Summary of Safety and Clinical Performance
for
Web™ Aneurysm Embolization System
SSCP22-0001, Rev B

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

Revision	Date	Description
A	8/18/2022	Initial Release
B		Moved to new template, updated SRN for MVE as legal manufacturer, added new sizes

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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.
Following this information there is a summary intended for patients.

1.1 Device Identification and General Information

Table 1.1 Device Identification and General Information

Device Names:	
Device Trade Name	WEB™ Aneurysm Embolization System
EMDN Code	C010402020399, EMBOLISATION DEVICES - OTHER
Medical Device Nomenclature (Description/Text)	60941, Non-neurovascular Embolization Coil
Device Class	III
Basic UDI-DI	MicroVention, Inc. WEB™ Aneurysm Embolization System (MVI): 08402732WEBTL WEB™ Detachment Controller (MVE): 37015174DETACHCTRLGU WEB™ Detachment Controller (MVI): 08402732DETACHCTRLF8
Year when first certificate (CE) was issued	2010
Legal Manufacturer:	
Name & Address	**MicroVention, Inc. (MVI)** 35 Enterprise Aliso Viejo, California 92656, USA **MicroVention Europe SARL (MVE)** 30 bis, rue du Vieil Abreuvoir 78100 Saint Germain-en-Laye, France
Manufacturer SRN	MVI: US-MF-000016658 MVE: FR-MF-000004449
Name & Address	**MicroVention Europe SARL** 30 bis, rue du Vieil Abreuvoir 78100 Saint Germain-en-Laye, France
Manufacturer SRN	FR-MF-000004449
Authorised Representative	

Name & Address	**MicroVention Europe SARL**[1] 30 bis, rue du Vieil Abreuvoir 78100 Saint Germain-en-Laye, France
Authorised Representative SRN	FR-AR-000004448
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August-Schanz-Straße 21 D-60433 Frankfurt am Main Germany
Notified Body Number	0297

1 EU Representative for MVI

1.2 Intended Purpose of the Device

Table 1.2 Intended Use

Intended Purpose	
Intended Purpose/Indications for Use	The WEB™ Aneurysm Embolization System is intended for the endovascular embolization of ruptured and unruptured intracranial aneurysms and other neurovascular abnormalities such as arteriovenous fistulae (AVF). The WEB™ Aneurysm Embolization System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation.
Target Population	Patients who have ruptured and unruptured intracranial aneurysms that are saccular in shape, sidewall or bifurcation aneurysms, with aneurysm diameter, location, neck size, and Dome-to-Neck ratio, are appropriate for treatment with the WEB™ Aneurysm Embolization System. The aneurysm embolization using WEB™ devices shall be performed according to the WEB™ Aneurysm Embolization System Instructions for Use. Each of the WEB™ devices included in this report is designed to treat the same medical conditions as the previously certified WEB™ Aneurysm Embolization System models.
Contraindications and/or Limitations	None

1.3 Device Description

Table 1.3 Device Description

<table>
<tr><th colspan="2">Device Description</th></tr>
<tr><td>Description of the Device</td><td>The WEB™ Aneurysm Embolization System (referred to hereafter as WEB™ System) consists of an implantable device attached to a delivery system. The delivery system is navigated through compatible microcatheters with a specified minimum inner diameter to the intracranial aneurysm (IA). Please refer to Table below for the WEB™ sizes and compatible microcatheters. An introducer sheath can be used to assist in the placement of the delivery system into the microcatheter. The WEB™ implant is electro-thermally detached by the physician with a hand-held, battery-powered detachment controller device designed specifically for the WEB™ Aneurysm Embolization System. The WEB™ Detachment Controller (WDC) is provided separately and is for single use only.
<table>
<tr><th>Embolization Device (Diameter) Range</th><th>Minimum Microcatheter Inner Diameter (inch)</th><th>Recommended VIA™ Microcatheter</th></tr>
<tr><td>W2 – WEB Single 8 – 9 mm</td><td>0.027</td><td>VIA 27</td></tr>
<tr><td>W2 – WEB Single 10 – 11 mm</td><td>0.033</td><td>VIA 33</td></tr>
<tr><td>W4 – WEB Single 4 – 7 mm</td><td>0.021</td><td>VIA 21</td></tr>
<tr><td>W5 – WEB Single 3 – 7 mm</td><td>0.017</td><td>VIA 17</td></tr>
</table></td></tr>
<tr><td>Design Characteristics of the Device</td><td>The WEB™ device is designed to have a soft, compliant structure yet have sufficient radial force exerted by the self-expanded WEB™ mesh volume distributed across the entire surface of the aneurysm wall to brace the WEB™ device itself within the aneurysm after deployed, and bridge the neck completely, when the (shape and size of) WEB™ device is appropriately selected based on the aneurysm size, neck, and aneurysm dome morphology. The WDC utilizes a bi-color LED indicator and beeper to provide visible and audible signals upon proper insertion of the WEB™ delivery pusher connectors into the funnel to ensure the electrical continuity between the WEB™ device system and WDC. The user activates the WDC by pressing the button on the side of the WEB Detachment Controller (WDC) handle to deliver electrical energy to the heater of the WEB™ delivery system, generating an electro-thermal detachment, the polyolefin elastomer filament that connects the WEB™ implant and delivery pusher is severed by heat upon the WDC activation, thereby the WEB™ device is detached from the WEB™ delivery pusher. Upon placement in the aneurysm sac, the WEB™ device provides instant yet consistent inflow disruption and rapid flow hemostasis with the metallic structure inside the sac, leading to thrombus formation within the WEB™ implant and re-endothelialization across the aneurysm neck along the mesh surface of the permanently placed WEB™ device. The thrombus and device structure present a mechanical obstruction to keep blood from flowing into the aneurysm while preserving flow in the parent artery, thereby protecting the weakened aneurysm wall from arterial blood pressure and rupture.

The purpose of aneurysm embolization with the WEB™ Embolization System is to exclude the aneurysm from the intracranial circulation while preserving flow in the parent artery. This is accomplished by permanently placing the WEB™ embolization device within the</td></tr>
</table>

aneurysm. Following placement, the embolization device fills the aneurysm and seals the neck with a tight mesh of filaments. This structure allows the patient's blood to fill the space within the aneurysm and form a reinforcing structure for thrombus created by stagnant blood flow. The thrombus and device structure present a mechanical obstruction that keeps blood from flowing into the aneurysm; thereby protecting the weakened aneurysm walls from arterial blood pressure.

