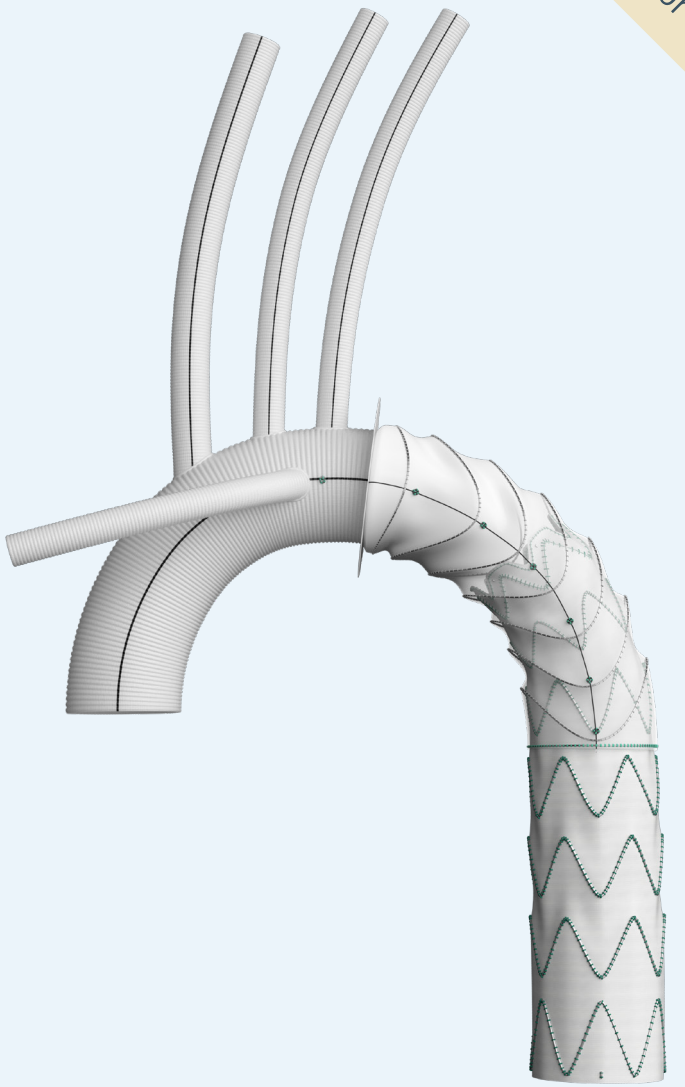
TERUMO AORTIC

CE MARK

The only **FDA** approved endovascular device indicated for extending Thoraflex™ Hybrid



