

PRODUCT BROCHURE

TREO[®]: Clinical Outcomes

When Experience Meets Evidence

The NEXT Evolution of EVAR is Here

The TREO® Abdominal Stent-Graft System is indicated for use in the endovascular treatment of patients with **infrarenal abdominal aortic and aorto-iliac aneurysms** with the following characteristics:

Proximal aortic landing zone with:

- ▶ Infrarenal landing neck length of $\geq 15\text{mm}$
- ▶ Suprarenal neck angle of ≤ 45 degrees
- ▶ Infrarenal neck angle of ≤ 60 degrees
- ▶ Aortic neck diameters $\geq 17\text{mm}$ and $\leq 32\text{mm}$

Distal iliac landing zone with:

- ▶ An inside diameter of $8\text{mm} - 13\text{mm}$ and a length of $\geq 10\text{mm}$
- ▶ An inside diameter of $>13\text{mm} - 20\text{mm}$ and a length of $\geq 15\text{mm}$

Adequate iliac or femoral access compatible with the required delivery systems and accessories

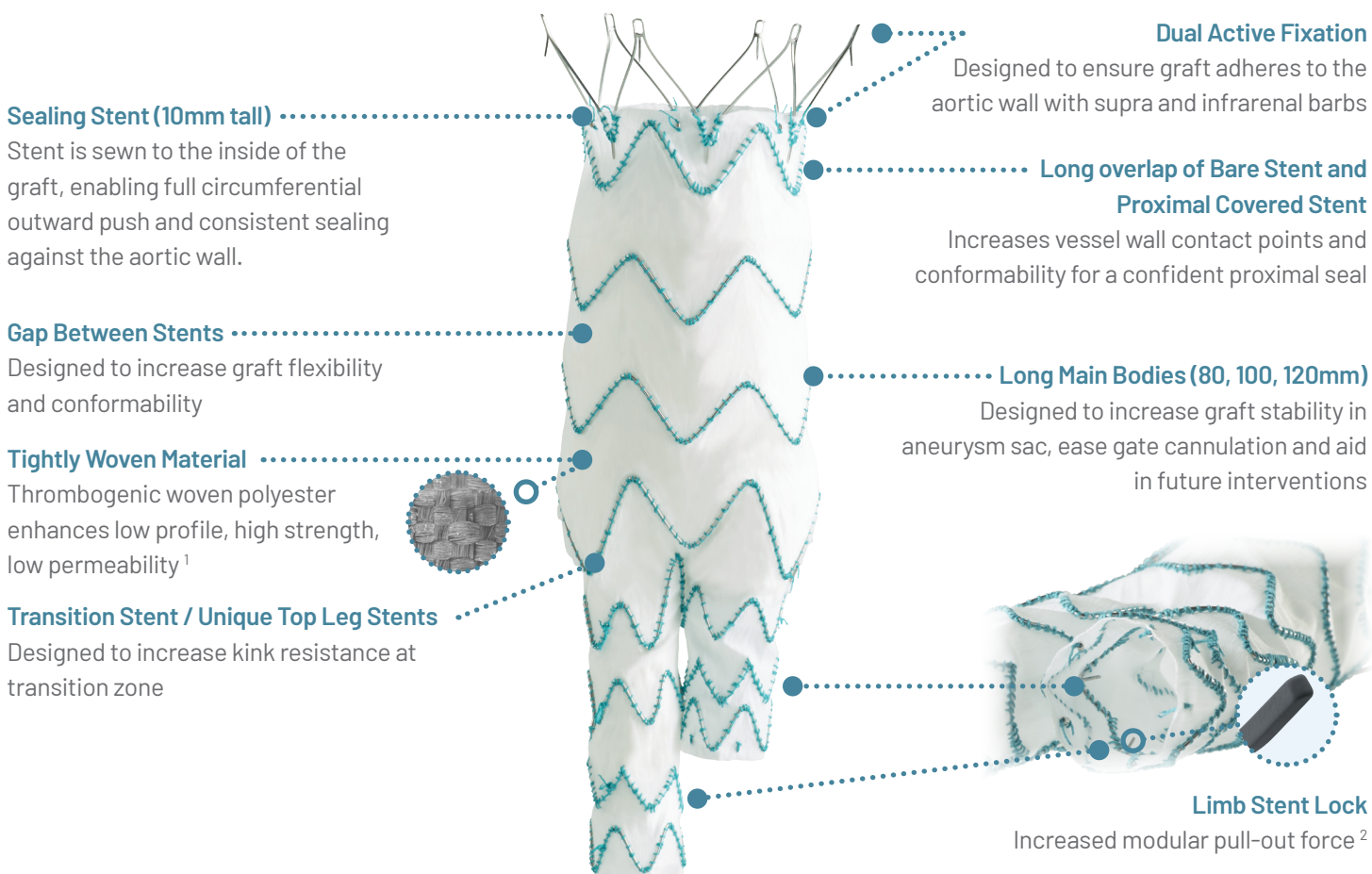
Minimum overall AAA treatment length: **130mm**

