Summary of Safety and Clinical Performance

for

AZUR™ Vascular Plug

SSCP23-0011

Rev. D

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DOCUMENT CHANGE HISTORY

SSCP Revision	Change Description	NB approved/verified
A	Initial Release	☐Yes ☒ No* Validation language:
B	External Standards Revised	☐Yes ☒ No* Validation language:
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D	Annual update due to new clinical evaluation.	☐Yes ☒ No* Validation language:

*Annual entries must be included. An entry stating such must be added if a revision is not required.

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1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

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	AZUR Vascular Plug
EMDN Code	C010402020301
Medical Device Nomenclature (EMDN)	Embolization Coils
Device Class	Class IIb
Basic UDI-DI	08402732AZURPLUG4X
Year when first certificate (CE) was issued for the device	2019
Legal Manufacturer	
Name & Address	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA, 92656, USA
Manufacturer SRN	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 60433 Frankfurt am Main Germany
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

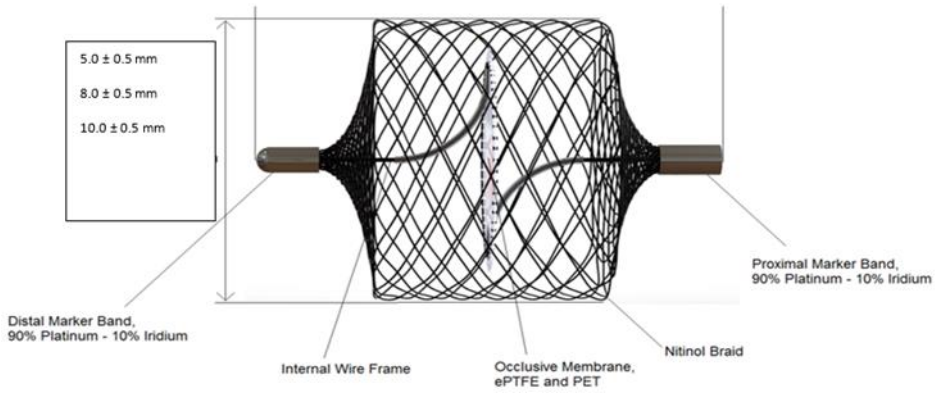
Table 1.2 Intended Use

Intended Purpose	
Intended Purpose	The AZUR Vascular Plug is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature.
Intended User	This device should only be used by physicians who have undergone training in the use of the AZUR system for embolization procedures as prescribed by a representative from Terumo or a Terumo-authorized distributor.
Target Population	The AZUR Vascular Plug is intended for patients who require a reduction or blockage in flow rate of blood flow in vessels of the peripheral vasculature.
Contraindications and/or Limitations	Use of the AZUR Vascular Plug is contraindicated in any of the following circumstances: • When patient has known hypersensitivity to nickel-titanium. • When end vessels lead directly to nerves. • When vessels supplying the lesion to be treated are not large enough to accept emboli. • In the presence of severe atheromatous disease. • In the presence of vasospasm (or likely onset of vasospasm).

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	The AZUR Vascular Plug (Figure 1.1) is an embolization device consisting of a conformable, self-expanding nitinol braided wire frame surrounding a flexible, occlusive membrane. The implant is secured at both ends with radiopaque markers to provide visual confirmation of deployment location during the interventional treatment. The implant proximal marker band is attached to a delivery pusher by a monofilament. The pusher is used to deliver the implant through a microcatheter to the intended treatment site. After satisfactory deployment of the implant at the treatment site, the handheld, battery powered AZUR detachment controller (provided separately) is used to release the implant in the vessel. The AZUR Vascular Plug is used by trained interventionalists to reduce or block the rate of blood flow in the peripheral vasculature. **Figure 1-1: AZUR Vascular Plug Diagram**

