pdf20/P200045B





- **14% profile reduction**
  Optimised radiopaque marker positioning
- **24% profile reduction**
  New thin wall coiled primary introducer outer sheath
- **21% profile reduction**
  Reduction of inner sheath diameter

GORE: C-TAG with Active Control System,
21-45mm diameter, 18-22F introducer sheath, 24F for 45mm diameter grafts

Observational Study > J Endovasc Ther. 2020 Jun;27(3):421-427.
doi: 10.1177/1526602820913007. Epub 2020 Mar 20.

One-Year Results From the SURPASS Observational Registry of the CTAG Stent-Graft With the Active Control System

Giovanni Federico Torsello [1,2], Angeliki Argyriou [1], Konstantinos Stavroulakis [1], Michel J Bosiers [1], Martin Austermann [1], Giovanni B Torsello [1]; SURPASS Registry Collaborators

- **Conclusion:** In the SURPASS registry, the use of the CTAG device with ACS showed promising outcomes despite the challenging pathologies. The new delivery system enables a controlled staged delivery with in situ adjustments during positioning, facilitating the treatment of complex aortic disease.

U.S. IDE Clinical Trials: Five year data across ALL etiologies

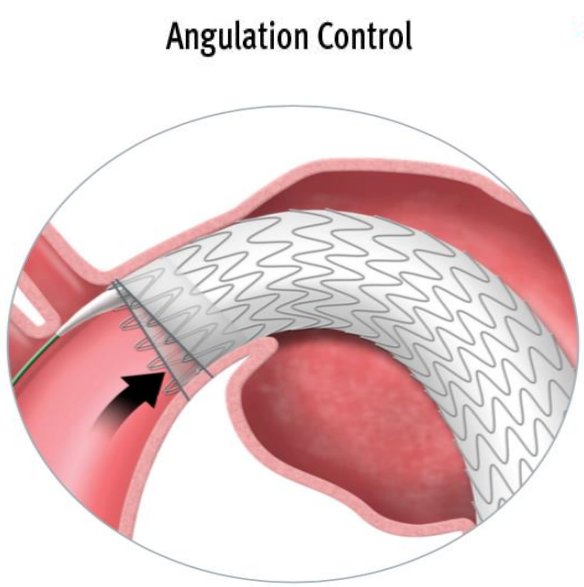
The Annals of Thoracic Surgery (2021).

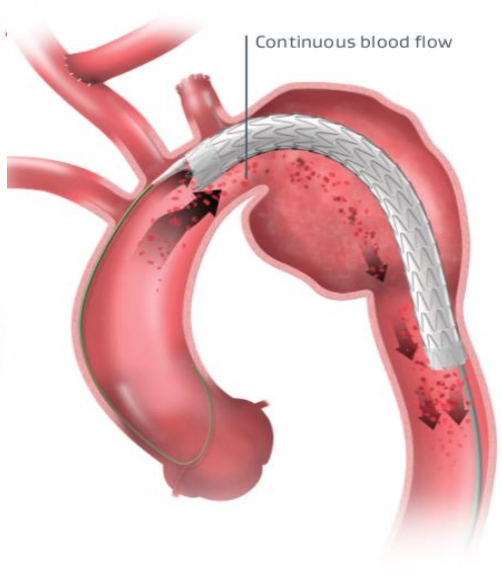
ZERO
- Migrations*
- Fractures
- Compressions
- Type III endoleaks
- Erosions

100% Procedural survival

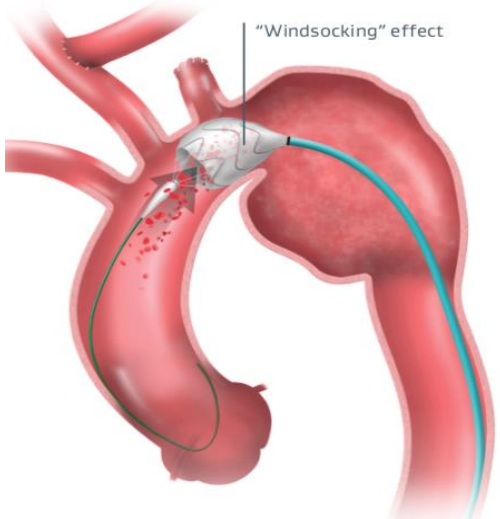
↓↓ Low rates of
- Endoleaks requiring reintervention
- Device-related reinterventions

