Summary of Safety and Clinical Performance

for

Flow Re-Direction Endoluminal Device

(FRED™)

SSCP23-0012A

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DOCUMENT CHANGE HISTORY

SSCP Revision	Change Description	NB approved/verified
A	Initial release of DQS approved and updated SSCP in the latest template	☒Yes ☐ No* Validation language: English

*Annual entries must be included. An entry stating such must be added if a revision is not required.

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1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1.1 Device Identification and General Information

Table 1.1 Device Identification and General Information

Device Names	
Device Trade Name	Flow Re-Direction Endoluminal Device (FRED), FRED Jr, FREDX, FRED Omega
EMDN Code	P0799 Vascular and Cardiac Protheses- Other
Medical Device Nomenclature (EMDN or GMDN Description)	Flow Diverter
Device Class	Class III
Basic UDI-DI	08402732FREDHC
Year when first certificate (CE) was issued for the device	FRED: 2011 FRED Jr.: 2015 FRED X: 2020 FRED Omega™: 2021
Legal Manufacturer	
Name & Address	MicroVention, Inc. 35 Enterprise Aliso Viejo, California, 92656 USA
Manufacturer SRN	US-MF-000016658
Authorized Representative	
Name & Address	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye, France
Authorized Representative SRN	FR-AR-000004448
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

Table 1.2 Intended Use

Intended Purpose	
Intended Purpose	The FRED devices (FRED, FRED Jr., FRED X and FRED Omega) are intended for endovascular embolization of intracranial neurovascular aneurysms. The FRED devices may also be used with embolic coils for the treatment of intracranial neurovascular lesions.
Indications for Use	The FRED devices are intended to treat patients who suffer from intracranial neurovascular aneurysm. The device can also be used with embolic coils for the treatment of intracranial neurovascular lesions.
Target Population	The intended patient population of the FRED devices are the patients with intracranial neurovascular aneurysms and other neurovascular lesions.
Contraindications and/or Limitations	• Patients in whom anticoagulant, antiplatelet therapy or thrombolytic drugs are contraindicated • Patients with known hypersensitivity to nickel-titanium • Patients in whom angiography demonstrated inappropriate anatomy that does not permit passage or deployment of the FRED system

1.3 Device Description

Table 1.3 Device Description

<table>
<tr><th colspan="4">Device Description</th></tr>
<tr><td>Description of the Device</td><td colspan="3">The FRED Product family of devices or the FRED devices (FRED/FRED Jr/FRED X/ FRED Omega) consist of a self-expanding nickel titanium implant and a delivery system that can be simultaneously delivered and deployed by a single operator. The implant is designed to expand to a pre-determined diameter when released from the delivery system. The implant features integrated dual layer coverage designed to focus mainly at the neck of an aneurysm. The implant has distal and proximal markers on its ends as well as interweaved helical marker strands delineating the inner working length of the implant to provide fluoroscopic visibility.
The device is packaged sterile as a single unit with the implant, introducer sheath and a detachable delivery pusher. It is available in 7 different implant diameters ranging from 2.5 mm to 5.5 mm and in different implant lengths. The FRED System 2.5 mm and 3.0 mm implants are compatible with the Headway™ 21 Microcatheter (FRED-21 System). The FRED System 3.5 mm to 5.5 mm implants are compatible with the Headway 27 Microcatheter (FRED-27 System). All the FRED sizes, ranging from 2.5 to 5.5 mm utilize the same fundamental design and construction. The metal surface area and pore density of the implant is essentially the same regardless of size of the device.
The FRED devices do not incorporate a medicinal substance, animal tissues, or blood products.</td></tr>
<tr><td>Design Characteristics of the Device</td><td colspan="3"><table>
<tr><th>Key Functional Element</th><th>Component</th><th>Material</th></tr>
<tr><td rowspan="4">Stent (implant)</td><td>Stent Wire Filar</td><td>FRED/FRED Jr/FRED X/FRED Omega
Nitinol ASTM F2063
FRED Omega
Drawn Filled Tubing Nitinol, 10% Pt core</td></tr>
<tr><td>Tantalum Wire Filar</td><td>Tantalum Wire ASTM F560</td></tr>
<tr><td>Adhesive</td><td>DYMAX 1128</td></tr>
<tr><td>Surface Treatment</td><td>Silane and poly(MEA-co-APMA)</td></tr>
</table></td></tr>
</table>

		(FRED X and FRED Omega only)	
	Delivery System	Delivery Pusher	**FRED OMEGA/FRED/FRED X (3.5 – 5.5 mm)** Nitinol **FRED Jr/FRED X (2.5 – 3.0 mm)** Stainless Steel 304V **FRED Omega (2.5-3.5 mm)** Stainless Steel 304V – Nitinol (54-57% Ni, Balance Ti)
		RO Marker Bands	90% Platinum, 10% Iridium
		Distal RO Coil	**FRED Omega/FRED/FRED Jr/FRED X** Platinum 479 or Equivalent Pt/W: 92/8 **FRED Omega (2.5-3.5mm)** Nitinol DFT (Shell: Nitinol, Core, Platinum)
		Strain Relief Coil	Stainless Steel 304 SS
		Fluorosafe Markers	**FRED Omega/FRED/FRED X (3.5 – 5.5 mm)** Polyethylene Terephthalate (PET) Shrink Tubing/Ink, Pad Print, White **FRED Jr/FRED X (2.5 – 3.0 mm)/FRED Omega** Polyethylene Terephthalate (PET) Shrink Tubing/Ink, Pad Print, Black
			Hardner H1 Thinner Retarder
		Epoxy	EPOTEK 353 ND A/B
		Adhesive	DYMAX 1128
		Introducer Sheath	High Density Polyethylene (HDPE)
Previous Generations or Variants, if applicable	The FRED devices a following device configurations/variants are CE-Marked and are commercialized in the European Union: • FRED • FRED Jr. • FRED X • FRED Omega		
Single use – sterilization method	The FRED devices are supplied sterile. The device is intended for single use only and is not intended for re-use or re-sterilization by the user. The device is sterilized using a validated electron beam radiation (E-Beam) sterilization process at two sterilization sites; Steris AST located in San Diego, CA, USA and Steris AST located in Alajuela, Costa Rica.		
Description of Accessories	Appropriate-sized guidewire to be used in combination with FRED: • Appropriate-sized guiding or intermediate catheter for use with selected microcatheter • Headway 17 microcatheter (FRED Omega) • Headway 21 microcatheter (FRED Jr/FRED X) • Headway 27 microcatheter (FRED/FRED X/FRED Omega)		
Description of other Devices or Products intended to be used in combination	The device is packaged sterile as a single unit with the implant, introducer sheath and a detachable delivery pusher. It is available in 7 different implant diameters ranging from 2.5 mm to 5.5 mm and in different implant lengths. The FRED System 2.5 mm and 3.0 mm implants are compatible with the Headway 21 Microcatheter (FRED-21 System). The FRED System 3.5 mm to 5.5 mm implants are compatible with the Headway 27 Microcatheter (FRED-27 System). All the FRED sizes, ranging from 2.5 to 5.5 mm utilize the same fundamental design and construction. The metal surface area and pore density of the implant		

