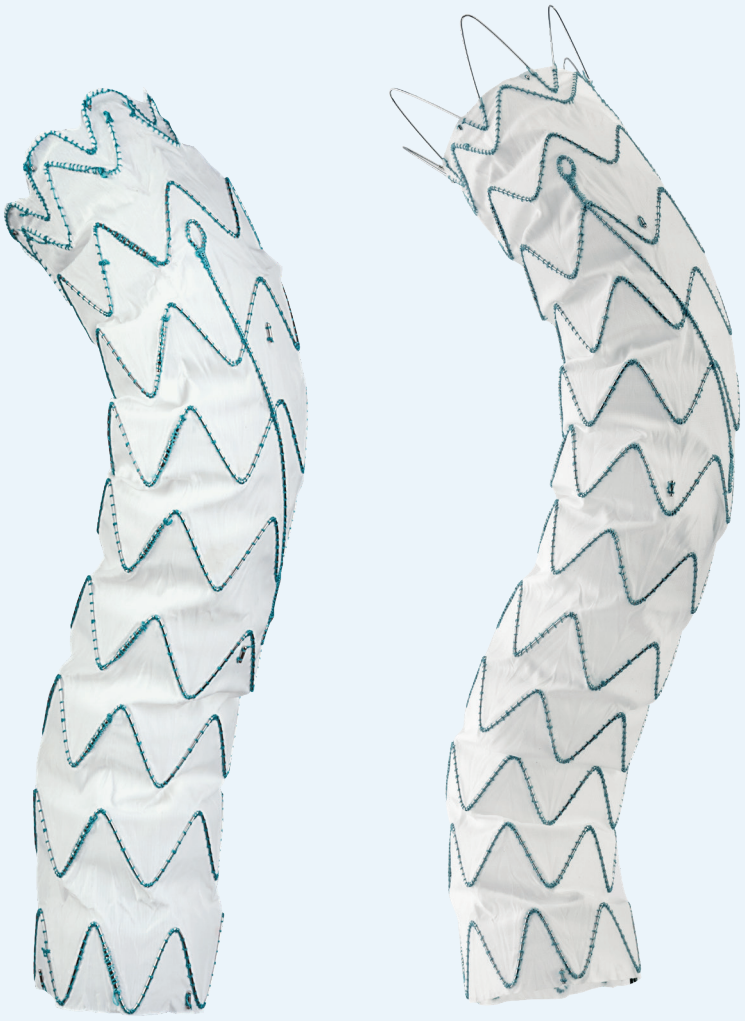
TERUMO AORTIC

USA



PRODUCT BROCHURE

Relay®Pro: Key Studies

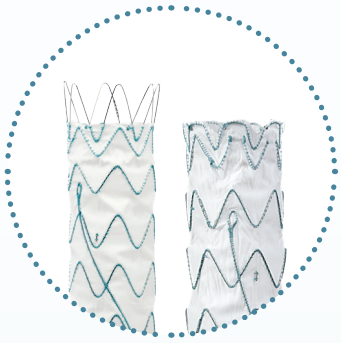
When Experience Meets Evidence

For more information, visit
terumoaortic.com/relaypro

RELAY® PRO
THORACIC STENT-GRAFT SYSTEM

Engineered Design with Latest Device Technology

Relay®Pro is Terumo Aortic's **latest generation thoracic stent-graft system** specifically designed for the thoracic aorta.



Two Proximal Configurations

- Bare-stent
- Non-Bare stent (NBS)

Low Profile

OD* 19Fr - 22Fr (23Fr NBS)

