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:

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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	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	These devices are used for treating a bulge in the wall of a blood vessel that has either burst or has not yet burst by blocking the blood supply to the bulge. These devices are also used to block the blood flow to the bulge that supply the brain or spinal cord.
Indications for Use	These devices are placed inside the blood vessel bulge to stop the flow of blood into it and stop or prevent the blood vessel from bursting into the brain and spinal cord. These devices have many different sizes to for the physician's use. During your procedure, the physician will pick the most appropriate device size based on the size, shape, and location of the blood vessel bulge to be blocked.
Intended Patient Group(s)	Patients who have a blood vessel bulge in the brain or spinal cord that has burst or has not yet burst (aneurysms)
Contraindications and/or Limitations	None

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	These devices are placed inside your body using a delivery system, it is steered through tiny tubes that can be used with the device which has a specific inside measurement across to the blood vessel bulge in the brain. An introducer case can be used to help place the delivery system into the tiny tub. The device that goes inside the body is cut with heat by the physician using a hand-held, battery-powered device designed specifically for the WEB Aneurysm Embolization System. The Controller is provided separately and can only be used one time.
Materials or substances in contact with the patient's tissues	The device parts and materials used to make the WEB System is made of the following parts and are detailed in the following table. The device that goes into the body (WEB implant) touches the blood all the time. The WEB Delivery System only touches the blood for a short time (between 60 minutes and 30 days).

Material
Nitinol & Nitinol with a Platinum Core (DFT)
Platinum 90%/Iridium (10%)
Platinum 90%/Iridium (10%)
PET (Polyethylene Terephthalate)
Epoxy

Information about medicinal substances in the device	The devices does not contain any drugs, animal tissues or blood products.
Description of how device	The purpose of blocking the blood flow in a blood vessel bulge is to cut off blood from entering into the bulge while allowing blood to flow to the rest of the brain. This is

Device Description	
achieves its intended mode of action	accomplished by placing the device into the body within the blood vessel bulge forever. After the WEB device is placed within the blood vessel bulge, the mesh allows the patient's blood to fill the space in the bulge where the blood clots form and stay in place to slow down/ stop bleeding into the bulge.
Description of Accessories	The WEB Detachment Controller (WDC) is an accessory to be used with the WEB System. This has everything it needs to work and is thrown away after one use. It is packaged and sold separately as a sterile device for one patient only.
Description of other Devices or Products intended to be used in combination	Small tubes and wires are used to put the device in the body properly.

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 gives a thorough estimate of what might happen when the device is used. A list of possible harms and what might cause them is compiled. The Instructions of Use also describes any warning or precautions. These may be associated with remaining risk. Reports of any harms are tracked in a complaint database. Reports can come from users or other health care professionals or from publications. The database is assessed on a regular basis. Harms are investigated if rates are increasing or at a certain level. Actions such as changes in labelling or recall can be taken if needed.

- **Remaining risks and undesirable effects**

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

  The device Instructions of Use identified the following known potential side effects of WEB System:

  • Blood clot at the site of entry site of the device

  • Blood vessel bulge rupture

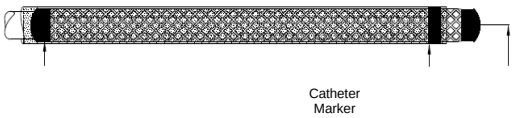
  • Clot in the blood vessel

- Tear on the inside of the blood vessel- perforation
- Main blood vessel block
- Blood clot
- Reduced blood supply
- Tightness of the blood vessel
- Blood clot formation
- Misplacement of the device
- Early detachment of the device
- Hard to remove the device

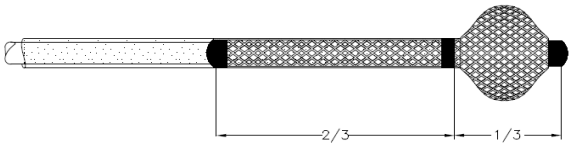
- **Warnings and precautions**
  - CAUTION: This device should be used only by physicians trained in surgical procedures in the blood vessels of the brain and spinal cord at medical centers/hospitals with the correct imaging equipment.
  - CAUTION: The WEB embolization device should be used by physicians who have had proper training for this device.
  - CAUTION: Using this device in a flexible tube (catheter) that is not recommended or required may result in extreme heat (friction) and damage to the device.
  - The WEB Aneurysm Embolization device is provided clean (sterile) and free from fever causing substances (non-pyrogenic) unless the unit package is opened or damaged. Do not use if the packaging is damaged. Use before expiration date noted on the product packaging.
  - The WEB Aneurysm Embolization device is to be used one time on one patient. The Detachment Control Device is to be used one time on one patient. Do not re-clean (resterilize) and/or reuse the device because that can increase risk of germs getting in the body and making it sick (infection), cause a fever (pyrogenic response) or other risks that can kill (life-threatening) you. If the device is reused and/or cleaned again after use, it can damage the device, and it won't work properly. Throw all devices away by following hospital/medical or government rules.
  - The WEB embolization device must be delivered only through a tiny tube that can be used with the WEB (compatible) microcatheter and have a plastic (PTFE) inner surface layer. Damage to the WEB device and the delivery device can occur which can lead to having to remove both the WEB device and the tiny tube(microcatheter) from the patient.
  - The physician should be aware that ≥0.021" tiny tubes, in back end of the blood vessels, may increase risk of having a blood clot in the vein (thromboembolism).