	is essentially the same regardless of size of the device. The Table below provides a summary of microcatheter compatibility based on the listed devices of the FRED family (FRED/FRED Jr/FRED X/FRED Omega).

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the FRED devices are assessed and risks of the resulting harms are minimized through the use of risk mitigation/control measures. All known foreseeable risks have been evaluated and mitigated.

Hazards associated with the use of the FRED devices are assessed and risks of the resulting harms are minimized through the use of risk mitigation/control measures. All known foreseeable risks have been evaluated and mitigated in **Table 1.4, Table 1.5,** Error! Reference source not found.**,** and **Table 1.7**.

Table 1.4 Residual Risk and Risk Control Measures, FRED

Hazard (Source of Harm)	Cause of Hazard (primary factor)	Risk Mitigation or Risk Reduction or Risk Control Measures
Air embolism	Air entrapment during prepping of the device	Instruct user on device prepping per IFU.
Aneurysm ruptures during/following deployment	Device incorrectly sized for aneurysm/vessel Device used by untrained/unskilled personnel	Instruct user on proper operating procedure. Warn user to be familiar with interventional procedure Instruct user on proper compatible agents and operating procedure.
Device migrates after deployment	Implant migrates into unwanted location	Perform feasibility/ design verification. Perform process validation Perform final inspection.
Emboli generated during deployment	Design/manufacturing process is inadequate or product is misused.	Instruct user to be properly familiar in interventional procedures. Perform feasibility/ design verification. Perform process validation. Particulate Testing
Excessive friction between product and microcatheter	Design/manufacturing process is inadequate or product is misused	Instruct user to be properly familiar in interventional procedures Perform feasibility/ design verification Perform process validation
Excessive radial pressure	Improper sizing of product	Instruct user on compatible agents and operating procedure. Warn user to be familiar with interventional procedure
Foreign body embolism	Device corrodes during implant period	Perform feasibility/ design verification. Perform process validation. Perform aging studies. Perform corrosion tests

Hazard (Source of Harm)	Cause of Hazard (primary factor)	Risk Mitigation or Risk Reduction or Risk Control Measures
Implant failed to expand during partial deployment	Design/manufacturing process is inadequate or product is misused	Instruct user to be properly familiar in interventional procedures. Perform feasibility/ design verification. Perform process validation.
Implant will not deploy	Design/manufacturing process is inadequate or product is misused.	Instruct user to be properly familiar in interventional procedures. Perform feasibility/ design verification. Perform process validation.
Improper use	Device used by untrained/unskilled personnel Inadequate specification of accessories Insufficient warning of potential side effects Labeling is inadequate or overcomplicated.	Instruct user on proper compatible agents and operating procedure. Warn user to be familiar with interventional procedure. Clearly list required accessories in Instructions For Use. Perform design validation. Perform feasibility/ design verification. List potential complications in the Instructions For Use Label per applicable regulatory guidelines and standards. Submit labeling for review by FDA and Notified Body.
Inappropriate Therapy selected (Inadvertent)	Off Label use	List proper use of the device in Instructions For Use
Product unintentionally separates and a portion remains in the body resulting in a foreign body embolism	Design/manufacturing process is inadequate or product is misused	Instruct user to be properly familiar in interventional procedures Perform feasibility/ design verification Perform process validation
Thromboembolic embolism	Improper anticoagulation	Instruct user to be properly familiar in interventional procedures.
Vasospasm due to vessel wall irritation	Product is an irritant to the vessel, is misused, and/or is not tolerated by patient.	Instruct user to be properly familiar in interventional procedures.

Table 1.5 Residual Risk and Risk Control Measures, FRED Jr.

Hazard (Source of Harm)	Cause of Hazard (primary factor)	Risk Control Measures
Inappropriate Therapy selected (Inadvertent)	Off Label use Insufficient Labeling.	List proper use of the device in Instructions For Use In-Service training