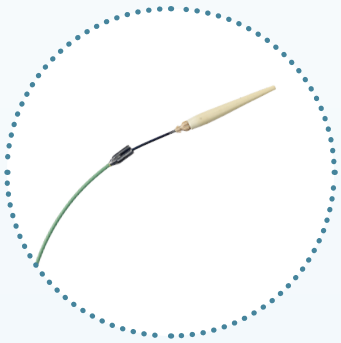
*Outer Diameter

Multiple Size Options

- 164 standard configurations
- 2,224 Upon-Request

Dual Sheath Technology

Navigating the arch with care



Pre-Curved Inner Catheter

For proper alignment of the stent-graft

NBS Exclusive

Support wires, flared end, and asymmetrical proximal clasping

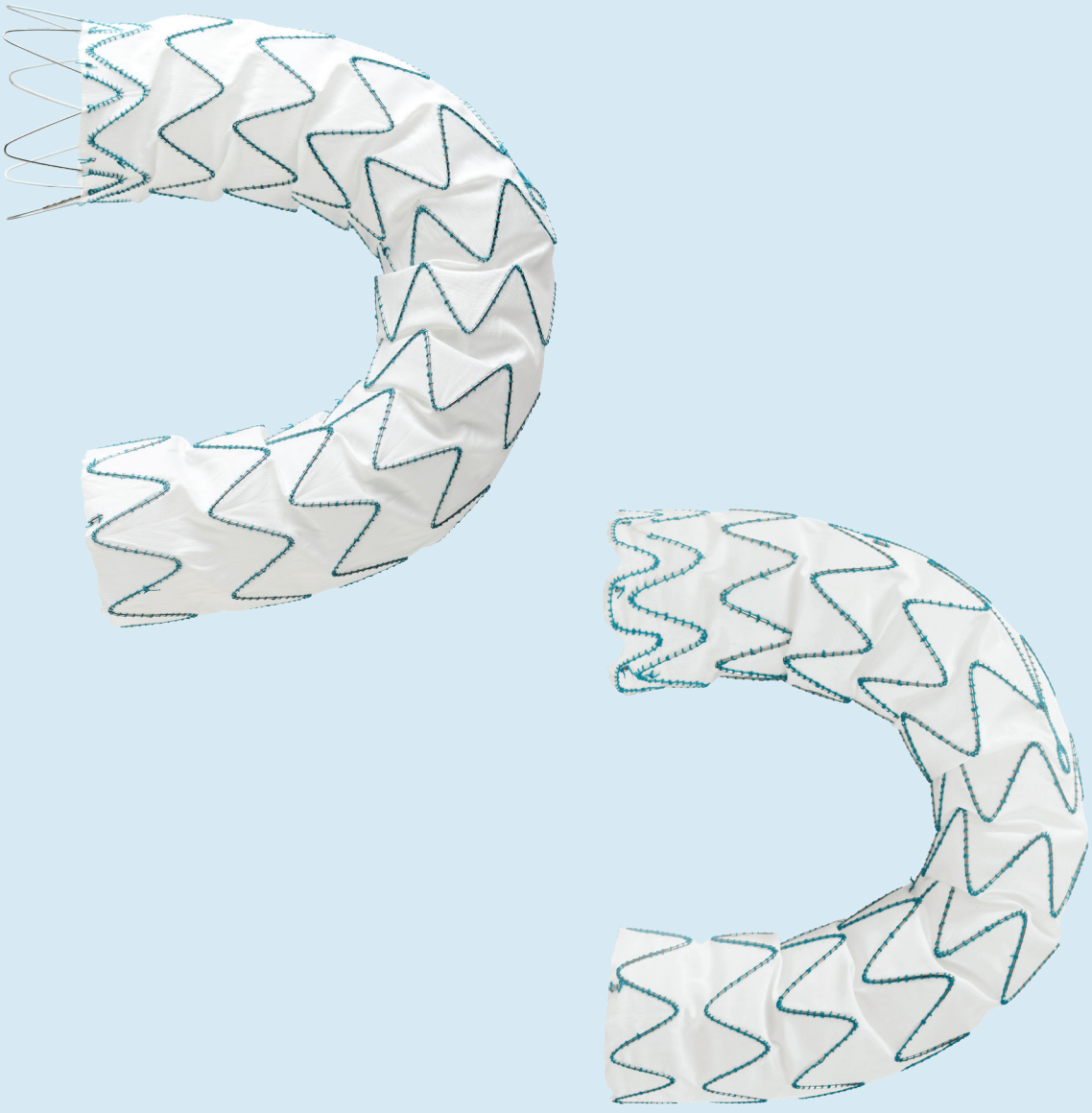
Indications

The Relay®Pro Thoracic Stent-Graft System is indicated for the endovascular repair of **all lesions of the descending thoracic aorta** (including aneurysm, PAU, dissection and transection) in patients having appropriate anatomy.