	
Design Characteristics of the Device	The AZUR Vascular Plug is an embolization device consisting of a conformable, self-expanding nitinol braided wire frame surrounding a flexible, occlusive membrane (Figure 1.1). The AZUR Vascular Plug is deployed in an appropriately sized vessel to reduce or block the flow of blood. The implant has radiopaque markers to provide visual confirmation of deployment location during the interventional treatment. The implant is deliverable through a microcatheter on a detachable delivery system with a delivery pusher, and AZUR Detachment Controller is used to detach the implant.
Previous Generations or Variants, if applicable	None.
Single use – sterilization method	Single use, EtO Sterilized
Description of Accessories	AZUR Vascular Plug is not packaged with any accessories. The AZUR Vascular Plug implant is deliverable through a catheter on a detachable delivery system. The delivery pusher is powered by an AZUR Detachment Controller to detach the implant. The catheter and AZUR Detachment Controller are provided separately.
Description of other Devices or Products intended to be used in combination	The AZUR Vascular Plug implant is deliverable through a microcatheter on a detachable delivery system with a delivery pusher, and AZUR Detachment Controller is used to detach the implant. The microcatheter and AZUR Detachment Controller are provided separately.

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the AZUR Vascular Plug 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 subject device include the following:

1.4.2 Warnings and Precautions

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.

- Refer to instructions supplied with all interventional devices to be used with the AZUR Vascular Plug for their intended uses, contraindications, and potential complications.
- This device is intended for single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- Angiography is required for pre-embolization evaluation, operative control, and post-embolization follow up.
- Do not advance the delivery pusher with excessive force. Determine the cause of any unusual resistance, remove the AZUR system, and check for damage.
- Advance and retract the AZUR system slowly and smoothly. Remove the entire AZUR system if excessive friction is noted. If excessive friction is noted with a second AZUR system, check the catheter for damage or kinking.
- The implant must be properly positioned within a maximum of 3 positioning attempts. If the implant cannot be properly positioned after 3 attempts, simultaneously remove the device and the catheter.
- If repositioning is necessary, take special care to retract the implant under fluoroscopy in a one-to-one motion with the delivery pusher. If the implant does not move in a one-to-one motion with the delivery pusher, or if repositioning is difficult, gently remove and discard the entire device.
- Tortuosity or complex vessel anatomy may affect accurate placement of the implant.
- The long-term effect of this product on extravascular tissues has not been established so care should be taken to retain this device in the intravascular space.
- Always ensure that at least two AZUR Detachment Controllers are available before starting an AZUR system procedure.
- The implant cannot be detached with any power source other than an AZUR Detachment Controller.
- Do NOT place the delivery pusher on a bare metallic surface.
- Always handle the delivery pusher with surgical gloves.
- Do NOT use in conjunction with radio frequency (RF) devices.

1.4.3 Potential Complications / Adverse Effects

Potential complications for AZUR Vascular Plug include but are not limited to: hematoma at the site of entry, vessel perforation, unintended parent artery occlusion, incomplete filling, vascular thrombosis, hemorrhage, ischemia, vasospasm, edema, implant migration or misplacement,

premature or difficult implant detachment, clot formation, revascularization, post-embolization syndrome, and neurological deficits including stroke and possibly death.

The physician should be aware of these complications and instruct patients when indicated. Appropriate patient management should be considered.

1.4.4 Other Aspects of Safety

None.