Key Functional Element	Component	Material
Implant	Wire Mesh	Nitinol & Nitinol with a Platinum Core (DFT)
	Markers	Platinum 90%/Iridium (10%)
	Coupler	Platinum 90%/Iridium (10%)
	Filament	PET (Polyethylene Terephthalate)
	Adhesive	Epoxy
Delivery Systems	Core Wire Subassembly	Core Wire (306 Stainless Steel) Lead Wire (Polyimide Coated Copper Wire) Polyimide Coating (Polyimide)
	Electrical Heater Coil	Platinum Alloy, Coated Platinum Tungsten Wire
	Various Layer	Polyimide Tubing
	Shrink Tubing	PET (Polyethylene Terephthalate)
	Outer Overcoil	Stainless Steel
	Proximal Section	304 Stainless Steel Hypotube
	Middle Section	304 Stainless Steel Coil
	Distal Section	304 Stainless Steel Coil
	Connectors	Gold-Plated Stainless Steel
	Adhesive	Acrylic UV Curable Adhesive
	Epoxy	Epoxy
	Solder	96.5% Sn/ 3.5% Ag

		Introducer Tubing	HDPE (High Density Polyethylene)
		Introducer Tubing	Polyimide (for 3/3.5mm WEBs ONLY)
	WDC	Funnel	Acrylonitrile Butadiene Styrene (ABS)
		Housing (TOP and Bottom)	Acrylonitrile Butadiene Styrene (ABS)
		Printed Circuit Board	Fiberglass, Copper Pads, Leads Free Solder, Resistors, Capacitors and Diodes
		Battery Clips	Stainless Steel
		Battery	Manganese Dioxide-Zinc

Previous Generations or Variants, if applicable

	Model Name	**Implant Characteristics**	**Status**
Original Device	WEB DL	Wires =Nitinol Markers = Platinum	Superseded by WEB SL/SLS EV
Incremental Development	WEB SL/SLS	Wires =Nitinol Markers = Platinum Lower Profile	Superseded by WEB SL/SLS EV
Current Device	WEB SL/SLS EV 3 mm Models with 017 Delivery System 4-7 mm Models with 017 or 021 Delivery System 8-11mm Models with 027 Delivery System	Wires =Nitinol, Nitinol with Platinum Core Markers = Platinum Lower Profile	Currently Manufactured

<table>
<tr><td>Single use – sterilization method</td><td>The WEB™ Aneurysm Embolization System sterilized by Gamma or E-beam Irradiation and is intended for single use only. The detachment control device is intended to be used for one patient. Do not re-sterilize and/or reuse the device. Reuse and/or re-sterilization can increase risk of infection, cause a pyrogenic response or other life-threatening complications. Reuse and/or re-sterilization can degrade product performance, leading to device malfunction. Dispose of all devices in accordance with applicable hospital, administrative and/or local government policy.</td></tr>
<tr><td>Description of Accessories</td><td>The WEB™ Detachment Controller (WDC) is an accessory to be used with the WEB Aneurysm Embolization System.

The WEB™ Detachment Controller is self-contained, disposable, hand-held, battery-powered unit which provides the controlled electrical energy for the detachment of the coil from the Delivery Pusher. The detachment controller is packaged and sold separately as a sterile device for single patient only.</td></tr>
<tr><td>Description of other Devices or Products intended to be used in combination</td><td>• Wire-reinforced microcatheter with distal tip RO marker (see Table below)
• Guide catheter compatible with microcatheter
• Steerable guidewire compatible with microcatheter
• Two rotating hemostatic Y valves (RHV)
• One three-way stopcock
• One one-way stopcock
• Sterile saline
• Pressurized sterile saline drip

<table>
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</table>
[1] Use of a different catheter may result in extreme friction and damage to the device</td></tr>
</table>

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the WEB™ Aneurysm Embolization System 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.

Risks associated with the WEB™ Aneurysm Embolization System include the following:

- Implant not inspected prior to use

- Difficulty to remove the WEB™ device protective tube
- Sheath pinched by hemostatic valve
- Tyvek pouch or product box damage or sterilization indicator does not work
- Label has incorrect information, product tampering not included
- Device not biocompatible or not sterile
- Not Magnetic Resonance Imaging (MRI) compatible
- Inadequate radiopacity
- Aging issue; packaging failure
- Delivery system not checked with WEB™ Detachment Controller (WDC) prior to use
- Introducer sheath not fully bottomed out in hub
- Catheter positioned too far proximal (outside aneurysm)
- Fluoro not on during implant deployment
- Device not fully seated in WDC
- Pusher pulled back too quickly after detachment
- Inadequate strength of dispenser coil for protective cover of device during transport/storage/handling
- Incorrect WEB™ device shape
- Unable to deploy the WEB™ device or does to fully expand the WEB™ device into aneurysm
- Unable to recapture device
- Device not corrosion resistant
- Tether damaged or weakened during post inspection retraction into sheath
- Incorrect catheter size used
- Damaged connector by connector retainer not staying attached in dispenser coil
- Aging issue: Material or component failure
- Delivery System damaged during removal of package
- Catheter positioned too close to aneurysm wall
- Incorrect WEB™ device type or WEB™ device size used
- Connectors damaged during insertion into WDC
- Implant held under too much tension during detachment
- Rotating Hemostasis Valve (RHV) too tight during detachment

WEB Detachment Controller

- The controller funnel fails to connect to the Pusher proximal end
- The controller takes more than 0.82 seconds to detach the WEB™ device
- Implant detaches when not intended by user (premature detachment)
- Biological hazard
- Contamination in manufacturing environment resulting in foreign body embolism
- Contamination during shipping, distribution, or storage

- Contamination during use
- Light-Emitting Diode (LED) indicator light or beeper fails to function
- LED light does not turn green and beeper does not sound once the pusher is inserted into the controller funnel
- The LED light does not flash yellow three times and the beeper does not sound three times at the end of the detachment cycle
- Heat of detachment burns patient
- Electric shock to patient
- Electric shock to operator, bystander
- Battery pull tab torn during removal
- Environment hazard
- Controller fails to detach the WEB™ implant form the pusher
- Electromagnetic interference with hospital equipment

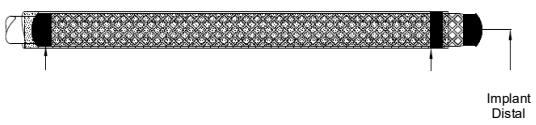
1.4.2 Warnings and Precautions

The warnings / precautions for the WEB™ Device:

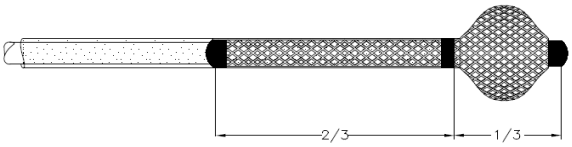
- **CAUTION**: This device should be used only by physicians trained in percutaneous, intravascular and neurovascular techniques and procedures at medical facilities with the appropriate fluoroscopic equipment.
- **CAUTION**: The WEB™ embolization device should be used by physicians who have received appropriate training for this device.
- **CAUTION:** Using this device in a catheter that is not recommended or required may result in extreme friction and damage to the device.
- The WEB™ Aneurysm Embolization System is provided sterile and 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 System is intended for single use only. The detachment control device is intended to be used for one patient. Do not resterilize and/or reuse the device. Reuse and/or resterilization can increase risk of infection, cause a pyrogenic response or other life-threatening complications. Reuse and/or resterilization can degrade product performance, leading to device malfunction. Dispose of all devices in accordance with applicable hospital, administrative and/or local government policy.
- The WEB™ embolization device must be delivered only through a compatible microcatheter with a PTFE inner surface coating. Damage to the embolization and delivery device may occur and necessitate removal of both the device and microcatheter from the patient.
- The operator should be aware that ≥0.021" microcatheters, in distal blood vessels, may increase the risk of thromboembolism.