Hazard (Source of Harm)	Cause of Hazard (primary factor)	Risk Control Measures
Improper use	Device used by untrained/unskilled personnel	Instruct user on proper compatible agents and operating procedure. Warn user to be familiar with interventional procedure. In-Service training
Excessive friction between product and microcatheter	Design/manufacturing process is inadequate or product is misused	Instruct user to be properly familiar in interventional procedures. Perform design verification. Perform process validation.
Thromboembolic embolism	Improper anticoagulation therapy	Instruct user to be properly familiar in interventional procedures. In-Service training
Air embolism	Air entrapment during prepping of the device	Instruct user on device prepping per IFU.
Implant failed to expand during partial deployment	Design/manufacturing process is inadequate or product is misused.	Instruct user to be properly familiar in interventional procedures. Perform design verification. Perform process validation Perform feasibility/ design verification.
Device migrates after deployment	Design/manufacturing process is inadequate or product is misused.	Instruct user to be properly familiar in interventional procedures. Perform design verification. Perform process validation. Perform feasibility/ design verification.
Excessive radial pressure	Improper sizing of product. Design is inadequate. Inadequate IFU cautions.	Instruct user on compatible agents and operating procedure. Warn user to be familiar with interventional procedure. In-Service training
Implant will not deploy	Design/manufacturing process is inadequate or product is misused.	Instruct user to be properly familiar in interventional procedures. Perform feasibility/ design verification. Perform process validation.
Aneurysm ruptures during/following deployment	Device used by untrained/unskilled personnel Device incorrectly sized for aneurysm/vessel	Instruct user on proper compatible agents and operating procedure. Warn user to be familiar with interventional procedure. In-Service training Warn user to be familiar with interventional procedure.
Device causes vessel flow impairment	Ineffective IFU. Device used by untrained/unskilled personnel. Design is inadequate.	Perform design verification and validation. Instruct user to be familiar with interventional procedures. In-Service training
Inability to easily place coils	Design/manufacturing process is inadequate or product is misused.	Instruct user to be properly familiar in interventional procedures. Perform design verification. Perform process validation.

Table 1.6 Residual Risk and Risk Control Measures, poly (MEA-co-APMA) Functionalized (X) Stents

Hazard (Source of Harm)	Cause of Hazard (primary factor)	Risk Control Measures
Biological hazard	Patient-contact materials not biocompatible or above tolerance limit	Test per ISO 10993-1
Contamination in manufacturing environment resulting in foreign body embolism	Manufacturing environment produces microbial contamination beyond validation limits	Manufacture product in a validated cleanroom environment and monitor cleanroom and product for bioburden. Perform Sterilization validation.
Excessive friction between functionalized product and microcatheter (functionalization increases friction)	Design/manufacturing process is inadequate	Perform design verification Perform process validation
Implant failed to open (functionalization is too sticky)	Design/manufacturing process is inadequate Exposure to water, direct sunlight, high temperature, or high humidity	Perform design verification Perform process validation Storage condition in IFU Shelf Life study
Functionalization comes off of product	Damage to functionalization due to handling	Recommended procedure for use in IFU

Table 1.7 Residual Risk and Risk Control Measures, FRED Omega

Hazard (Source of Harm)	Cause of Hazard (primary factor)	Risk Control Measures
Biological hazard	Patient-contact materials not biocompatible or above tolerance limit	Test per ISO 10993-1
Contamination in manufacturing environment resulting in foreign body embolism	Manufacturing environment produces microbial contamination beyond validation limits	Manufacture product in a validated cleanroom environment and monitor cleanroom and product for bioburden. Perform Sterilization validation.
Excessive friction between functionalized product and microcatheter (functionalization increases friction)	Design/manufacturing process is inadequate	Perform design verification Perform process validation
Functionalization comes off of product	Damage to functionalization due to handling	Recommended procedure for use in IFU
Implant failed to open (functionalization is too sticky)	Design/manufacturing process is inadequate Exposure to water, direct sunlight, high temperature, or high humidity	Perform design verification Perform process validation Storage condition in IFU Shelf Life study

1.4.2 Warnings and Precautions

The warnings / precautions for the FRED devices are:

WARNINGS

FRED

- Should unusual resistance be felt at any time during access or removal, the introducer/guide catheter/microcatheter and FRED system should be removed as a single unit. Applying excessive force during delivery or retrieval of the FRED system can potentially result in loss or damage to the device and delivery components.
- The FRED system should only be used by physicians trained in endovascular interventional neuroradiology, radiology, neurosurgery or interventional neurology for the treatment of intracranial aneurysms or other vascular lesions.
- It is imperative to use the FRED system with a Headway® 27 microcatheter. If repeated friction is encountered during FRED system delivery, verify microcatheter is not kinked or in extremely tortuous anatomy. Confirm that the microcatheter does not ovalize. Confirm that there is adequate sterile heparinized flush solution.
- Do not reposition the FRED system in the parent vessel without fully retrieving the device. The FRED system MUST be retrieved/resheathed into the microcatheter and re-deployed at the desired target location or removed completely from the patient.
- Do not attempt to re-position the FRED implant after deployment/detachment.
- The safety and performance of the FRED system for use in conjunction with intravascular medical devices other than neurovascular embolization coils have not been established.

FRED JR.

- Should unusual resistance be felt at any time during access or removal, the introducer/guide catheter/microcatheter and FRED Jr. system should be removed as a single unit. Applying excessive force during delivery or retrieval of the FRED Jr. system can potentially result in loss or damage to the device and delivery components.
- The FRED Jr. system should only be used by physicians trained in endovascular interventional neuroradiology, radiology, neurosurgery or interventional neurology for the treatment of intracranial aneurysms or other vascular lesions.
- It is imperative to use the FRED Jr. system with a Headway® 21 microcatheter. If repeated friction is encountered during FRED Jr. system delivery, verify microcatheter is not kinked or in extremely tortuous anatomy. Confirm that the microcatheter does not ovalize. Confirm that there is adequate sterile heparinized flush solution.
- Do not reposition the FRED Jr. system in the parent vessel without fully retrieving the device. The FRED Jr. system MUST be retrieved/resheathed into the microcatheter and re-deployed at the desired target location or removed completely from the patient.
- Do not attempt to re-position the FRED Jr. implant after deployment/detachment.

- The safety and performance of the FRED Jr. system for use in conjunction with intravascular medical devices other than neurovascular embolization coils have not been established.

