FRED™
Flow Re-direction
Endoluminal Device

MicroVention™
TERUMO

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Brazilian FRED Registry: A Prospective Multicenter Study for Brain Aneurysm Treatment—The BRED Study

Between June 2016 and August 2018, a total of 100 consecutive patients with 131 aneurysms were treated in 107 procedures.

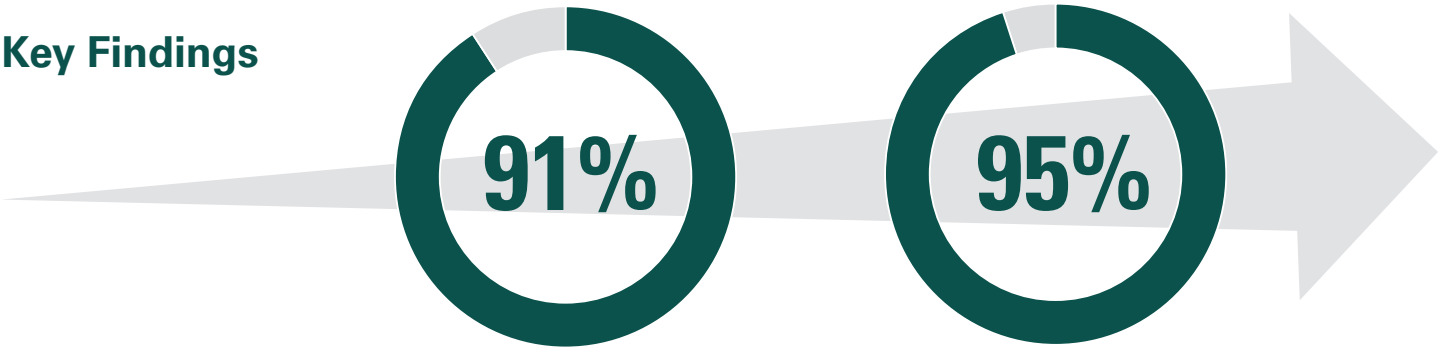
L.B. Manzato, R.B. Santos, P.M.M. Filho, G. Miotto, A.M. Bastos, and J.R. Vanzin

This study was conducted in Brazil. FRED device indications for use may vary by region.

Study Purpose

A single-arm, multi-center (3 centers), prospective, observational study assessing aneurysm treatment with the FRED device. The primary outcome was complete aneurysm occlusion at 6 and 12 months, and the secondary outcome was to evaluate the safety of the FRED with respect to stroke and death rates.

Key Findings



Complete occlusion at 6 months

Complete occlusion at 12 months

100	131	1.8%	4.6%
Patients	Aneurysms	Morbidity Rate	Complication Rate

Safety Discussion

"Treatment was successful in all cases. All procedures were performed using only 1 FRED for each patient."

Author's Comments & Conclusion

"There were no cases of recanalization after complete occlusion. The rate of residual aneurysm filling did not change from 6 to 12 months."

"FRED has proved to be a safe and effective tool for the treatment of intracranial aneurysms, with high occlusion rates at 6 and 12 months."

Study limitations are outlined in the full article, available at: http://www.ajnr.org/content/42/10/1822

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.

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.

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).

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