Current US Status and Results with the RelayPro NBS Endograft for TEVAR: Advantages and Limitations

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Disclosures

Consultant: Terumo, Medtronic, Gore, Shockwave, Penumbra
Research: Terumo, Gore, Medtronic, Penumbra

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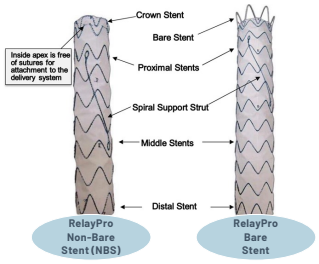
RelayPro Thoracic Stent-Graft System



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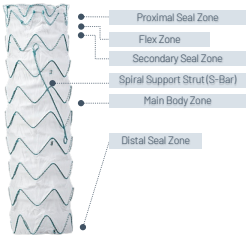
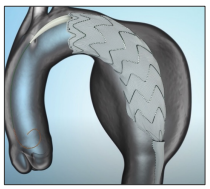
RelayPro Non-Bare Stent





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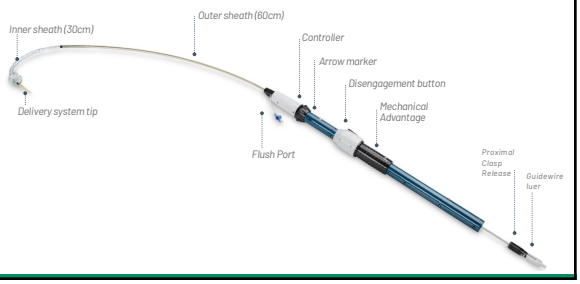
RelayPro Non-Bare Stent Delivery System



Overview RelayPro IDE Clinical Studies

RelayPro Aneurysm

Aneurysm Pivotal Study Implantations

		N=110
Devices Implanted	1	51.8% (57/110)
	2	43.6% (48/110)
	3	4.5% (5/110)
Total Devices Implanted		168
Non-Bare Stent (NBS)		77

RelayPro Transection

Transection Pivotal Study Implantations

		N=50
Devices Implanted	1	90.0% (45/50)
	2	8.0% (4/50)
	3	2.0% (1/50)
Total Devices Implanted		56
Non-Bare Stent (NBS)		41

RelayPro Dissection

Dissection Pivotal Study Implantations

		N=56
Devices Implanted	1	39.3% (22/56)
	2	46.4% (26/56)
	3	14.3% (8/56)
Total Devices Implanted		98
Non-Bare Stent (NBS)		64

182 RelayPro NBS Stent-Grafts implanted between A-, D-, and T-Clinical Studies

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RelayPro Dissection Pivotal Study

(G040175/S086)

Study Design: Prospective, multicenter, non-blinded, non-randomized study

Primary Objective: The primary objectives of this study are to evaluate the safety and effectiveness of the RelayPro Thoracic Stent-Graft in subjects with acute, complicated Type B aortic dissections

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Study Design

Patient Population	The treatment of patients with **acute, complicated Type B dissections** with the **RelayPro** Thoracic Stent-Graft System.
Sample Size	Up to **80 subjects**
Investigational Sites	Up to **40 US investigational sites** Maximum of 15% of enrollment at each site

Follow-up	**5-year follow-up** from index procedure • 30 days • 6 months • 12 months • Annually through 5 years
Additional Study Reviews	• Core Laboratory review • Clinical Events Committee (CEC) for specific safety events & endpoints

*Please note the study could stop for success according to the interim analysis plan and based on a sample size of 50 subjects (which provides at least 80% power to detect one or more rare adverse events that occur at a population rate of 3.2% or greater) and with a p-value ≤0.01317 to cross the boundary

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Primary Endpoint

Relay®Pro Dissection Pivotal Study

- The primary objectives of this study are to evaluate the safety and effectiveness of the RelayPro Thoracic Stent-Graft in subjects with acute, complicated Type B aortic dissections.
- The primary endpoint is all-cause mortality at 30-days post-procedure
- The primary endpoint was compared to a Performance Goal (PG) of 25%.

	Statistics	Pro-D Subjects (N=50)
All-cause mortality at 30 days	% (n/N)	2.0% (1/50)
	Upper 95% CI	–, 9.1%
	p-value*	< .0001

The performance goal for the primary endpoint was met

Results published in The Annals of Thoracic Surgery

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

Peter J. Rossi, MD,[1] Nimesh D. Desai, MD,[2] S. Chris Malaisrie, MD,[3] Sean P. Lyden, MD,[4] Nakem Nassiri, MD,[1] T. Brett Reece, MD,[1] Joshua D. Adams, MD,[1] Sina L. Moanis, MD,[5] and Christian C. Shults, MD,[1] on behalf of the RelayPro-D Investigators*

ABSTRACT

BACKGROUND: The safety and effectiveness of the RelayPro endograft (Terumo Aortic) was assessed for the treatment of acute, complicated type B aortic dissection (TBAD).

