



**Summary of Safety and Clinical Performance
for
Web™ Aneurysm Embolization System
SSCP22-0001**

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DOCUMENT CHANGE HISTORY

Revision	Change Description	NB approved/verified
A	Initial Release	☒ Yes ☐ No* Validation language: English
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 symbols after first mention per internal guidelines.	☐ Yes ☒ No* Validation language: N/A
G	External standard references were revised per section 1.8.	☐ Yes ☒ No* Validation language: N/A
H	External standard references were revised per section 1.8 and updated the validation language for the Initial release.	☐ Yes ☒ No* Validation language: N/A
J	Annual update, including revisions to match IFU, updated clinical, PMS, and literature review summaries (no change to safety or benefit/ risk), and updated list of standards and references.	☐ 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 primary document for ensuring the safe use of the device, nor is it intended to provide diagnostic or therapeutic recommendations 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
Medical Device Nomenclature (EMDN)	EMBOLISATION DEVICES – OTHER
Device Class	III
Basic UDI-DI	MicroVention, Inc. WEB Aneurysm Embolization System (MVI): 08402732WEBTL
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
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/ Indications	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	The WEB Aneurysm Embolization System is intended for patients with ruptured and unruptured intracranial aneurysms and other neurovascular abnormalities such as arteriovenous fistulae (AVF).
Contraindications and/or Limitations	None

1.3 Device Description

Table 1-3 Device Description

Device Description											
Description of the Device	The WEB Aneurysm Embolization 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). 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.										
Design Characteristics of the Device	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. The WEB embolization device is manufactured from nitinol wires in a braided, self-expanding mesh configuration. The WEB device that remains in the patient following detachment consists of the following materials: <table><tr><th colspan="2">Implant Materials</th><th>Mass (mg)*</th></tr><tr><td>Metallic Components</td><td>Nitinol, Platinum, Platinum-Iridium Alloy</td><td>≤ 40</td></tr><tr><td>Non-metallic Components</td><td>Epoxy, PET</td><td>≤ 0.1</td></tr></table>		Implant Materials		Mass (mg)*	Metallic Components	Nitinol, Platinum, Platinum-Iridium Alloy	≤ 40	Non-metallic Components	Epoxy, PET	≤ 0.1
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Non-metallic Components	Epoxy, PET	≤ 0.1									
*Approximate content											

Device Description																			
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.																		
Description of Accessories	The WEB Detachment Controller (WDC) is an accessory to be used with the WEB Aneurysm Embolization System. The WDC 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.																		
Description of other Devices or Products intended to be used in combination	• 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><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>				Embolization Device (Diameter) Range	Minimum Microcatheter Inner Diameter (inch)	Recommended VIA Microcatheter	W2 – WEB Single 8 – 9 mm	0.027	VIA 27	W2 – WEB Single 10 – 11 mm	0.033	VIA 33	W4 – WEB Single 4 – 7 mm	0.021	VIA 21	W5 – WEB Single 3 – 7 mm	0.017	VIA 17
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W5 – WEB Single 3 – 7 mm	0.017	VIA 17																	

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.

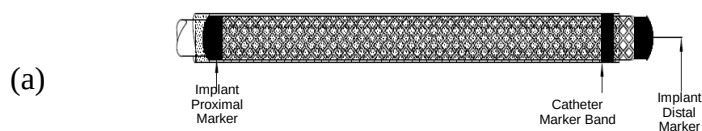
Undesirable effects are addressed in the IFU as potential complications, which include but are not limited to the following: hematoma at the site of entry, aneurysm rupture, emboli, vessel perforation, parent artery occlusion, hemorrhage, ischemia, vasospasm, clot formation, device migration or misplacement, premature or difficult device detachment, non-detachment, incomplete aneurysm filling, revascularization, post-embolization syndrome, and neurological deficits including stroke and death.

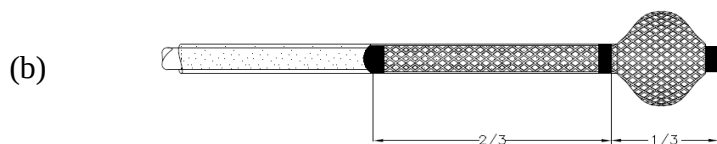
Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State or Local Health Authority in which the user and/or patient is established.

1.4.2 Warnings and Precautions

- **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 and distal markers 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).

