Published online in JNIS October 8, 2018.

MicroVention® TERUMO

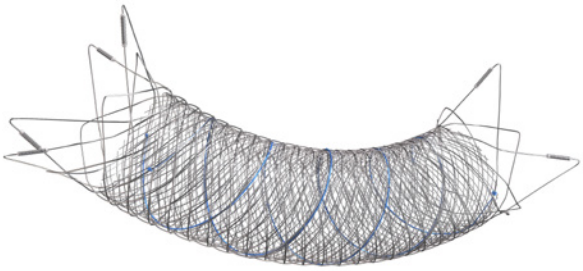
# The SAFE Study

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 Intraluminal Device (FRED®) system at 13 French neurovascular centers.*

## Study Purpose

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



## Key Findings at 12 month follow-up

**73.3%**
Complete Occlusion

**81.1%**
Adequate Occlusion

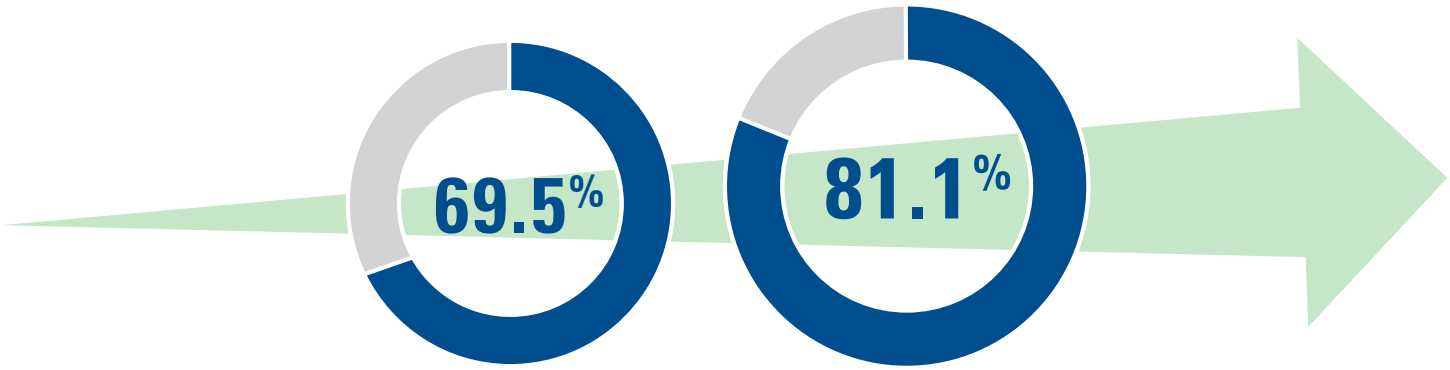
**1.9%**
Mortality

* No device related mortality

**2.9%**
Morbidity

## Progressive Occlusion Observed Over Time

*Measured by 3-Point Raymond-Roy Scale




**Adequate Occlusion at 6 months***

**Adequate 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 LOCATION** | |
| Supraclinoid ICA | 68.9% (71) |
| Cavernous ICA | 14.6% (15) |
| MCA | 7.8% (8) |
| ACA or ACom | 8.7% (9) |
| **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 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

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.

**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.

CE 0297

MicroVention TERUMO

www.microvention.com

**MicroVention USA**
35 Enterprise
Aliso Viejo, CA 92656
USA
+1 714 247 8000
PH 1 800 990 8368

**MicroVention United Kingdom**
Suite 3, The Barracks Building
10 Cliords Fort, North Shields
Tyne and Wear, NE30 1JE
United Kingdom
PH +44 (0) 191 258 6777
F +44 (0) 191 258 5999

**MicroVention Europe SARL**
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France
RCS Versailles B 440 775674 00029
PH +33 (1) 39 21 52 17
F +33 (1) 39 21 16 01

**MicroVention**
Deutschland GmbH
Hildebrandtstr. 4 F
D-40215 Düsseldorf
Germany
PH +49 211 210 798-0
F +49 211 210 798-29