

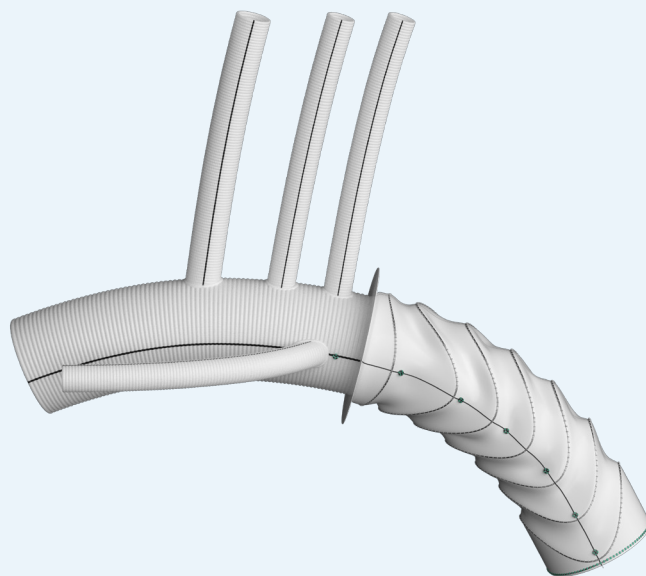


SAFETY & EFFICACY



thoraflex™ hybrid

Conforming Arch
Surgery to the
Gold Standard



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Aortic



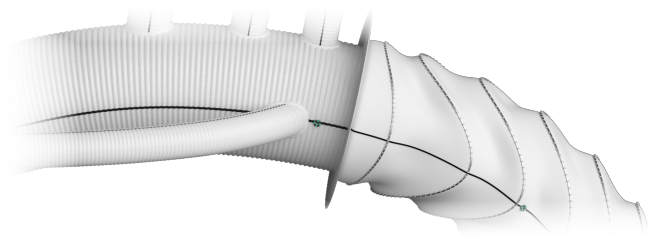
Gold Standard, Safety in the Arch

Multiple configurations to provide optimal outcomes for broad patient population

*“Because of the **unique design of the Thoraflex Hybrid graft**, reperfusion of the lower body can be started immediately after completion of the distal anastomosis. This may help in **reducing HCA duration and the risk for spinal cord injury.**”²*

INDIVIDUAL SUPRA-AORTIC BRANCHES

- ▶ Enables independent replacement of dissected or diseased vessels
- ▶ Improved visualisation in case of suture line bleeding³



SIDE PERFUSION BRANCH

- ▶ Early rewarming³
- ▶ Facilitates reduced systemic, cerebral and cardiac arrest times³



WATCH ON VUMEDI

One Year Results from the Thoraflex Hybrid US IDE Trial: Breakthrough

8.1%

30 day
mortality rate¹
(Acute Thoracic
Aortic Syndrome)

REDUCED MORTALITY

*“The FET technique does allow some total aortic arch repairs to become a **single-stage procedure** and thus **reduce the potential mortality associated with two-stage procedures.**”⁴*

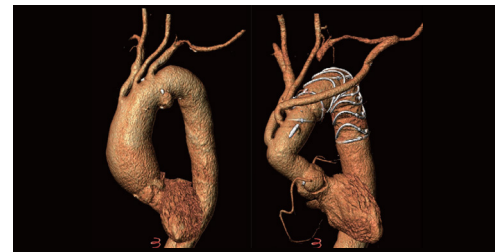


Figure 1: Separate branch technique. (A) Preoperative 3D-reconstructed CT-scan. (B) Postoperative 3D-reconstructed CT-scan. Supracoronary ascending aorta and total arch repair with 4-branch graft hybrid prosthesis as FET. The left subclavian artery is revascularised using an extra-anatomic transpleural dacron graft. CT, computed tomography; FET, frozen elephant trunk.¹

1. Results from Thoraflex Hybrid Post-Market Study (THOR) - NCT03414866 (unpublished).

2. Shrestha, M *et al.* 2016. Total aortic arch replacement with a novel 4-branched frozen elephant trunk prosthesis: single-center results of the first 100 patients. *The Journal of thoracic and cardiovascular surgery*, 152(1), pp.148-159.

3. Smith, T and Heijmen, R.H, 2023. Is a four-branched prosthesis advantageous over a straight prosthesis in Frozen elephant trunk surgery?. *Cardiovascular Diagnosis and Therapy*, 13(1), pp. 61-66.