METHODS: A prospective pivotal trial analyzed a primary end point of all-cause mortality at 30 days. Secondary end points included technical success, major adverse events (bleeding stroke, renal failure, and paraplegia/paralysis), endoleaks, patency, rupture, device integrity, false lumen perfusion, reinterventions, aortic expansion, and migration evaluated to 5 years.

One-Year Results of a Low-Profile Endograft in Acute, Complicated Type B Aortic Dissection. Ann Thorac Surg. 2024 Feb 117(2):338–343. doi: 10.1016/j.athoracsur.2023.08.035. Epub 2023 Sep 27. PMID: 37769702

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Demographics (Site Reported)

	% (n/N) or Mean ± SD (n)
Age (years) at Treatment	59.5 ± 11.42 (56)
Sex	
Male	73.2% (41/56)
Female	26.8% (15/56)
Race	
Caucasian	42.9% (24/56)
Black	53.6% (30/56)
Asian	1.8% (1/56)
Unknown	1.8% (1/56)

Data cut of 04 DEC 2023

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Comorbidities (Site Reported)

	% (n/N)
History of Smoking	**82.1% (46/56)**
Current Smoker	47.8% (22/46)
Documented CAD	**21.4% (12/56)**
Stable Angina	3.6% (2/56)
Unstable Angina	1.8% (1/56)
Myocardial Infarction	3.6% (2/56)
Arrhythmias	1.8% (1/56)
Congestive Heart Failure	5.4% (3/56)
Other	12.5% (7/56)
History of Gastrointestinal Complications	**19.6% (11/56)**
GERD	12.5% (7/56)
Other	7.1% (4/56)

Data cut of 04 Dec 2023.

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Comorbidities Cont. (Site Reported)

	% (n/N)
Hypertension (treated or untreated)	89.3% (50/56)
Hypercholesterolemia	37.5% (21/56)
Current Antiplatelet/Anticoagulant Medication	37.5% (21/56)
Diabetes Mellitus	17.9% (10/56)
Renal Insufficiency	12.5% (7/56)
History of Vascular Intervention	12.5% (7/56)
History of Limb Ischemia	8.9% (5/56)
History of Peripheral Vascular Disease	7.1% (4/56)

Data cut of 04 Dec 2023.

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Index Procedural Details (Site Reported)

	% (n/N) or Mean ± SD (n)	Range
Anesthesia Type		
• General Anesthesia	100.0% (56/56)	
Vascular Access		
• Left Femoral	36.4% (20/55)	
• Right Femoral	63.6% (35/55)	
Vascular Access Method		
• Percutaneous	85.5% (47/55)	
• Surgical Cut Down	14.5% (8/55)	
CSF Drainage	33.9% (19/56)	
Mean Hospital Stay (days)	8.8 ± 4.74 (56)	2 – 35
Mean ICU Stay (hours)	122.5 ± 201.7 (56)	7 – 1536
Duration of Procedure (min)	138.4 ± 81.44 (56)	49 – 429
Duration of Implantation (min)	23.9 ± 29.78 (54)	1 – 180
Estimated Blood Loss (mL)	167.2 ± 264.1 (53)	10 – 1500
Transfusion Required	11.1% (6/54)	

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Data cut of 04 Dec 2023.

Follow-up Compliance (Site Reported)

	Eligible for Follow-Up	Visit Performed	CT Scan	X-Ray
Procedure	56	NA	NA	NA
30 Days	56	53	52	49
6 Months	50	37	35	33
12-months	45	38	35	31
2-Years	42	31	27	25
3-Years	31	19	17	17

Total 56 subjects enrolled in RelayPro Dissection IDE

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Data reported as the number of subjects (n). Preliminary Data. Data may change. Data cut of 04 Dec 2023.

Technical Success (Site Reported)

	% (n/N)
Technical Success at Index Procedure	**56 (100.0%)**
Evaluation of RelayPro System	
• Stent-Graft Deployed	56 (100.0%)
• Accuracy of Relay System Deployment Acceptable	56 (100.0%)
• Stent-graft patent	56 (100.0%)
• Stent-Graft Integrity Maintained (no wire fracture)	56 (100.0%)

Technical success is 100% (56/56) with all primary entry tears covered (56/56, 100%)

100% Deployment, Accuracy, Patency, & Device Integrity

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Data cut of 04 Dec 2023.