- Nitinol stents and ePTFE layers
- Partially covered proximal rounded bare stents

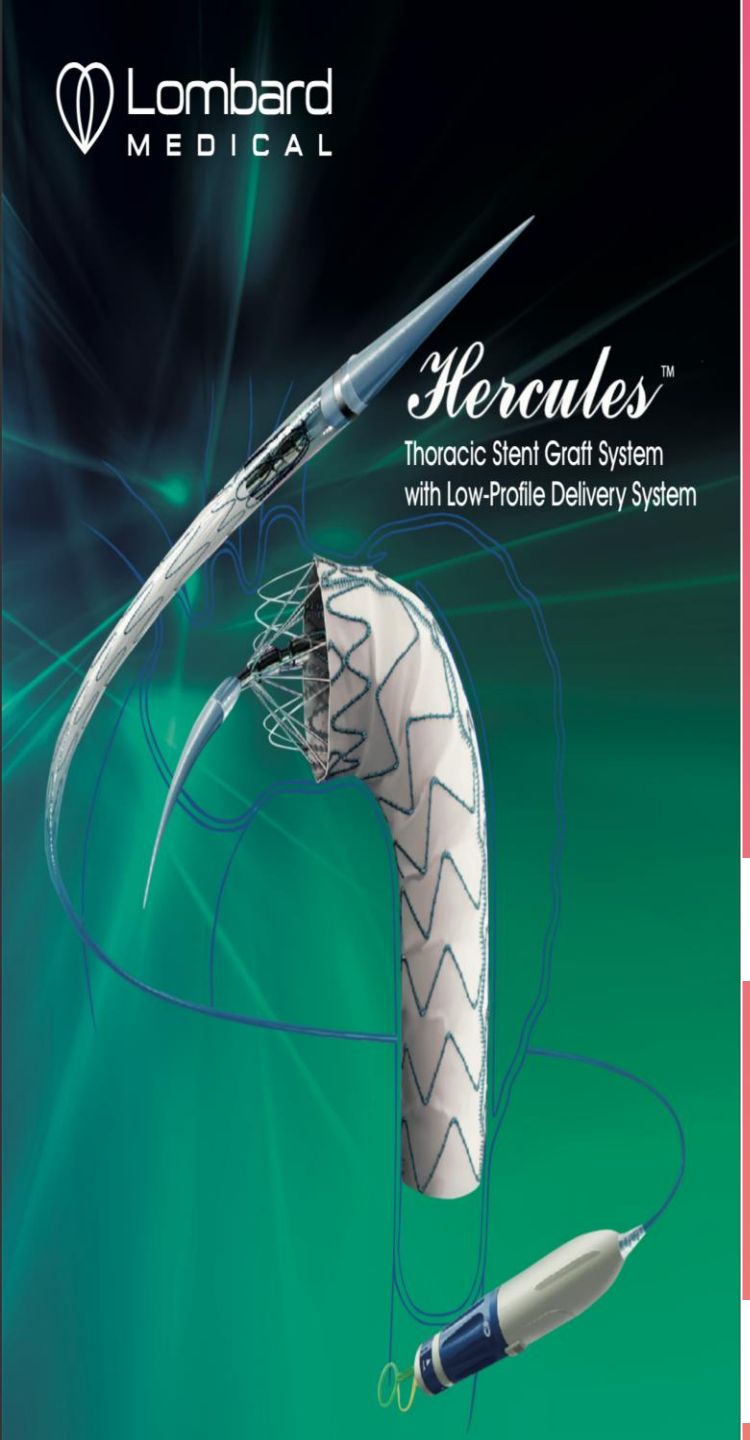




Staged Deployment

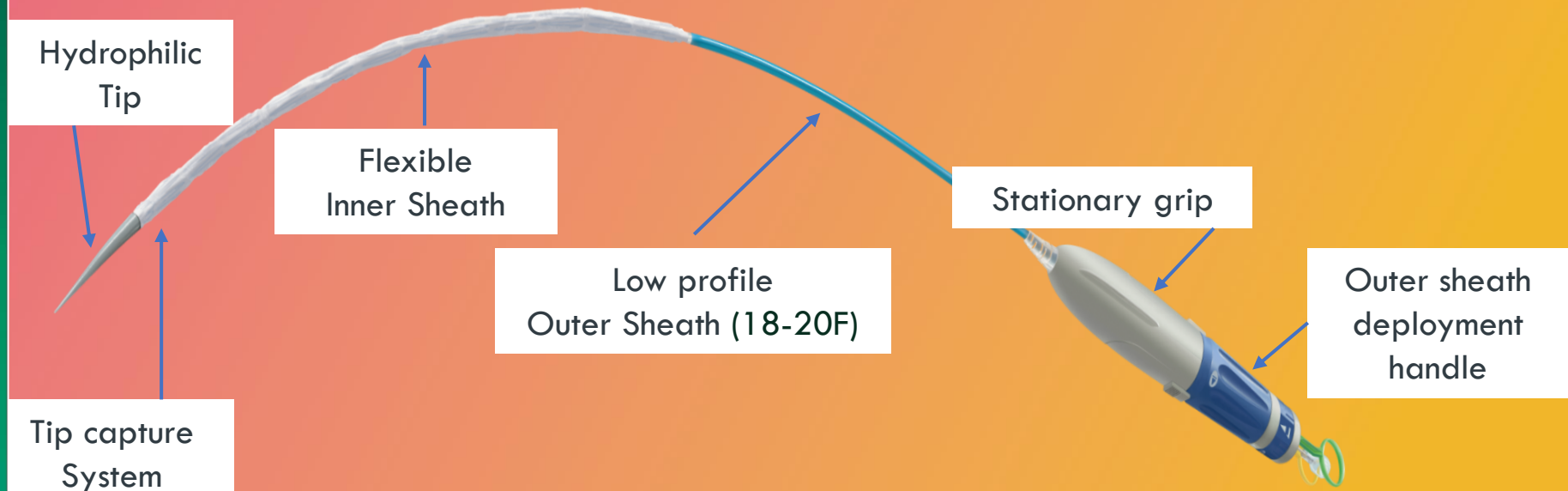


LOMBARD MEDICAL: HERCULES, 18-20F