- Steam shaping 0.021" and greater microcatheters may result in improper WEB™ embolization device delivery and deployment, depending on the degree of shaping and catheter deflection during WEB™ embolization device delivery.
- High quality, digital subtraction fluoroscopic road mapping, with orthogonal views, is mandatory to achieve correct placement of the embolization device.
- Advance and retract the device slowly. Do not advance the delivery device with excessive force. Determine the cause of any unusual resistance. Remove the device if excessive friction is noted and check for damage.
- If repositioning is required, take special care to retract or to advance the device under fluoroscopy, including new road map to confirm catheter position.
- Do not rotate the delivery device during or after delivery of the embolization device. Rotating the device may result in damage or premature detachment.
- If an embolization device must be retrieved from the vasculature after detachment, retrieval devices (e.g. alligator and snare) should be used per their manufacturer's instructions.
- The WEB™ embolization device foreshortens during delivery (~60%) (e.g. see Figure 2a in IFU, a properly deployed 11mm wide x 9mm long device will measure ~20 mm long in a 0.032" microcatheter).
- When properly deployed, the two radio-opaque markers should be separated and fluoroscopically visible (e.g. **see Figure b**, depending on working projection and placement in the aneurysm, the distance between the proximal to distal marker should approximate the labeled WEB™ embolization device length).
- WEB™ embolization device visibility may vary with diameter; larger sizes may be more visible than smaller sizes. Examples are shown in **Figure c** .
- The pictures in (a) through (c) below illustrate WEB™ embolization device deployment. Initially, the distal implant marker band exits the microcatheter (a). As the implant is advanced, it begins to expand in diameter (b). When the distance between the catheter marker band and implant tip is about 1/3 of the total implant marker-marker distance, the implant diameter is generally about 1/2 of its fully deployed diameter (b). When the implant distal marker band to catheter distal marker band distance is about 2/3 of the total implant marker-marker distance, the implant has reached about 4/5 of its fully deployed diameter and the distal marker band begins moving into the distal recess (c).

(a)



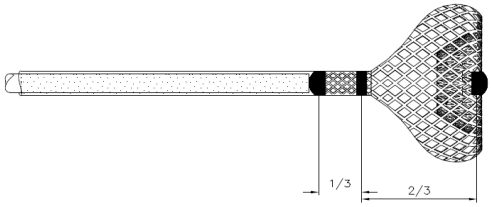
(b)



Note:

- WEB™ embolization devices are available in both wide neck and spherical shapes.
- VIA 17 Microcatheters have a proximal marker band not shown in the drawings or photos below. This proximal catheter marker band is not used for WEB embolization device delivery.

(c)



- If the radio-opaque markers are clustered (i.e. a shorter distance between markers than expected), retract WEB™ embolization device into the microcatheter and evaluate the microcatheter/aneurysm position with multiple fluoroscopic angles.
- The embolization device cannot be detached with any other power source other than a MicroVention Inc. detachment control device. Ensure that at least two detachment control devices are available before initiating an embolization procedure.
- Batteries are pre-loaded into the detachment control device. Do not attempt to remove or replace the batteries.
- Do not use in conjunction with radio frequency (RF) devices.
- Patients who are allergic to nickel may have an allergic reaction to this device.

1.4.3 Potential Complications / Adverse Effects

Potential complications include but are not limited to the following:

- Hematoma at the site of entry,
- Aneurysm rupture,
- Emboli,
- Vessel perforation,
- Parent artery occlusion,

- Hemorrhage,
- Ischemia,
- Vasospasm,
- Clot formation,
- Device migration or misplacement,
- Premature or difficult device detachment,
- Non-detachment,

WEB Aneurysm Embolization System with WEB™ Detachment Controller

- Incomplete aneurysm filling,
- Revascularization,
- Post-embolization syndrome, and
- Neurological deficits including stroke and death

1.4.4 Other Aspects of Safety

Data relevant to the clinical safety and performance of the WEB™ family of devices was collected and evaluated from routine data sources from PMS such as complaints, Corrective and Preventative Action (CAPA) and SCAR, as well as post-market clinical follow-up (PMCF).

The data has demonstrated the clinical safety of the subject devices:

- The subject device has an overall complaint rate of 0.036%, based on over 130,000 units shipped
- During the PMS evaluation period, only six events were deemed reportable to the FDA and other authorities.
- No escalations of SCARs, CAPAs or Field Actions were identified.
- PMCF concluded the safety and efficacy of the subject device

The clinical evidence generated through this PMS will be used in the clinical evaluation of WEB™ Aneurysm Embolization System, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks.

1.5 Summary of the Clinical Evaluation and PMCF

A Clinical Evaluation of the WEB™ Aneurysm Embolization System is continuously updated in conducted in accordance with the requirements in MEDDEV.2.7.1 Revision 4– Guidelines on Medical Devices – Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies. It includes the following:

- Literature Based Safety Appraisal
- A search of published relevant and available scientific literature was performed to assess the risks and benefits associated with other competitive predicate devices.
- Summary of Clinical Studies
- MicroVention has gathered data from post-market Trials/ Studies/ Registries under its sponsorship in which WEB™ Aneurysm Embolization System implants were utilized
- Performance and Safety - Design Verification and Validation Data Analysis
- Product Literature and Instructions for Use
- The CER includes the methodology, literature references and conclusions and are reviewed and signed by an appropriately qualified physician.

The Clinical Evaluation Report, documents available clinical data relevant to the WEB™ Aneurysm Embolization System. The available clinical data was collected, appraised, and analyzed, and it was determined that there is sufficient clinical evidence on the safety and performance in accordance with the intended purpose.

The Clinical Evaluation Report documents the benefit-risk profile, including side-effects, in the intended target patient populations and medical indications by assessing the clinical evidence against the hazards and patient harms as informed by the Risk Management and Post-Market Surveillance (PMS) documentation. The report also demonstrates the acceptability of the benefit-risk profile based on the current knowledge and state of the art in the concerned medical fields. Therefore, the clinical evaluation has established that the available clinical data are sufficient to establish conformity with all relevant Safety and Performance Requirements (Annex I) of EU MDR 2017/745 and confirm the safety and performance of the WEB™ Aneurysm Embolization System.

