Real World Outcomes With The TREO Endograft (Terumo Aortic): Results From The TIGER Registry

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

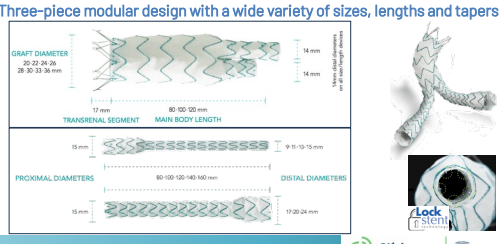
One overarching protocol utilising a modular system

- All patients included
- Common Endpoints

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

TREO® Abdominal Stent Graft System

Three-piece modular design with a wide variety of sizes, lengths and tapers



Preliminary interim data as of September 30th, 2024

TiGER Post Market Registry

Enrolled w/ **TREO®** **330**

Indication for Treatment (Site Reported)

	% (n/N)
Penetrating Atherosclerotic Ulcer (PAU)	2.7% (9/330)
Aortic Aneurysm	**94.8%** (313/330)
Fusiform	**79.6%** (215/270)
Saccular	20.4% (55/270)
Intramural Hematoma	0% (0/330)
Pseudoaneurysm	0.3% (1/330)
Unknown/Other	2.1% (7/330)

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

Demographics (Site Reported)

	% (n/N) or Mean ± SD (n)
Age (years) at Treatment	**73**.8 ± 7.3 (272)
Sex	
Male	**90.3%** (298/330)
Female	9.7% (32.330)
Race	
Caucasian	**83.0%** (273/330)
Non-caucasian	0.9% (3/330)
Missing	16.4% (54/330)

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

Comorbidities (Site Reported)

	% (n/N) or Mean ± SD (n)
Smoking History	
Current Smoker	26.5% (87/328)
Former Smoker	56.7% (186/328)
Never Smoked	16.8% (55/328)
ASA Grade	
I	1.8% (1/329)
II	18.8% (62/329)
III	**63.8%** (210/329)
IV	14.9% (49/329)
V	0.6% (2/329)
SVS/AAS Comorbidity Score	0.8 ± 0.5 (329)

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Medical History (Site Reported)

	% (n/N)
Type 2 Diabetes	18.8% (62/330)
Previous Endovascular or Open Surgery	15.8 % (52/330)
Other Vascular interventions	14.5% (48/330)
History of Stroke	13.0% (43/330)
Current use of Antiplatelet/Anticoagulant medications	78.2% (258/330)
Chronic Obstructive Pulmonary Disorder (COPD)	18.8% (61/330)
Claudication	4.3% (14/330)
Hypercholesterolemia	36.9% (120/330)
Hyperlipidemia	25.2% (82/330)
Hypertension	**76.0%** (247/330)
Neurological Disease	7.1% (23/330)
Peripheral Vascular Disease	14.5 (47/330)
Renal Insufficiency	13.8% (45/330)
Coronary Artery Disease	40.3% (133/330)
Gastrointestinal Complications	4.2% (14/330)

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Procedural (Site Reported)

	% (n/N) or Mean ± SD (n)	Range
Surgical Acuity		
• Elective	94.5% (312/330)	
• Emergent	5.5% (18/330)	
Anesthesia Type		
• General Anesthesia	72.1% (238/330)	
• Local Anesthesia	26.1% (86/330)	
• Other	1.8% (6/330)	
Mean Hospital Stay (days)	5.3± 4.7 (327)	1 — 35
Mean ICU Stay (hours)	6.9 ± 20.6 (326)	0 — 175
Total Surgery Time (min)	105.5 ± 48.3 (330)	0 — 298
Total Endovascular Time (min)	87.1 ± 39.1 (275)	3 — 298
Estimated Blood Loss (mL)	140.4 ± 186.6 (197)	0 — 1100
Transfusion Required	22.7% (75/330)	
Vascular Access		
• Cut Down	10.6% (35/330)	
• Percutaneous	89.1% (294/330)	
• Conduit	0.3% (1/330)	
Discharge Destination		
• Temporary Ambulatory Care Center	0.3% (1/327)	
• Return to pre-op living location	97.6% (319/327)	
• Other	2.1% (7/327)	

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Technical Success (Site Reported)