PRODUCT BROCHURE

Thoraflex™ Hybrid & Relay®Pro

Thinking Ahead with On-Label Endovascular Extension

thoraflex™ hybrid

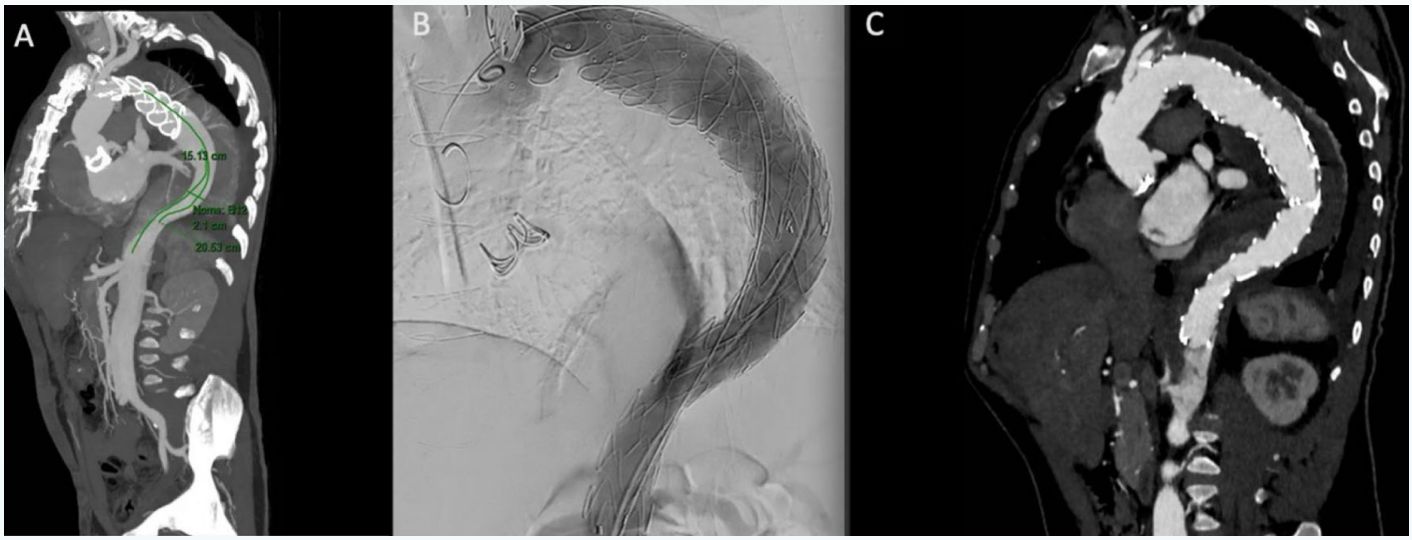
RELAY® PRO
THORACIC STENT-GRAFT SYSTEM

THINKING AHEAD

Advancing Repair – Endovascular Extension after FET Procedure

Frozen Elephant Trunk (FET), originally designed as a one-step procedure to treat complex arch and descending thoracic aorta pathology, has shown a frequent need for reintervention, often managed with thoracic endovascular aortic repair (TEVAR), thanks to the secure proximal landing zone it provides.

> *"The need for TEVAR after FET is a common occurrence"* [1]



TEVAR extension after FET for residual dissection. **A:** Preoperative Computed Tomography (CT) scan and planning for endovascular extension. **B:** Angio-graphic control after TEVAR. **C:** Postoperative CT scan. [1] Images sourced from Di Marco et al. 2023.[1]

> *"Though TEVAR extension is often required after FET, it is a safe and effective procedure with excellent post- operative outcomes in the short-, mid-, and long-term and allows successful treatment of complex aortic pathologies."* [1]

Post-Operative Outcome [1]

32.1%
Required TEVAR extension [1]
119/371

1.7%
In hospital death (intraoperative) [1]
2/119

0%
Spinal Cord Ischemia [1]
0/119

These outcomes represent a retrospective, single-center analysis of FET procedures followed by TEVAR extension, and reflect real-world results that are not specific to any one device or manufacturer.

1. Di Marco, Luca, *et al.* "Staging TEVAR after FET—an exception or the rule?." *Indian Journal of Thoracic and Cardiovascular Surgery* 39.Suppl 2 (2023): 224-232.

THINKING AHEAD

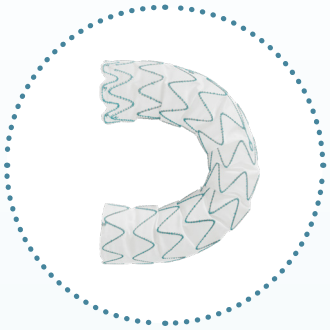
Relay®Pro NBS: The Only On-Label Extension for Thoraflex™ Hybrid

Relay®Pro NBS is the **only approved** endovascular solution for extending treatment in Thoraflex™ Hybrid patients with more extensive disease, thanks to several design features engineered to ensure reliable device compatibility.

Non Bare Stent Configuration

Low-Profile Delivery System

Wide Range of Sizes Available



Indications across disease types

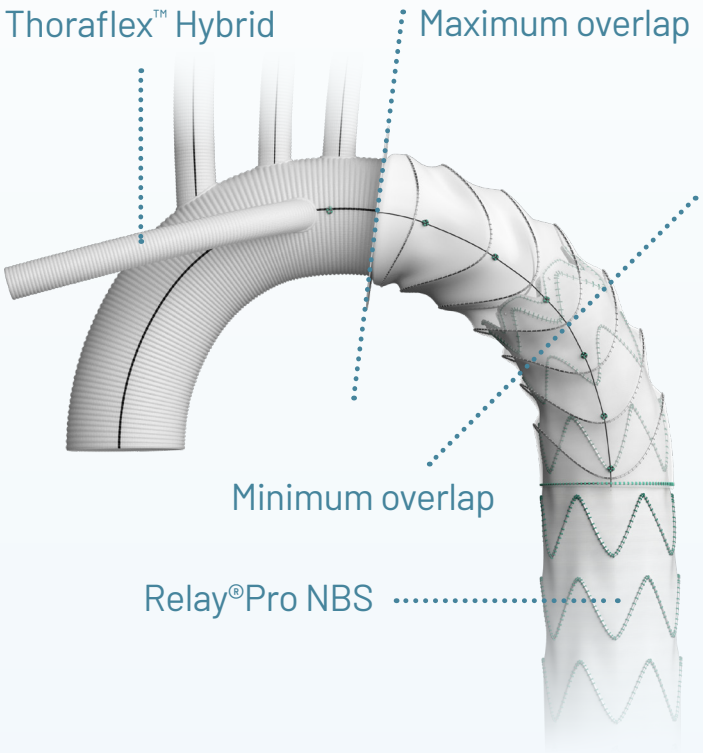
Thoraflex™ Hybrid and Relay®Pro NBS were tested to validate the use of Relay®Pro NBS as an endovascular extension following Thoraflex™ Hybrid implant.

