



Summary of Safety and Clinical Performance
for
Web™ Aneurysm Embolization System
SSCPPT22-0001

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DOCUMENT CHANGE HISTORY

SSCP Revision	Change Description	NB approved/verified
A	Initial Release	☐ Yes ☒ No* Validation language:
B	Annual update, including updated wording for clarity and updated summary of clinical safety and performance data with no change to benefit/ risk.	☐ Yes ☒ No* Validation language:

*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 [PATIENT VERSION]

Document Revision: B

Date Issued: August 2026

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 a separate 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	WEB Aneurysm Embolization System
Device Class	III
Basic UDI-DI	08402732WEBTL (MVI)
Year when first certificate (CE) was issued	2013
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 D-60433 Frankfurt am Main Germany

1.2 Intended Use of the Device

Table 1.2 Intended Use

Intended Use

Intended Purpose/ Indications for Use	The WEB Aneurysm Embolization System (WEB device) is used to block or close off a bulging blood vessel. The blood vessel may have burst or not burst (ruptured or unruptured aneurysm). The WEB device can be used to close off an abnormal blood vessel connection (neurovascular abnormality or vascular malformation).
Intended Patient Group(s)	Patients who have a blood vessel bulge or abnormal blood vessel connection in the brain or spinal cord.
Contraindications and/or Limitations	None.

1.3 Device Description

Table 1.3 Device Description

Device Description											
Description of the Device	The WEB device is placed inside your body using a delivery device that helps steer it through tiny tubes that fit in the blood vessels. The WEB device is pushed through these tiny tubes to reach the bulge or abnormal blood vessel connection in the brain. The WEB device is left in the body to block or close off the blood vessel. The delivery device and tiny tubes are removed.										
Materials or substances in contact with the patient's tissues	The WEB device is made of materials that touch the blood and stay in the body. These materials are listed below. <table> <tr> <th colspan="2">Implant Materials</th><th>Mass (mg)*</th></tr> <tr> <td>Metallic Components</td><td>Nitinol, Platinum, Platinum-Iridium Alloy</td><td>≤ 40</td></tr> <tr> <td>Non-metallic Components</td><td>Epoxy, PET</td><td>≤ 0.1</td></tr> </table> *Approximate content		Implant Materials		Mass (mg)*	Metallic Components	Nitinol, Platinum, Platinum-Iridium Alloy	≤ 40	Non-metallic Components	Epoxy, PET	≤ 0.1
Implant Materials		Mass (mg)*									
Metallic Components	Nitinol, Platinum, Platinum-Iridium Alloy	≤ 40									
Non-metallic Components	Epoxy, PET	≤ 0.1									
Information about medicinal substances in the device	The WEB device does not contain any drugs, animal tissues or blood products.										
Description of how device achieves its intended mode of action	The WEB device blocks or closes off blood flow into the blood vessel bulge or abnormal blood vessel connection. This stops blood from flowing into the bulge while allowing blood to flow to the rest of the brain. The patient's blood inside the bulge fills the space around the WEB device to help it stay in place and block bleeding into the bulge.										
Description of Accessories	The WEB Detachment Controller (WDC) is used to help place the WEB device. It is a clean (sterile) device used for one patient only.										
Description of other Devices or Products	Tiny tubes and guiding wires are used to place the device in the body properly.										

Device Description	
intended to be used in combination	

1.4 Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

How potential risks have been controlled or managed

The company uses a standard process to predict device risk. The process estimates what might happen when the device is used. A list is made of possible harms and what might cause them. The doctor's Instructions for Use describes warnings and precautions and any remaining risks. Reports of harms are tracked by the manufacturer. Reports can come from users or other health care professionals or from published papers. The harms are reviewed on a regular basis. Actions such as changes in labeling or recall can be taken if needed.

Remaining risks and undesirable effects

There is always a risk of undesirable side effects when you have surgery. It can be difficult to know the exact source of some side effects.

Potential side effects of surgery with the WEB device are listed below.

- Blood leak (hematoma) at the skin site where the tiny tubes are placed
- Blood vessel bulge (aneurysm) rupture
- Clog/ clot (emboli) in the blood vessel
- Tear on the inside of the blood vessel (perforation)
- Block (occlusion) of the main blood vessel
- Bleeding from a damaged blood vessel (hemorrhage)
- Reduced blood supply (ischemia)
- Tightness of the blood vessel (vasospasm)
- Blood clot formation
- Device moving from where it was placed
- Difficulty placing the device
- Not being able to place the device

Warnings and precautions

These warnings and precautions are in the doctor's Instructions for Use. The device is not handled by the patient at any time.