In addition, Post-Market Surveillance (PMS) is a continuous process at MicroVention to gather, record, and analyze relevant data on the quality, performance and safety of a device throughout its entire lifetime actively and systematically. The planning and execution of PMS are conducted in accordance with the European Medical Device Regulation (MDR (EU) 2017/745), Chapter VII, Section 1 Post-Market Surveillance and MicroVention Post Market Procedures.

Given the evidence and data presented in the clinical evaluation and post market surveillance, and when the WEB™ Aneurysm Embolization System is used according to the manufacturer's Instructions for Use, the risk to benefit profile is deemed acceptable.

1.5.1 Equivalent Device Clinical Data

Equivalency is not claimed in the clinical evaluation for the WEB™ Aneurysm Embolization System with WEB Detachment Controller.

1.5.2 Pre-CE-Mark Clinical Data

There were no EU pre-market clinical studies conducted for the WEB™ Aneurysm Embolization System devices.

1.5.3 Clinical Data

Clinical data sources to evaluate the safety and performance of the WEB™ device was collected from the following reputable data sources:

- Post-Market Clinical Studies
  - WEB French Observational Study
  - WEBCAST Study
  - WEBCAST-2 Study
  - CLARYS Registry
  - WEB IT Study
  - CLEVER Study
  - RISE Study
- Published Peer-reviewed Clinical Literature
- Relevant data collected from PMCF activities in the PMCF Report described as routine data sources were integrated into the above data sections. These data sources include,
  - Scientific Literature
  - Registries
  - Sponsor-initiated post-market clinical studies
  - Investigator-initiated post-market clinical studies
  - There were no additional PMCF activities initiated to address specific findings of the previous clinical evaluation.

1.5.4 Clinical Performance and Safety

The clinical safety data presented in this document, collected from published literature, post-market clinical studies, and post-market surveillance, demonstrates the overall safety of the WEB™ Aneurysm Embolization System with WEB™ Detachment Controller. The literature review demonstrated acceptable clinical safety outcomes with no new hazards found. Post-market

clinical studies demonstrated acceptable clinical safety outcomes of the WEB™ Aneurysm Embolization System with WEB™ Detachment Controller. The post-market surveillance data demonstrate low rates of reportable complaints of the WEB™ Aneurysm Embolization System and zero reportable complaints for the WEB™ Detachment Controller (WDC), showing the safety of the subject devices. The data collected is considered sufficient to determine that the WEB™ Aneurysm Embolization System with WEB™ Detachment Controller does not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.

The clinical performance data presented in this document, collected from published literature, post-market clinical studies, and post-market surveillance demonstrates the overall performance of the WEB™ Aneurysm Embolization System with WEB™ Detachment Controller. The literature review demonstrated acceptable clinical performance outcomes, shown in high technical success rates and target aneurysm complete or near complete occlusion rates, with low morbidities and lower recurrence / recanalization rates associate with the use of the WEB™ devices. The post-market clinical studies demonstrated acceptable periprocedural, medium- and long-term clinical performance outcomes in aneurysm occlusion and post WEB™ embolization patients' neurological outcomes. The post-market surveillance data demonstrates acceptable overall clinical performance through the high technical success and WEB™ embolization durability in the vast majority of the patients receiving the WEB™ devices, as evidenced by the extremely low rates of vigilance reportable complaints and adverse events that are attributable to the subject devices. The data collected is considered sufficient to determine that the WEB™ Aneurysm Embolization System with WEB™ Detachment Controller achieves the performance intended and is suitable for the intended purpose.

1.5.5 Post-Market Clinical Follow-up

From the evidence provided in this clinical evaluation, no PMCF studies are required for the WEB™ Aneurysm Embolization System with WEB™ Detachment Controller. The level of clinical evidence presented in this report is sufficient to support conformity to the relevant Essential Requirements, including a favorable benefit/risk ratio. No potential residual risks and/or unclarity on long term clinical performance that may impact the benefit/risk ratio were identified. No concerns were identified regarding the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication(s). This clinical evaluation has demonstrated that the WEB™ Aneurysm Embolization System with WEB™ Detachment Controller maintains an acceptable safety and performance profile and did not identify any questions relating to clinical safety or performance (i.e., residual risks) when used in accordance with its approved labelling

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

Both surgical and transluminal innovations have been developed over the past years to treat the intracranial aneurysm. Contemporary options include microsurgical clipping, endovascular coiling alone, balloon-assisted coiling, stent-assisted coiling, Flow-Diverting stenting, liquid embolic embolization, intrasaccular flow disruption. In addition, 'Wait and See' strategy for microaneurysms, and regular angiographic follow-up are also proposed and supported in clinical practice.

- Microsurgical clipping

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 to 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. Surgical clipping is suitable for most IAs, such as saccular IAs, Giant IAs, and fusiform IAs. However, not all patients are candidates for microsurgical clipping procedures due to aneurysm location, patient condition, and aneurysm morphology[11]: aneurysms in the posterior circulation are more difficult to access surgically; patients in poor medical condition for whom surgery is contraindicated must seek alternate therapies; Surgical clipping of wide-necked and fusiform aneurysms is more difficult to clip than saccular aneurysms. For all aneurysm locations, the rate of death or dependency is significantly higher in surgically treated aneurysms compared to those treated endovascularly[11].

- Endovascular coiling

Simple coiling refers to transluminal navigation of a microcatheter into the aneurysmal dome with the help of micro-guidewires and the delivery and packing of detachable coils within the aneurysmal sac. The goal in coiling is to achieve dense packing and induce rapid blood clot formation within the aneurysmal sac, hence isolating it from active circulation. Balloon-assisted coiling (BAC) was initially described in treating IAs with a wide neck. BAC refers as using one or multiple nondetachable temporarily inflated balloons to block the aneurysmal neck during coil placement. The BAC was used frequently in IAs with unfavorable dome-to-neck ratio (≤1.5, >1.0). Data from two clinical studies (Endovascular approach of Non-ruptured Aneurysms [ARETA][1] and Clinical and Anatomical Results in the Treatment of Ruptured Intracranial Aneurysms [CLARITY]) suggested higher thromboembolic rate, morbidity, and mortality in BAC group than coiling alone.