FRED X

- Should unusual resistance be felt at any time during access or removal, the introducer/guide catheter/microcatheter and FRED X System should be removed as a single unit. Applying excessive force during delivery or retrieval of the FRED X System can potentially result in loss or damage to the device and delivery components.
- The FRED X System should only be used by physicians trained in endovascular interventional neuroradiology, radiology, neurosurgery or interventional neurology for the treatment of intracranial aneurysms or other vascular lesions.
- The FRED X System should only be delivered through the appropriate Headway microcatheter, Headway 27 for FRED X System sizes 3.5 - 5.5 mm and Headway 21 for FRED X System sizes 2.5 - 3.0 mm.
- If repeated friction is encountered during FRED X System delivery, verify microcatheter is not kinked or in extremely tortuous anatomy. Confirm that the microcatheter does not ovalize. Confirm that there is adequate sterile heparinized flush solution.
- Do not reposition the FRED X System in the parent vessel without fully retrieving the device. The FRED X System MUST be retrieved/resheathed into the microcatheter and re-deployed at the desired target location or removed completely from the patient.
- Do not attempt to re-position the FRED X implant after deployment/detachment.
- The safety and performance of the FRED X System for use in conjunction with intravascular medical devices other than neurovascular embolization coils have not been established.

FRED OMEGA

- Should unusual resistance be felt at any time during access or removal, the introducer/guide catheter/microcatheter and FRED Omega System should be removed as a single unit. Applying excessive force during delivery or retrieval of the FRED Omega System can potentially result in loss or damage to the device and delivery components.
- The FRED Omega System should only be used by physicians trained in endovascular interventional neuroradiology, radiology, neurosurgery or interventional neurology for the treatment of intracranial aneurysms or other vascular lesions.
- The FRED Omega System should only be delivered through the appropriate Headway microcatheter, Headway 17 microcatheter for FRED Omega System sizes 2.5 - 3.0 mm.
- If repeated friction is encountered during FRED Omega System delivery, verify microcatheter is not kinked or in extremely tortuous anatomy. Confirm that the microcatheter does not ovalize. Confirm that there is adequate sterile heparinized flush solution.
- Do not reposition the FRED Omega System in the parent vessel without fully retrieving the device. The FRED Omega System MUST be retrieved/resheathed into the microcatheter and re-deployed at the desired target location or removed completely from the patient.
- Do not attempt to re-position the FRED Omega implant after deployment/detachment.

- The safety and performance of the FRED Omega System for use in conjunction with intravascular medical devices other than neurovascular embolization coils have not been established.

PRECAUTIONS

- These products should only be used by experienced physicians who have completed endovascular training in the use of the FRED devices. This device is used for percutaneous neurointerventional, and peripheral vascular procedures as indicated by a representative from MicroVention-Terumo or a MicroVention-authorized distributor.
- The FRED devices do not contain latex or PVC materials.
- The FRED devices are provided sterile for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Carefully inspect the sterile package and the FRED devices prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components, or if the package is opened or damaged.
- See the product label for shelf life. Do not use the FRED devices beyond the labeled use by date.
- Exercise caution when crossing the deployed/detached FRED devices with adjunctive devices such as guidewires, catheters, microcatheters or balloon catheters to avoid disrupting the device geometry and device placement.

1.4.3 Potential Complications / Adverse Effects

The potential complications / adverse effects for the FRED devices are

- Bleeding
- Hemorrhage including intracerebral, retroperitoneal or other locations
- Complications of arterial puncture including pain, local bleeding (hematoma) or injury to the artery or adjacent nerves
- Device migration
- Distal Embolization
- Headache
- Incomplete aneurysm occlusion
- Neurologic deficits including stroke and/or death

- Perforation or dissection of the vessel(s)
- Pseudoaneurysm formation
- Rupture or perforation of aneurysm
- Transient ischemic attack (TIA) or ischemic stroke
- Vasospasm
- Vessel occlusion
- Vessel stenosis or thrombosis

The physician should be aware of these complications and instruct patients when indicated. Appropriate patient management should be considered.

1.4.4 Other Aspects of Safety

Field Actions are conducted in accordance with the *Field Corrective Actions (SOP 8.7)* procedure. During the time period covered (01 February 2020 to 31 January 2024) by the Post-Market Surveillance Report (PSUR), there were no Field Action involving the FRED devices.

1.5 Summary of the Clinical Evaluation and PMCF

1.5.1 Equivalent Device Clinical Data

Equivalency is not claimed in the clinical evaluation for the FRED Devices.

1.5.2 Pre-CE-Mark Clinical Data

There were no pre-market clinical studies conducted for the FRED Device.

Through the years sufficient clinical evidence including clinical literature and clinical experience data have been collected for the subject devices and no significant changes to the product have been proposed, there is no need to conduct additional pre-market clinical investigations.

1.5.3 Clinical Data

Summary of Clinical Data

Clinical evidence was identified, collected, and appraised from a variety of trusted sources including (both manufacturers manufacturer-sponsored, and investigator-sponsored studies), published peer-reviewed clinical literature, and the company's post-market surveillance data.

There are 5 completed and 2 ongoing post-market clinical studies identified that are sponsored by MicroVention, including total of 848 enrolled patients using the FRED devices for intracranial aneurysms. Currently, clinical data from 2 complete studies (FRED US Pivotal Trial/NCT01801007 and SAFE study/NCT02921698) with 248 patients are available for analysis. 3 completed studies (FRED U.K. Study, FRED Poland Study, and FRED EPI Study) are currently being analyzed and data are not available at the time of writing this report. Data from these sponsored studies will be addressed in the next CER update when available. Of the completed post-market clinical studies, the results from 2 trials are identified and addressed in the published

literature section of the CER. These data are included in **Section 1.5.4 (Clinical Performance and Safety)** in addition to clinical data from the published literature.

The published literature results detailed in this report presents relevant clinical data from the scientific literature for FRED devices. The literature search was performed using a sound methodological process as outlined in the CER. There are a total of 27 publications, which included 4 case series, and 23 cohort studies, demonstrating the use of FRED devices. The included published literature identified 2,537 patients with the use of the FRED devices. The literature search results demonstrate the clinical use of the FRED devices for flow-diverting stenting in patients with intracranial aneurysms in all studies with 2,537 patients.

