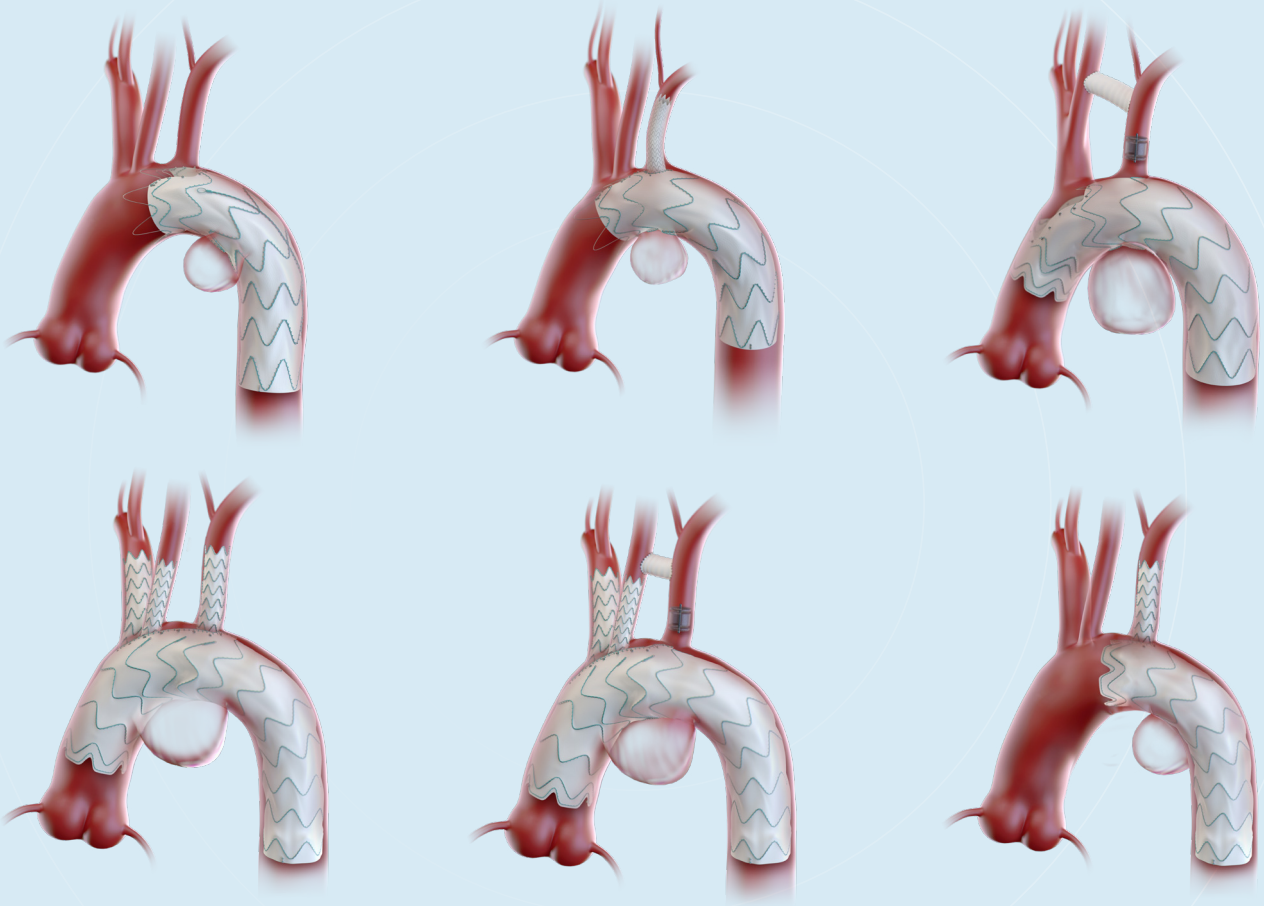
TERUMO AORTIC

Custom Solutions



PRODUCT BROCHURE

Custom-Made Relay®

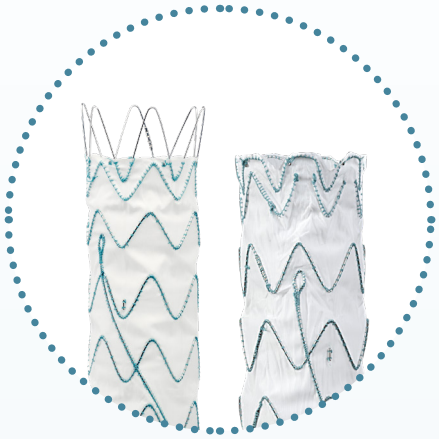
One Program. Multiple Options. Fully Tailored.