Wide neck aneurysms are difficult to treat with embolic coils because the aneurysm neck size is insufficient to support the coil mass within the aneurysm fundus, thus there is risk of embolic coil protrusion into the parent vessel. The use of self-expanding stents providing a potential solution to the challenge of simple coiling, allowing increased packing density with coils, creating flow

diversion, and potentially providing a scaffold for endothelialization1. However, wide-neck aneurysms located at the arterial bifurcations, especially in aneurysms where the bifurcating branches emanate directly from the base of the aneurysm, may not be amenable to treatment with a single stent. For aneurysms located at bifurcations it is often necessary to place two stents in a Y configuration, so that the neck of the aneurysm is covered [2,5]. There are limited studies available regarding the use of coils and stents in the treatment of wide neck bifurcation aneurysms. Another limitation of stenting and coiling is the required use of dual antiplatelet therapy. Thus, stent-assisted coiling is used mostly to treat unruptured aneurysms. Intracranial stenting is contraindicated in patients who have suffered subarachnoid hemorrhage (SAH).

The treatment of wide-neck bifurcation aneurysms remains challenging despite the use of complex techniques like the double balloon remodeling technique or Y-stent placement. These methods are, however, frequently technically difficult and their use remains relatively limited. While stenting and coiling may offer an acceptable rate of aneurysm occlusion and stability, the use of stents is limited in terms of location and aneurysm rupture status.

- Intra-luminal Flow Diverters

Flow-diverters are a new generation of stents designed to treat IAs with few coils or without the need of coil placement following stent delivery by isolating the aneurysmal lumen from the circulation via recanalization. These intra-luminal stents have very tight mesh structure that are able to promote spontaneous aneurysm thrombosis, the clinical utility of endovascular treatment of complex aneurysms was demonstrated[4]. The Flow diverters are suitable for both wide-necked and fusiform IAs. Limitations in the use of flow diverters includes the inability to treat aneurysms of some geometries, for example, bifurcation, as well as the need for the use of dual antiplatelet therapy. Further limiting its use is in ruptured aneurysms[10].

In addition, liquid embolic agent was used in intra-saccular filling. Onyx is a liquid embolic filler containing ethylene vinyl alcohol (EVOH) copolymer and dimethyl sulfoxide (DMSO) in a volume ratio of 3:2 and tantalum powder as radiopaque marker. Currently, liquid embolic is recommended in the embolization of intracranial arteriovenous malformation. It is suitable for complex irregularly shaped IAs, however, concerns arise where fragments of filling may break off and become embolic after withdrawal of balloon.

As indicated above, surgical and endovascular treatment modalities demonstrated utility in effective intracranial aneurysmal management. The preferred treatment strategy for ruptured and unruptured IAs shall consider morphology of the aneurysm, patients' co-morbidities, and patient's condition at presentation, as well as following applicable treatment guidelines.

1.6.2 Available Technologies

Commercially available embolization coils that have similar indications as the WEB™ Aneurysm Embolization System devices are: .

- Penumbra™ Coil System 400 (Penumbra)
- Micrus Deltapaq™ (Micrus Endovascular)
- Codman Micrus Deltamax™ (Codman Neurovascular)
- MicroPlex™ Coil System (MicroVention, Inc)

In addition, a recent emerged intra-aneurysmal flow disruption device, Artisse ™ (formerly called LUNA, Medtronic), is also included as a similar device to WEB™ Aneurysm Embolization System.

The listed marketed coil devices, including Penumbra Coil System 400, Micrus Deltapaq microcoil system, and Codman Micrus Deltamax, are large-volume embolization coil devices, designed to achieve higher packing density using fewer coils, as compared to conventional microcoils. MicroPlex Coil System (MCS, MicroVention) family comprises different coil sizes, MCS-18 system, with larger primary coil filament diameter than MCS 10-system, is designed to facilitate increased packing density.

The efficacy and safety of coil embolization has been demonstrated in numerous studies. However, post-treatment aneurysm recanalization remained a significant challenge. Use of large sized coils and adjunctive devices (stent-assisted coiling and balloon-assisted coiling) have been developed to augment coil embolization. Balloon-assisted coil embolization reduces the risk of coil prolapse into the parent artery and can provide immediate proximal control with balloon inflation in case of intraprocedural aneurysm rupture. Similarly, stent-assisted coiling allows for increased coil packing density, critical for the treatment of wide-necked, large and giant aneurysms, thereby significantly improving the aneurysm occlusion rate[15]. Despite these technological developments, aneurysms with unfavorable parameters such as large or giant, wide neck bifurcated, small dome-to-neck ratios (<2), still remain significant treatment challenge[15].

These listed marketed coil devices have been in clinical use for intracranial aneurysm embolization for over ten years. The clinical outcomes and risks/benefits associated with the use of the similar devices have contributed to the abovementioned conclusions made for coil embolization of intracranial aneurysms.

Artisse (also known as LUNA Aneurysm Embolization System, Medtronic) is also a flow disruption device, in addition to WEB™ Aneurysm Embolization System. Artisse is a self-expanding, mechanically detachable device, with a double-layer nitinol mesh and platinum markers. This device was evaluated for small and medium aneurysms for safety and efficacy in Europe in a prospective multicenter trial, named the LUNA AES Post-Market Clinical Follow-up[15]. Adequate occlusion in 78.0% by 12 months and 79.2% by 36 months. The authors also compare LUNA AES and the WEB device, with comments on the similar occlusion rates observed in studies of both devices, based on the Woven EndoBridge Intrasaccular Therapy (WEB-IT) Study for wide-neck bifurcation aneurysm (WNBAs), which showed Adequate Occlusion (complete occlusion or residual neck) rate ranging from 51.7% to 96%, with a mean follow-up time ranging from 1.7 to 39.0 months. However, the WEB-IT Study was the first FDA premarket approval trial for an intrasaccular aneurysm (flow disruption) device, and the first trial for a device used to

specifically treat WNBAs, while Artisse device has been only studied for small and medium aneurysms. The study or clinical evidence of the Artisse device use in large and wide-neck aneurysms is lacking. As such, Artisse has not yet achieved the US FDA approval.

Table 1.4 Similar Devices

Device	Manufacturer	Intended Use
Artisse (formerly known as Luna Aneurysm Embolization System)	Medtronic	The LUNA AES is indicated for endovascular embolization of saccular intracranial bifurcation and sidewall aneurysms with a height of 4.7–12.6mm, a width of 3.0–8.5mm, and is not limited based on aneurysm dome-to neck ratio.
MicroPlex Coil System	MicroVention, Inc	The MicroPlex Coil System (MCS) is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The MCS is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolization in the peripheral vasculature.
Micrus Deltapaq	Micrus Endovascular	Micrus Deltapaq Microcoil System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula and is also intended for arterial and venous embolization in the peripheral vasculature.
Penumbra Coil System, Penumbra Coil 400	Penumbra	The Penumbra Coil System is intended for the endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula. It is also used for arterial and venous embolization in the peripheral vasculature.
Codman Micrus Deltamax	Codman Neurovascular	The DELTAMAXX Microcoil System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and it is also intended for arterial and venous embolization in the peripheral vasculature.