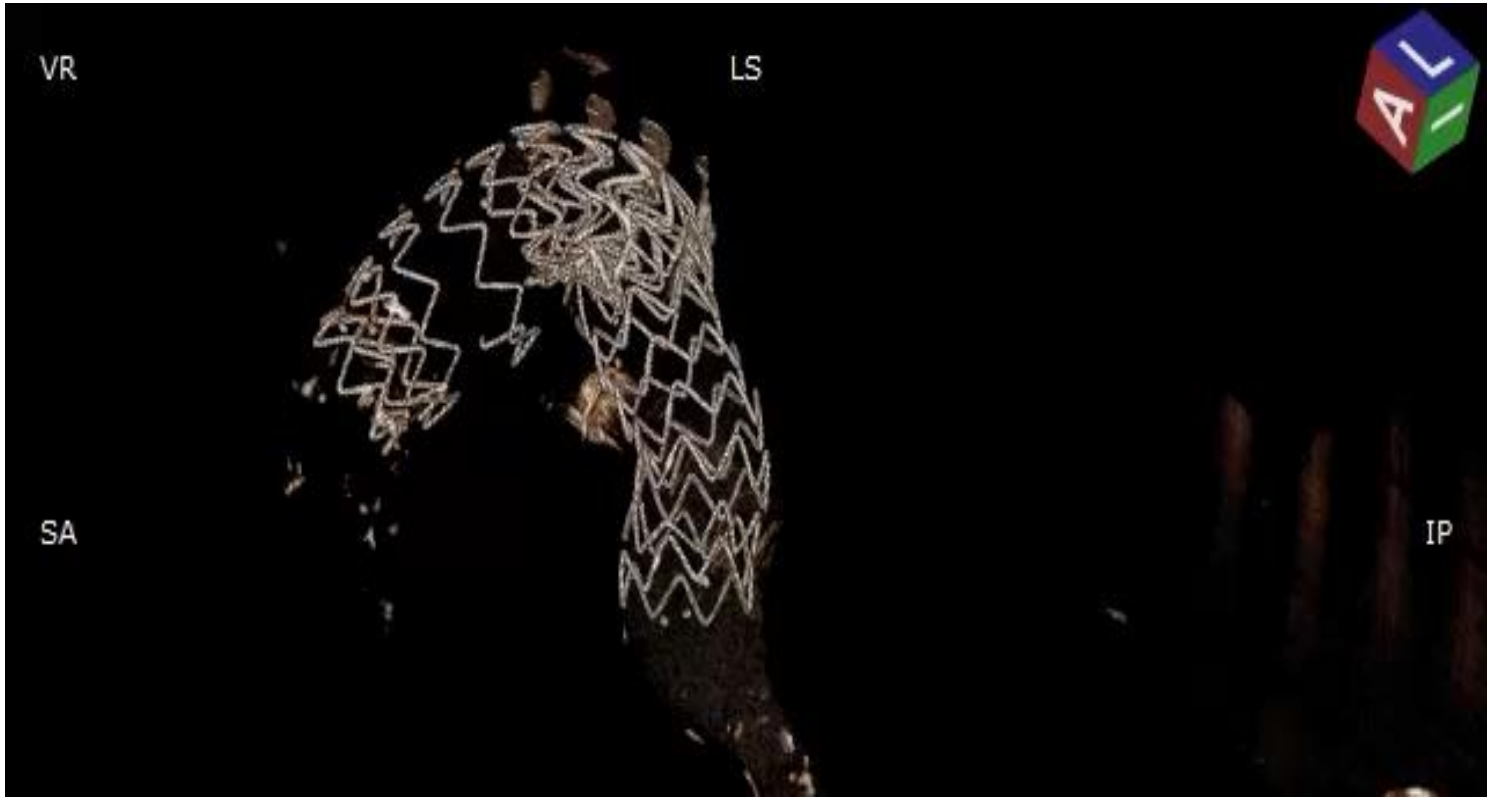
- Electropolished Nitinol and monofilament Polyester, Pt-Ir markers
- Range of diameters between 20mm and 44mm
- 100mm, 160mm and 200mm llong devices
- Tapered design: 2, 4, 8mm of taper