For more information, visit
terumoaortic.com/custom-solutions

CUSTOM RELAY®

Precision Built on Proven Performance

The Custom-Made Relay® Program builds upon the **core features** of the **standard Relay®Pro platform**, incorporating the same advanced technology and design principles but with added customisation options to better address specific patient anatomical requirements.



Two Proximal Configurations

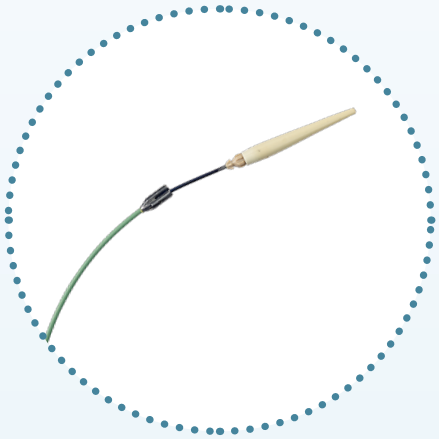
- Bare Stent
- Non-bare Stent

Low Profile

Outer Diameter 19Fr - 22Fr *(23Fr NBS)**

Dual Sheath Technology

Navigating the arch with care



Pre-Curved Inner Catheter

For proper alignment of the stent-graft

Proximal Clasping

For repositioning of the device and facilitating perpendicular deployment

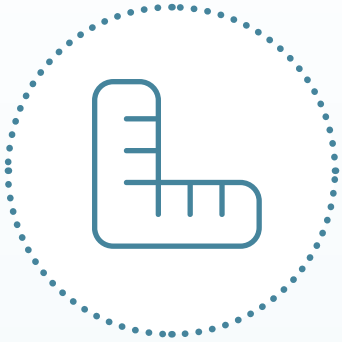
NBS Exclusive

Support Wires and Flared End: Engineered for Accuracy

* 25Fr for Relay®Branch NBS. 26Fr on Relay®Plus Platform

One Program. Multiple Options. Fully Tailored.

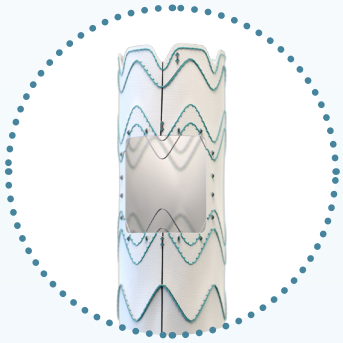
The Relay® Custom-Made Program offers a range of **personalised treatment options**, equipping clinicians with a versatile solution to address even the most complex anatomical challenges, precisely **tailored to each patient's unique anatomy**.



Custom Lengths, Diameters and Tapers*

Delivery System Customisation

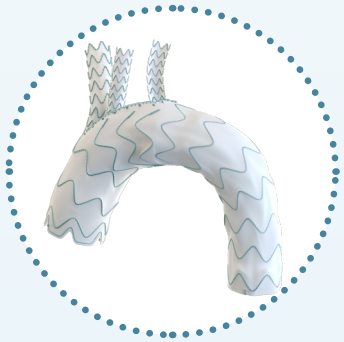
Scallop (Proximal, Distal)



Squared/Rounded Fenestration (Proximal, Distal)

Multi-Feature (Scallop+Fenestration)