RELAY®PRO

2021: FDA approval for Aneurysm, Penetrating Atherosclerotic Ulcer

P200045



One-Year Results with a Low-Profile Endograft in Subjects with Thoracic Aortic Aneurysm and Ulcer Pathologies[1]

OBJECTIVE

Evaluation of safety and effectiveness of Relay®Pro for the treatment of descending thoracic aortic aneurysms or penetrating atherosclerotic ulcers

STUDY DESIGN

36 Centers
25 in USA, 11 in Japan

110 Patients
68 in USA, 42 in Japan

74.9 ±8.3
Mean Age (Years)

91%
(100/110) Patients with Aneurysm

9%
(10/110) Patients with PAU

82.7%
(91/110) Patients treated with NBS Configuration

RESULTS

100%
Technical Success through 24 Hours
110/110

73.5%
Patients treated with a percutaneous femoral approach in the US Cohort
50/68

3.6%
Stroke Rate at 1 Year
4/110

1.8%
Type Ia endoleak at 1 year
2/110

98.9%
Absence of aneurysm expansion at 1 year
109/110

94.1%
Absence of secondary intervention at 1 year
104/110

1. Szeto WY, Vallabhajosyula P, Matsuda H, Moainie SL, Sharafuddin MJ, Corvera J, Smolock CJ, Miyamoto S, Naslund T, Ramaiah V; on behalf of the RelayPro-A Investigators. One-year results with a low-profile endograft in subjects with thoracic aortic aneurysm and ulcer pathologies. J Thorac Cardiovasc Surg. 2022 May;163(5):1739-1750.e4. doi: 10.1016/j.jtcvs.2021.10.071. Epub 2022 Feb 1. PMID: 35241276.

Absence of: Rupture, Migration, Loss of Patency, Stenosis/Thrombosis, Fractures, Conversion, Retrograde Dissection, dSINE at 1-year

Patient with a type III arch and descending thoracic aortic aneurysm: (A) preoperative CT 3-dimensional reconstruction shows a 58-mm aneurysm with proximal landing zone in the distal arch; (B and C) postoperative CT 3-dimensional reconstruction shows conformability of 2 Relay®Pro NBS devices.

CONCLUSION

Relay®Pro demonstrated satisfactory 30-day **safety** and 1-year **effectiveness** for the treatment of patients with aneurysms of the DTA and PAUs.

RELAY®PRO

2023: FDA approval for Dissection and Transection

P200045/S002

One-Year Results of a Low-Profile Endograft in Acute, Complicated Type B Aortic Dissection[2]

OBJECTIVE

Evaluation of safety and effectiveness of Relay®Pro for the treatment of acute, complicated **type B aortic dissection (TBAD)**

STUDY DESIGN

22 Centers
All in USA

56 Patients

59.5 ±11.4
Mean Age (Years)

14.3%
(8/56) Patients with proximal extent of dissection in zone 1 or 2

78.6%
(44/56) Patients with proximal extent of dissection in zone 3

62.5%
(35/56) Patients with distal extent of dissection to the iliac arteries

65.3%
(64/98) NBS configurations used

RESULTS

100%
Technical Success through 24 Hours
56/56

85.5%
Patients treated with a percutaneous femoral approach
47/56

1.8%
Disabling stroke rate at 30 days with no stroke during 1-year follow up
2/56

1.8%
Type Ia endoleak at 1 year
1/56

1.8%
Operative vascular access complications
1/56

100%
Absence of false lumen perfusion from 30 days to 1 year
30/30

2. Rossi PJ, Desai ND, Malaisrie SC, Lyden SP, Nassiri N, Reece TB, Adams JD, Moanie SL, Shults CC; On behalf of the RelayPro-D Investigators. One-Year Results of a Low-Profile Endograft in Acute, Complicated Type B Aortic Dissection. Ann Thorac Surg. 2024 Feb;117(2):336-343. doi: 10.1016/j.athoracsur.2023.08.035. Epub 2023 Sep 27. PMID: 37769702.

Absence of: Bird beak, Rupture, Loss of Patency, Stenosis/Thrombosis, and Fractures at 1-year

(A) Preoperative volume-rendered scan of a 73-year-old man with an acute, complicated type B aortic dissection and a history of diabetes mellitus, hypertension, hypercholesterolemia, smoking, renal insufficiency, limb ischemia (left and right asymptomatic), gastrointestinal complications, bowel obstruction, and vascular intervention. (B) Volume-rendered follow-up scan at 2 years shows successful repair with 2 Relay®Pro NBS devices deployed distal to the left subclavian artery.

CONCLUSION

Relay®Pro demonstrated the **safety and effectiveness for the treatment of acute, complicated TBAD.** The NBS configuration may be a beneficial addition to dissection treatment options.

