Summary of Safety and Clinical Performance

for

Web™ Aneurysm Embolization System

SSCP22-0001

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	Change Description	NB approved/verified
A	Initial Release	☒Yes ☐ No* Validation language: N/A
B	Updated SSCP to include SRN for MVE Legal Manufacturer	☐Yes ☒ No* Validation language: N/A
C	Moved to new template, added new sizes	☐Yes ☒ No* Validation language: N/A
D	Corrected revision history, updated Header, and verified MVE Legal Manufacturer SRN.	☐Yes ☒ No* Validation language: N/A
E	External standard references were revised per section 1.8. Add verbiage and removed extra texts to align with template.	☐Yes ☒ No* Validation language: N/A
F	Annual Update to the SSCP in new template with updates to sections 1.4.4 and 1.5 and 1.6. Removed trademark symbol next to the device name after the first mention of the device as suggested by Legal. Removed trademark symbol next to microvention logo in the first page and headers as suggested by legal based on new guidelines.	☐Yes ☒ No* Validation language: N/A
G	External standard references were revised per section 1.8.	☐Yes ☒ No* Validation language: N/A

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

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.

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 (EMDN)	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 for the device	2013
Legal Manufacturer	
Name & Address	MicroVention, Inc. 35 Enterprise Aliso Viejo, California, 92656 USA
Manufacturer SRN	MVI: US-MF-000016658 MVE: FR-MF-000004449
Authorized Representative	
Name & Address	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye, France
Authorized Representative SRN	FR-AR-000004448
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August-Schanz-Straße 21 D-60433 Frankfurt am Main Germany
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

Table 1.2 Intended Use

Intended Purpose	
Intended Purpose	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.
Indications for Use	Ruptured and unruptured intracranial aneurysms, and neurovascular abnormalities such as arteriovenous fistula (AVF)
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 the Table below for the WEB device 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>
</table>

Device Description

Design Characteristics of the Device

The WEB device is designed to have a soft, compliant structure yet have a 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 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 the 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

Device Description

	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 WEB devices 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

Generations	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

Single use – sterilization method

The WEB Aneurysm Embolization System is 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 the 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.

Description of Accessories

The WEB Detachment Controller (WDC) is an accessory to be used with the WEB Aneurysm Embolization System.

The WEB Detachment Controller is a 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 a single patient only.

<table>
<tr><th colspan="2">Device Description</th></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

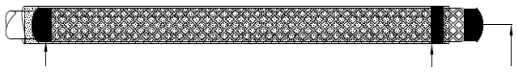
the device may result in damage or premature detachment.

- 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).

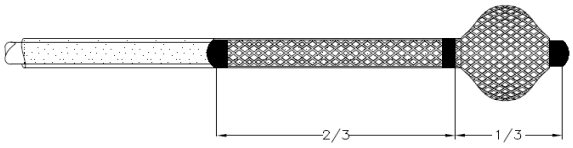
WEB embolization device visibility may vary with diameter; larger sizes may be more visible than smaller sizes. Examples are shown in **Figure c**

- 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)

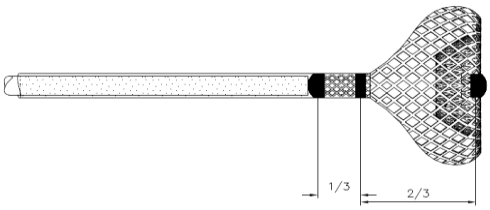


(b)



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

The potential complications / adverse effects for the WEB System are :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) , as well as post-market clinical follow-up (PMCF) for the review period 01 November 2020 to 31 October 2024.

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

- The subject device has an overall complaint rate of 4.20%, based on over 33,040 units shipped and 1,389 complaint records
- The FDA MAUDE database revealed 459 reports of the subject device, of which all had been identified in the MicroVention complaint system and were reported. Similar device reports identified no novel potential outcomes relevant to the subject device.
- During the current review period, eight (8) CAPAs were opened that pertained to the WEB Aneurysm Embolization devices**.** As of the preparation of this document, Six (6) CAPAs were closed, one (1) is being implemented and one (1) is in effectiveness check 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 of 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
    - VS-WEB
    - WAVE Study
- **Published Peer-reviewed Clinical Literature**

  The literature search detailed in this report presents relevant clinical data from the scientific literature for the WEB Aneurysm Embolization System. The literature search was performed using a sound methodological process as outlined in Sections 4.1.1 and 7.5. The literature search results demonstrate clinical use of the WEB Aneurysm Embolization System for treatment of intracranial aneurysm in 53 articles with 11,689 patients with an average follow up of 2-3 years. There were 24 retrospective studies, seven (7) systematic reviews, 14 cohort studies and eight (8) case series As such, the overall quality of the data from the published clinical studies was high quality. The analysis of the published literature demonstrates clinical performance outcomes, Complete occlusion ranging from 55.6% to 100% and adequate occlusion ranging from 54.4% to 81.1%

- 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 demonstrate 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 associated 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, and 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 labeling

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 of 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 a risk of embolic coil protrusion into the parent vessel. The use of self-expanding stents provides 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 for coil placement following stent delivery by isolating the aneurysmal lumen from the circulation via recanalization. These intra-luminal stents have very tight mesh structures 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 include 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 a 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 the 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

WEB Aneurysm Embolization System with WEB Detachment Controller is well established medical devices with numerous types and styles available from a variety of manufacturers. Examples of devices similar to the WEB Aneurysm Embolization System devices are listed in Table 1.4.