(Proximal Landing location to distal landing location)

Minimum overall length: **90mm**

(Lowest renal artery to the aortic bifurcation)

Design Goals: Enhanced Durability, Expanded Patient Applicability



TiGER Registry³

Real World Outcomes with the TREO® Endograft (Terumo Aortic): Results from the European TiGER Registry

STUDY DESIGN

Real World

All-Comers Study

Site Reported

Peer Reviewed

330 Subjects

312 Elective; 18 Emergent

23 Sites

European Sites

2 Year Follow-up

(Mean follow-up 464.3 ± 362.4 days)

RESULTS

97%

High technical success rates

318/327

0%

No device aortic-related mortality

0/330

0%

No migration or stent fractures

0/330

2%

Consistently low type I endoleaks

7/330

1%

Consistently low type III endoleaks

3/330

6%

Low reintervention rates

20/330

CONCLUSION

Adding to the growing body of evidence, the TiGER registry confirms consistent and durable outcomes for TREO® in real-world practice. Overall, these findings align closely with previous studies and reinforce TREO® as a reliable choice for durable outcomes – even in emergent settings

US IDE Study- 5-Year Results ⁴

Long Term Safety And Effectiveness of the TREO® Stent Graft for the Endovascular Treatment of Infrarenal Abdominal Aortic Aneurysms

STUDY DESIGN

Multi-center, non-blinded, non-randomized study of treatment in patients with abdominal aortic aneurysms.

29 US Hospitals

150 Patients

RESULTS

100%

Technical Success at Index Procedure ⁴

150/150

93%

Successful Aneurysm Treatment at 12 months ⁵

123/132

0.7%

MAE Rate at 30 days ⁴

1/150

Through 5-Years (0/150)

0%

- ▶ Aneurysm-related mortality ⁵
- ▶ Conversion to open repair ⁵
- ▶ Type III, IV endoleaks* ⁵
- ▶ Device related MAE's ⁵
- ▶ Occlusion* ⁵
- ▶ Renal Failure ** ⁵
- ▶ Paraplegia ⁵

CONCLUSION

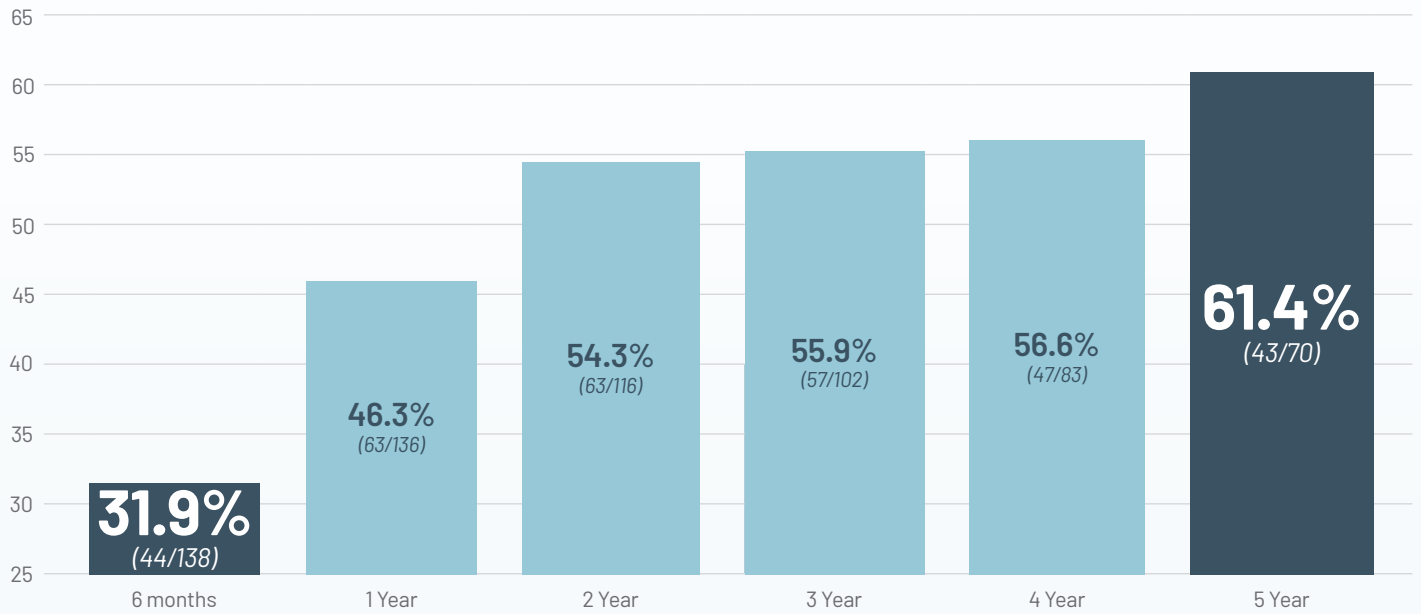
5-year follow-up for the TREO® Stent-Graft System demonstrated durable performance, with low rates of long-term morbidity and mortality, and high rates of long-term sac shrinkage, confirming sustained long-term safety and effectiveness in the repair of infrarenal abdominal aortic aneurysms.