Gold Standard, The Effective Solution

Ring Stent designed to cater to different anatomies with positive remodelling in both elective and acute settings ²

“Total aortic arch replacement with a Thoraflex Hybrid prosthesis is the most effective operative technique for type A aortic dissection.” ⁵

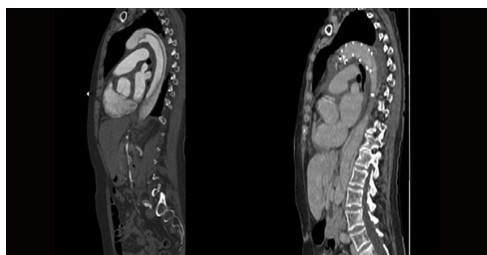


Figure 2: Preoperative and postoperative computed tomography angiographies showing a type A acute aortic dissection case with its subsequent (final) treatment with a Thoraflex hybrid graft.¹

“It causes rapid thrombosis of the false lumen and promotes a beneficial remodeling of the distal aorta.” ⁵

Thoraflex Hybrid

Global regulatory approvals including
EU (2012), US (2022), Japan (2023)

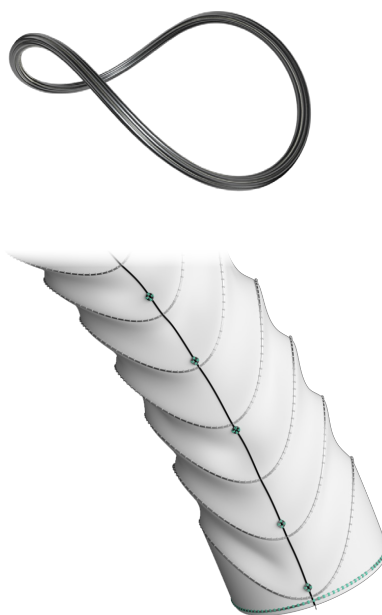


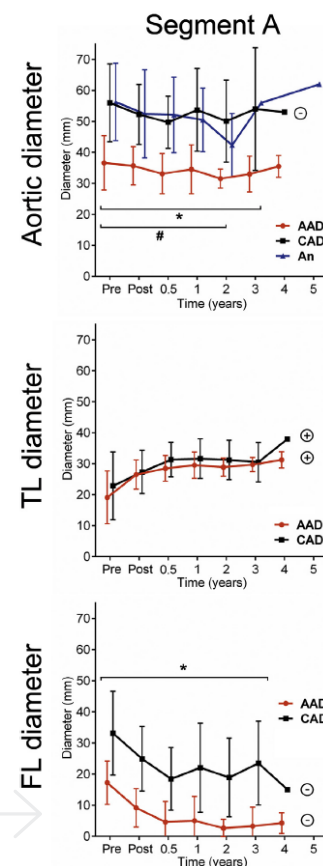
Figure 3: Changes of aortic diameters after frozen elephant trunk treatment with Thoraflex Hybrid graft (Vascutek, Inchinnan, Scotland). Aortic diameters according to measurements at the level of the stent graft in computed tomography angiography (CTA) during follow-up. Diameter changes over time were assessed by linear mixed models analysis. AAD, Acute aortic dissection; CAD, chronic aortic dissection; An, aneurysm; TL, true lumen; FL, false lumen. *P<.05, AAD versus CAD. #P<.05 versus An. +Significant increase during follow-up (P<.05). Significant decrease during follow-up (P<.05).²

100%

False Lumen
Thrombosis

(within 2 years*)²

* at the level of the stent graft



4. Leeuwerke, S.J et al. 2022. Frozen Elephant Trunk Completion: Endovascular Extension in The Distal Thoracic Aorta. *Surgical technology international*, 40.

5. Wisniewski, K et al. 2022. Single-Center Experience With the Thoraflex™ Hybrid Prosthesis: Indications, Implantation Technique and Results. *Frontiers in Cardiovascular Medicine*, 9, p.924838.

6. Mariscalco, G et al. 2019. Reflection from UK aortic group: Frozen elephant trunk technique as optimal solution in type A acute aortic dissection. *Seminars in Thoracic and Cardiovascular Surgery*, 31 (4), pp. 686-690.



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