Components of Technical Success	% (n/N)
• Device introduction into the entry site acceptable	100% (327/327)
• Advancement of device to the lesion site acceptable	99.4% (325/327)
• Device deployment from the delivery system acceptable	100.0% (327/327)
• Accuracy of the device system deployment acceptable	100.0% (327/327)
• Stent-graft patent	100.0% (327/327)
• Device integrity maintained (no tears, fractures, etc.)	100% (327/327)
• Stent-graft deployed without kinking or twisting	99.1% (324/327)
• Absence of Type Ia, Type Ib, Type IIIa and Type IIIb endoleak	98.8% (326/330)

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

Mortality (Site Reported)

	Procedure (POD 0 – POD 29)	Early Follow-up	12 Months	2 Years	3 Years	4 Years	Total (subjects)
Visits Performed	330	212	191	106	38	5	330
All-Cause Mortality	0.9% (3/330)	1.4% (3/212)	5.2% (10/191)	3.8% (4/106)	7.9% (3/38)	40% (2/5)	7.6% (25/330)
Aortic-Related Mortality	0.9% (3/330)	0.5% (1/212)	0	0	0	0	1.2% (4/330)

- Aortic Related Death (n=4)
- 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 012-043 (POD 3), Microembolization
  - Subject 072-003 (POD 3), Due to myocardial infarction Impella procedure attempted but failed
  - Subject 001-004 (POD 16), Complicated kidney cyst
  - Subject 025-012 (POD 30), Suspicion of sepsis

No Aortic-related mortality was reported as device or lesion related

Endoleaks (Site Reported)

	Early Follow-up	12 Months	2 Years	3 Years	Total (subjects)
Subjects w/ Adequate Imaging*	189	160	89	33	330
Total Type I & Type III	2.1% (4/189)	1.3% (2/160)	3.3% (3/89)	3.0% (1/33)	3.0% (10/330)
Type Ia					
New	1.1% (2/189)	0	0	3.0% (1/33)	0.9% (3/330)
Type Ib					
New	0.5% (1/189)	1.3% (2/160)	1.1% (1/89)	0	1.2% (4/330)
Type III					
New	0.5% (1/189)	0	2.2% (2/89)	0	0.9% (3/330)

Patency (Site Reported)

	Early Follow-up	12 Months	2 Years	3 Years
Subjects w/ Adequate Imaging	195	169	97	33
Patent Stent-Graft	98.0% (191/195)	97.0% (164/169)	95.9% (93/97)	100% (33/33)
Limb Occlusions				
New	2.1% (4/195)	2.4% (4/169)	4.1% (4/97)	0
Persistent	0	0.6% (1/169)	0	0
Kinking	0	0	0	0

Aortic Remodeling (Site Reported)

	Early Follow-up	12 Months	2 Years
Subjects w/ Adequate Imaging	189	138	82
Increase > 5mm			
New	NA	3.6% (5/138)	1.2% (1/82)
Persistent	NA	0	0
Decrease	NA	43.5% (60/138)	30.5% (25/82)
Stable	NA	52.9% (73/138)	68.3% (56/82)

Secondary Interventions (Site Reported)

	After Index Procedure* (POD 0 – POD 29)	Early Follow-up	12 Months	2 Years	Total
Visits Performed	330	212	191	106	330
Subjects w/ any Intervention	1.8% (6/330)	3.3% (7/212)	2.1% (4/191)	2.8% (3/106)	6.1% (20/330)
Total number of Interventions	8	8	7	3	26

Reasons for Secondary Interventions

- **Endoleak (n=7)**
- **Limb Occlusion (n=3)**
- **Limb Ischemia (n=4)**
- **Other (n=12)**
- 12 reinterventions were due to reasons such as:
  - 2 limb compressions resolved w/ stenting
  - 2 PAU's w/ stenting
  - Persistent anemization resolved w/ embolization
  - Popliteal aneurysm resolved w/ stenting
  - Spurium aneurysma resolved w/ peri card patch
  - Hematoma drainage
  - Covered rupture w/ explantation
  - A two-, third- stage procedure

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Summary

TiGER Post Market Registry

A total of **330 subjects** are enrolled in **TiGER TREO®**

- *Enrollment and follow-up remain ongoing across all TiGER Modules*
- *100% Acceptable device introduction, deployment, accuracy, patency, and integrity at the index procedure*
- *No aortic-related mortalities related to the device or lesion*
- *No stent fractures were reported at follow-up*
- *No migration >10mm*

Preliminary results continue to support the safety and effectiveness of the TREO® Abdominal Stent-Graft System

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