Mortality (CEC Adjudicated)

	30 Days	6 Months	12 Months	2 Years	3 Years
Number Eligible for Follow-Up	56	50	45	42	31
All-Cause Mortality	8.9% (5/56)	2.0% (1/50)	2.2% (1/45)	4.8% (2/42)	0.0% (0/31)
Dissection-Related Mortality*	1.8% (1/56)	0.0% (0/50)	0.0% (0/45)	0.0% (0/42)	0.0% (0/31)

*Preliminary Data. Data may change. Data cut of 15 Dec 2023. *Dissection-related mortality definition includes deaths within 30 days: POD 0 – POD 30. All-cause mortality is based on study visit windows as defined by the protocol.*

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Endoleaks (Core-Lab Reported)

	30 Days	6 Months	12 Months	2 Years	3 Years
Subjects w/ Adequate Imaging*	49	31	32	25	15
Any Endoleaks (Total)	0.0% (0/49)	3.2% (1/31)	6.3% (2/32)	4.0% (1/25)	0.0% (0/15)
Type Ia					
New	0	1	0	0	0
Persistent	NA	0	1	0	0
Type Ib					
New	0	0	0	0	0
Persistent	0	0	0	0	0
Type II					
New	0	0	1	0	0
Persistent	NA	0	0	1	0
Type III					
New	0	0	0	0	0
Persistent	0	0	0	0	0

0% Type Ib, Type III, Type IV, or endoleaks of unknown type have been reported by the Core Laboratory at any timepoint

*Preliminary Data. Data may change. Data cut of 15 Dec 2023. *Adequate imaging was determined by the Core Laboratory. In general, images with contrast and non-contrast series were regarded as adequate for interpretation of endoleaks.*

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False Lumen Perfusion (Core Lab Reported)

	1 Month	6 Months	12 Months	2 Years	3 Years
False Lumen Perfusion through Primary Intimal Tear	4.2% (2/48)	0	0	0	0

- No Core Laboratory observations of false lumen perfusion through the primary intimal tear after the 1-month visit

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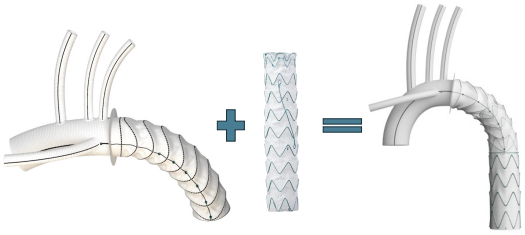
Preliminary Data. Data may change. Data cut of 23 Jan 2024.

Thoraflex Hybrid with RelayPro NBS Extension



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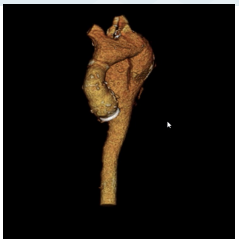
Case Review

- 34 yo M with Marfans with prior mechanical aortic root and Asc Ao replacement for Type A dissection
- Persistent Arch Dissection and Dilatation (6.5 cm)



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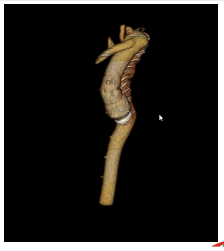
Case Review

- Redo Sternotomy
- Total Arch replacement with FET
- Thoraflex 26x28x150
- Follow up CTA post repair with residual distal aneurysm set up for TEVAR



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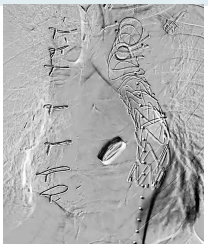
Case Review

- Distal Extension with NBS
- Distal Extension of 5 cm
- Percutaneous and staged 4 weeks



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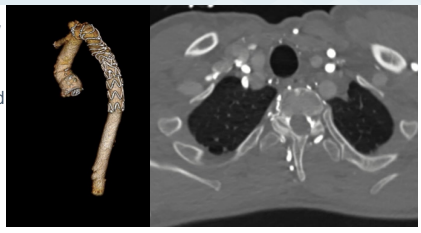
Case Review

- 6 & 12 month follow up CTA
- Doing well
- Aneurysm Excluded
- No EL



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Conclusion

A total of **56 subjects** are enrolled in **RelayPro Dissection IDE**

- *Enrollment complete. Follow-up remains ongoing*
- *100% device deployment, accuracy, patency, & device Integrity during the index procedure*
- *No observations of stenosis, kinking, twisting, misalignment or bird beak*
- *No ruptures of the dissection septum or fistula formation*

Post-market data is currently being collected regarding use of RelayPro NBS with Thoraflex Hybrid (EXTEND)

Clinical data from **RelayPro Dissection** IDE continues to support the **Safety and Effectiveness** for the labeled patient population

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