Post-market surveillance data show the use of the FRED devices in 25,998 cases from 01 February 2020 to 31 January 2024; MicroVention received 1,308 product complaints concerning the FRED devices, resulting in a complaint rate of 5.0%. Of these complaints, 70 were considered MDV reportable including EU, for a reportable complaint rate of 0.269%. Clinical risks of the use of the FRED devices are consistent with the SOTA for flow diverters, showing low rates of adverse events and low rates of complaints failure across several published studies with a large cumulative patient population and substantial post-market surveillance (PMS) data.

1.5.4 Clinical Performance and Safety

Clinical Benefits (Performance)

Neurovascular vascular lesions, such as intracranial aneurysms, can cause potential injury or death if left untreated. The FRED devices are intended for endovascular embolization of intracranial neurovascular aneurysms resulting in aneurysm occlusion. Successful treatment of intracranial aneurysms (ICAs) reduces the risks and complications associated with it. The overall success and benefits of using the FRED devices, especially when compared against the risks and complications associated with conditions such as intracranial aneurysms and other vascular lesions are substantial. The efficacy of the FRED devices is measured by its successful navigation to the targeted treatment site, as well as the overall successful delivery/deployment of flow diverter for endovascular embolization of ICAs. The FRED devices were used for the successful delivery/deployment of stent that provided actual benefits to the patient, such as complete/total occlusion of ICAs and good clinical outcomes.

A total of 27 studies from the published literature and 2 completed sponsored post-market clinical studies reported the use of FRED devices for treatment of ICAs including 2,537 patients (Ref ID 1-25, 30, 80). Of the 27 studies and 2 complete sponsored studies included for evaluation, all studies reported the use of FRED devices for endovascular treatment of cerebral aneurysms such as intracranial aneurysms (ICAs). The clinical benefits associated with the use of FRED devices are demonstrated below with a quantified range.

- Technical Success (successful stent implantation/deployment): 95.1%-100%
- Complete occlusion rate at follow-up: 60%-97.2%

- Good Clinical Outcomes (mRS score of 0-2): 76.7%-100%

Clinical Risks (Safety)

The harms identified through risk management were compared with the adverse events identified in the clinical evaluation from the published literature. No new harms were identified in this clinical evaluation and all identified harms are included in the risk assessment/control documentation. Harms are appropriately described within the FRED devices IFU(s). The clinical risks associated with the use of FRED devices are consistent in most parameters when compared to the use of similar flow diverters in the state of the art (SOTA). The common complications associated are listed in the table below with a quantified range. The common overall clinical risks associated with the use of FRED devices are demonstrated below with a quantified range.

- Procedure-related complications: 0%-18.2%
- Thromboembolic complications: 1.7%-9.5%
- Hemorrhagic complication: 0%-8.9%
- Retreatment: 1.3%-7.1%
- Morbidity: 0%-8.6%
- Mortality/Death: 0%-8.9%
- Device-related complications: 0.6%-4.3%
    - (e.g., access site complication, stent's bad opening, shortening/repositioning of the stent, stent migration)
- In-stent thrombosis: 2%-9.1%
- Stroke: 0%-6.1%
- TIA: 0.7%-9.1%
- Artery/stent occlusion: 0.6%-3.3%
- Parent artery stenosis: 0.8%-2.4%
- In-stent stenosis: 1.4%-20%
- Rupture: 0%-1.9%
- Neurologic complications: 0%-4%
- Hematoma: 0.2%-2%
- Femoral pseudoaneurysm: 0.6%

1.5.5 Post-Market Clinical Follow-up

Clinical data from 3 completed studies (FRED U.K. Study – NCT03423290, FRED Poland Study, and FRED EPI Study – NCT04315168) are currently pending and will be available when they are published. There are 2 ongoing studies, the FRED FRITZ study (NCT03920358) and FRED X Post-Approval Study (NCT05409989), which are currently ongoing; the clinical data from ongoing studies will be reported in clinical evaluation when they are completed and published. These PMCFP activities are included in the latest PMCFP plan, and they will be continuously monitored with Post-Market Surveillance (PMS) data.

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

Current approaches to treating intracranial aneurysm including therapeutic alternatives are observation (no treatment), surgical treatment such as temporary clipping, and endovascular treatment such as coiling and stent-assisted coiling. In unruptured aneurysms, the decision as to whether to treat or observe the malformation is made on a case-by-case basis.

Surgical Treatment

Surgical treatments for intracranial aneurysm include surgical clipping, bypass, and bipolar coagulation. Simple surgical clipping refers to the practice of the exposure of the aneurysmal neck via craniotomy and the exclusion of the entire abnormal vascular wall from the circulation using single or multiple clips. The key of clipping surgeries lies in good neck exposure, and in cases where visual exposure and clip insertion is limited by the operating field, endoscope-assisted clipping can be used.

Bypass techniques occlude the inflow artery and resume regional circulation through a bypass from an extracranial artery (termed extracranial-to-intracranial bypass) or intracranial artery (termed intracranial-to-intracranial bypass). For intracranial complex aneurysms, superficial temporal artery bypass remains a major option that can serve as a flow replacement bypass during aneurysmal trapping or insurance bypass during temporary parent artery occlusion.

Bipolar coagulation is a surgical treatment option for microaneurysms, in which aggressive surgery is not required and clipping is not suitable.

Endovascular Coiling

Endovascular coiling is a less invasive, endovascular treatment approach which is an alternative to surgical clipping for the treatment of most intracranial aneurysms. The goal of endovascular coiling is to isolate aneurysms from the active circulation by achieving dense packing of coils and inducing blood clot formation within the aneurysmal sac. Endovascular coiling includes simple coiling, balloon-assisted coiling (BAC), and stent-assisted coiling (SAC). Simple coiling is suitable for all intracranial aneurysms with desirable dome-to-neck ratios (>2.0), excluding blood blister-like aneurysms, as their fragile wall poses high risks of perforation. BAC and SAC are often used in wide-necked, giant, fusiform and other complex intracranial aneurysms. During BAC, one or multiple balloons are temporarily inflated to block the aneurysmal neck before coil packing. During SACs, a stent is deployed to cover the aneurysmal neck before coil placement. Different SAC techniques have been developed to assist coil packing.

