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MicroVention™ TERUMO

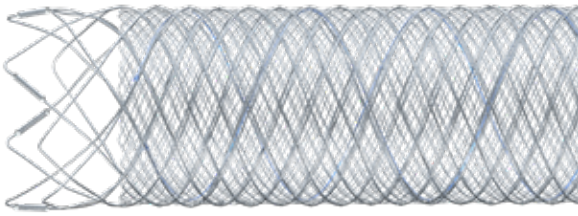
The EuFRED Study

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 Endoluminal Device (FRED) system at 15 European neurovascular centers.

Study Purpose

To evaluate the safety and efficacy of the Flow-Redirection Endoluminal 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

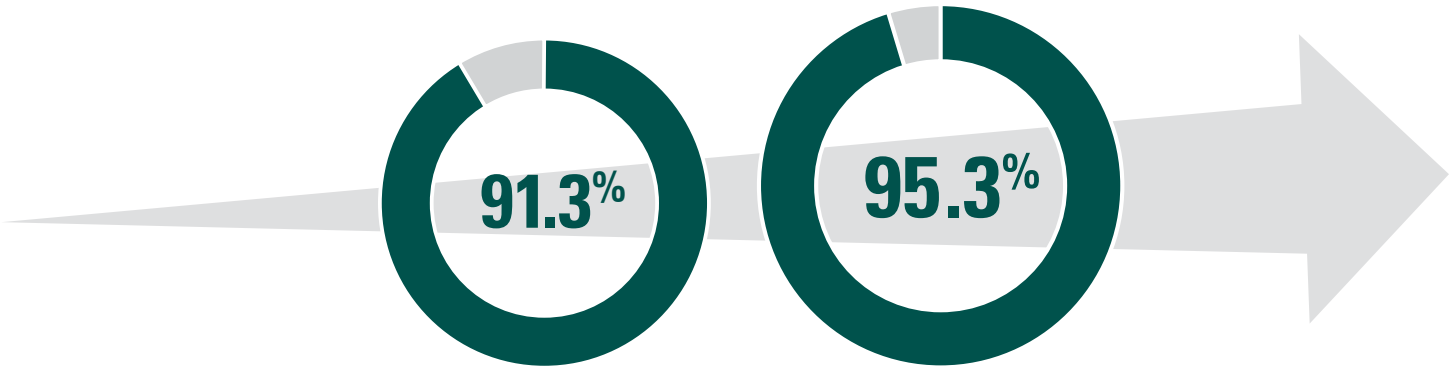
0.8%
Overall Permanent Morbidity

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



Complete Occlusion at 1 year*

Complete Occlusion at greater than 1 year*

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 SIZE	
Small (<10 mm)	76.9%
Large (10-20 mm)	17.4%
Giant (>20 mm)	5.7%
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

The EuFRED Study was conducted in accordance with European indications for use, including use of FRED with embolic coils. Occlusion and safety findings do not necessarily correlate with FRED results in other geographies.

INDICATIONS FOR USE

USA

The Flow Re-Direction Endoluminal Device (FRED™) System is indicated for use in the internal carotid artery from the petrous segment to the terminus for the endovascular treatment of adult patients (22 years of age or older) with wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysms arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm.

Use of the FRED System is contraindicated under these circumstances: Patients in whom anticoagulant, anti-platelet therapy, or thrombolytic drugs are contraindicated; patients with known hypersensitivity to metal such as nickel-titanium and metal jewelry; patients with anatomy that does not permit passage or deployment of the FRED System; patients with an active bacterial infection; patients with a pre-existing stent in place at the target aneurysm; patients in whom the parent vessel size does not fall within the indicated range; patients who have not received dual anti-platelet agents prior to the procedure.

Canada

The Flow Re-Direction Endoluminal Device (FRED) System is indicated for use with or without embolic coils for the treatment of intracranial aneurysms that are not amenable to treatment without surgical clipping with parent vessels that are ≥ 2.0 mm and ≤ 5.0 mm in diameter.

EMEA/APLA

The FRED and FRED Jr. systems are intended for endovascular embolization of intracranial neurovascular aneurysms. The FRED and FRED Jr. systems may also be used with embolic coils for the treatment of intracranial neurovascular lesions.

This product is not approved in all EMEA or APLA countries. Indications may vary by country.

For complete indications, contraindications, potential complications, warnings, precautions, and instructions, see instructions for use (IFU provided in the device).

Caution: Federal law restricts these devices to sale by or on the order of a physician.
RX Only: Federal law restricts this device to sale by or on the order of a physician.
For Healthcare professional intended use only.

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