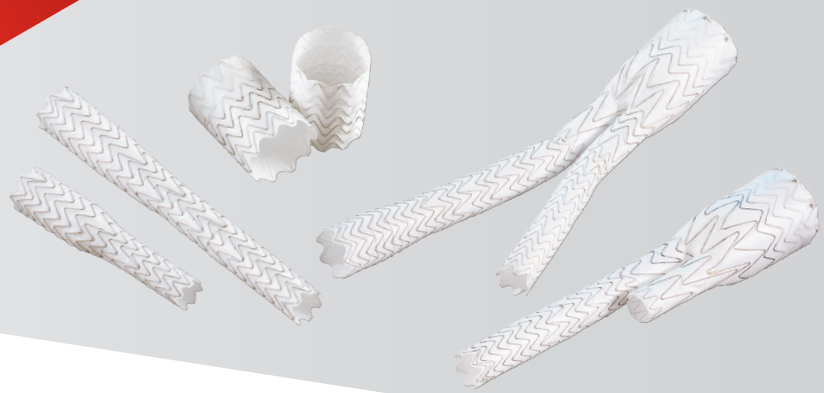
**GORE® EXCLUDER®**
AAA Endoprosthesis

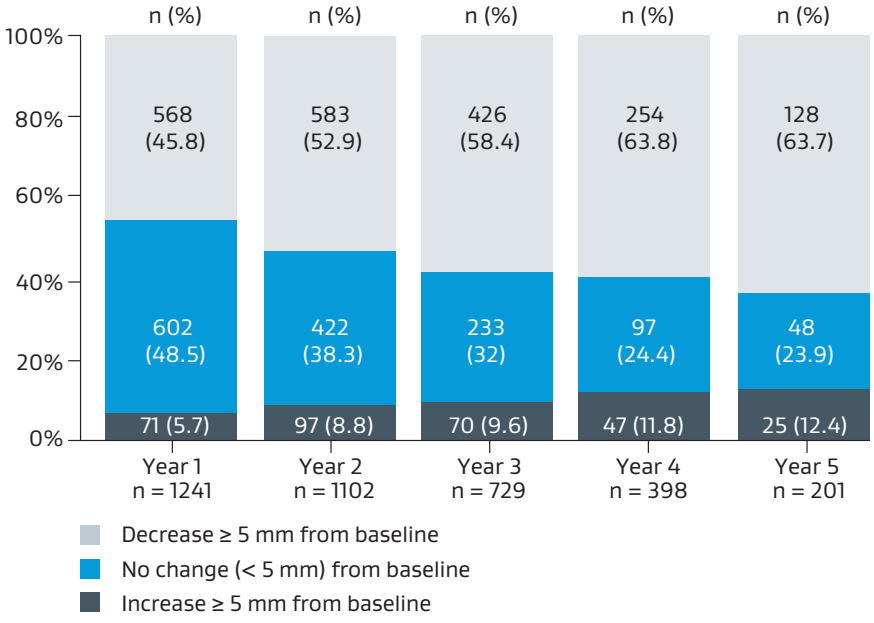


# ANEURYSM REGRESSION WITH THE **GORE® EXCLUDER®** AAA ENDOPROSTHESIS

Recent studies[1,2] suggest there is an independent association between aneurysm sac behavior and patient mortality after EVAR. Deery et al., states that sac regression predicted a decrease in late mortality and O'Donnell et al., states that any failure of the sac to regress is associated with higher long-term mortality, independent of reinterventions or endoleaks.

Data from the Global Registry for Endovascular Aortic Treatment (GREAT) shows that AAA's treated with the GORE® EXCLUDER® AAA Endoprosthesis compare favorably to one-year data from the Vascular Quality Initiative (VQI). In the VQI analysis of 14,817 patients done by O'Donnell et al., 40% of AAA sacs regressed, 35% remained stable and 25% expanded.[2]

**Change in aneurysm sac diameter (mm) in patients treated with the GORE® EXCLUDER® AAA Device**




The change in aneurysm sac diameter (mm) from the baseline (one month) measurement is shown at each year follow-up (FU) window, up to the five year FU window.

*Together, improving life*

# Durable Outcomes. Proven Performance.

The GORE® EXCLUDER® AAA Device is associated with low reintervention rates, a 71.1% freedom from all-cause mortality* through 5 years and has been proven through clinical trials, registries and site reported use, to be a safe, effective and durable solution, earning the trust of physicians worldwide.

**GORE® EXCLUDER® AAA Device data from GREAT†**

| | |
|---|---|
| Length of follow-up (through) | 5 years |
| Number of patients possible | 3,274 |
| Freedom from aneurysm-related mortality | 98.8% |
| Freedom from all reintervention | 92.0% |
| Freedom from device related reintervention | 94.7% |
| Conversion to open repair | 0.8% |
| Aneurysm-related rupture | 0.3% |
| Migration‡ | 0.0% |
| Type Ia endoleak | 0.9% |
| Type Ib endoleak | 0.7% |
| Type III endoleak | 0.2% |
| Limb occlusion | 0.7% |
| Renal complication§ | 0.4% |

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* Kaplan Meier estimate of Freedom from Mortality of 71.1% with a 95% CI of 68.5–73.5%. Analysis is a point estimate through 5 years.

† To calculate the overall event rates from procedure through end of study period, all subjects who could have had events, regardless of length of follow-up, were included. For outcome data, GREAT only collects site reported serious adverse events. Therefore, all reported endoleaks are defined as serious and require reintervention.

‡ One peri-procedural migration reported. Zero migrations reported during follow-up through 5 years.

§ Inclusion for renal complication rate: Subjects with renal complication were identified with MedDRA code. Of those identified with MedDRA code as having a renal complication, only those who showed the SAE occurring within 75 days of the procedure AND were reported by the site/physician as being related to the device or procedure were included in the renal complication rate.

1. Deery SE, Ergul EA, Schermerhorn ML, Siracuse JJ, Schanzer A, Goodney PP, *et al*. Aneurysm sac expansion is independently associated with late mortality in patients treated with endovascular aneurysm repair. *Journal of Vascular Surgery* 2018;67:157-64.

2. O'Donnell TFX, Deery SE, Boitano LT, *et al*. Aneurysm sac failure to regress after endovascular aneurysm repair is associated with lower long-term survival. *Journal of Vascular Surgery* 2019;69:414-422.

Consult Instructions for Use
**eifu.goremedical.com**

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.



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