



Summary of Safety and Clinical Performance
for
Flow Re-Direction Endoluminal Device
(FRED™)
SSCPPT23-0012

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1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE [PATIENT VERSION]

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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 information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

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 |
| Device Class | Class III |
| Basic UDI-DI | 08402732FREDHC |
| Year when first certificate (CE) was issued | FRED: 2011 FRED Jr.: 2015 FRED X: 2020 FRED Omega™: 2021 |
| Legal Manufacturer | |
| Name & Address | MicroVention, Inc. 35 Enterprise Aliso Viejo, California, 92656 USA |
| Authorized Representative | |
| Name & Address | MicroVention Europe SARL 30 bis, rue du Vieil Abreuvair 78100 Saint-Germain-en-Laye, France |
| Notified Body | |
| Name & Address | DQS Medizinprodukte GmbH August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany |

1.2 Intended Use of the Device

Table 1.2 Intended Use

| Intended Use | |
|--------------------------------------|--|
| Intended Purpose | The FRED devices (FRED, FRED Jr., FRED X and FRED Omega) are used to block the blood vessels of the brain when there is a bulge in the blood vessel. The device can also be used with coils to treat other blood vessels or nerves in the brain. |
| Indications for Use | The device is used to treat the bulge in the blood vessel of the brain. The device can also be used with coils to treat other blood vessels or nerves in the brain lesions. |
| Intended Patient Group(s) | For patients with a bulge in the blood vessels or other nerves in the brain. |
| Contraindications and/or Limitations | <ul style="list-style-type: none"> • Patients who are not allowed to use blood thinner medications (anticoagulant, antiplatelet therapy or thrombolytic drugs) • Patients who are sensitive to nickel or titanium • X-rays found something wrong with the blood vessel that does not allow passage of the FRED system |

1.3 Device Description

Table 1.3 Device Description

| Device Description | |
|--|---|
| Description of the Device | The FRED devices include metals and a delivery system that can be delivered and positioned at the same time. The device expands when released from the delivery system. There are two layers joined together, which are designed to focus mainly on the neck of the bulge in the wall of the artery. The device has markers that shows body structure with X-rays. The device is packaged clean with a protective cover and a delivery pusher. It is available in different sizes. The device can be used with other small surgical tubes. The FRED devices do not have drugs, animal tissues, or blood products. |
| Materials or substances in contact with the patient's tissues | The device includes two joined inner and outer layers, which are made of metal alloy, and forms a small mesh tube. In addition, the outer layer could contain a platinum core to show blood vessels with X-rays. Two wires are interwoven between the two layers along the length of the inner layer to show body structure with X-rays. |
| Information about medicinal substances in the device | The device does not include any drugs. |
| Description of how device achieves its intended mode of action | The device gets to the target by a delivery pusher. The protective cover is used to protect the device and help guide to the tiny hub. During the treatment, your doctor selects the device size based on the size and shape of the bulge. After positioning, the device opens and pushes against the vessel wall and across the neck of the bulge. By reducing and changing the direction of blood flow away from the bulge, the device causes blood clots in the bulge. The resulting blood clots create a blockage to keep blood from flowing into the bulge and lower the risk of break. |
| Description of Accessories | The FRED devices can be used with other sized tubes. |
| Description of other Devices or Products | The device is packaged clean with a protective cover and detachable delivery pusher. It is available in different sizes. It can be used with other surgical tubes. |

| | |
|------------------------------------|--|
| intended to be used in combination | |
|------------------------------------|--|

1.4 Risks and Warnings

Reach out to your doctor if you have side effects related to the device or worries about its risks. Do not use this document to replace a doctor's consultation.

- **How potential risks have been controlled or managed**
 - Harms related to using the FRED devices are checked, and risks are minimized by using various measures. All known predictable risks are checked and adjusted.
- **Remaining risks and undesirable effects**
 - Bleeding around or in the brain
 - Complications of arterial hole such as break, pain, bleeding, or damage to nearby nerves
 - Device moves out of place
 - Blockage of the blood vessel in the back of the brain
 - Headache
 - Incomplete bulge in the blood vessel caused by bleeding that has not been reduced or stopped
 - Brain-related problems including bleeding in the brain and/or death
 - Hole in the organ or blood vessel splits
 - Damage to the blood vessel
 - Break or hole in the bulge
 - Blood supply to the brain is blocked briefly or reduced or blocked completely
 - Sudden narrowing of blood vessels
 - Vessel block
 - Vessel narrowing or blood clotting
- **Warnings and precautions**

WARNINGS)

 - FRED/FRED Jr./FRED X/FRED Omega
 - The surgical tubes and the FRED device should be removed together if there is any resistance during the procedure. Too much force can damage the device and delivery system.
 - Only trained doctors should use this device.