1.5 Summary of the Clinical Evaluation and PMCF

1.5.1 Equivalent Device Clinical Data

A total of 24 articles were discovered regarding the safety and performance of the equivalent device, AZUR Peripheral Coils System. There were no articles discovered relevant to the safety or performance of the subject device, AZUR Vascular Plug. The literature search results demonstrate clinical use of the AZUR Peripheral Coil System for Peripheral Aneurysms, arteriovenous fistulas (AVFs), arteriovenous malformations (AVMs) in 101 patients with an average follow up of less than 1 year (Hongo et al., 2021, Mosquera-Klinger et al., 2021, Finch et al., 2021, Harada et al., 2019, Greben et al., 2010, López-Benítez et al., 2013, Yamagata, 2020, Abdel-Aal et al., 2011, Çakır et al., 2019, Cho et al., 2023, García-Gimeno et al., 2013, Huynh et al., 2016, Imagami et al., 2021, Khilchuk et al., 2019, Martens et al., 2015, Nakano et al., 2024, Reddy and Metwalli, 2019, Vaillant et al., 2016, Walters et al., 2019, Yu et al., 2025, Panagrosso et al., 2024, Kippenberger et al., 2024, Solano et al., 2024, Luo et al., 2024). As such, the overall quality of the data from the published clinical studies was moderate. The analysis of the published literature demonstrates clinical performance outcomes technical or procedural success rate is 94.7% - 100% and clinical safety outcomes ranged from 0.0% to 5.1%.

1.5.2 Pre-CE-Mark Clinical Data

There are no pre-market clinical investigations for the AZUR Vascular Plug.

1.5.3 Clinical Data

Post-market surveillance

For the evaluation period of 01 January 2021 to 31 December 2024, 5,731 units of the AZUR Vascular Plug have been sold worldwide. The number of product complaints reported to MicroVention is 51, giving a device complaint rate of 0.88%. The total number of complaints reported to EU vigilance authorities is 11, giving a device reportable complaint rate of 0.19%.

Physician Performance Testing (PPT)

Physicians were asked to use the AZUR Vascular Plug and then complete a PPT evaluation form for each case to evaluate the performance of both devices.

A total of 33 cases were conducted. These cases covered a variety of indications such as PAVM, GDA, Splenic embolization, GI embolization, aneurysm, AVF and Pseudoaneurysm etc.

The scores of AZUR Vascular Plug for all the evaluation metrics met the acceptance criteria (≥75% of Responses must be ≥ 3.0) and the average scores were all ≥ 4. (**Table 1.4**)

In 19 cases, physicians considered AZUR Vascular Plug as a better device compared with their commonly used plugs. No physician rated AZUR Vascular Plug as a worse device.

In 25 cases, physicians were willing to switch to AZUR Vascular Plug from their commonly used coils. No physician answered not willing to switch.

The results from the 33 physician surveys met the acceptance criteria that ≥75% of Responses must be ≥ 3.0.

Table 1.4 Physician Performance Testing Results

Performance Criteria	Average	Percentage of Score ≥ 3.0	Acceptance Criteria	Pass/Fail
Package/device prep	4.6	100%	≥75% of Responses must be ≥ 3.0	Pass
Clarity of label	4.4	88%	≥75% of Responses must be ≥ 3.0	Pass
Ease of intro into MC	4.6	97%	≥75% of Responses must be ≥ 3.0	Pass
Ease of tracking	4.4	91%	≥75% of Responses must be ≥ 3.0	Pass
Radiopacity	4.5	94%	≥75% of Responses must be ≥ 3.0	Pass
Ease of deployment	4.7	97%	≥75% of Responses must be ≥ 3.0	Pass
Placement accuracy	4.5	97%	≥75% of Responses must be ≥ 3.0	Pass
Conformability	4.7	97%	≥75% of Responses must be ≥ 3.0	Pass
Ease of recapture	4.8	100%	≥75% of Responses must be ≥ 3.0	Pass
Ease of re-deployment	4.8	100%	≥75% of Responses must be ≥ 3.0	Pass
Ease of detachment	4.8	100%	≥75% of Responses must be ≥ 3.0	Pass
Stability post detachment	4.8	97%	≥75% of Responses must be ≥ 3.0	Pass
Acute occlusion	4.3	97%	≥75% of Responses must be ≥ 3.0	Pass
Overall performance	4.6	100%	≥75% of Responses must be ≥ 3.0	Pass

1.5.4 Clinical Performance and Safety

For the evaluation period of 01 January 2021 to 31 December 2024, 5,731 units of the AZUR Vascular Plug have been sold worldwide. The number of product complaints reported to MicroVention is 51, giving a device complaint rate of 0.89%. The total number of complaints reported to EU vigilance authorities is 11, giving a device reportable complaint rate of 0.19%.