- Double sheath concept
  - Outer sheath to provide pushability to advance through the access vessels
  - Flexible inner sheath to cross the thoracic aorta and the arch



In February 2021, Medtronic's Valiant Navion™ endograft was recalled partially because of type IIIb endoleaks (T3bE). In a letter dated May 21, 2021, Medtronic reported 8 total T3bE identified among 404 clinical trial participants and commercial patients.

de Jesus Hernandez E *UPDATED Patient Management Recommendations Medtronic Valiant Navion™ Thoracic Stent Graft System Global Voluntary Product Recall*. May 21, 2021.



4 years F-UP CT post TEVAR (Valiant Navion, Medtronic)

Interdiscip Cardiovasc Thorac Surg. 2023 May 4;36(5):ivad058. doi: 10.1093/icvts/ivad058.

Lower-profile stent graft reduces the risk of embolism during thoracic endovascular aortic repair in shaggy aorta

Yoshimasa Seike [1], Kenta Masada [1], Tetsuya Fukuda
Mio Kasai [1], Yosuke Inoue [1], Hiroaki Sasaki [1], Hitosh

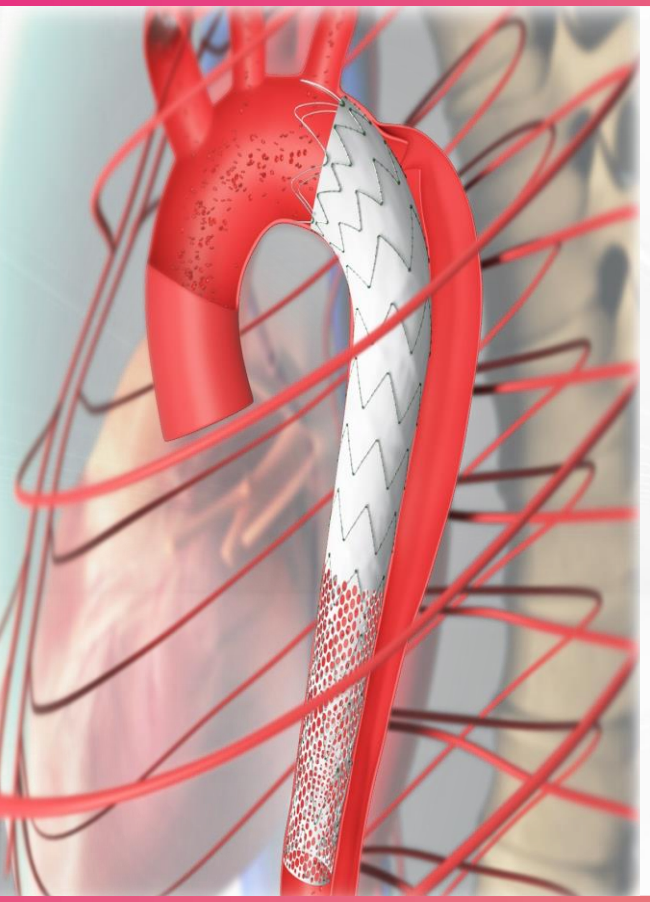
Objectives: This study aimed to reveal the association between lower-profile stent graft (LPSG) and embolism during thoracic endovascular aortic repair for non-dissecting distal arch and descending thoracic aortic aneurysm.