1.7 Suggested Profile and Training for Users

This device should only be used by physicians who have undergone training in the use of the WEB Aneurysm Embolization System for embolization procedures.

1.8 Reference to any Harmonized Standards and CS

Region	**Compliance**	**Regulation**	
European Union	☒ Full ☐ Partial	Medical Device Regulations 2017/745	
Standards	**Compliance**	**Name**	**Edition**
Quality System			
EN ISO 13485	☒ Full ☐ Partial	Medical devices - Quality management systems - Requirements for regulatory purposes	2016/AC:2016
EN ISO 14971	☒ Full ☐ Partial	Medical devices - Application of risk management to medical devices	2012
EN 62366-1	☒ Full ☐ Partial	Medical devices - Application of usability engineering to medical devices	2015/AC:2015
ISO 14644-1	☒ Full ☐ Partial	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness	2015
ISO 14644-2	☒ Full ☐ Partial	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	2015
Packaging, Labeling, and Sterilization			
EN 1041	☒ Full ☐ Partial	Information supplied by the manufacturer of medical devices	2008+A1:2013

Standards	Compliance	Name	Edition
EN ISO 11607-1	☒ Full ☐ Partial	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2009
EN ISO 11607-2	☒ Full ☐ Partial	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2006
EN ISO 15223-1	☒ Full ☐ Partial	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2021
EN ISO 11137-1	☒ Full ☐ Partial	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2015
EN ISO 11137-2	☒ Full ☐ Partial	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	2015
ISTA 3A	☒ Full ☐ Partial	ISTA (International Safe Transit Association) Procedure 3A – Performance Tests for Packaged-Products for Parcel Delivery System 150 lbs. (70 kg) or Less	2018
Biocompatibility			
AAMI/ISO 10993-1	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018
EN ISO 10993-3	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014
EN ISO 10993-4	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	2009
EN ISO 10993-5	☒ Full	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009

Standards	Compliance	Name	Edition
	☐ Partial		
ISO 10993-6	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	2016
ISO 10993-10	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010
EN ISO 10993-11	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2018
EN ISO 10993-12	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012
EN ISO 10993-17	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	2009
EN ISO 10993-18	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2009
EN ISO 10993-23	☒ Full ☐ Partial	Biological evaluation of medical devices - Part 23: Tests for irritation	2021
Product Specific			
ASTM F88	☒ Full ☐ Partial	Standard Test Method for Seal Strength of Flexible Barrier Materials	2015
ASTM F2063	☒ Full ☐ Partial	Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants	2018
ASTM B561	☒ Full ☐ Partial	Standard Specification for Refined Platinum	2018
ASTM A908	☒ Full ☐ Partial	Standard Specification for Stainless Steel Needle Tubing	2003

Standards	Compliance	Name	Edition
ASTM B684	☒ Full ☐ Partial	Standard Specification for Platinum-Iridium Electrical Contact Materials	2016

Guidance	Compliance	Title	Edition
MEDDEV 2.7/1	☒ Full ☐ Partial	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	Revision 4
MDCG 2019-8	☒ Full ☐ Partial	Guidance Document Implant Card relating to the application of Article 18	2020
MDCG 2019-9	☒ Full ☐ Partial	Summary of Safety and Clinical Performance A Guide for Manufacturers and Notified Bodies	2019
MDCG 2020-5	☒ Full ☐ Partial	Clinical Evaluation-Equivalence	2020
MDCG 2020-6	☒ Full ☐ Partial	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies	2020
MDCG 2020-7	☒ Full ☐ Partial	Guidance on PMCF Plan Template	2020
MDCG 2020-8	☒ Full ☐ Partial	Guidance on PMCF Evaluation Report Template	2020

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1.10 Revision History

SSCP Revision	Date Issued	Change Description	NB Validation
A	8/18/2022	Initial Release	☒Yes ☐ No* Validation language: English
B		Updated SSCP to new template included SRN for MVE and Legal Manufacturer	☐ Yes ☐ No* Validation language: English

*only applicable for class IIa or some IIb implantable devices for which the SSCP is not yet validated by the NB

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2 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE [PATIENT VERSION]

Document Revision: B
Date Issued: TBD

This short summary of safety and medical doing (Safety and Clinical Performance ,SSCP) is to put forward and give the public the ability to get an updated summary of the main manner of the safety and medical doing of the device. The news given in this short account is for patients or non-medical persons. More news of the device's safety and medial doing for healthcare professionals is found in the first part of this document.

The SSCP is not 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.

2.1 Device Identification and General Information

Table 2.1 Device Identification and General Information

Device Names:	
Device Trade Name	WEB Aneurysm Embolization System
EMDN Code	C010402020399, EMBOLISATION DEVICES - OTHER
Medical Device Nomenclature (Description/Text)	60941, Non-neurovascular Embolization Coil
Device Class	III
Basic UDI-DI	08402732WEBTL (MVI) 37015174WEBUA (MVE)
Year when first certificate (CE) was issued	2010
Legal Manufacturer:	
Name & Address	**MicroVention, Inc. (MVI)** 35 Enterprise Aliso Viejo, California 92656, USA
Manufacturer SRN	US-MF-000016658
Name & Address	**MicroVention Europe SARL** 30 bis, rue du Vieil Abreuvoir 78100 Saint Germain-en-Laye, France
Manufacturer SRN	FR-MF-000004449

Authorised Representative	
Name & Address	**MicroVention Europe SARL**[2] 30 bis, rue du Vieil Abreuvoir 78100 Saint Germain-en-Laye, France
Authorised Representative SRN	FR-AR-000004448
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August-Schanz-Straße 21 D-60433 Frankfurt am Main Germany
Notified Body Number	0297

2.2 Intended Use of the Device

Table 2.2 Intended Use

Intended Use	
Reason the Device is Used (Intended Purpose)	The WEB™ Aneurysm Embolization System is used for treating a bulge in the wall of an artery (Aneurysm) by purposefully blocking the blood (embolization) within the blood vessel bulge that has either burst or has not yet burst within the brain or other blood vessels that supply blood and oxygen to the brain and spinal cord. An example is an abnormal connection between an artery and a vein (arteriovenous fistula). The WEB™ Aneurysm Embolization System is also used to purposefully block blood vessels that supply the brain or spinal cord (neurovascular system) to permanently block blood flow to a blood vessel bulge (aneurysm) or other blood vessel defect.
Indications for Use	The WEB™ Aneurysm Embolization System is used inside the blood vessel bulge (aneurysm) to stop the flow of blood into it to stop or present the blood vessel from bursting into the brain and spinal cord. The WEB™ embolization devices have many different sizes (diameters and lengths) to satisfy the needs of the physician. During your procedure, the physician will pick the most appropriate device size based on the size, shape and location of the blood vessel bulge (aneurysm or other blood vessel defect) 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)