- Shaping the tip of the tiny catheters by 0.021" or more may result in the WEB embolization device and delivery system not being placed or put in place correctly.
- The physician is required to use high quality imaging machine (digital subtraction fluoroscopic road mapping) to see exactly where the device needs to go and where the device is while moving through the body and to make sure it is placed in the correct spot inside the body.
- The device should be steered and removed from the body slowly and not push or pull too hard. If the device won't move anymore, the cause needs to be found before moving it again. If the device gets too warm it needs to be removed and checked to make sure it's not damaged.
- If the device needs to have its position changed, high quality imaging is needed to see where it needs to go and to make sure it can be seen to confirm that it is where it needs to be.
- Do not twirl the delivery device during or after delivery of the embolization device. Twirling the device may damage it or cause it to become disconnected to soon.
- If the WEB device must be taken out of the blood vessel, (retrieved from the vasculature) after the WEB has been cut off from the delivery device, other devices to get it out can be used. They include a grasper device (called alligator) or a lasso device called a snare should be used per their manufacturer's instructions.
- The WEB embolization device becomes shorter during delivery (~60%) a correctly deployed 11mm wide x 9mm long device will measure ~20 mm long in a 0.032" microcatheter).
- If the Device is moving through the body correctly, the markers that allow the physician to see where it is in the body should be seen separately on the image depending on the pathway to the blood vessel bulge and where the blood vessel bulge is located. The length between the front marker should estimate the labeled WEB device length.
- WEB Embolization Device ability to be seen may vary with width ; larger sizes may be seen more easily than smaller sizes.
- The pictures in (a) through (c) below show the WEB embolization device and how it is installed. First, the marker band at the back of the WEB device exits the tiny tube (microcatheter) (a). As the WEB device is moved forward, it begins to get bigger in width (diameter) (b). When the distance between the tube (catheter) marker band and tip of the WEB™ device is about 1/3 of the total WEB device marker-marker distance, the WEB device width (diameter) is generally about 1/2 of its fully pushed out width (b). When the WEB device back marker band to tube (catheter) back marker band distance is about 2/3 of the total WEB device marker-marker distance, the WEB device has reached about 4/5 of its fully deployed width and the back marker band begins moving into the back section (c).

- (a)

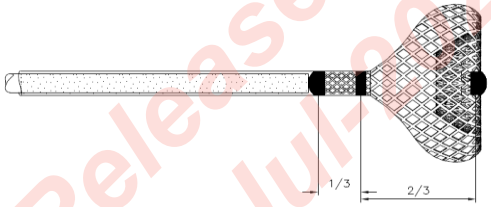


- (b)



- Note:
  - WEB embolization devices are available in both wide neck and round shapes.
  - VIA 17 tiny tubes (Microcatheters) have a front end marker band not shown in the drawings or photos below. This front end tube (catheter) marker band is not used for WEB embolization device delivery.

- (c)



- If the markers are clumped together (i.e. a shorter distance between markers than expected), pull back the WEB embolization device into the tiny tube (microcatheter) and take into account the tiny tube (microcatheter) and blood vessel bulge(aneurysm) position using many different angles on the imaging machine.
- The embolization device cannot be separated with any other power source other than a MicroVention Inc. detachment control device. Make sure to have at least two detachment control devices are available before starting the surgical procedure to block the blood vessel (embolization).
- Batteries are pre-loaded into the detachment control device. Do not attempt to remove or replace the batteries.
- Do not use together with devices that use electrical/magnetic waves (radio frequency (RF) devices.
- Patients who are allergic to nickel may have an allergic reaction to this device

- **<u>Summary of any field safety corrective action, (FSCA including FSN) if applicable</u>**

No escalations of Supplier Corrective Action Reports (SCARs), or Field Actions were identified. There were eight (8) Corrective and Preventative Actions (CAPAs) identified and six (6) were closed and two (2) are in implementing and effectiveness check phase.

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

- **Clinical background of the device**

These devices were first placed in the market in 2013.

- **The clinical evidence for the CE-marking**

A thorough search of journals was done to find studies where the WEB System was used. The date range for the search was 01 July 2013 to 31 July 2024. The literature search results demonstrate clinical use of the device for treatment of blood vessel bulge in brain in 53 articles with 11,689 patients with an average follow up of 2-3 years. Several outcomes were studied to evaluate how well the device works. Outcomes measured how well the device cleared the blood vessel bulge.

- **Safety**

When compared, WEB System was safe and successful as other similar devices. Rates of undesirable side effects were low and similar. No new or unknown risks were found, benefit will be more the risk when used as they should be.

1.6 Possible Diagnostic or Therapeutic Alternatives

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

- General description of therapeutic alternatives

Treatment other than surgical interventions may be best for some patients, you and your doctor will decide what is right for you. When symptoms are more severe and non-surgical interventions does not work, mechanical procedures may be an option. There are advantages and disadvantages to each treatment option.

1.7 Suggested Training for Users

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