The literature search detailed in the CER presents relevant clinical studies in the published literature for this CER. A total of 24 articles were discovered regarding the safety and performance of the equivalent device, AZUR Peripheral Coils System. There were no articles discovered relevant to the safety or performance of the subject device, AZUR Vascular Plug. The literature search results demonstrate clinical use of the AZUR Peripheral Coil System for Peripheral

Aneurysms, arteriovenous fistulas (AVFs), arteriovenous malformantions (AVMs) in 101 patients with an average follow up of less than 1 year (Hongo et al., 2021, Mosquera-Klinger et al., 2021, Finch et al., 2021, Harada et al., 2019, Greben et al., 2010, López-Benítez et al., 2013, Yamagata, 2020, Abdel-Aal et al., 2011, Çakır et al., 2019, Cho et al., 2023, García-Gimeno et al., 2013, Huynh et al., 2016, Imagami et al., 2021, Khilchuk et al., 2019, Martens et al., 2015, Nakano et al., 2024, Reddy and Metwalli, 2019, Vaillant et al., 2016, Walters et al., 2019, Yu et al., 2025, Panagrosso et al., 2024, Kippenberger et al., 2024, Solano et al., 2024, Luo et al., 2024). As such, the overall quality of the data from the published clinical studies was moderate. The analysis of the published literature demonstrates clinical performance outcomes technical or procedural success rate is 94.7% - 100% and clinical safety outcomes ranged from 0.0% to 5.1%.

Physician performance testing showed in 19 out of the 33 cases, physicians considered AZUR Vascular Plug as a better device compared with their commonly used plugs. No physician rated AZUR Vascular Plug as a worse device. Acceptance criteria was met for assess performance criteria.

1.5.5 Post-Market Clinical Follow-up

The manufacturer continuously monitors published clinical data for the device to ensure the benefits of the use of the device for the patient do not outweigh any possible risk that include systematic literature searches for published clinical data.

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

Table 1.5: Benefits and Risks for Therapeutic Alterantives

Treatment Option	Pro/Benefit	Con/Risks	Notes
Surgical Treatment			
Supra Orbital Keyhole (SOK) surgery (Abdulateef et al., 2023)	SOK was introduced as an alternative approach for clipping Internal Carotid Artery (ICA) aneurysms. SOK surgery provides adequate aneurysmal access while minimizing trauma to the surrounding structures, including the skin, bone, dura, and, most importantly, the brain.	The residual neck is the most documented complication of SOK, due to a lack of visualization of the clip condition and it usually occurs in posterity-located or directed aneurysms so it will require more careful checking for aneurysmal dome direction and origin before selection of the approach, high rates of visual impairment generally after aneurysm clipping had been reported, as found that 39% experienced postoperative visual complications.	None Available
Surgical Clipping (Shao et al., 2019)	Surgical clipping is widely applied treatment method for patients with IA. Angiographic occlusion rate is higher for surgical clipping and is associated with lower mortality. surgical clipping might exert a beneficial effect on rebleeding in patients with specific characteristics.	Studies found that unruptured IA that received surgical clipping was associated with a high incidence of cognitive impairment, neurologic morbidity, and mortality. In this condition, an additional effective strategy should be used to avoid potential adverse events.	The decreased rate of retreatment provided by open clipping is still a determinant factor in selecting microsurgical treatment as the best therapeutic option for many aneurysms, especially in young patients with relatively easily accessed aneurysms such as in the middle cerebral artery distribution (Martinez-Perez et al., 2021)
Type of Endovascular Repair (EVSR)			
Flow-Diverter stents (FDs)	FD is designed to provide sufficient metal coverage across the neck of the aneurysm to physiologically exclude the lesion from the circulation. More importantly, flow	A major limitation of flow diversion is ischemic stroke associated with stent thrombogenicity, necessitating	Endovascular repair has become an established treatment of aneurysm, with a demonstrated perioperative