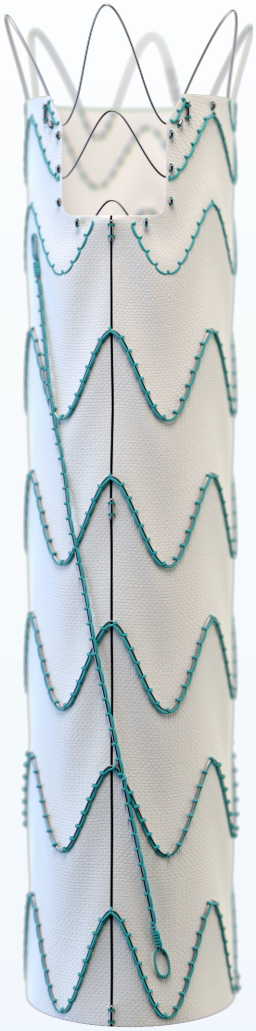
Custom Relay for Ascending Aorta



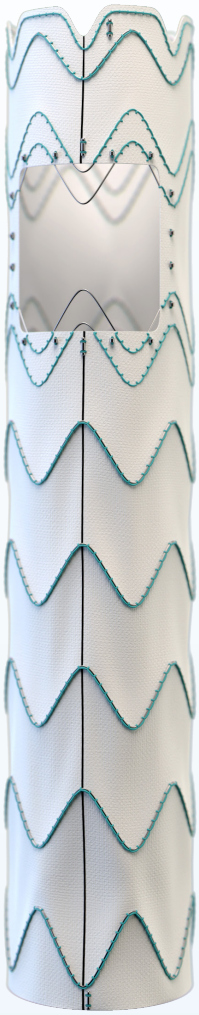
Branch Solutions (Single, Double, Triple)

* Including Reverse Taper (distal larger than proximal), Severe Taper (>4mm reduction), and Light Taper (2mm reduction)

Proximal sealing in the aortic arch for inner curve disease using the Custom Relay® scalloped and fenestrated stent-graft [1]



Proximal Scallop



Proximal Fenestration

OBJECTIVE

To analyse early and midterm results of custom-made proximal scallop and fenestrated stent-grafts with a proximal landing zone in the aortic arch.

1. Sica et al. (2024) - *Proximal sealing in the aortic arch for inner curve disease using the Custom Relay scalloped and fenestrated stent graft.* J Vasc Surg.

STUDY DESIGN

10 Centres

49 Patients*

70.1 ±11.8
Mean Age (Years)

36.3 ±21.3
Mean Follow-up (Months)

44.9%
Proximal Scallop Configuration^
22/49

55.1%
Proximal Fenestration Configuration
27/49

RESULTS

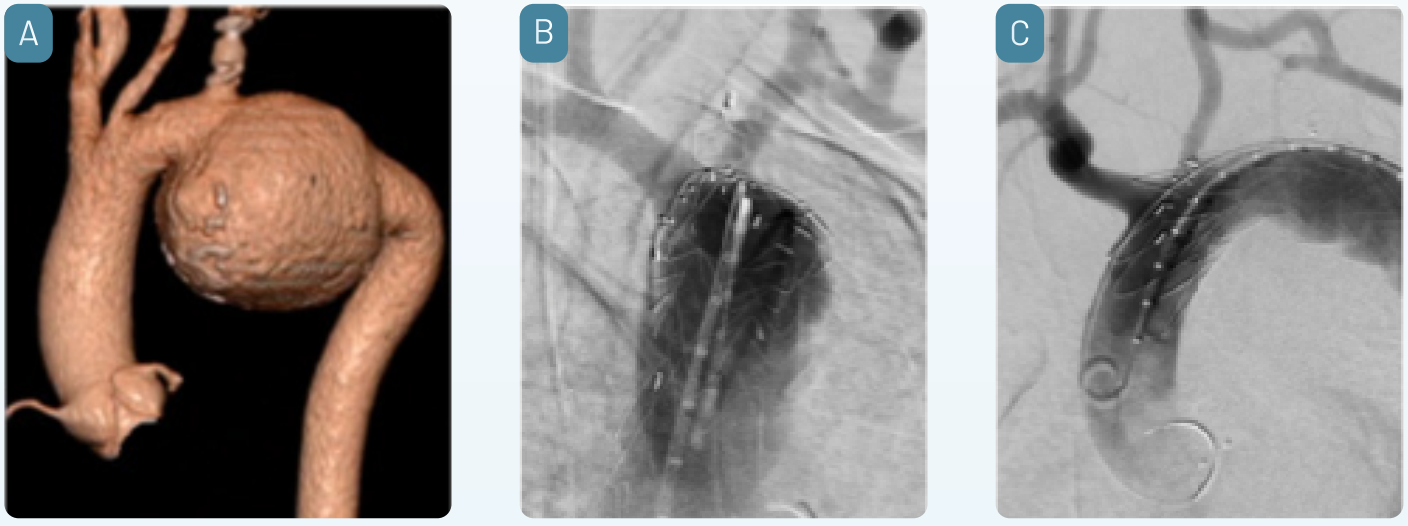
Absence of:

- Intraoperative Major Adverse Events
- Intraoperative Stroke
- Intraoperative Death
- Early (30-day) Spinal Cord Ischemia
- Early (30-day) Retrograde Dissection
- Early (30-day) Mortality
- Early (30-day) Major Stroke§

97.9%
Technical Success
48/49

6.1%
Minor stroke at 30 days with complete resolution of symptoms§
3/49

2%
Type Ia Endoleak at 30 days
1/49



Preoperative three-dimension volume rendering or post-traumatic chronic aortic isthmus pseudoaneurysm (A) treated with debranching and scallop TEVAR in proximal landing zone 1, with final angiography showing the correct position of the stent-graft and the patency of the supra-aortic trunks without endoleaks (B and C)

CONCLUSION

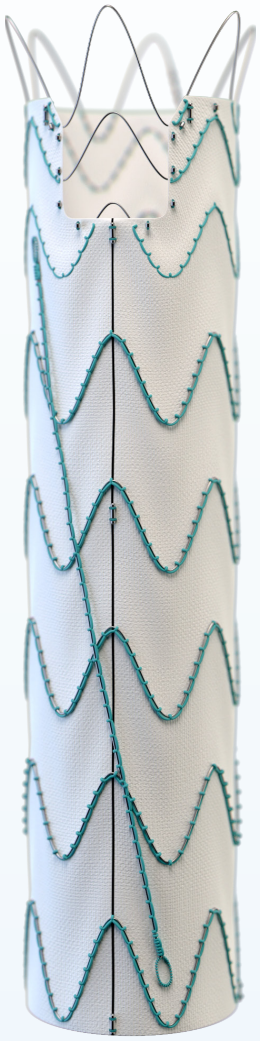
"Our early and midterm outcomes suggest that scalloped and fenestrated TEVAR may provide an acceptable alternative treatment option for aortic arch pathologies."

* The treated pathologies were thoracic aortic aneurysm in 29 patients (59.2%), penetrating aortic ulcer in 11 cases (22.4%), dissections in 3 cases (6.1%), relining of previous TEVAR in 3 cases (6.1%), pseudoaneurysm in 2 cases (4.1%) and brachiocephalic trunk dissection aneurysm in 1 case (2%).

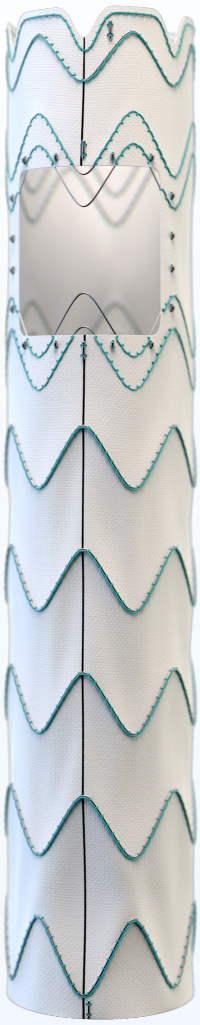
^ One case of proximal scallop for the left common carotid artery included a small fenestration for the left subclavian artery.

§ Major is NIHSS score >=21 and Minor is NIHSS score <=4

Evaluation of custom-made Relay® stent-grafts for aortic arch landing zones 0 and 1: experience from two high-volume aortic centres[2]



Proximal Scallop



Proximal Fenestration

Branch Solutions

OBJECTIVE

To report experience with a Relay® stent-graft custom-made platform in treating different aortic arch pathology in 2 high-volume aortic centres.