[2] If MicroVention Europe SARL is the Legal Manufacturer, Authorised Representative is not applicable

Contraindications and/or Limitations	None

2.3 Device Description

Table 2.3 Device Description

<table>
<tr><th colspan="4">Device Description</th></tr>
<tr><td>Description of the Device</td><td colspan="3">The WEB™ Aneurysm Embolization System (referred to hereafter as WEB™ System) is a device that goes inside your body (implant) that is connected to a device that delivers the device into the body. The delivery system is steered through tiny tubes (microcatheters) that can be used with the WEB™ System with a specific inside measurement across to the blood vessel bulge in the brain (intracranial aneurysm). An introducer case can be used to help place of the delivery system into the tiny tube (microcatheter). The device that goes inside the body (implant) is cut with heat by the physician with a hand-held, battery-powered detachment controller device designed specifically for the WEB™ Aneurysm Embolization System. The WEB(tm) Detachment Controller (WDC) is provided separately and can only be used one time.</td></tr>
<tr><td>Materials or substances in contact with the patient’s tissues</td><td colspan="3">The device parts and materials used to make the WEB(tm) System is made of the following parts and detailed in following table. The device that is goes into the body (WEB™ implant) touches the blood all the time. The WEB(tm) Delivery System only touches the blood for a short time (between 60 minutes and 30 days).
<table>
<tr><th>Key Functional Element</th><th>Component</th><th>Material</th></tr>
<tr><td rowspan="5">Implant</td><td>Wire Mesh</td><td>Nitinol & Nitinol with a Platinum Core (DFT)</td></tr>
<tr><td>Markers</td><td>Platinum 90%/Iridium (10%)</td></tr>
<tr><td>Coupler</td><td>Platinum 90%/Iridium (10%)</td></tr>
<tr><td>Filament</td><td>PET (Polyethylene Terephthalate)</td></tr>
<tr><td>Adhesive</td><td>Epoxy</td></tr>
<tr><td rowspan="4"></td><td>Core Wire Subassembly</td><td>Core Wire (306 Stainless Steel) Lead Wire (Polyimide Coated Copper Wire) Polyimide Coating (Polyimide)</td></tr>
<tr><td>Electrical Heater Coil</td><td>Platinum Alloy, Coated Platinum Tungsten Wire</td></tr>
<tr><td>Various Layer</td><td>Polyimide Tubing</td></tr>
<tr><td>Shrink Tubing</td><td>PET (Polyethylene Terephthalate)</td></tr>
</table></td></tr>
</table>

	Delivery Systems	Outer Overcoil	Stainless Steel
		Proximal Section	304 Stainless Steel Hypotube
		Middle Section	304 Stainless Steel Coil
		Distal Section	304 Stainless Steel Coil
		Connectors	Gold-Plated Stainless Steel
		Adhesive	Acrylic UV Curable Adhesive
		Epoxy	Epoxy
		Solder	96.5% Sn/ 3.5% Ag
		Introducer Tubing	HDPE (High Density Polyethylene)
		Introducer Tubing	Polyimide (for 3/3.5mm WEBs ONLY)
	WDC	Funnel	Acrylonitrile Butadiene Styrene (ABS)
		Housing (TOP and Bottom)	Acrylonitrile Butadiene Styrene (ABS)
		Printed Circuit Board	Fiberglass, Copper Pads, Leads Free Solder, Resistors, Capacitors and Diodes
		Battery Clips	Stainless Steel
		Battery	Manganese Dioxide-Zinc
Information about medicinal substances in the device	The WEB™ Aneurysm Embolization System does not contain any drugs, animal tissues or blood products.		
Description of how device achieves its intended mode of action	The purpose of blocking the blood flow in a blood vessel bulge (aneurysm) is to cut off blood (occlude) from entering into the bulge while allowing blood to flow to the rest of the brain. This is accomplished by placing the WEB™ embolization device into the body (implant) within the blood vessel bulge (aneurysm) forever. After the WEB™ device in placed within the blood vessel bulge, the mesh allows the patients blood to fill the space in the bulge where the blood clots form and stay in place (thrombus) 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™ Aneurysm Embolization System. The WEB™ Detachment Controller has everything it needs to work, is thrown away after use, hand-held, battery-powered unit which provides the controlled electrical energy for the cutting coil away from the Delivery Pusher. The detachment controller 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	During a surgical procedure, the implant component of the WEB Aneurysm Embolization System is delivered to the target treatment site and the front end of the delivery pusher is inserted into the hand-held battery powered WEB Detachment Controller. When the Detachment Controller is turned on, the flow of electrical current heats the plastic (polyolefin elastomer) filament, which then separates from the detachment of the implant segment. The WEB Detachment Controller has everything it needs to work, can be thrown away, hand-held, battery-powered unit which provides the controlled electrical energy for the detachment of the coil from the Delivery Pusher. The detachment controller is packaged and sold separately as a clean (sterile) device for one patient only.

2.4 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 to be used instead of talking with your healthcare professional.

MicroVention has a risk management process where it takes into account how the device is made and on the important design features of the device including how it's used by the physician. As a result of this process, all potential hazards and their risks have been taken into account for WEB Aneurysm Embolization System with WEB Detachment Controller. These risks have been prevented by testing the designed device to make sure it meets specific requirements in the laboratory and through animal testing, patient use and by making sure the information on labels is clear and understandable. These actions help to reduce the risks as much as possible and are considered acceptable.

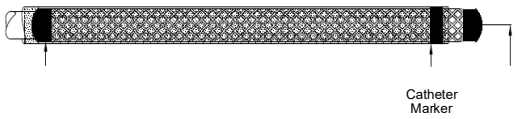
Warnings and precautions

- **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.

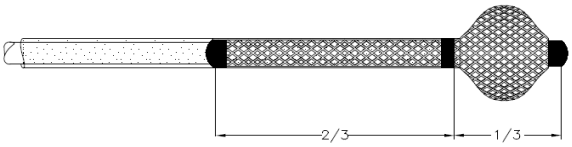
- **CAUTION:** Using this device in a flexible tube (catheter) that is not recommended or required may result in extreme heat (friction) and damage to the device.
- The WEB™ Aneurysm Embolization System is provided clean (sterile) and free from fever causing substances (non-pyrogenic) unless the unit 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 System is to be used one time on one patient. The Detachment Control Device is to be used one time on one patient. Do not reclean (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 using, 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)

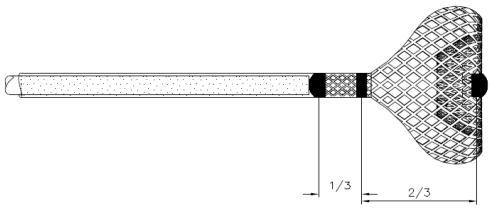


(b)



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.