- Integral Water Permeability
- Kink Testing
- Separation Force
- Distal Ring Dislodgment
- Deployment
- Fatigue and Durability – In-vitro Testing
- Magnetic Resonance Imaging (MRI) Compatibility

Thinking Ahead: Sizing Thoraflex™ Hybrid with Relay®Pro NBS

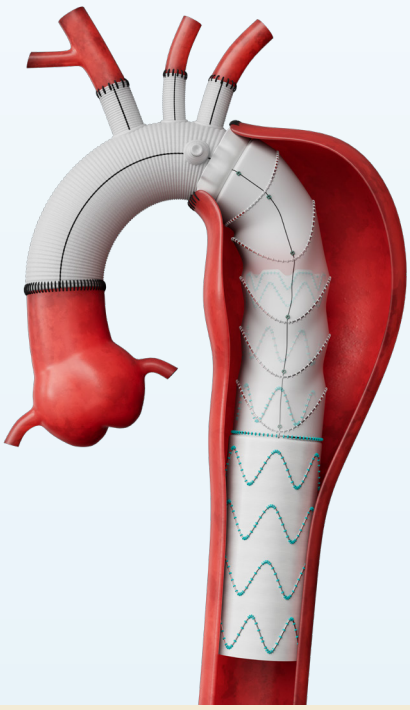
'Thinking ahead' means choosing the appropriate Thoraflex™ Hybrid size by first considering the Relay®Pro NBS device needed distally.

Post-FET planning must be an essential part of patient selection and procedure preparation, taking into consideration the pathology, sizing and positioning requirements. [2]



Overlapping Length*

- The minimum recommended overlap between a Relay®Pro NBS device and a Thoraflex™ Hybrid is 3 overlapping covered stents (approximately 50mm)



Diameter – 'Unsupported' Extension*

- For modular, unsupported junctions (i.e. where the Thoraflex™ Hybrid distal stent-graft region is within an aneurysm sac), a Relay®Pro NBS device with a proximal outer diameter 2mm greater than the nominal outer diameter of the in-situ Thoraflex™ Hybrid must be used.

* Thoraflex™ Hybrid IFU (FDA approved: Ref 301-226-Usen; CE-marked: Ref 301-225)

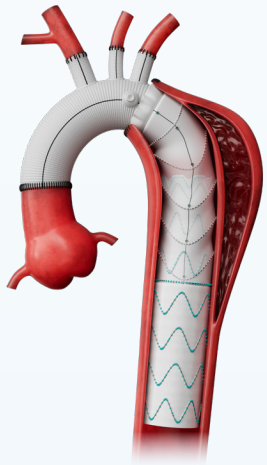
2. Leeuwerke, Steven JG, *et al.* "Frozen Elephant Trunk Completion: Endovascular Extension in The Distal Thoracic Aorta." *Surgical technology international* 40 (2022): 249-256.

Thinking Ahead: Sizing Thoraflex™ Hybrid with Relay®Pro NBS

Unsupported Junction Sizing Chart for Thoraflex™ Hybrid Implant with Relay®Pro NBS Extension Device

Thoraflex™ Hybrid Stent-Graft OD (mm)	Relay®Pro Stent-Graft Proximal OD (mm)
24	26
26	28
28	30
30	32
32	34
34	36
36	38
38	40
40	42

This sizing is applicable to all Thoraflex™ Hybrid configurations, Plexus and Ante-Flo.
The distal end of the RelayPro NBS Extension Device should be landed in healthy vessel within the descending thoracic aorta according to distal sizing and landing zone length recommendations. Please refer to IFU.



Diameter – 'Supported' Extension*

- For modular, supported junctions (i.e. where the Thoraflex™ Hybrid distal stent-graft region is within dissection), a Relay®Pro NBS device with a proximal outer diameter equal to the nominal outer diameter of the in-situ Thoraflex™ Hybrid must be used.

Supported Junction Sizing Chart for Thoraflex™ Hybrid Implant with Relay®Pro NBS Extension Device

Thoraflex™ Hybrid Stent-Graft OD (mm)	Relay®Pro Stent-Graft Proximal OD (mm)
24	24
26	26
28	28
30	30
32	32
34	34
36	36
38	38
40	40

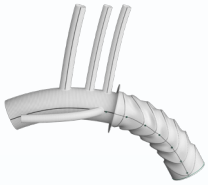
This sizing is applicable to all Thoraflex™ Hybrid configurations, Plexus and Ante-Flo.

