Published online in AJNR, March 15, 2018 (open-access)

MicroVention® TERUMO

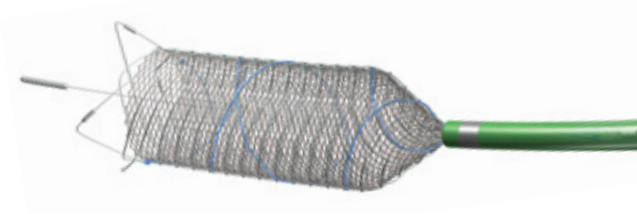
The EuFRED Study

European Multicenter Study for the Evaluation of a Dual-Layer Flow-Diverting Stent for Treatment of Wide-Neck Intracranial Aneurysms: The European Flow-Redirection Intraluminal Device Study

A multicenter, retrospective, post-market study of 531 consecutive patients with intracranial aneurysms treated with the Flow-Redirection Intraluminal Device (FRED®) system at 15 European neurovascular centers.

Study Purpose

To evaluate the safety and efficacy of the Flow-Redirection Intraluminal device, (FRED®) system in real-world patients treated for intracranial aneurysms.



Key Findings

69.2%
Overall Complete Occlusion Rate
6.6 month median follow-up

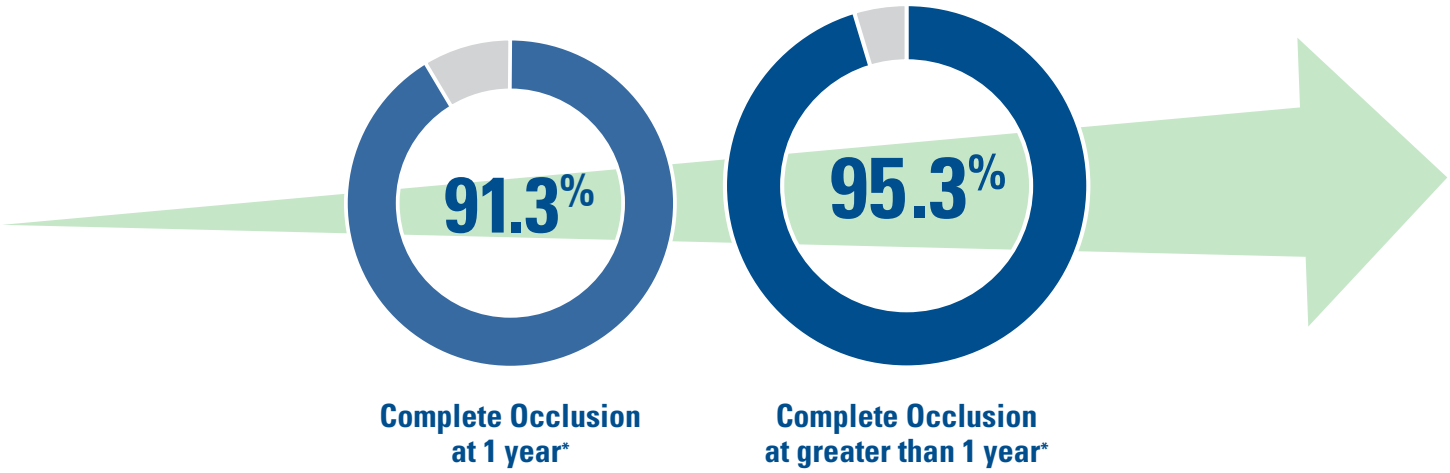
0.8%
Overall Permanent Morbidity

1.5%
Overall Mortality

96.4%
Single Device Implanted

Progressive Occlusion Observed Over Time

*Measured by 3-Point Raymond-Roy Scale and O'Kelly-Marotta Grading Scale



Author's Conclusion

"The EuFRED is the largest study to date assessing the safety and efficacy of the FRED® flow-diverting stent. Applied to what may be considered a real-world patient population, the FRED® system performed favorably regarding aneurysm obliteration and complications."

Safety Findings

0%	0.5%	97%
In-Stent Stenosis ≥50%	Overall Major Stroke	Good Clinical Outcomes (mRs 0-2) at 6.6 month median follow-up

EuFRED STUDY POPULATION	
Population	579 aneurysms / 531 patients
Age	13 to 86 years old (median = 54)
ANEURYSM LOCATION	
ICA	74.5%
MCA	6.4%
ACA or ACom	5.8%
Posterior or PCom	13.3%
ANEURYSM SIZE	
Median diameter	7.6mm
Median neck diameter	4.5mm
TREATMENT CHARACTERISTICS	
Technical Success	98.3%

Study limitations are outlined in the full article, available at: http://www.ajnr.org/content/early/2018/03/15/ajnr.A5592

Killer-Oberpfalzer, M., N. Kocer, C. J. Griessenauer, H. Janssen, T. Engelhorn, M. Holtmannspötter, J. H. Buhk, T. Finkenzeller, G. Fesl, J. Trenkler, W. Reith, A. Berlis, K. Hausegger, M. Augustin, C. Islak, B. Minnich and M. Möhlenbruch (2018). "European Multicenter Study for the Evaluation of a Dual-Layer Flow-Diverting Stent for Treatment of Wide-Neck Intracranial Aneurysms: The European Flow-Redirection Intraluminal Device Study." Am J Neuroradiol 2018; doi.org/10.3174/ajnr.A5592

INDICATIONS FOR USE:
The system is intended for endovascular embolization of intracranial neurovascular aneurysms. The FRED and FRED Jr. system may also be used with embolic coils for the treatment of intracranial neurovascular lesions.

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RX Only: For health care professional use only. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. The FRED flow diversion device should only be used by physicians who have received appropriate training for the device. The FRED System is not approved in the U.S. by the FDA.