

**VEITH SYMPOSIUM™**  
Advancing The Value of Endovascular

**AIM**  
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Details Of A Novel Low Profile Stent-Graft For The TEVAR Of All Thoracic Aortic Segments: What Makes It Unique And Clinical Status

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## Faculty Disclosure

**Disclosure**

**Speaker name: Francesco Setacci, MD**

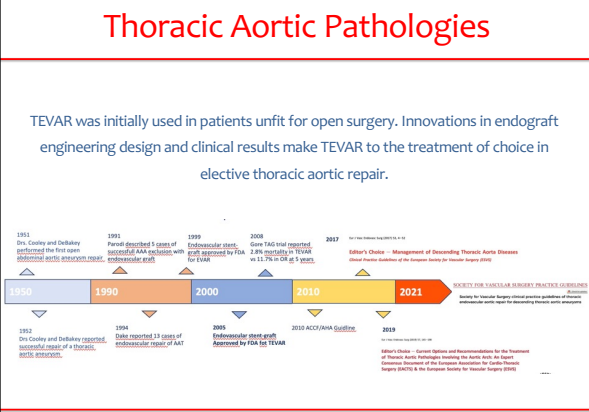
**I have the following potential conflicts of interest to report:**

- Consulting
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

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## Thoracic Aortic Pathologies

TEVAR was initially used in patients unfit for open surgery. Innovations in endograft engineering design and clinical results make TEVAR to the treatment of choice in elective thoracic aortic repair.



1951 Drs. Cooley and DeBakey performed the first open abdominal aortic aneurysm repair.

1993 Powell described a series of endovascular stents with stent supported by Dacron for EVAR.

1999 Endovascular stents were approved by FDA for EVAR.

2008 Gore TAG trial reported 3.8% mortality in TEVAR vs 13.7% in OR at 5 years.

2007 Editor's Choice - Management of Descending Thoracic Aortic Diseases (United States) Guidelines of the American Society for Thoracic Surgery (ASTS).

1992 Drs Cooley and DeBakey reported successful repair of a thoracic aortic aneurysm.

1994 Data reported 19 cases of endovascular repair of AAT.


2005 Endovascular stent-graft approved by FDA for TEVAR.

2010 ACCU/AAVQ Guideline.


2019 Editor's Choice - Current Status and Recommendations for the Treatment of Thoracic Aortic Pathologies involving the Aortic Arch, the Descending Aorta and the Common Arteries for Cardiothoracic Surgery (ASTS) & the European Society for Thoracic Surgery (ESTS).

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## Thoracic Aortic Pathologies



**ELECTIVE SETTING**  
IN PATIENTS WITH FAVOURABLE ANATOMY,  
TEVAR SHOULD BE CONSIDERED FOR DTAA >  
60 MM DIAMETER



Recommendation 46a	Class	Level of evidence	References
In fit and unfit patients with favourable anatomy, endovascular repair may be considered for descending thoracic aorta aneurysms between 56 and 59 mm diameter.	IIb	B	88,211–215
<b>Recommendation 46a</b>			
In fit and unfit patients with favourable anatomy, endovascular repair should be considered for descending thoracic aorta aneurysms >60 mm diameter.	IIa	B	88,211–215

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## Thoracic Aortic Pathologies

**Editor's Choice** Management of Descending Thoracic Aortic Diseases  
Journal of Vascular Medicine and Biology, Volume 35, Number 4, August 2023

**URGENT SETTING**  
 IN CASES OF COMPLICATED ACUTE TYPE B AD,  
 ANEURYSM RUPTURE OR TRAUMATIC AORTIC INJURY  
 TEVAR SHOULD BE PERFORMED AS THE FIRST LINE  
 TREATMENT

**7. TEN POINTS DESCRIBING WHEN TO CHOOSE WHAT KIND OF APPROACH**

Table 3. Factors favoring one or the other approach	Endovascular repair	Open repair
Factors favoring one or the other approach		
Previous coronary artery bypass grafting with patent IMA graft at risk at reentry	+	-
Poor left ventricular or right ventricular function	+	-
Poor pulmonary function	+	-
Poor liver function	+	-
Connective tissue disorder in patients with landing zones in aortic stent	-	+
Aortic aneurysm (femoral and iliac) diameter > 2 cm	-	+
Native ascending aorta diameter > 38 mm	-	+
Valvular heart disease necessitating concomitant repair	-	+
Previous mechanical aortic valve replacement	-	+
Proximal ascending aorta aortic or linked	-	+

+, favoring; -, disfavoring.