* Thoraflex™ Hybrid IFU (FDA approved: Ref 301-226-Usen; CE-marked: Ref 301-225)

THINKING AHEAD

Product Ordering Information: Thoraflex™ Hybrid

Plexus Configuration



Catalogue Number Explanation

THP	26	28	150	x	E
Thoraflex™ Hybrid Plexus	Proximal graft ID (mm)	Distal stent-graft OD (mm)	Stent-graft length (mm)		Designation

100mm Stent Length

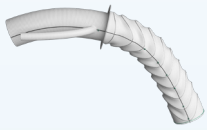
Catalogue Number	Graft ID - D1 (mm)	Stent-graft OD - D2 (mm)
THP2224 x 100E*	22	24
THP2426 x 100E*	24	26
THP2628 x 100E	26	28
THP2830 x 100E	28	30
THP3032 x 100E	30	32
THP3034 x 100E	30	34
THP3036 x 100E	30	36
THP3038 x 100E	30	38
THP3040 x 100E	30	40
THP3240 x 100E	32	40

150mm Stent Length

Catalogue Number	Graft ID - D1 (mm)	Stent-graft OD - D2 (mm)
THP2224 x 150E*	22	24
THP2426 x 150E*	24	26
THP2628 x 150E	26	28
THP2830 x 150E	28	30
THP3032 x 150E	30	32
THP3034 x 150E	30	34
THP3036 x 150E	30	36
THP3038 x 150E	30	38
THP3040 x 150E	30	40
THP3240 x 150E	32	40

* The branches on THP2224x100E, THP2426x100E, THP2224x150E and THP2426x150E are as follows: 10mm, 8mm & 8mm.
(All other sizes have standard branch diameter configurations: 12mm, 8mm & 10mm)

Ante-Flo™ Configuration



Catalogue Number Explanation

THA	26	28	150	x	E
Thoraflex™ Hybrid Ante-Flo™	Proximal graft ID (mm)	Distal stent-graft OD (mm)	Stent-graft length (mm)		Designation

100mm Stent Length

Catalogue Number	Graft ID - D1 (mm)	Stent-graft OD - D2 (mm)
THA2224 x 100E	22	24
THA2426 x 100E	24	26
THA2628 x 100E	26	28
THA2830 x 100E	28	30
THA3032 x 100E	30	32
THA3034 x 100E	30	34
THA3036 x 100E	30	36
THA3038 x 100E	30	38
THA3040 x 100E	30	40
THA3240 x 100E	32	40

150mm Stent Length

Catalogue Number	Graft ID - D1 (mm)	Stent-graft OD - D2 (mm)
THA2224 x 150E	22	24
THA2426 x 150E	24	26
THA2628 x 150E	26	28
THA2830 x 150E	28	30
THA3032 x 150E	30	32
THA3034 x 150E	30	34
THA3036 x 150E	30	36
THA3038 x 150E	30	38
THA3040 x 150E	30	40
THA3240 x 150E	32	40

THINKING AHEAD

Product Ordering Information: Relay®Pro NBS

Relay®Pro list with the allowable proximal ODs for Thoraflex™ Hybrid Distal Extension. Thoraflex™ Hybrid IFU indicates supported or unsupported junctions ranging from 24-42mm Relay®Pro.

Non Bare Stent Configuration

Catalogue Number Explanation

28	N4	36	154	36	S
Product Id.	Device Type N4 NBS	Stent Proximal Diameter	Length Category	Stent Distal Diameter	Product Id.

Straight

Vessel	Stent-graft		Delivery System		
Thoracic Proximal Vessel Size	Proximal/ Distal Diameter	Covered Length	Profile OD	Made to Order ^	Catalogue Number
20-21	24	99	19Fr		28-N4-24-099-24S
22-23	26	104	19Fr		28-N4-26-104-26S
24-25	28	104	20Fr		28-N4-28-104-28S
26-27	30	104	20Fr		28-N4-30-104-30S
28-29	32	104	21Fr		28-N4-32-104-32S
30-31	34	109	21Fr		28-N4-34-109-34S
32-33	36	109	22Fr		28-N4-36-109-36S
34	38	109	22Fr		28-N4-38-109-38S
35-36	40	114	22Fr		28-N4-40-114-40S
37-38	42	114	23Fr	•	28-N4-42-114-42S
20-21	24	159	19Fr		28-N4-24-159-24S
22-23	26	164	19Fr		28-N4-26-164-26S
24-25	28	164	20Fr		28-N4-28-164-28S
26-27	30	164	20Fr		28-N4-30-164-30S
28-29	32	164	21Fr		28-N4-32-164-32S
30-31	34	154	21Fr		28-N4-34-154-34S
32-33	36	154	22Fr		28-N4-36-154-36S
34	38	154	22Fr		28-N4-38-154-38S
35-36	40	154	22Fr		28-N4-40-154-40S
37-38	42	159	23Fr		28-N4-42-159-42S