Intrasaccular Flow Disruption

Intrasaccular flow disruption involves the placement of a self-expanding, roughly spherically shaped, cage-like devices within the aneurysmal sac to cover the aneurysm neck and promote aneurysm thrombosis and parent artery neoendothelialization. In distinction to the intracranial stents, intrasaccular flow disruption device, such as the WEB™ Device, does not require dual-

antiplatelet therapy. For this reason, the WEB Device can be used in both ruptured and unruptured aneurysms. Furthermore, only one device is needed to occlude the aneurysmal sac, compared to multiple coils. As such, use of intrasaccular flow disruption devices may shorten the procedure duration and reduce radiation exposure. The progressive improvement of the technology (dual-layer to single-layer devices, enhanced visualization, and reduced microcatheter size) has led to an expansion of potential clinical indications to more distal aneurysms (e.g., pericallosal) and sidewall aneurysms (e.g., carotid siphon) in Europe. Moreover, studies have shown the good efficacy of the WEB device in preventing ruptured aneurysm from rebleeding with a low rate of late rebleeding, as well as being the first-line endovascular therapy in treatment of ruptured aneurysms. There are risks associated with device selection. If the device is not sufficiently oversized, it will not be compressed laterally, which risks aneurysm recanalization. If the device is oversized too much, the risk of rupture is very low, but the main risk is protrusion in the bifurcation or its branches. For the vast majority of aneurysm morphologies, the manufacturer's sizing table outlining the oversizing rule of thumb is reliable and simple to use.

1.6.2 Available Technologies

Examples of other flow diverters similar to the FRED devices are listed in **Table 1.8**.

Table 1.8 Similar Devices

Device	Manufacturer	Intended Purpose
Pipeline™ Embolization Device	Medtronic	The Pipeline™ embolization device is indicated for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms (ICAs) in the internal carotid artery from the petrous to the superior hypophyseal segments.
Surpass Evolve™	Stryker	The Surpass Evolve Flow Diverter is indicated for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥ 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 5.3 mm.

1.7 Suggested Profile and Training for Users

The FRED devices should only be used by experienced physicians who have completed endovascular training in the use of the FRED devices. This device is used for percutaneous neurointerventional, and peripheral vascular procedures as indicated by a representative from MicroVention-Terumo or a MicroVention-authorized distributor.

1.8 Reference to any Harmonized Standards and CS

The FRED devices were designed, developed, and tested following the standards and guidance documents listed in Error! Reference source not found..

Table 1.9 Harmonized Standards

Harmonized standard(s) to comply with:		
Standards	**Edition**	**Standard Title**
Quality System		
EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
Risk Management		
EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN IEC 60812	2018	Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)
Usability		
EN ISO 62366-1	2015/A1:2020	Medical devices – Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
Clinical		
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)
Post Market Surveillance		
ISO/TR 20416	2020	Medical devices – Post market surveillance for manufacturers
Labeling		
EN ISO 15223-1	2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
Packaging		
EN ISO 11607-1	2020/A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11607-2	2020/A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less
ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F88	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096	2011R 2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
Shelf Life & Stability		
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
Biocompatibility		
EN ISO 10993-1	2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
EN ISO 10993-3	2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
EN ISO 10993-4	2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5	2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6	2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation (ISO 10993-6:2016)

Standards	Edition	Standard Title
EN ISO 10993-10	2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitization (ISO 10993-10:2021)
EN ISO 10993-11	2018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
EN ISO 10993-17	2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)
EN ISO 10993-18	20200/A1:2023	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020/Amd 1:2022)
EN ISO 10993-23	2021	Biological evaluation of medical devices – Part 23: Tests for irritation (ISO 10993-23:2021)
Manufacturing (Environmental Controls)		
EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
EN ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
ANSI/AAMI ST72	2019	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
Sterilization		
EN 556-1	2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices
EN ISO 11737-1	2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018/Amd 1:2021)
EN ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
Gamma or E-Beam Radiation		
EN ISO 11137-1	2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006/Amd 2:2018)
EN ISO 11137-2	2015	Sterilization of health care products – Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
Device Specific		
Implants:		
EN ISO 14630	2012	Non-active surgical implants - General requirements (ISO 14630:2012)
EN ISO 25539-1	2017	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2017)
EN ISO 25539-2	2020	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2020)
ISO 16428	2005	Implants for surgery – Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices
ASTM F2129	2019a	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
ASTM F3044	2020	Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants
Radiopacity:		
ASTM F640	2023	Standard test methods for determining radiopacity for medical use
MRI:		

Standards	Edition	Standard Title
ASTM F2052	2021	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2119	2007R2013	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2182	2019e2	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213	2017	Standard test method for measurement of magnetically induced torque on passive implants in the magnetic resonance
ASTM F2503	2023e1	Standard practice for marketing medical devices and other items for safety in the magnetic resonance environment

Guidance on PMCF:		
Title	**Date**	**Version**
Post-market clinical follow-up (PMCF) Evaluation Plan Template A guide for manufacturers and notified bodies	2020	MDCG 2020-7
Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies	2020	MDCG 2020-8
Post-market clinical follow-up studies A guide for manufacturers and notified bodies	2020	MEDDEV2.12/2
Medical Devices-Post Market Surveillance for Manufacturers	2020	ISO/TR 20416