2. Dabravolskaite (2024) - Evaluation of custom-made Relay® stent-grafts for aortic arch landing zones 0 and 1: experience from two high-volume aortic centres. *European Journal of Cardio-Thoracic Surgery.*

STUDY DESIGN

2 High Volume Centres

35 Patients*

70 ±11
Mean Age (Years)

35 ±26
Mean Follow-up (Months)

25.6%
Proximal Scallop (9/35)

48.8%
Branch Device^ (17/35)

25.6%
Proximal Fenestration (9/35)

RESULTS

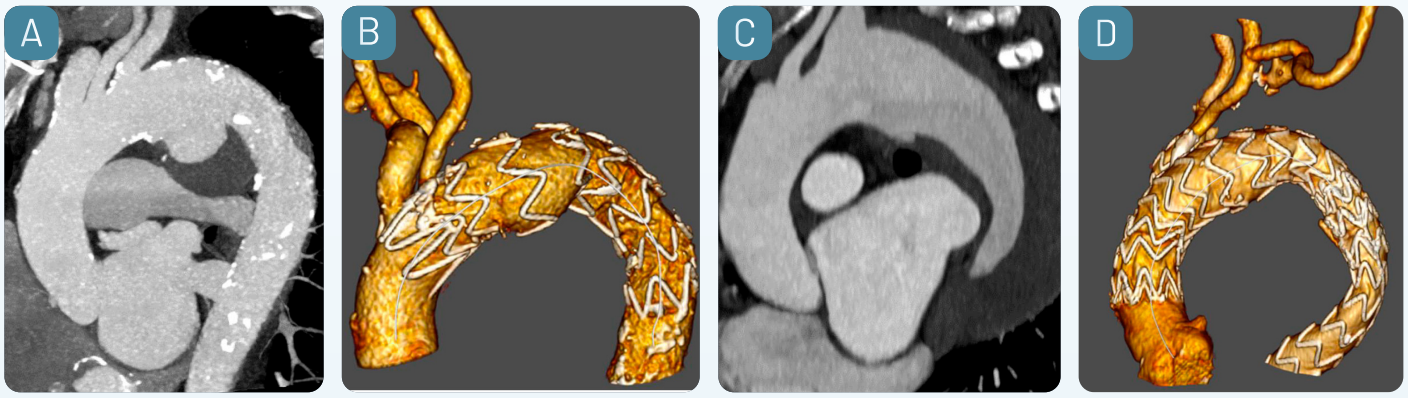
Absence of:

- 30-day mortality
- Late stroke (>30 days postoperatively)
- Reintervention due to Type Ia EL
- Bridging stent occlusion

100%
Technical Success
35/35

5.7%
Postoperative stroke rate recovered without disabling effects
2/35

0%
Aortic related mortality during follow-up
0/35



A. Preoperative CT-angiography with PAU in the distal aortic arch
B. Relay® Proximal Scallop for the Left Common Carotid Artery – 3D Reconstruction of CT Angiography after 2 years - side view
C. Preoperative CT-angiography with distal arch/proximal descending post-dissection aneurysm
D. Relay® Double Branch (anterior branch for th left common carotid artery, posterior branch for the brachiocephalic trunk - 3D reconstruction of CT-angiography after 1 year - side view

CONCLUSION

"The Relay® stent-graft custom-made platform showed a good performance in our study with a high technical success rate, low perioperative stroke and mortality, and low reintervention rates during the follow-up."

* The treated pathologies included Penetrating Aortic Ulcers (PAU) in 14 patients (40%), aneurysm in 11 patients (31%), aortic dissection in 10 patients (28.6%). 28 patients (80%) had proximal sealing in zone 0, and 7 (20%) had proximal sealing in zone 1.
^ 1 single, 15 double, 1 triple branch.

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Custom Solutions

View Custom-Made device IFU at **eifu.terumoaortic.com** for more information on use, indications, contraindications and warnings/precautions.

Custom-Made devices are specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications; which gives (1) specific design characteristics provided under that person's responsibility and (2) is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. Custom-Made devices are not available in the US and availability is subject to local regulatory approval.

PM-09746

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