Summary of Safety and Clinical Performance

for

Flow Re-Direction Endoluminal Device

(FRED™)

SSCPPT23-0012

MicroVention, Inc.
35 Enterprise
Aliso Viejo, California 92656, USA

MicroVention Europe SARL
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye, France

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.

Sign Page

Document Author: Youngun Jun

Signature: Signed by: Youngun Jun
Signer Name: Youngun Jun
Signing Reason: I am the author of this document
Signing Time: 6/6/2025 | 2:56:03 PM PDT
B6D2C0FA26DB47258D464D5CE6B73C81

Date: 6/6/2025

RA Approver: Vidhi Bhatt

Signature: Signed by: Vidhi Bhatt
Signer Name: Vidhi Bhatt
Signing Reason: I approve this document
Signing Time: 6/9/2025 | 4:26:42 PM PDT
01ED5563570C451CABFFF604522DEBD0

Date: 6/9/2025

Legal Approver: Young Tang

Signature: Signed by: Young Tang
Signer Name: Young Tang
Signing Reason: I approve this document
Signing Time: 6/9/2025 | 4:43:00 PM PDT
6FFB5174FCFF412B86EE76417409B00E

Date: 6/9/2025

TABLE OF CONTENTS

LIST OF TABLES

1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE [PATIENT VERSION]

Document Revision: A
Date Issued: 3/17/2023

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 Abreuvoir 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 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	• 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 interweaved 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 guiding 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 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 precaution**

  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 tube (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 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.

Certificate Of Completion

Envelope Id: 06F07066-FE7D-4BE3-B632-46256C8D2ACF
Status: Completed
Subject: Complete with Docusign: SSCPPT23-0012A FRED clean.docx
Source Envelope:
Document Pages: 9
Signatures: 3
Envelope Originator:
Certificate Pages: 5
Initials: 0
Youngun Jun
AutoNav: Enabled
youngun.jun@microvention.com
EnvelopeId Stamping: Disabled
IP Address: 2600:4040:a3a1:
Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Record Tracking

Status: Original
6/6/2025 2:51:41 PM
Holder: Youngun Jun
youngun.jun@microvention.com
Location: DocuSign

Signer Events	Signature	Timestamp
Vidhi Bhatt vidhi.bhatt@microvention.com Project Manager MicroVention - CFR Part 11 Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 01ED5563-570C-451C-ABFF-F604522DEBD0 Using IP Address: 136.52.17.203 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 6/6/2025 2:55:25 PM Viewed: 6/9/2025 4:26:13 PM Signed: 6/9/2025 4:26:45 PM
Electronic Record and Signature Disclosure: Not Offered via Docusign		
Young Tang young.tang@microvention.com Sr. Director, Intellectual Property Security Level: Email, Account Authentication (Required)	 Signature Adoption: Drawn on Device Signature ID: 6FFB5174-FCFF-412B-86EE-76417409B00E Using IP Address: 172.56.177.144 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I approve this document	Sent: 6/6/2025 2:55:25 PM Viewed: 6/9/2025 4:42:34 PM Signed: 6/9/2025 4:43:05 PM
Electronic Record and Signature Disclosure: Accepted: 10/16/2024 10:54:58 AM ID: 7c4b11ce-89a9-4d9d-8531-913d6dccb8d0		
Youngun Jun youngun.jun@microvention.com Microvention Terumo Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: B6D2C0FA-26DB-4725-8D46-4D5CE6B73C81 Using IP Address: 72.90.252.200 With Signing Authentication via Docusign password With Signing Reasons (on each tab): I am the author of this document	Sent: 6/6/2025 2:55:25 PM Viewed: 6/6/2025 2:55:43 PM Signed: 6/6/2025 2:56:05 PM

Signer Events	Signature	Timestamp

Electronic Record and Signature Disclosure:
Not Offered via Docusign

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	6/6/2025 2:55:25 PM
Certified Delivered	Security Checked	6/6/2025 2:55:43 PM
Signing Complete	Security Checked	6/6/2025 2:56:05 PM
Completed	Security Checked	6/9/2025 4:43:05 PM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, MicroVention - CFR Part 11 (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact MicroVention - CFR Part 11:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
To contact us by email send messages to: sarah.yu@microvention.com

To advise MicroVention - CFR Part 11 of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at sarah.yu@microvention.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from MicroVention - CFR Part 11

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to sarah.yu@microvention.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with MicroVention - CFR Part 11

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to sarah.yu@microvention.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify MicroVention - CFR Part 11 as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by MicroVention - CFR Part 11 during the course of your relationship with MicroVention - CFR Part 11.