

Trust is Earned



over
350,000 Patients
Treated*

20 Years
of Experience

Literature Summary



AAA ENDOPROSTHESIS

* Based on the number of Trunk-Ipsilateral Legs distributed.

Long Term Experiences with the GORE® EXCLUDER® AAA Endoprosthesis.

1. **Ten-year outcome analysis of the Italian Excluder Registry with the Gore Excluder endograft for infrarenal abdominal aortic aneurysms.** *Journal of Vascular Surgery* 2018.

Objectives

The objective of this study was to report the 10-year outcomes of the multicenter Italian Excluder Registry for elective endovascular aneurysm repair (EVAR).

Summary of Results

461 PATIENTS, 10-YEARS FOLLOW-UP

63% Cumulative survival

88% Estimated freedom from EG-related complication

81% Freedom from reintervention

Cumulative freedom from endoleak rate was significantly different between the two different follow-up intervals (0 to 5 year, 2.6% vs. 6 to 10 year, 0.8%, $P < .001$).

Summarized Conclusion

The Italian Excluder Registry outcomes confirmed sustained EVAR effectiveness at 10-year follow-up using the [GORE® EXCLUDER® AAA Endoprosthesis]. Freedom from EG-related complications, endoleaks, and reinterventions was satisfactory and remained acceptable beyond 5 years of follow-up, supporting a reasonable long-term durability of this device.

2. **Long-Term Outcome of the GORE EXCLUDER AAA Endoprosthesis for Treatment of Infrarenal Aortic Aneurysms.** *Journal of Vascular and Interventional Radiology* 2017.

Objectives

To evaluate long-term outcome of [GORE® EXCLUDER® AAA Endoprosthesis] for elective treatment of infrarenal aortic aneurysms and to evaluate performance of different generations of the device.

Summary of Results

248 PATIENTS, UP TO 10-YEARS FOLLOW-UP

76% reintervention-free survival

97% Technical success

49% Overall survival with no aneurysm-related deaths

0.4% limb occlusion, rupture, migrations

Summarized Conclusion

Treatment with the [GORE® EXCLUDER® AAA Endoprosthesis] is effective with acceptable reintervention rates in the long-term and few device-related adverse events or ruptures up to 10 years.

3. Single-centre experience with the Gore C3 Excluder stent-graft in 200 consecutive patients. *Journal of Cardiovascular Surgery* 2016.

Objectives

To present short and mid-term outcomes from 200 consecutive patients treated prospectively with the [GORE® EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System] in a single institution.

Summary of Results

200 PATIENTS, MEAN FOLLOW-UP OF 17.8 MONTHS

98% Technical success, no failures associated with stent-graft malfunction

0% Mortality at 30 days for elective cases

0% Limb occlusion, Type I or III Endoleaks, Migrations

95% of the patients had a sac shrinkage or a stable sac diameter

Summarized Conclusion

The [GORE® EXCLUDER® AAA Endoprosthesis] showed excellent early and mid-term outcomes with no mortality, low reintervention rates and favorable sac remodeling.

4. Long term performance of Gore® EXCLUDER® AAA Endoprosthesis: a single center's experience. *Italian Journal of Vascular and Endovascular Surgery* 2015.

Objectives

The aim of this study was to assess the effectiveness of EVAR, specifically assessing the durability of EVAR utilizing the [GORE® EXCLUDER® AAA Endoprosthesis] by analyzing the long-term performance.

Summary of Results

144 PATIENTS WITH LONGEST FOLLOW-UP OF 67.6 MONTHS

15% of patients treated were female

0% Type I or III Endoleaks

0% Migrations

0% Limb occlusions (1 patient)

0.8% Rupture post-implant

Summarized Conclusion

Long-term data associated with the GORE® EXCLUDER® AAA Endoprosthesis is relevant because of the consistent device design throughout the duration of the study. As evidenced by high patency, low reinterventions and consistent rupture prevention, [GORE® EXCLUDER® AAA Endoprosthesis] can be offered as a durable solution for EVAR treatment.

Italian Excluder Registry Investigators.

5. Italian Excluder Registry and results of Gore Excluder endograft for the treatment of elective infrarenal abdominal aortic aneurysms.

Journal of Vascular Surgery 2014.

Objectives

To report the midterm results of elective EVAR of abdominal aortic aneurysms. It is the largest clinical unsponsored registry using a single [GORE® EXCLUDER® AAA Endoprosthesis], with the longest follow-up period so far.

Summary of Results

872 PATIENTS UP TO 5-YEARS FOLLOW-UP

97.9% Estimated freedom from AAA-related death

86.5% Freedom from all reintervention

Only 1 reported Type III endoleak

1.1% Limb Thrombosis

0.5% Migrations

Summarized Conclusion

The present experience confirms the near-term effectiveness of EVAR using the [GORE® EXCLUDER® AAA Endoprosthesis] with low mortality rate, as well as the high rate of technical success and the low rate of endograft-related complication.

6. Ten years of experience with the GORE EXCLUDER® stent-graft for the treatment of aortic and iliac aneurysms: outcomes from a single center study.

CardioVascular and Interventional Radiology 2012.

Objectives

This study was designed to assess the long-term outcome of selected patients with aortic, aortoiliac, and isolated common iliac aneurysms treated with the GORE EXCLUDER® stent-graft.

Summary of Results

121 PATIENTS WITH MEAN FOLLOW-UP OF 4.98 YEARS

- 66% Aortic aneurysm
- 21% Aortoiliac aneurysm
- 13% Isolated common iliac aneurysm

0% Late Aneurysm Rupture

0% Early or late Type III endoleaks identified

Summarized Conclusion

[GORE® EXCLUDER® AAA Endoprosthesis] Demonstrated DURABILITY over a long-term follow-up period with NO aneurysm rupture or Type III endoleaks.

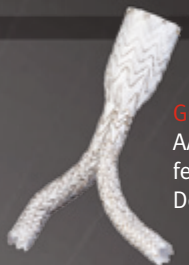
Continuing the pattern of **PERFORMANCE**

Continue to count on the GORE® EXCLUDER® Device family to help you move EVAR forward.

Built on a foundation of best-in-class ePTFE technology, proven outcomes data, and decades of real-world experience. Inspired by your commitment to performance.



GORE® EXCLUDER®
Conformable AAA
Endoprosthesis with
ACTIVE CONTROL System**



GORE® EXCLUDER®
AAA Endoprosthesis
featuring C3®
Delivery System



GORE® EXCLUDER®
Iliac Branch
Endoprosthesis†

* The GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System is CE Mark approved. Caution: Investigational device in United States. Limited by United States law to investigational use.

† The GORE® EXCLUDER® Iliac Branch Endoprosthesis is indicated for use with the GORE® EXCLUDER® AAA Endoprosthesis only. Please refer to *Instructions for Use* at goremedical.com.

Discover more



References

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6. Maleux G, Claes H, Van Holsbeeck A, Janssen R, Laenen A, Heye S, Houthoofd S, Fourneau I. Ten years of experience with the GORE EXCLUDER® stent-graft for the treatment of aortic and iliac aneurysms: outcomes from a single center study. *Cardiovascular & Interventional Radiology* 2012;35(3):498-507.

The articles listed here may include outcome descriptions that reflect use of devices outside the approved Instructions for Use (IFU), including data registries intended to provide broader information about patient outcomes. Gore does not promote the off-label use of devices. Physicians should consult the IFU for complete device information, including contraindications, warnings and cautions.

Additional literature references available upon request.
To receive access to reprints or full text version of these papers, please refer to a Gore Associate.

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