- It is important to use the device with other surgical tubes (FRED – Headway 27, FRED JR – Headway 21, FRED X – Headway 27, FRED Omega – Headway 17). Check if the tube is twisted with repeated friction during delivery.
- Confirm that the tiny tube does not become circular in shape. Confirm that there is enough clean heparinized (to treat with heparin) flush solution.
- Do not place this device in the parent vessel again without taking back the device from the patient.
- Do not try to place the device again after positioning.
- There is no established safety and performance data for use of this device with other devices other than coils in the brain.

PRECAUTIONS)

- The FRED devices should only be used by trained doctors in treating the brain bulge. This device is used for procedures with blood vessels in the body and through the skin as indicated by a MicroVention-Terumo representative or a MicroVention-authorized distributor.
 - The device does not contain latex or PVC materials.
 - The devices are provided clean for single use only. Do not use the device again because it can affect the structure of device and cause device failure. This can cause damage to the patient or even death. It can also contaminate the device and cause infection.
 - Check the clean package and the device carefully before using. Do not use it if the package is opened or damaged.
 - See the product label for shelf life. Do not use the device beyond expiration.
 - Be careful when using the devices with other small surgical tubes or guidewires. They can disrupt the device placement.
- **Summary of any field safety corrective action**
 - There were no safety or corrective actions from the company for the FRED devices.

1.5 Summary of Clinical Evaluation and Post-Market Clinical Follow-up

- **Clinical background of the device**
 - The FRED device has been CE marked since 2011 and has been on the market since then.
- **The clinical evidence for the CE-marking:** There are 27 studies with 2,537 patients found in the journals for the FRED devices. The company also completed 5 studies and currently running 2 studies including 848 patients. The combined available clinical data is shown below.

- Clinical Benefits:
 - 95.1%-100% with successful use of the device
 - 60%-97.2% successful blockage of the blood vessels at follow-up (6-24 months)
 - 76.7%-100% good clinical results (mRS 0-2) at follow-up (6 months-27 months)
- **Safety:** Using the FRED devices were just as good as other similar devices. There are no new risks found and side effects were minimal. There were more benefits than risks. The company received 1,308 device complaints (5.0%) from 01 February 2020 to 31 January 2024. Such risks were consistent with other similar devices.
 - Clinical Risks
 - Side effects related to the surgery: 0%-18.2%
 - Side effects related to the blood clots: 1.7%-9.5%
 - Side effects related to bleeding: 0%-8.9%
 - Retreatment: 1.3%-7.1%
 - Sick or unhealthy state: 0%-8.6%
 - Death: 0%-8.9%
 - Device-related side effects (e.g., difficult access to the area, positioning, or device moving): 0.6%-4.3%
 - Device related blood clots: 2%-9.1%
 - Bleeding in brain: 0%-6.1%
 - Bleeding in brain (resolved in 24 hours): 0.7%-9.1%
 - Blockage of the device/artery: 0.6%-3.3%
 - Narrowing of artery: 0.8%-2.4%
 - Narrowing related to the device: 1.4%-20%
 - Break/damage: 0%-1.9%
 - Side effects related to the nervous system: 0%-4%
 - Abnormal pooling of blood: 0.2%-2%
 - Blood collection in femoral artery wall: 0.6%

1.6 Possible Diagnostic or Therapeutic Alternatives

Talk to your doctor about other options for this device. They will know what is best for your overall condition.

- **General description of therapeutic alternatives:** there are other surgical options such as clipping, bypass, and clotting blood, coiling alone, and flow disruption. Sometimes it is better to just wait and see the conditions with your doctor. You and your doctor will decide what is right for you.

1.7 Suggested Training for Users

This device is not used directly by the patient. No training is required.