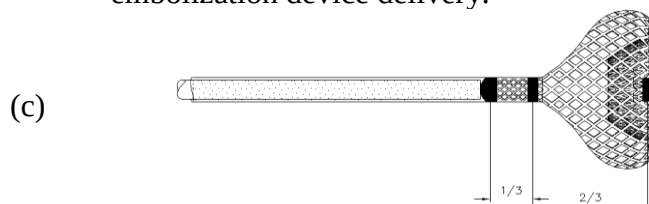




Note:

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.



- 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, incomplete aneurysm filling, revascularization, post-embolization syndrome, and neurological deficits including stroke and death.

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State or Local Health Authority in which the user and/or patient is established.

1.4.4 Other Aspects of Safety

There have been 3 field safety actions for the WEB Aneurysm Embolization System since 2021 which are all closed.

1.5 Summary of the Clinical Evaluation and PMCF

A Clinical Evaluation of the WEB Aneurysm Embolization System is continuously updated and conducted in accordance with the requirements of the European Medical Device Regulation (MDR (EU) 2017/745).

The clinical evaluation demonstrates that the clinical data are sufficient to establish conformity with all relevant Safety and Performance Requirements (Annex I) of EU MDR 2017/745 and confirms the safety, performance, and acceptability of benefit/ risk for the WEB Aneurysm Embolization System.

1.5.1 Equivalent Device Clinical Data

Not applicable; there is no equivalent device for the WEB Aneurysm Embolization System.

1.5.2 Pre-CE-Mark Clinical Data

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

1.5.3 Clinical Data

Clinical data sources used to evaluate the safety and performance of the WEB Aneurysm Embolization System included post market clinical studies and published literature.

Post Market Clinical Studies

There are 7 completed manufacturer-sponsored post-market clinical studies for the WEB Aneurysm Embolization System. Five of these studies (#1—#5 below) were registries, one (#6) was a pivotal study conducted in the United States after the WEB Aneurysm Embolization System was CE marked, and one (#7) was an interventional study conducted in China. These studies are published.

1. WEB French Observational Study (NCT01975233)
2. WEBCAST Study (NCT01778322)
3. WEBCAST-2 Study (NCT01778322)
4. CLARYS Registry (NCT02687607)
5. CLEVER Study (NCT03844334)
6. WEB-IT Study (NCT02191618)
7. WEB-IT China (NCT03207087)

There is one completed investigator-sponsored post-market study (VS-WEB; NCT04621552) that is also published.

Published Peer-reviewed Clinical Literature

A systematic literature search and review were conducted in accordance with the principles of MEDDEV 2.7/1 (Revision 4). This search identified 85 published peer-reviewed clinical articles

reporting clinical safety and performance data for the WEB Aneurysm Embolization System. Of these 85 publications, there were 15 publications that reported data from the post market clinical studies listed above.

1.5.4 Clinical Performance and Safety

Clinical evidence identified, collected, and appraised from post market clinical studies and published peer reviewed literature provided safety and performance data for more than 11,500 patients treated with the WEB Aneurysm Embolization System.

Regarding safety, commonly reported complications were thromboembolic and ischemic complications, hemorrhagic events, retreatment, and all-cause mortality. Other complications included aneurysm perforation or vascular dissection, brain/ cerebral edema, hydrocephalus, neurologic/ deficit, vasospasm, rebleeding, device protrusion into the parent artery. Rates for these complications ranged from 0% to 30%, which is consistent with the rates for these complications reported for other standards of care used to treat intracranial aneurysms. Some studies reported device compression/ shape modification, which was also reported for the Artisse™ Intracapsular Device, a competitor which is most similar to the WEB Aneurysm Embolization System.

Regarding performance, technical success for the WEB device ranged from 79% to 100%; immediate complete occlusion ranged from 8% to 100%; and complete occlusion during follow-up of at least 1–2 years ranged from 31% to 94%. There were 73% to 100% of patients who had modified Rankin Scale (mRS) scores of 0–2 during follow-up after treatment with the WEB Aneurysm Embolization System. These outcomes were also comparable to the standard of care.

The substantial clinical evidence demonstrates the safety and performance of the WEB Aneurysm Embolization System and confirms the acceptability of benefit/ risk in terms of the state of the art.

