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MicroVention™ TERUMO

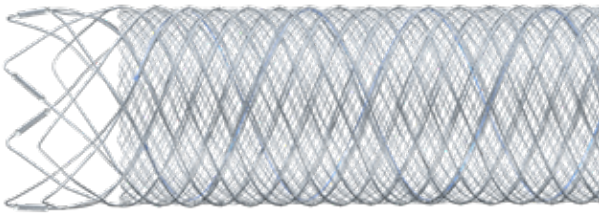
The SAFE Study

Safety and Efficacy Analysis of FRED™ Embolic Device in Aneurysm Treatment: One-year Clinical and Anatomical Results

A single arm, multicenter, prospective, GCP study of 103 patients with intracranial aneurysms treated with the Flow-Redirection Endoluminal Device (FRED) system at 13 French neurovascular centers.

Study Purpose

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



Key Findings at 12 month follow-up

73.3%
Complete Occlusion

81.1%
Complete Occlusion + >90% Occlusion

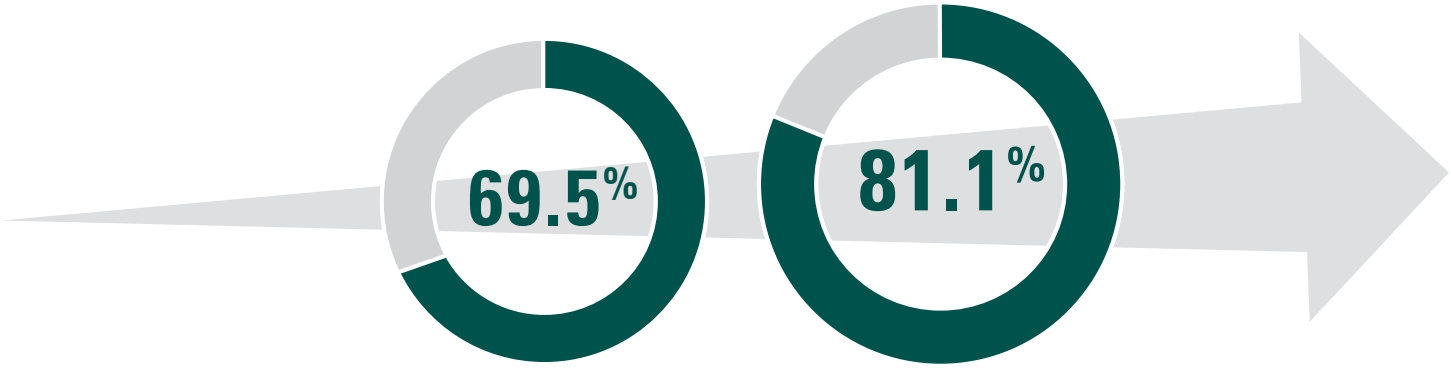
1.9%
Mortality

No device related mortality

2.9%
Morbidity

Progressive Occlusion Observed Over Time

*Measured by 3-Point Raymond-Roy Scale



Complete Occlusion + >90% Occlusion at 6 months*

Complete Occlusion + >90% Occlusion at 1 year*

Author's Conclusion

"SAFE study analysis at one year confirms the excellent safety profile of FRED device for aneurysm treatment with low morbidity and mortality rates (2.9% and 1.9% respectively) and demonstrates its efficacy (adequate occlusion in 81.1%)."

Safety Findings

2.2%
Retreatment

95.1%
Good Clinical Outcomes (mRs 0-2)

SAFE STUDY POPULATION	
Population	103 aneurysms / 103 patients
Age	25 to 80 years old (mean = 52.4)
ANEURYSM SIZE	
Small (<10mm)	68.9% (71)
Large (10-24mm)	28.2% (29)
Giant (>/=24mm)	2.9% (3)
Wide Neck	96.1% (99)
TREATMENT CHARACTERISTICS	
Technical Success	95.1%
SAFETY FINDINGS	
Thromboembolic Complications	6.8%
Morbidity	2.9%
Mortality	1.9%

Safety Discussion:

"Noticeably, the safety of aneurysm treatment is now, at least with the FRED device, very close to the safety of standard coiling as reported for example in ATENA (with one-month morbidity and mortality being 1.7% and 1.4% respectively)"

Study limitations are outlined in the full article, available at: https://jnis.bmj.com/content/early/2018/10/08/neurintsurg-2018-014261.share

* Pierot L, Spelle L, Berge J, et al. SAFE study (Safety and Efficacy Analysis of FRED Embolic Device in Aneurysm Treatment): One-year Clinical and Anatomical Results.. J Neurointervent Surg Epub ahead of print. October 9, 2018. doi = 10.1136/neurint

The SAFE 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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