Current Status And Results Of The Terumo Relay Branched Endograft Device For Aortic Arch Lesion Repairs: Unique Features And When Will It Be available In The US

TiGER Post Market Registry

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Disclosures

I have the following potential conflicts of interest to report:

- ☒ Consulting: Terumo Aortic, Medtronic, Cook Medical, iVascular, W.L. Gore, VB Devices, Lifetech, Möller Medical, Aortyx, Balt Medical.
- ☒ Stockholder of a healthcare company: Aortyx, VB Devices
- ☒ PI of TIGER Postmarket Registry

TiGER Global Site Overview

As of April 4th, 2024

Total Subject Enrollment is 1190

Site Enrollment by County

- Spain - 4 sites
- Portugal – 2 sites
- Netherlands - 7 sites
- Germany – 7 sites
- Belgium – 1 sites
- France – 2 sites
- Italy – 7 sites
- Switzerland- 1
- UK – 3 sites
- USA – 18 sites

52 Sites active across 10 Countries

TiGER Overview

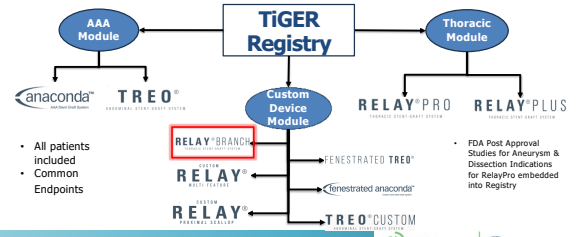
- **Study Size**
  - Minimum of **1000 patients at up to 80 sites** globally
  - No upper limit set
- **Study Duration**
  - **Enrolment opened Nov 2019**, no closure date
  - Data will be collected at the following time points:
    - Baseline (Procedure)
    - Early follow-up (Discharge/30 days to six months)
    - One-year post index procedure
    - Post index procedure mid- to long-term follow-up annually through subject lifetime or until lost to follow up (LTFU)
  - For Thoracic cohort, a **minimum of 5 Years** annual follow-up is required

Key Study Contacts

- Prof Vincent Riambau – Hospital Clinic i provincial de Barcelona (Coordinating Investigator – Global)
- Prof Michele Reijnen -Rijnstate, Arnhem, Netherlands (Regional PI – Europe)
- Mr David Murray – Manchester University Hospital, United Kingdom (CI - UK)

Module Overview

One overarching protocol utilising a modular



- All patients included
- Common Endpoints

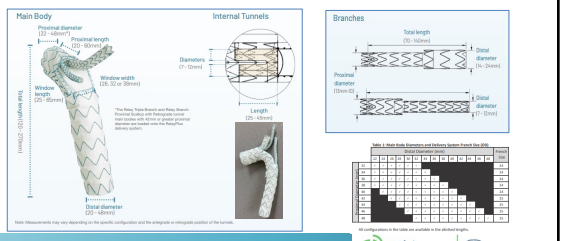
- FDA Post Approval Studies for Aneurysm & Dissection Indications for RelayPro embedded into Registry

Relay®Branch Thoracic Stent-Graft System

(Outside US)

- Builds upon the **core features** of the standard Relay®Pro platform
- Incorporating the same advance technology and design principles
- Added customization*
- Benefits of this platform include

Relay®Branch Thoracic Stent-Graft System



Preliminary interim data as of September 30th, 2024

TiGER Post Market Registry

Enrolled w/ **Relay®Branch** **19**

Indication for Treatment (Site Reported)

	% (n/N)
Chronic Dissection	**15.9% (3/19)**
DeBakey Type I (Standford Type A)	5.3% (1/19)
Debakey Type III (Standford Type B)	5.3% (2/19)*
Aortic Aneurysm	**78.9% (15/19)**
Fusiform	52.6% (10/19)
Saccular	15.8% (3/19)
Not collected	10.5% (2/19)
Penetrating Aortic Ucler (PAU)	**10.5% (2/19)**

Preliminary Data. Data may change. Data cut of 30 Sep 2024.

Demographics (Site Reported)

	% (n/N) or Mean ± SD (n)
Age (years) at Treatment	72.0 ± 9.6 (18)
Sex	
Male	**89.5%** (17/19)
Female	10.5% (2/19)
Race	
Caucasian	**63.2%** (12/19)
Non-Caucasian	5.3% (1/19)
Not collected	31.6% (6/19)

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Comorbidities (Site Reported)

	% (n/N) or Mean ± SD (n)
Smoking History	
Current Smoker	21.1% (4/19)
Former Smoker	31.6% (6/19)
Never Smoked	47.4% (9/19)
ASA Grade	
I	0
II	5.3% (1/19)
III	**84.2%** (16/19)
IV	10.5% (2/19)
V	0
SVS/AAS Comorbidity Score	0.7 ± 0.4 (19)

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Medical History (Site Reported)

	% (n/N)
Type 2 Diabetes	15.8% (3/19)
Previous Endovascular or Open Surgery	31.6% (6/19)
Other Vascular interventions	47.4% (9/19)
History of Stroke or Neurological Defecit	10.5% (2/19)
Current use of Antiplatelet/Anticoagulant medications	**94.7%** (18/19)
Chronic Obstructive Pulmonary Disorder (COPD)	15.8% (3/19)
Hypercholesterolemia	21.1% (4/19)
Hyperlipidemia	47.4% (9/19)
Hypertension	**89.5%** (17/19)
Neurological Disease	15.8% (3/19)
Peripheral Vascular Disease	26.3% (5/19)
Renal Insufficiency	21.1% (4/19)
Coronary Artery Disease	15.8% (3/19)
Gastrointestinal Complications	5.3% (1/19)