Recommendation 16	Class	Level of evidence	References
In patients with complicated acute type B aortic dissection, endovascular repair with thoracic endografting should be the first line intervention	I	C	8,15-85,92-94,96-99, 103,109


Recommendation 23	Class	Level of evidence	References
In patients with ruptured descending thoracic aortic aneurysm, endovascular repair should be the first treatment option when the anatomy is appropriate	I	B	127

Recommendation 29	Class	Level of evidence	References
In patients with traumatic thoracic aortic injury and suitable anatomy, endovascular repair should be performed as the first option	I	C	153,159,160


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## Terumo Relay Pro

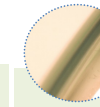
RelayPro is the latest generation **low profile** thoracic Stent-Graft system, designed to treat **thoracic aorta diseases**, showing a high level of **performance and safety** in the clinical outcomes.




**Fabric**  
Woven Polyester with an optimized weave pattern:  
 ▶ Low profile  
 ▶ High strength  
 ▶ Low permeability



**Suture**  
5-0 braided polyester surgical suture impregnated with PTFE  
 ▶ High wear resistance  
 ▶ High tensile strength



**Stents**  
Electropolished Nitinol  
 ▶ Super-elastic properties  
 ▶ Proven fatigue endurance



**Radiopaque Marker**  
Platinum Iridium  
 ▶ Radiopaque material for enhanced visibility

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## Terumo Relay Pro

The RelayPro is Terumo Aortic's next generation thoracic stent-graft system "with a 3- to 4-Fr outer profile reduction employing the same stent design and fabric material."<sup>1</sup>  
Gennai et al., 2022

**0%**  
Type III/IV endoleak through 1 year<sup>2,3</sup>

2: 0/110  
3: 0/58

**0%**  
Stent fractures through 1 year<sup>2,3</sup>

2: 0/110  
3: 0/58

**0%**  
Stenosis/thrombosis through 1 year<sup>2,3</sup>

2: 0/110  
3: 0/58

**0%**  
Loss of patency through 1 year<sup>2,3</sup>

2: 0/110  
3: 0/58

2: Thoracic Aortic Aneurysm and Penetrating Atherosclerotic Ulcer Cohort  
 3: Acute Complicated Type B Aortic Dissection Cohort

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## Terumo Relay Pro IFU

### Indication For Use

The RelayPro Thoracic Stent-Graft System is indicated for the treatment of **thoracic aortic pathologies** such as **aneurysms, pseudoaneurysms, dissections, penetrating ulcers, and intramural hematoma**, in adult patients with the following characteristics:

Stent-Graft Diameter (mm)	Proximal Length Bare Stent Configuration (mm)	Proximal Length NBS Configuration (mm)	Distal Length Bare Stent & NBS Configuration (mm)
22-28	15	22	25
30-38	20	25	
40-46	25	30	30

**48%**  
of REGENERATION<sup>4</sup> patients treated in Zo-Z3 of the thoracic aorta

4: 19/31

**100%**  
Technical Success<sup>4</sup>

Primary 90% Assisted Primary 10%  
4: 31/31

**97%**  
Freedom from secondary intervention at 1 year<sup>4</sup>

4: 30/31

**94%**  
Freedom from device-related MAEs at 30 days<sup>4</sup>

4: 29/31

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### Terumo Relay Pro Key Features

The RelayPro stent-graft builds on the proven RelayPlus design, described as:

“The Relay thoracic stent-graft system has been developed as a flexible stent-graft specifically designed for the thoracic aorta.”<sup>5</sup>  
Yunoki et al., 2014

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### Terumo Relay Pro Multiple Size Options

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### Performance Zone: Designed To Respect The Thoracic Anatomy