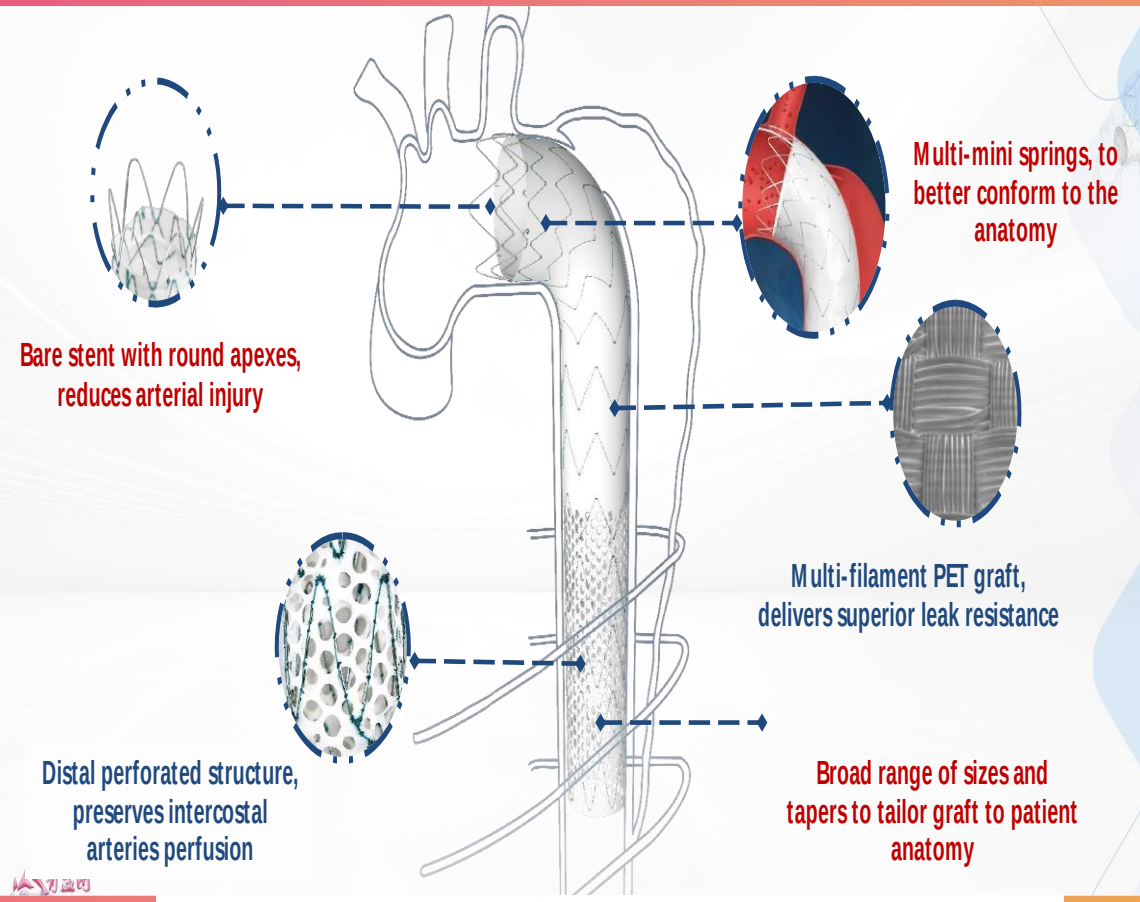
Methods: This study reviewed data of 35 patients who underwent thoracic endovascular aortic repair with LPSG (27 males; age: 77 ± 9.2 years) and 312 who underwent thoracic endovascular aortic repair with conventional-sized stent graft (CSSG) (247 males; age: 77 ± 7.4 years) from 2009 to 2021.