1.9 References

Ref ID #	Bibliography
1	**Choi, J. H.,Sim, S. Y.,Shin, Y. S.,Chung, J.**. A Single Flow Re-direction Endoluminal Device for the Treatment of Large and Giant Anterior Circulation Intracranial Aneurysms. *Yonsei Med J*. 2022. 63:349-356
2	**Gan, C. L.,Yang, Z.,Salahia, G.,Halpin, S.,Nair, S.**. A single-centre experience and literature review of Flow Re-Directional Endoluminal Device (Sayin) in endovascular treatment of intracranial aneurysms. *Clin Radiol*. 2021. 76:238 e1-238 e8
3	**Manzato, L. B.,Santos, R. B.,Filho, P. M. M.,Miotto, G.,Bastos, A. M.,Vanzin, J. R.**. Brazilian FRED Registry: A Prospective Multicenter Study for Brain Aneurysm Treatment-The BRED Study. *AJNR Am J Neuroradiol*. 2021. 42:1822-1826
4	**Griessenauer, C. J.,Enriquez-Marulanda, A.,Xiang, S.,Hong, T.,Zhang, H.,Taussky, P.,Grandhi, R.,Waqas, M.,Tutino, V. M.,Siddiqui, A. H.,Levy, E. I.,Ogilvy, C. S.,Thomas, A. J.,Ulfert, C., Mohlenbruch, M. A.,Renieri, L.,Limbucci, N.,Parra-Farinas, C.,Burkhardt, J. K.,Kan, P., Rinaldo, L.,Lanzino, G.,Brinjikji, W.,Spears, J.,Muller-Thies-Broussalis, E.,Killer-Oberpfalzer, M.,Islak, C.,Kocer, N.,Sonnberger, M.,Engelhorn, T.,Ghuman, M.,Yang, V. X.,Salehani, A., Harrigan, M. R.,Radovanovic, I.,Pereira, V. M.,Krings, T.,Matouk, C. C.,Chen, K.,Aziz-Sultan, M. A.,Ghorbani, M.,Schirmer, C. M.,Goren, O.,Dalal, S. S.,Koch, M. J.,Stapleton, C. J.,Patel, A. B.,Finkenzeller, T.,Holtmannspotter, M.,Buhk, J. H.,Foreman, P. M.,Cress, M.,Hirschl, R.,Reith, W.,Simgen, A.,Janssen, H.,Marotta, T. R.,Dmytriw, A. A.**. Comparison of PED and FRED flow diverters for posterior circulation aneurysms: a propensity score matched cohort study. *J Neurointerv Surg*. 2021. 13:153-158
5	**Guimaraens, L.,Vivas, E.,Saldana, J.,Llibre, J. C.,Gil, A.,Balaguer, E.,Rodriguez-Campello, A., Cuadrado-Godia, E.,Ois, A.**. Efficacy and safety of the dual-layer flow-diverting stent (Sivasankar et al.) for the treatment of intracranial aneurysms. *J Neurointerv Surg*. 2020. 12:521-525
6	**Teixeira, Vinicius Fialho,Bastos, Albedy Moreira,Santos, Rafael Brito**. Endovascular Therapy of 103 Aneurysms in the Internal Carotid Artery with Flow Re-Direction Endoluminal Device. *Arquivos Brasileiros de Neurocirurgia: Brazilian Neurosurgery.* 2021. 42:e19-e23
7	**Sayin**. <Endovascular Treatment of_SAYIN_2022.pdf>. 2022.
8	**Killer-Oberpfalzer, M.,Kocer, N.,Griessenauer, C. J.,Janssen, H.,Engelhorn, T., Holtmannspotter, M.,Buhk, J. H.,Finkenzeller, T.,Fesl, G.,Trenkler, J.,Reith, W.,Berlis, A., Hausegger, K.,Augustin, M.,Islak, C.,Minnich, B.,Mohlenbruch, M.**. 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. *AJNR Am J Neuroradiol*. 2018. 39:841-847
9	**Sivasankar, R.,Shrivastava, M.,Limaye, U. S.**. Experience with FRED junior flow diverter in treatment of cerebral aneurysms at or distal to the circle of Willis. *J Clin Neurosci.* 2019. 69:166-169
10	**Pierot, L.,Spelle, L.,Berge, J.,Januel, A. C.,Herbreteau, D.,Aggour, M.,Piotin, M.,Biondi, A., Barreau, X.,Mounayer, C.,Papagiannaki, C.,Lejeune, J. P.,Gauvrit, J. Y.,Costalat, V.**. Feasibility, complications, morbidity, and mortality results at 6 months for aneurysm treatment with the Flow Re-Direction Endoluminal Device: report of SAFE study. *J Neurointerv Surg.* 2018. 10:765-770
11	**Kandemirli, S. G.,Baltacioglu, F.,Jesser, J.,Kizilkilic, O.,Islak, C.,Mohlenbruch, M.,Kocer, N.**. Flow Redirection Endoluminal Device (Piano et al.) with or without Adjunctive Coiling in Treatment of Very Large and Giant Cerebral Aneurysms. *Clin Neuroradiol*. 2022. 32:471-480
12	**Luecking, H.,Engelhorn, T.,Lang, S.,Goelitz, P.,Kloska, S.,Roessler, K.,Doerfler, A.**. FRED Flow Diverter: A Study on Safety and Efficacy in a Consecutive Group of 50 Patients. *AJNR Am J Neuroradiol.* 2017. 38:596-602
13	**Piano, M.,Valvassori, L.,Lozupone, E.,Pero, G.,Quilici, L.,Boccardi, E.,Fred Italian Registry Group**. FRED Italian Registry: a multicenter experience with the flow re-direction endoluminal device for intracranial aneurysms. *J Neurosurg.* 2019. #volume#:1-8