* Core Lab Reported.

** Requiring Renal Replacement Therapy.

US IDE Study- 5-Year Results ⁴

Sac Regression 5-year outcomes ⁴

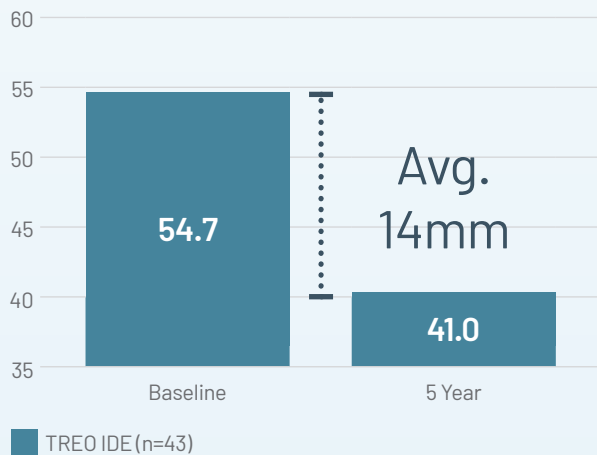


0%
Aneurysm Rupture Through 5-years ⁴
(0/150)

97%
Absence of Type I Endoleak through 5 years ⁴
(146/150)

89%
Absence of Reinterventions through 5 years ⁴
(134/150)

TREO® IDE 5-Year Aneurysm Sac Average Maximum Diameter
Sub-cohort: Subjects w/ Decrease >5mm (Core Lab Reported) ⁶



26%
Aneurysm Sac Average Diameter Reduction

Single Center Study ⁷

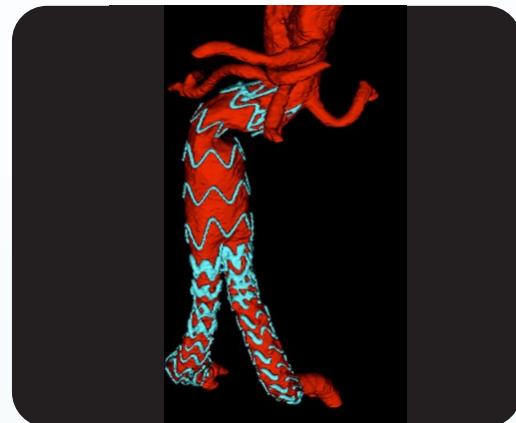
Five-Year Outcomes of Endovascular Aortic Repair With the TREO® Abdominal Endograft

OBJECTIVE

Show the long-term outcomes of endovascular aortic repair of both standard and hostile AAAs with the TREO® endograft.

STUDY DESIGN

37 Patients **27** patients considered hostile anatomy



RESULTS

100%

Technical Success

(37/37)

0%

Sac Expansion through 5 years

(0/37)

71%

Sac shrinkage at 5 years

(22/31)

100%

Survival at 6 months

(37/37)

92%

Survival at 5 years

(34/37)

3%

Type 1 Endoleak through 5 Years

(1/37)

6%

Overall Reintervention rate at 5 years

(2/37)

**11mm**

Aneurysm Sac Average Diameter Reduction (Mean 11.25±8.30 mm)

CONCLUSION

This case series contributes to the scientific validation of the TREO® abdominal aortic endograft over the long-term, focusing especially on its performance in treating AAAs with hostile anatomy.

TREO's 5-year outcomes confirm the optimal results previously reported at short- and mid-term follow-up.

Summary of Results

Clinical Study Summary Table

RESULTS

	TIGER European Registry - 2 years ³	TREGO® US IDE Study - 5 years ⁴	Single Center Marone Study - 5 years ⁷
Technical Success	97% (318/327)	100% ⁵ at index procedure (150/150)	100% (37/37)
Freedom from Device Related Mortality	100% (330/330)	100% (150/150)	100% (37/37)
Sac Regression	N/A	61% (43/70)	71% (22/31)
Freedom from Type I Endoleak	98% (323/330)	97% (145/150)	97% (36/37)
Freedom from Reintervention Rate	94% (310/330)	89% (134/150)	94% (35/37)

TREGO® CLINICAL OUTCOMES SUMMARY

Across multiple data sources—including the TIGER European Registry, the TREGO® US IDE, and a 5-year single-center experience – TREGO® demonstrates consistently strong performance with high technical success, low aneurysm-related mortality, durable outcomes, and meaningful aneurysm sac regression over long-term follow-up.

These results reinforce TREGO® as a reliable EVAR platform designed to perform across a wide range of anatomies and clinical scenarios.

Versatile by Design. Fit for Any Anatomy.*

* Per IFU

References

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4. Eagleton MJ, et al. "Long-term safety and effectiveness of the TREO stent graft for the endovascular treatment of infrarenal abdominal aortic aneurysms." Journal of Vascular Surgery (2025) ; ISSN 0741-5214, <https://doi.org/10.1016/j.jvs.2025.08.032>.
5. TREO US IFU Rev D
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PM-10171

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