Table 1.4 Similar Devices

Device	Manufacturer	Intended Purpose
Artisse	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

Device	Manufacturer	Intended Purpose
(formerly known as Luna Aneurysm Embolization System)		width of 3.0–8.5mm, and is not limited based on aneurysm dome-to neck ratio.

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.

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

WEB Aneurysm Embolization System:

Category	Standard Number	Edition	Standard Title (equivalent edition)
Quality System	EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
Risk Management	EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
Risk Management	EN IEC 60812	2018	Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)
Usability	EN ISO 62366-1	2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
Clinical	EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)
Post Market Surveillance	ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers
Labeling	EN ISO 15223-1	2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
Labeling	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)

Packaging	EN ISO 11607-1	2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019/Amd 1:2023)
Packaging	EN ISO 11607-2	2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019/Amd 1:2023)
Packaging	ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less
Packaging	ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
Packaging	ASTM D4332	2022	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
Packaging	ASTM F88	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials
Packaging	ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
Packaging	ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
Packaging	ASTM F2096	2011R2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

Shelf Life & Stability	ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
Biocompatibility	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
Biocompatibility	EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
Biocompatibility	EN ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
Biocompatibility	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
Biocompatibility	EN ISO 10993-6	2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
Biocompatibility	EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
Biocompatibility	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
Biocompatibility	EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

Biocompatibility	EN ISO 10993-17	2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)
Biocompatibility	EN ISO 10993-18	2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020/Amd 1:2022)
Biocompatibility	EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
Manufacturing (Environmental Controls)	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
Manufacturing (Environmental Controls)	EN ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
Manufacturing (Environmental Controls)	ANSI/AAMI ST72	2019	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
Sterilization	EN 556-1	2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices

Sterilization	EN ISO 11737-1	2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018/Amd 1:2021)
Sterilization	EN ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
Sterilization (Bacterial Endotoxin Testing)	ISO 11737-3	2023	Sterilization of health care products - Microbiological methods - Part 3: Bacterial Endotoxin testing
Sterilization (Gamma or E-Beam Radiation)	EN ISO 11137-1	2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006/Amd 2:2018)
Sterilization (Gamma or E-Beam Radiation)	EN ISO 11137-2	2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013/Amd 1:2022)
Device Specific (Implants)	EN ISO 14630	2012	Non-active surgical implants - General requirements (ISO 14630:2012)
Device Specific (Implants)	ISO 16428	2005	Implants for surgery – Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices
Device Specific (Implants)	ASTM F2129	2019a	Standard Test Method for Conducting Cyclic

			Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
Device Specific (Implants)	ASTM F3044	2020	Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants
Device Specific (Implants)	ASTM G16	2013	Standard Guide for Applying Statistics to Analysis of Corrosion Data
Device Specific (Implants - Stents)	ASTM F2081	2006R2022	Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents
Device Specific (Implants - Stents)	ASTM F2477	2023	Standard Test Method for in vitro Pulsatile Durability Testing of Vascular stents
Device Specific (Radiopacity)	ASTM F640	2023	Standard test methods for determining radiopacity for medical use
Device Specific (MRI)	ASTM F2052	2021	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
Device Specific (MRI)	ASTM F2119	2007R2013	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
Device Specific (MRI)	ASTM F2182	2019e2	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
Device Specific (MRI)	ASTM F2213	2017	Standard test method for measurement of magnetically induced torque on passive

			implants in the magnetic resonance
Device Specific (MRI)	ASTM F2503	2023e1	Standard practice for marketing medical devices and other items for safety in the magnetic resonance environment

Detachment Controller:

Category	**Standard Number**	**Edition**	**Standard Title (equivalent edition)**
Quality System	EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
Risk Management	EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
Risk Management	EN IEC 60812	2018	Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)
Usability	EN ISO 62366-1	2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
Post Market Surveillance	ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers
Labeling	EN ISO 15223-1	2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
Labeling	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)

Packaging	EN ISO 11607-1	2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019/Amd 1:2023)
Packaging	EN ISO 11607-2	2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019/Amd 1:2023)
Packaging	ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less
Packaging	ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
Packaging	ASTM F88	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials
Packaging	ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
Packaging	ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
Packaging	ASTM F2096	2011R2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
Shelf Life & Stability	ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Biocompatibility	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
Biocompatibility	EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
Biocompatibility	EN ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
Biocompatibility	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
Biocompatibility	EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
Biocompatibility	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
Biocompatibility	EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
Biocompatibility	EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
Manufacturing (Environmental Controls)	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)

Manufacturing (Environmental Controls)	EN ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
Manufacturing (Environmental Controls)	ANSI/AAMI ST72	2019	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
Sterilization	EN 556-1	2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices
Sterilization	EN ISO 11737-1	2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018/Amd 1:2021)
Sterilization	EN ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
Sterilization (Bacterial Endotoxin Testing)	ISO 11737-3	2023	Sterilization of health care products - Microbiological methods - Part 3: Bacterial Endotoxin testing
Sterilization (Biological Indicators)	EN ISO 11138-1	2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)

Sterilization (Ethylene Oxide)	EN ISO 11135	2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014/Amd 1:2018)
Sterilization (Ethylene Oxide)	EN ISO 10993-7	2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008/Amd 1:2019)
Device Specific (Software)	EN 62304	2006/A1:2015	Medical device software — Software life-cycle processes (IEC 62304:2006/A1:2015)
Device Specific (Medical Electrical Equipment)	EN 60601-1	2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A2:2020)
Device Specific (Medical Electrical Equipment)	EN 60601-1-2	2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014/A1:2020)

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