No escalations of Supplier Corrective Action Reports (SCARs), Corrective and Preventative Actions (CAPAs) or Field Actions were identified.

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

2.5.1 Clinical background of the device

Bulges in the blood vessels of the brain (Intracranial aneurysms (IAs)) result in weakening the blood vessel walls which can lead to the blood vessel bursting. This results in bleeding into the brain. A blood vessel that has not yet burst (unruptured IAs) is not common and is between 2% and 3.2% in the general population with a women being twice as likely as men. It is the leading cause of bleeding uncontrollably inside of your brain or between your brain and skull. (hemorrhagic stroke), and responsible for 85% of bleeding in the space between the brain and skull (subarachnoid hemorrhages (SAH)) [1]. Although death rates of bleeding in the space between the brain and skull (subarachnoid Hemorrhages) have gotten lowering the past 30 years, it is still causing a lot of damage in the brain resulting in disability. An estimated 10-15% of patients die before reaching the hospital.

Approximately 25% of patients die within 24 hours, with or without medical attention. Hospitalized patients have an average death rate of 40% in the first month. About half of the people with this die in the first 6 months. with 10% to 20% of these patients having severe illness. If left this is not treated by a doctor, a second place of bleeding may happen within the first three weeks is about 40% and bears significant consequences. Rebleeding, a major harmful effect , carries a high rate of death 51-80%.[3, 4]

Standard treatments for bulges in the blood vessels of the brain (IAs) are either to have a surgery where the physician cuts you open to create a window in the skull or at the side of the chest or breastbone (open surgery) or by using a surgical procedure in which two small cuts are made at the hip to get to the blood vessels (endovascular). The surgical procedure using the small cuts to get to the blood vessels (Endovascular treatment) is now the preferred treatment for a blood vessel bulge that has burst (ruptured aneurysm) and is important in the treatment of blood vessel bulges that have not yet burst (unruptured aneurysms[6,7,8)]. The use of coils to reduce the blood flow in the blood vessel bulge (Endovascular coiling of the aneurysm) has become another treatment that is accepted instead of to using clips to close off the blood vessel (surgical clipping). The use of coils has lower risk of side effects and lower risk of dying. [11]

The idea t of slowing/stopping the blood flow into a blood vessel bulge by inserting a device into the bulge (intra-aneurysmal flow disruption) has become as a new standard for the treatment of blood vessel bulges (aneurysm) near two blood vessel branches (bifurcation aneurysms)[12,13,14]. The Woven Endoluminal Bridge (WEB) Aneurysm Embolization System is a devices that was created to change blood flow within the blood vessel bulge (aneurysm sac) and at the bulge neck (aneurysm neck) to reduce/stop the flow of blood and encourage blood clot formation across the bulge neck. The barrel or round shapes allow the WEB™ device to treat either bulges near two branches of blood vessels (bifurcation) or to support the weakened side wall of the blood vessel bulge (aneurysm) . Much data published in the expert reviewed literature have shown the usefulness of the WEB™ device treatment in blood vessel bulges with a wide-neck located where there are two branches of blood vessels (bifurcation aneurysms).[19,20,21,22,23,24] Both short-term and long-term data have shown the WEB™ Aneurysm Embolization System is safe and performs as expected.

2.5.2 The clinical evidence for the CE-marking

The clinical data presented in the clinical evaluation have been thoroughly evaluated and deemed enough, based on, 1) A search for published papers was done using good methods. The articles in the literature review were included based on a set of situations agreed upon before doing the search. 2) A total of 27 published articles included 9 high quality studies/reviews 18 medium quality studies 2. 3) A total of 8 clinical studies were conducted after the WEB™ device was placed on the market. .

In the evaluation of clinical evidence in the clinical evaluation document, the risks associated with the appropriate use of the WEB™ Aneurysm Embolization System devices have been addressed. Therefore, the report found that when the WEB™ Aneurysm Embolization System is used the way the Manufacturer instructs, the benefits to the patient are more than the risks of using the device.

Therefore, the requirements of the EU MDR 2017/745 that require a device be safe and does what it is supposed to do is met.

2.5.3 Safety

Studies collected in this report show patient data for the WEB™ device was collected in research studies that test new treatments on patients and included the WEB™ Aneurysm Embolization System with WEB™ Detachment Controller and studies reported in published papers to determine the safety and performance of the WEB™ Aneurysm Embolization System and the WEB™ Detachment Controller.

The evaluation of the patient data shows the WEB™ system was successful with a high rate of complete or adequate blood vessel blockage (aneurysm occlusion) with low rates of side effects during the surgical procedure and during patient follow up with the physician for the WEB™ embolization device to treat blood vessel bulge in the brain (intracranial aneurysm). The benefit from use of the WEB™ device is greater than the risks and is very similar to the benefits and risk seen with other types of treatments such as use of coils. The evidence gathered on the WEB™ device and other standard treatments shows the benefits to treatment outweigh the risks and shows the WEB™ device with Detachment Controller is acceptable as compared with other standards of care.

Overall, based on 1) the safety and performance reported in the literature associated with the WEB™ Aneurysm Embolization System with WEB™ Detachment Controller, 2) evaluation benefits to the patients by preventing the general risks seen with a bulge in the blood vessel of the bran that goes untreated (intracranial aneurysm untreated), and 3) comparing the general risks associated with the surgical procedure compared to other treatments it is concluded that the benefits outweigh the risks for the WEB™ Aneurysm Embolization System devices when used as instructed by the manufacturer.

2.6 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.

Commercially available coils that block blood in the blood vessels (embolization coils) that have similar uses (indications) as the WEB™ Aneurysm Embolization System devices are: .

- Penumbra Coil System 400 (Penumbra)
- Micrus Deltapaq (Micrus Endovascular)

- Codman Micrus Deltamax (Codman Neurovascular)
- MicroPlex Coil System (MicroVention, Inc)

In addition, a new device on the market, Artisse (formerly called LUNA, Medtronic), is also included as a similar device to WEB™ Aneurysm Embolization System.

The listed marketed devices (above), including Penumbra Coil System 400, Micrus Deltapaq microcoil system, and Codman Micrus Deltamax, are large-volume coil devices to block/reduce the blood flow into the vessel wall bulge (intracranial embolization), designed to achieve higher packing density using fewer coils, as compared to conventional microcoils. MicroPlex Coil System (MCS, MicroVention) family comprises different coil sizes, MCS-18 system, with larger primary coil filament diameter than MCS 10-system, is designed to facilitate increased packing density.

2.7 Suggested Training for Users

This device should only be used by physicians who have undergone training in the use of the WEB™ Aneurysm Embolization System for embolization procedures.