The RelayPro stent graft is divided into performance zones. Each zone is designed to serve a specific purpose and therefore distributes an appropriate radial load independent of other zones

Zone	Radial force	Zone
Alignment Zone	Very Low	Proximal Seal Zone
Proximal Seal Zone	Very High	
Flex Zone	None	Flex Zone
Secondary Seal Zone	High	Secondary Seal Zone
Main Body Zone	Medium	Main Body Zone
Distal Seal Zone	High	Distal Seal Zone

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### Performance Zone: Designed To Respect The Thoracic Anatomy

**98.9%**

Freedom from aneurysm expansion at 1 year<sup>2</sup>

2: 109/110


**100%**

Absence of false lumen perfusion from 30 days to 1 year<sup>3</sup>

3: 56/56

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### Proximal End Configuration



**Partial overlapping** of the bare stent with the first covered stent to **maximise** the number of **sealing points**

A **crown-shaped** nitinol stent overlapping with the proximal sealing stent, both covered with fabric, designed to maximise conformability and **minimize infolding**

Both proximal configurations are designed to deliver **high radial load** for an effective apposition and fixation of the graft against the aortic wall

2: Thoracic Aortic Aneurysm and Penetrating Atherosclerotic Ulcer Cohort  
3: Acute Complicated Type B Aortic Dissection Cohort

**1.8%**  
Type Ia endoleak at 12 months<sup>2,3</sup>

2: 2/110  
3: 1/56

**100%**  
Technical Success through 24 hours<sup>2,3</sup>


2: 110/110  
3: 56/56

**0%**  
Migration through 12 months<sup>2</sup>

2: 0/110

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### S-Bar Technology Ahead of The Curve




S-Bar, a **curved nitinol wire** that starts 25 mm from the proximal edge of the graft, intended to provide **columnar strength** to the endograft and to enhance conformability by adapting to the natural curvature of the aorta

**Shortened length** to optimize the treatment in tortuous aortas, enabling the more distal portion of the graft to flex in any direction.

The **shorter** RelayPro S-Bar builds on the proven RelayPlus longer S-Bar design described as:

*"[...] an outer curved Nitinol bar (S-bar) that allows for the gentle conformability of the device along the three-dimensional anatomy of the aortic arch."*

**AORTA**  
Riambau, 2015<sup>7</sup>



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### Low-Profile Delivery System

Device	Profile OD	Proximal Stent Graft Diameter
RelayPro	19 Fr	22* - 30mm
	20Fr	32 - 36mm
	21Fr	38 - 40mm
	22 Fr	42 - 46mm
RelayPro NBS	19 Fr	22* - 26mm
	20Fr	28 - 30mm
	21Fr	32 - 34mm
	22 Fr	36 - 40mm
	23 Fr	42 - 46mm

**UP TO 85.5%**  
patients treated with a percutaneous femoral approach<sup>2,3</sup>

2: 50/68  
3: 47/56

\*22 mm diameter stent-grafts are only approved to treat traumatic aortic injuries (transactions)  
\*\* For tapered devices, Fr size based on largest diameter of the stent-graft

2: Thoracic Aortic Aneurysm and Penetrating Atherosclerotic Ulcer Cohort  
3: Acute Complicated Type B Aortic Dissection Cohort

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### Low-Profile Delivery System

*"The 3-4 French profile reduction of the new RelayPro is expected to offer operative advantages in terms of stent- graft introduction and deployment, particularly in patients with narrow or tortuous access vessels"*

**Riambau et al., 2019<sup>4</sup>**

**Annals of Vascular Surgery**

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### Dual Sheath Technology

An integrated Dual Sheath system designed to minimise access vessel manipulation and provides atraumatic thoracic aorta navigation

**1.8%** Disabling stroke rate at 30 days with no stroke during 1-year follow-up<sup>3</sup> 3/158

**1.8%** Operative vascular access complications<sup>3</sup> 3/158

*"RelayPro's ability to navigate smoothly over the arch as a result of the Dual Sheath system enables accurate deployment, and combined with the low profile of the device, this allows me to successfully treat complex anatomy with precision"<sup>4</sup>*  
W. Szeto