- CAUTION: The WEB device should be used only by physicians trained in surgical procedures in the blood vessels of the brain and spinal cord. It should only be used at medical centers/hospitals with the correct imaging equipment.
- CAUTION: The WEB device should be used by physicians who have had proper training for this device.
- CAUTION: Using the WEB device in a flexible tube (catheter) that is not recommended or needed may cause extreme heat (friction) and damage the device.
- The WEB device is clean (sterile) and free from fever causing substances (non-pyrogenic) unless the unit package is opened or damaged. Do not use it if the package is damaged. Use before the expiration date on the product package.
- The WEB device is for one use on one patient. The detachment control device is for one use on one patient. Do not re-clean (resterilize) and/or reuse the device because that can increase risk of infection, fever (pyrogenic response), or other life-threatening risks. If the device is reused and/or cleaned again after use, it can damage the device and it will not work properly. Throw away all devices per hospital/medical or government rules.
- The WEB device must only be delivered through a tiny tube that can be used with it (compatible microcatheter). This tube should have a plastic (PTFE) inner surface layer. If the devices are damaged they should be removed from the body.
- Using tiny catheters sized 0.021 inches or larger in the far end of blood vessels may increase risk of having a blood clot in the vessel (thromboembolism).
- Shaping the tip of the tiny catheters sized 0.021 inches or larger may cause an issue with placing the WEB device correctly.
- The physician must use a high-quality imaging machine (digital subtraction fluoroscopic road mapping) to see where the device needs to go and place it correctly.
- The WEB device should be moved slowly through the body without force. If it feels stuck it should be removed and checked for damage.
- If the position of the WEB device needs to change, use high-quality imaging to see where it needs to go and be placed.
- Do not rotate the delivery device during or after placing the WEB device because it could damage the WEB device or cause it to be placed too soon. If the WEB device must be removed from the blood vessel after it is placed, other devices can be used to grasp it. Use these other devices (such as alligator or snare) per their manufacturer's instructions.
- The WEB device becomes about 60% shorter during delivery.
- The WEB device has 2 markers that can be seen on imaging (radio-opaque) to show the physician where it is in the body.
- Larger sizes of the WEB device may be seen more easily than smaller sizes.
- The doctor's Instructions for Use has pictures that show how the WEB device looks when it is pressed inside the tiny tube, when it is partially placed, and when it is fully placed. These pictures show the doctor where to look for the markers that can be seen on imaging.

If the doctor sees that the markers are close together, check the position of the WEB device using imaging.

- The WEB device must only be placed with the WEB detachment control device. There should be at least two WEB detachment control devices available before starting the surgery.
- Batteries are pre-loaded into the detachment control device. Do not attempt to remove or replace the batteries.
- Do not use the WEB device with other devices that use electrical/magnetic waves (radio frequency (RF) devices).
- Patients who are allergic to nickel may have an allergic reaction to the WEB device.

Summary of any field safety corrective action, if applicable

There have been 3 field safety actions for the WEB device since 2021 which are all closed (complete).

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

Clinical background of the device

The WEB device has been available for use since 2013.

The clinical evidence for the CE-marking

There are 8 completed clinical studies for the WEB device. There are also 85 published clinical papers with clinical data for the WEB device. These sources give safety and use data for WEB device in more than 11,500 patients. Complications for patients treated with WEB device were similar to complications for other devices used in the same surgery. The WEB device blocked the blood vessel bulge or abnormal blood vessel connection as expected in these patients.

Safety

The WEB device has similar safety to other devices used for the same surgery. The benefits of surgery to block or close off a bulging blood vessel are greater than the risks.

1.6 Possible Diagnostic or Therapeutic Alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can consider your individual situation.

General description of therapeutic alternatives

There are different options to treat a bulging vessel. Some options are placing surgical clips to block the area, placing tubes in the blood vessel to help blood flow away from the bulge, or placing surgical coils inside the bulge. There is another device that can be placed completely inside the bulge like the WEB device. Each device has risks and benefits.

1.7 Suggested Training for Users

This device is not handled by the patient. No training is required for the patient. The WEB device should only be used by physicians who have received appropriate training for this device.

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