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Procedural (Site Reported)

	% (n/N) or Mean ± SD (n)	Range
Surgical Acuity		
• Elective	**100%** (19/19)	
• Emergent	0	
Anesthesia Type		
• General Anesthesia	**100%** (19/19)	
• Local Anesthesia	0	
• Other	0	
Mean Hospital Stay (days)	12.5 ± 11.7 (19)	2 — 52
Mean ICU Stay (hours)	88.3 ± 97.9 (19)	72 — 336
Total Surgery Time (min)	292.8 ± 116.3 (19)	268 — 540
Total Endovascular Time (min)	206.5 ± 73.8 (17)	180 — 360
Estimated Blood Loss (mL)	772.2 ± 1028.7 (9)	500 — 3500
Transfusion Required	36.8% (7/19)	
Vascular Access		
• Cut Down	36.8% (7/19)	
• Percutaneous	**47.4%** (9/19)	
• Conduit	15.8% (3/19)	
Discharge Destination		
• Temporary Ambulatory Care Center	0	
• Return to pre-op living location	**89.5%** (17/19)	
• Other	10.5% (2/19)	

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Technical Success (Site Reported)

	% (n/N)
Components of Technical Success	
• Device introduction into the entry site acceptable	100% (18/18)
• Advancement of device to the lesion site acceptable	100% (18/18)
• Device deployment from the delivery system acceptable	100.0% (18/18)
• Accuracy of the device system deployment acceptable	100.0% (18/18)
• Stent-graft patent	100.0% (18/18)
• Device integrity maintained (no tears, fractures, etc.)	100% (18/18)
• Stent-graft deployed without kinking or twisting	100% (18/18)
• Absence of Type Ia, Type Ib, Type IIIa and Type IIIb endoleak	94.7% (18/19)
• Absence of unplanned coverage of aortic branch vessels	100% (19/19)

100% Acceptable Device Introduction, Deployment, Accuracy, Patency, and Integrity

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Mortality (Site Reported)

	Procedure (POD 0 – POD 29)	Early Follow-up	12 Months	2 Years	3 Years	Total (subjects)
Visits Performed	19	8	4	3	1	19
All-Cause Mortality	2	1	0	0	0	3
Aortic-Related Mortality	2	0	0	0	0	2

- **Aortic Related Death (n=2)**
- Definition: Aortic-related death is defined as any death occurring within 30 days of implant, due to rupture or following any procedure intended to treat the target lesion
  - Subject 004-016 (POD 13), acute liver failure
  - Subject 004-018 (POD 9), heart failure

No Aortic-related mortality was reported as device related

Preliminary Data. Data may change. Data cut of 30 Sep 2024.

Stroke (Site Reported)

	After Index Procedure (POD 1 – POD 29)	Early Follow-up	12 Months	2 Years	3 Years
Visits Performed	19	8	4	3	1
Stroke	0	0	0	2	0

Stroke (n=2)
- Subject 015-008, 2-year visit (01/27/2022), Site reported slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities
- Subject 024-028, 2-year visit (01/29/2024), Site reported a moderately severe disability. Unable to attend to own bodily needs without assistance & unable to walk unassisted

Preliminary Data. Data may change. Data cut of 30 Sep 2024.

Secondary Interventions (Site Reported)

	After Index Procedure (POD 1 – POD 29)	Early Follow-up	12 Months	2 Years	Total
Visits Performed	19	8	4	3	19
Subjects w/ any Intervention	2	0	2	0	4
Total number of Interventions	2	0	2	0	4

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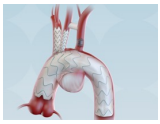
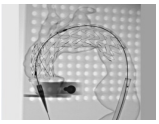
Reasons for Secondary Interventions (Site Reported)

- **4 subjects w/ 4 Secondary Interventions at Follow-up**
  - Major bleeding (POD 1) - Wound revision to achieve hemostasis of the arterial access
  - Type II Endoleak and Stenosis (POD 3) - Reintervention performed for Type II endoleak
  - Proximal kinking and suspected Type I Endoleak (POD 259) - embolization of the false lumen of the dissection, and dilatation of the slight collapse of the proximal edge of the endoprosthesis were performed
  - Extension of previous TEVAR (POD 275) - Extension of previous TEVAR due to distal aneurysm with an increased diameter of 47 to 55 mm





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More data…

- No ruptures or conversions to open surgery
- No device occlusions
- No clinically significant migration >10mm
- No wire frame fractures

Summary

A total of **19 subjects** are enrolled in TiGER **Relay®Branch**

- *Enrollment and follow-up remain ongoing across all TiGER Modules*
- *Most of the components of technical success (e.g., deployment, accuracy, delivery, etc.) were 100%*
- *No aortic-related mortalities related to the device or lesion*
- *No ruptures or conversions to open surgery*
- *No stent fractures or migration >10mm*

Preliminary results continue to support the safety and effectiveness of the Relay®Branch Thoracic Stent-Graft System

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