1.5.5 Post-Market Clinical Follow-up

Based on the substantial clinical evidence for the WEB Aneurysm Embolization System, the post-market clinical follow-up activities include ongoing review of the published clinical literature and post market surveillance data. In addition, clinical data will be gathered from 2 ongoing manufacturer-sponsored studies (NCT06511245 and NCT04839705) and an observational registry (NCT06494436).

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

Treatment options for intracranial aneurysms (IA) and other neurovascular abnormalities are surgical or endovascular, and contemporary options include microsurgical clipping, endovascular coiling alone, balloon-assisted coiling, stent-assisted coiling, flow diverting stenting, liquid embolic embolization, and intrasaccular flow disruption.

Surgical clipping is a widely applied treatment method for patients with IA, especially for young

patients with relatively easily accessed aneurysms, such as those in the middle cerebral artery. It is associated with a decreased rate of retreatment, but a higher incidence of cognitive impairment, neurologic morbidity, and mortality. (Shao B, 2019) (Martinez-Perez R, 2021)

Flow diverter stents provide metal coverage across the neck of the aneurysm to physiologically exclude the lesion from the circulation and induce thrombosis into the aneurysmal sac while preserving physiological flow in the parent vessel and adjacent branches (Wang Y, 2021). A major limitation of flow diversion is ischemic stroke associated with stent thrombogenicity, necessitating dual-antiplatelet therapy and its associated risk (Li YL, 2021).

Stent-assisted coiling is a well-established technique for endovascular treatment of intracranial aneurysms, especially for wide-necked aneurysms that are otherwise difficult to treat by non-assisted coiling alone, but the main limitation is recurrence (Goertz L, 2019).

Simple coiling aims to achieve dense packing through the delivery of detachable platinum wires into the IA lumen, resulting in an unorganized thrombus and granulation tissue formation. With balloon-assisted coiling a compliant balloon is inflated in the parent vessel lumen to create a temporary IA neck allowing the coil to frame inside the IA and preventing it from herniating out into the parent vessel. This technique is particularly useful when treating ruptured IAs with unfavorable anatomy for standalone coiling. (Lee KS, 2022)

Intrasaccular flow disruptors are associated with approximately 80% occlusion rates, and 10% recurrence and retreatment rates. There is little risk to surrounding perforators, and antiplatelet medication is not required after the procedure. However, unfavorable factors include torturous anatomy which is difficult to navigate with large microcatheters. (Lee J, 2022)

1.6.2 Available Technologies

The Artisse™ Intrasaccular Device is similar to the WEB Aneurysm Embolization System based on intended use as described in **Table 1-4**. Self-expanding intrasaccular devices like Artisse™ Intrasaccular Device are placed completely within the aneurysm, with the mesh across the neck of the aneurysm to isolate it from the parent artery blood flow (Hohenstatt S, 2026). They are meant for use as a standalone treatment without the need for adjunctive devices (Hecker C, 2025). However, device shape modification has been reported (Piotin M, 2022) and sizes are more limited than other devices used for similar purposes (Hecker C, 2025).

Table 1-4 Similar Devices

Device	Manufacturer	Intended Purpose
Artisse™ Intrasaccular Device (formerly known as Luna Aneurysm Embolization System)	Medtronic	The Artisse™ Intrasaccular Device is intended for the endovascular embolization of saccular intracranial aneurysms.

1.7 Suggested Profile and Training for Users

The WEB Aneurysm Embolization System should be used only by physicians trained in percutaneous, intravascular, and neurovascular techniques and procedures at medical facilities with appropriate fluoroscopic equipment.

The WEB embolization device should only be used by physicians who have received appropriate training for this device.

1.8 Reference to any Harmonized Standards and CS

Table 1-5 Standards for the 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 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/A11:2024	Clinical investigation of medical devices for human subjects - Good clinical practice
Post Market Surveillance	ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers
Labeling	EN ISO 15223-1	2021/A1:2025	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific
Labeling	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)

Category	Standard Number	Edition	Standard Title (equivalent edition)
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)

Category	Standard Number	Edition	Standard Title (equivalent edition)
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

Category	Standard Number	Edition	Standard Title (equivalent edition)
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	2025	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

Category	Standard Number	Edition	Standard Title (equivalent edition)
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	2024	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
Device Specific (Equipment)	ANSI T564	2021	Transparent Chart for the Estimation of Defect Size

1.9 References

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