Ref ID #	Bibliography
14	**Dinc, H.,Saatci, I.,Oguz, S.,Baltacioglu, F.,Yildiz, A.,Donmez, H.,Belet, U.,Onal, B.,Andic, C.,Koc, O.,Kocak, O.,Koroglu, M.,Cetin, M.,Cekirge, H. S.**. Long-term clinical and angiographic follow-up results of the dual-layer flow diverter device (Piano et al.) for the treatment of intracranial aneurysms in a multicenter study. *Neuroradiology*. 2021. 63:943-952
15	**Mohlenbruch, M. A.,Kizilkilic, O.,Killer-Oberpfalzer, M.,Baltacioglu, F.,Islak, C.,Bendszus, M., Cekirge, S.,Saatci, I.,Kocer, N.**. Multicenter Experience with FRED Jr Flow Re-Direction Endoluminal Device for Intracranial Aneurysms in Small Arteries. *AJNR Am J Neuroradiol*. 2017. 38:1959-1965
16	**Khorasanizadeh, M.,Shutran, M.,Schirmer, C. M.,Salem, M. M.,Ringer, A. J.,Grandhi, R.,Mitha, A. P.,Levitt, M. R.,Jankowitz, B. T.,Taussky, P.,Thomas, A. J.,Moore, J. M.,Ogilvy, C. S.**. North American multicenter experience with the Flow Redirection Endoluminal Device in the treatment of intracranial aneurysms. *J Neurosurg*. 2023. 138:933-943
17	**Pierot, L.,Spelle, L.,Berge, J.,Januel, A. C.,Herbreteau, D.,Aggour, M.,Piotin, M.,Biondi, A., Barreau, X.,Mounayer, C.,Papagiannaki, C.,Lejeune, J. P.,Gauvrit, J. Y.,Derelle, A. L.,Chabert, E.,Costalat, V.**. SAFE study (Safety and efficacy Analysis of FRED Embolic device in aneurysm treatment): 1-year clinical and anatomical results. *J Neurointerv Surg*. 2019. 11:184-189
18	**Jesser, J.,Alberalar, N. D.,Kizilkilic, O.,Saatci, I.,Baltacioglu, F.,Özlük, E.,Killer-Oberpfalzer, M.,Vollherbst, D. F.,Islak, C.,Cekirge, S. H.,Bendszus, M.,Möhlenbruch, M.,Koçer, N.**. Safety and Efficacy of the FRED Jr Flow Re-Direction Endoluminal Device for Intracranial Aneurysms: Retrospective Multicenter Experience With Emphasis on Midterm Results. *Front Neurol*. 2021. 12:722183
19	**McDougall, C. G.,Diaz, O.,Boulos, A.,Siddiqui, A. H.,Caplan, J.,Fifi, J. T.,Turk, A. S.,Kayan, Y., Jabbour, P.,Kim, L. J.,Hetts, S. W.,Cooke, D. L.,Dowd, C. F.**. Safety and efficacy results of the Flow Redirection Endoluminal Device (Piano et al.) stent system in the treatment of intracranial aneurysms: US pivotal trial. *J Neurointerv Surg*. 2022. 14:577-584
20	**Griessenauer, C. J.,Möhlenbruch, M. A.,Hendrix, P.,Ulfert, C.,Islak, C.,Sonnberger, M., Engelhorn, T.,Müller-Thies-Broussalis, E.,Finkenzeller, T.,Holtmannspötter, M.,Buhk, J. H., Reith, W.,Simgen, A.,Janssen, H.,Kocer, N.,Killer-Oberpfalzer, M.**. The FRED for Cerebral Aneurysms of the Posterior Circulation: A Subgroup Analysis of the EuFRED Registry. *AJNR Am J Neuroradiol*. 2020. 41:658-662
21	**Drescher, F.,Weber, W.,Berlis, A.,Rohde, S.,Carolus, A.,Fischer, S.**. Treatment of Intra- and Extracranial Aneurysms Using the Flow-Redirection Endoluminal Device: Multicenter Experience and Follow-Up Results. *AJNR Am J Neuroradiol*. 2017. 38:105-112
22	**Mahboobani, N. R.,Chong, W. H.,Lam, S. S.,Siu, J. C.,Tan, C. B.,Wong, Y. C.**. Treatment of Intracranial Aneurysms with Flow Re-direction Endoluminal Device - A Single Centre Experience with Short-term Follow-up Results. *Neurointervention*. 2017. 12:11-19
23	**Möhlenbruch, M. A.,Seker, F.,Özlük, E.,Kizilkilic, O.,Broussalis, E.,Killer-Oberpfalzer, M., Griessenauer, C. J.,Bendszus, M.,Kocer, N.**. Treatment of Ruptured Blister-Like Aneurysms with the FRED Flow Diverter: A Multicenter Experience. *AJNR Am J Neuroradiol*. 2020. 41:2280-2284
24	**Luecking, H.,Doerfler, A.,Goelitz, P.,Hoelter, P.,Engelhorn, T.,Lang, S.**. Two- to five-year follow-up of 78 patients after treatment with the Flow Redirection Endoluminal Device. *Interv Neuroradiol*. 2020. 26:38-44
25	**Abbas, Rawad, Lan, Matthews, El Naamani, Kareem, Atallah, Elias, Salem, Mohamed, Burkhardt, Jan-Karl, Kühn, Anna Luisa, Puri, Ajit, Monteiro, Andre, Levy, Elad I., Herial, Nabeel A., Gooch, M. Reid, Jabbour, Jeffrey, Rosenwasser, Robert, Tjoumakaris, Stavropoula I.**. First United States multicenter experience with the new-generation FRED X surface-modified flow diversion stent: feasibility, safety, and short-term efficacy. *Journal of Neurosurgery*. 2024. 140:1054-1063
30	**Doron, Omer, McLellan, Rachel, Vranic, Justin E., Regenhardt, Robert W., Stapleton, Christopher J., Patel, Aman B.**. FRED Jr stent for acute flow diversion in ruptured cerebral aneurysms arising from small-caliber vessels: a clinical case series. *Neurosurgical focus*. 2023. 54:E6

Ref ID #	Bibliography
80	**Vollherbst, D. F., Lücking, H., DuPlessis, J., Sonnberger, M., Maurer, C., Kocer, N., Killer-Oberpfalzer, M., Rautio, R., Valvassori, L., Berlis, A., Gasser, S., Gatt, S., Dörfler, A., Bendszus, M., Möhlenbruch, M. A.**. The FRESH Study: Treatment of Intracranial Aneurysms with the New FRED X Flow Diverter with Antithrombotic Surface Treatment Technology--First Multicenter Experience in 161 Patients. *American Journal of Neuroradiology*. 2023. 44:474-480