- Pre-curved Nitinol Catheter designed for self-alignment
- Soft Inner Sheath designed to provide navigability
- Coiled Outer Sheath designed to provide pushability

<sup>3</sup> Acute Complicated Type B Aortic Dissection Cohort

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### Support Wires, Asymmetrical Proximal Clasping, Flared End

#### Stop Birdbeaking and Retroflex

RelayPro NBS delivery system implements three features to provide the ability to reposition, prevent retroflex, and avoid birdbeaking

**100%** Accurate device deployment<sup>5</sup>

**0%** Bird-beak through 12 months<sup>3</sup>

Two clasping points, both located on the outer curve of the RelayPro NBS, for a precise and controlled deployment, preserving the ability to reposition

During deployment, two support wires\* guide the inferior portion toward the inner aortic wall, keeping it aligned with the landing zone and minimising the risk of retroflex

The Flared End configuration of the inner sheath enables partial expansion to improve the proximal alignment and precision for a correct apposition on the inner curve, avoiding birdbeaking

\* The support wires are only present in devices with 32 mm or greater proximal stent-graft diameters

<sup>3</sup> Acute Complicated Type B Aortic Dissection Cohort  
<sup>5</sup> Aortic dissection, aortic aneurysms, PTA and IM-N1 aortic erosion and aortic rupture, each. The RelayPro is NOT indicated for erosion or rupture.

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### Support Wires, Asymmetrical Proximal Clasping, Flared End

#### Stop Birdbeaking and Retroflex

*"Accurate deployment with favorable apposition even in hostile aortic arches contributed to low rates of early and mid-term complications."<sup>6</sup>*  
El Beyrouti et al., 2020

<sup>3</sup> Acute Complicated Type B Aortic Dissection Cohort  
<sup>6</sup> Aortic dissection, aortic aneurysms, PTA and IM-N1 aortic erosion and aortic rupture, each. The RelayPro is NOT indicated for erosion or rupture.

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### Catania Experience in Thoracic Aortic Pathologies

From 2019 to august 2024, a total of 311 patients with THORACIC AORTIC PATHOLOGIES underwent TEVAR.

Year	Number of Patients
2019	10
2020	15
2021	20
2022	25
2023	30
2024 (up to August)	11

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### Terumo Relay ProCatania Experience

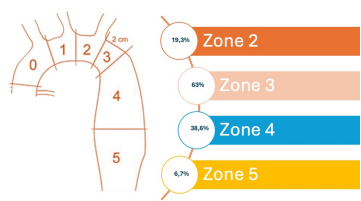


Between them, **165 consecutive patients** underwent TEVAR using a Relay Pro low profile stent graft.

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### Terumo Relay ProCatania Experience

N=165	N	%
Age (mean, y)	68.9 ± 9	
Male	129	78.1
Preop. Comorbidities		
CAD	33	20
Smokers	89	53.9
Renal disease	21	12.7
CCPD	23	13.9
Pathologies		
Aneurysms	68	41.2
Rupture	20	12.1
PAU	20	12.1
Post Dissect. An.	16	9.7
Pseudoaneurysms	3	1.8
Acute type B Dissection	16	9.7
Chronic Type B Dissection	22	13.3
Emergency	42	25.5
Hybrid Procedure	12	7.2
Local Anesthesia	119	72.1
Percutaneous access	161	97.5

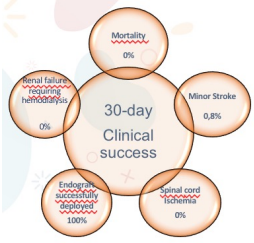


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### Terumo Relay Results

N=165	N	%
Local anesthesia success	152/165	92.1
Access related success	159/165	96.3


N=165	N	%
Mortality	0/165	0
Stroke (minor stroke)	1/165	0.6
Paraplegia	0/165	0



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### Conclusions

- The minimally invasive approach and the low-profile RelayPro thoracic endograft showed an early high rate of feasibility and technical success
- No evidence of spinal cord ischemia, low rates of stroke and death also in emergency setting and a promising efficacy profile up to 3 year were reported.
- This method may contribute to extend the indications to a larger cohort of patients



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