Early survival benefit of a low-profile endograft in blunt traumatic aortic injury[3]

OBJECTIVE

Demonstate the **safety and effectiveness** of Relay®Pro in subjects with blunt traumatic aortic injury (BTAI)

STUDY DESIGN

16 Centers
All in USA

50 Patients

42.4 ±17.2
Mean Age (Years)

4%
(2/50) Grade I BTAI

8%
(4/50) Grade II BTAI

76%
(38/50) Grade III BTAI

12%
(6/50) Grade IV BTAI

71%
(40/50) Number of RelayPro NBS configurations among all devices implanted

RESULTS

98%
Technical Success at 24 Hours
49/50

80%
Patients treated with a percutaneous femoral approach
40/50

98%
Absence of all-cause mortality at 30 days
49/50

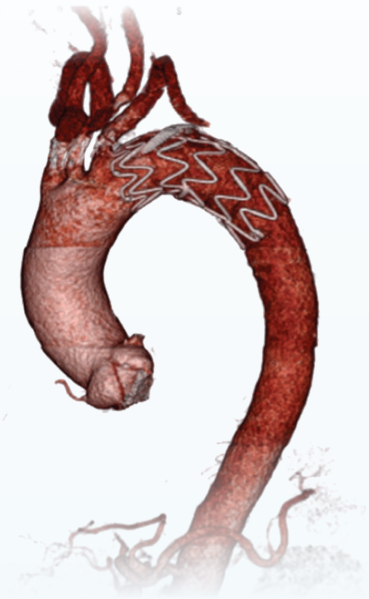
0%
Stroke rate at 30 days
0/50

98%
Estimated absence of major adverse events at 30 days
49/50

2%
Type Ia endoleak at 30 days
1/50

3. Starnes BW, Rajani RR, Rossi P, Singh N, Benarroch-Gampel J, Cho JS, Nassiri N, Smeds MR, Kalapatapu V, Stern JR, Kabutey NK, Corvera J; for the RelayPro Investigators. Early survival benefit of a low-profile endograft in blunt traumatic aortic injury. J Vasc Surg. 2024 Sep;80(3):678-684.e1. doi: 10.1016/j.jvs.2024.04.051. Epub 2024 Apr 25. PMID: 38677660.

Absence of: Aortic Ruptures, Endograft Infections, Aortic Dilation, Migration, Compression, Twisting, Extrusion/Erosion, Fracture, Suture Breaks, Type Ib endoleaks, or Type III endoleaks at any timepoint



Postoperative 3D reconstruction of a 66-year-old man involved in a high-speed motor vehicle collision with ejection treated with a 100-mm Relay®Pro non-bare stent (NBS) landing just distal to the left sub- clavian artery (LSA) in a type III arch with accuracy and good apposition

CONCLUSION

Relay®Pro offers some incremental improvements in the endovascular treatment of BTAI (lower profile and NBS configuration) and may provide an early survival benefit.

Summary Table

	Szeto et al. (2022)	Rossi et al. (2024)	Starnes et al. (2024)
Pathology	Aneurysm and PAU	Acute, Complicated TBAD	BTAI
Number of Patients	110	56	50
NBS Configurations	82.7% *Patients treated with NBS Configuration*	65.3% *Number of RelayPro NBS Configurations Among All Devices Implanted*	71% *Number of RelayPro NBS Configurations Among All Devices Implanted*
Percutaneous Femoral Approach	73.5% *In the US Cohort*	85.5%	80%
Technical Success	100% *Through 24 Hours*	100% *Through 24 Hours*	98% *At 24 Hours*
Type Ia Endoleak	1.8% *At 1 year*	1.8% *At 1 year*	2% *At 30 days*
Stroke Rate	3.6% *At 1 year*	1.8% *At 1 year*	0% *At 30 days*
Migration	0% *At 1 year*	1.8% *At 1 year*	0% *At 30 days*
Freedom from Secondary Intervention	94.1% *At 1 year*	82.1% *At 1 year*	94% *At 30 days*
Absence of Retrograde Dissection	100% *At 1 year*	96.4% *At 1 year*	NA

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Product availability subject to local regulatory approval.

PM-08876

For distributor information, visit terumoaortic.com/contact

Bolton Medical Inc.
799 International Parkway, Sunrise,
Florida 33325, USA