

Providing the platform

for confident stenting



PERFORMANCE by design

Clinical results from the US Gore EMPIRE Clinical Study and a multi-center study in Europe show stroke and death rates among the lowest reported in Carotid Artery Stenting (CAS) investigations. The results of these studies demonstrate that the GORE® Flow Reversal System is safe and effective when used for neuroprotection during CAS and that it provides benefits in broad patient populations.

| US Gore EMPIRE Clinical Study | | EU Clinical Study | |
|-------------------------------|----------------|---------------------|----------------|
| Number of Patients | 245 (32% Sx) | Number of Patients | 122 (28% Sx) |
| Stroke / Death / MI | 3.7% | Stroke / Death / MI | 1.6% |
| Stroke / Death | 2.9% | Stroke / Death | 1.6% |
| – Octogenarians | 2.6% | – Octogenarians | 0.0% |
| – Symptomatic | 2.6% | – Symptomatic | 0.0% |
| Technical Success | 96.3% | Technical Success | 97.5% |
| Intolerance+ | 1.2% | Intolerance+ | 1.6% |

+ Procedure could not be completed with GORE® Flow Reversal System

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US Gore EMPIRE Clinical Study results. One of the first carotid artery stenting studies that has reported death and stroke rates that are within the American Heart Association guidelines for carotid endarterectomy; asymptomatic < 3%, symptomatic < 6%. (Moore WS, Barnett HJ, Beebe HG, *et al.* Guidelines for Carotid Endarterectomy: A Multidisciplinary Consensus Statement From the Ad Hoc Committee, American Heart Association. *Circulation* 1995;91(2):566-579.)

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Indications for Use: The GORE Flow Reversal System is intended to provide embolic protection during carotid artery angioplasty and stenting for the patients diagnosed with carotid artery stenosis and who have appropriate anatomy as described in the *Instructions for Use*. Refer to the *Instructions for Use* for contraindications, warnings and precautions. Rx Only

Products listed may not be available in all markets.

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