Straight

Vessel	Stent-graft		Delivery System		
Thoracic Proximal Vessel Size	Proximal/ Distal Diameter	Covered Length	Profile OD	Made to Order ^	Catalogue Number
20-21	24	199	19Fr		28-N4-24-199-24S
22-23	26	204	19Fr		28-N4-26-204-26S
24-25	28	204	20Fr		28-N4-28-204-28S
26-27	30	209	20Fr		28-N4-30-209-30S
28-29	32	209	21Fr		28-N4-32-209-32S
30-31	34	209	21Fr		28-N4-34-209-34S
32-33	36	199	22Fr		28-N4-36-199-36S
34	38	199	22Fr		28-N4-38-199-38S
35-36	40	204	22Fr		28-N4-40-204-40S
37-38	42	204	23Fr		28-N4-42-204-42S
20-21	24	259	19Fr	•	28-N4-24-259-24S
22-23	26	259	19Fr	•	28-N4-26-259-26S
24-25	28	259	20Fr	•	28-N4-28-259-28S
26-27	30	259	20Fr	•	28-N4-30-259-30S
28-29	32	259	21Fr	•	28-N4-32-259-32S
30-31	34	259	21Fr	•	28-N4-34-259-34S
32-33	36	259	22Fr	•	28-N4-36-259-36S
34	38	259	22Fr	•	28-N4-38-259-38S
35-36	40	259	22Fr	•	28-N4-40-259-40S
37-38	42	259	23Fr	•	28-N4-42-259-42S

Tapered

	Vessel		Stent-graft		Delivery System		
	Proximal Diameter	Distal Diameter	Proximal/ Distal Diameter	Covered Length	Profile OD	Made to Order ^	Catalogue Number
150mm	24-25	20-21	28/24	164	20Fr		28-N4-28-164-24S
	26-27	22-23	30/26	164	20Fr		28-N4-30-164-26S
	28-29	24-25	32/28	164	21Fr		28-N4-32-164-28S
	30-31	26-27	34/30	154	21Fr		28-N4-34-154-30S
	32-33	28-29	36/32	154	22Fr		28-N4-36-154-32S
	34	30-31	38/34	154	22Fr		28-N4-38-154-34S
	35-36	32-33	40/36	154	22Fr		28-N4-40-154-36S
	37-38	34	42/38	159	23Fr		28-N4-42-159-38S
200mm	24-25	20-21	28/24	204	20Fr		28-N4-28-204-24S
	26-27	22-23	30/26	209	20Fr		28-N4-30-209-26S
	28-29	24-25	32/28	209	21Fr		28-N4-32-209-28S
	30-31	26-27	34/30	209	21Fr		28-N4-34-209-30S
	32-33	28-29	36/32	199	22Fr		28-N4-36-199-32S
	34	30-31	38/34	199	22Fr		28-N4-38-199-34S
	35-36	32-33	40/36	204	22Fr		28-N4-40-204-36S
	37-38	34	42/38	204	23Fr		28-N4-42-204-38S

Tapered

	Vessel		Stent-graft		Delivery System		
	Proximal Diameter	Distal Diameter	Proximal/ Distal Diameter	Covered Length	Profile OD	Made to Order ^	Catalogue Number
250mm	24-25	20-21	28/24	259	20Fr	•	28-N4-28-259-24S
	26-27	22-23	30/26	259	20Fr	•	28-N4-30-259-26S
	28-29	24-25	32/28	259	21Fr	•	28-N4-32-259-28S
	30-31	26-27	34/30	259	21Fr	•	28-N4-34-259-30S
	32-33	28-29	36/32	259	22Fr	•	28-N4-36-259-32S
	34	30-31	38/34	259	22Fr	•	28-N4-38-259-34S
	35-36	32-33	40/36	259	22Fr	•	28-N4-40-259-36S
	37-38	34	42/38	259	23Fr	•	28-N4-42-259-38S

^ Made to Order products are pre-existing device configurations and are not part of the custom-made device program. They will be built upon receipt of Purchase Order and are subject to extended lead times.

All measurements in mm unless otherwise specified. Select the appropriate device size based on artery outer diameter measurement taken from CT images.

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