Results: The rate of total embolic events was significantly lower in the LPSG group (0/35 [0%]) than the CSSG group (34/312 [11.2%]) (P = 0.035). Shaggy aorta (odds ratio: 5.220; P < 0.001) were identified as positive embolic event predictors. The rate of total embolic events in 68 patients with shaggy aorta (12 in LPSG/56 in CSSG) was significantly lower in the LPSG group (0/12 [0%]) than the CSSG group (19/56 [34%]) (P = 0.015). The rate of total embolic events in 279 patients with the non-shaggy aorta (23 in LPSG/256 in CSSG) reveals no difference between the 2 groups (0 [0%]/16 [6.3%]) (P = 0.377).

Conclusions: LPSG usage could reduce embolism in thoracic endovascular aortic repair, and the difference was more pronounced in patients with the shaggy aorta. LPSG might be beneficial in preventing embolism in thoracic endovascular aortic repair for patients with a shaggy aorta.

TALOS: NEW THORACIC ENDOGRAFT FOR TYPE B DISSECTION CASES- LOMBARD





A Breathing Stent-Graft

Talos™ Thoracic Aortic Stent-Graft and Delivery System

- ✓ Remodeling the distal true lumen with extended length
- ✓ Reserving the intercostal artery and preventing the spinal cord ischemia

20Fr	20-36
22Fr	38-44

BRANCHED AORTIC ARCH ENDOGRAFTS: 24F

Castor™

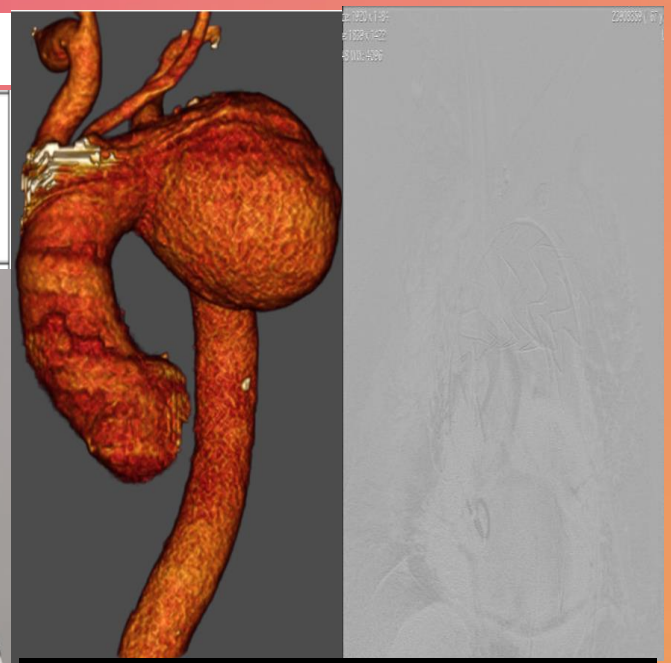
LOMBARD MEDICAL

Uni-body Design

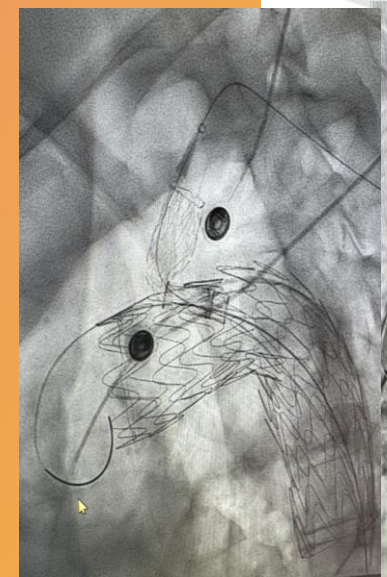
Reduces the risk of type III endoleak and migration

RELAY BRANCHED

TERUMO Aortic



GORE BRANCHED ENDOGRAFT



PENDING ISSUES - UNMET NEEDS

- GOOD CARACTERISTICS FROM OLDER GENERATION STENT GRAFTS SHOULD BE MAINTAINED
- CONFORMABILITY OF THE DEVICES, → AORTIC STIFFNESS POST TEVAR,
- DURABILITY OF THE DEVICES,
- AORTIC ARCH BRANCHED DEVICES REQUIRE LARGE DELIVERY SYSTEMS >24F
- ASCENDING AORTA STENT GRAFTS

NEED FOR:

- **MORE COMPLIANT AND DURABLE DEVICES**
- **PATHOLOGY SPECIFIC ENDOGRAFTS**
- **FURTHER ENDOGRAFT TECHNOLOGY DEVELOPMENTS**