Treatment Option	Pro/Benefit	Con/Risks	Notes
	diverters induce thrombosis into the aneurysmal sac while preserving physiological flow in the parent vessel and adjacent branches. This excellent function is based on the special structure of a braided mesh cylinder composed of individual platinum and cobalt chromium microfilaments (Wang et al., 2021)	dual-antiplatelet therapy and its associated risk (Li et al., 2021)	and early survival advantage over open surgical repair. Recent randomized clinical trials reporting long-term outcome data have shown that EVAR carries an increased risk of secondary intervention, aneurysm-related mortality, and aneurysm rupture compared with open surgery. Patients receiving EVAR require lifelong imaging surveillance, which aims to predict, detect, and rectify aneurysm-related complications (Antoniou, 2020)
Stent-assisted coiling (SAC)	SAC is a well-established technique for endovascular treatment of intracranial aneurysms, in particular for wide-necked aneurysms that are otherwise difficult to treat by non-assisted coiling alone (Goertz et al., 2019).	The principal limitation SAC is the high IA recurrence rate.	
Balloon Assisted Coiling (BAC) (Lee et al., 2022b)	Balloon remodeling during endovascular coiling involves the temporary inflation of a balloon catheter across the aneurysm neck during the placement of coils. Balloon-assisted coiling (BAC) or balloon remodeling is a method originally described in the cardiac literature and subsequently adapted for use in the cerebrovascular field for the treatment of IAs with a wide neck	BAC is associated with an increased risk of long-term coil compaction and recanalization due to limited filling of the IA volume.	During placement of the coil, 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. Several special types of balloons such as hypercompliant, round-shaped, and double lumen balloons are used depending on the situation
Simple Coiling (Lee et al., 2022b)	In 1990, a detachable bare platinum coil device (Guglielmi) was introduced into clinical practice. Since then, endovascular	Coiling is increasingly popular but does come with several shortcomings. Not all IAs are	There are several major complications associated with coil embolization: thromboembolism,

Treatment Option	Pro/Benefit	Con/Risks	Notes
	treatment with coils has gained worldwide acceptance as an effective treatment for IAs. The goal in coiling is to achieve dense packing through the delivery of detachable platinum wires, resulting in an unorganized thrombus and granulation tissue formation, to limit blood circulation to the IA lumen.	completely cured at first treatment necessitating post-treatment surveillance imaging and, in a minority, may require retreatment. Another drawback of coiling is the need for retreatment due to coil compaction or IA recurrence, hence also further necessitating follow-up.	perforation of the IA, early rebleeding, parent artery obstruction, collapsed coils, coil malposition, even coil migration
Intrasaccular flow disruptor (Lee et al., 2022a)	80% occlusion rates • 10% recurrence rate • 10% retreatment rate There is little risk posed to surrounding perforators, and antiplatelet medication is not required after the procedure	Unfavorable factors include Aneurysm-specific factors: • Tortuous anatomy, e.g., ACommA aneurysms, as difficult to navigate with the large microcatheters	Aneurysm-specific factors: • Not amenable to simple coiling or BAC/SAC • Primarily for wide-necked IAs, bifurcation IAs, and sidewall IAs

1.6.2 Available Technologies

Peripheral vascular plugs such as the AZUR Vascular Plug, are well established medical devices with numerous types and styles available from a variety of manufacturers. A few examples of peripheral vascular plugs similar to the AZUR Vascular Plug are listed in **Table 1.6**.

Table 1.6 Similar Devices

Device	Manufacturer	Intended Use
MVP Microvascular Plug Systems	Medtronic	The MVP micro vascular plug system is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.
Amplatzer™ Vascular Plug	Abbott	The Amplatzer™ Family of Vascular Plugs are indicated for arterial and venous embolization in the peripheral vasculature.
AZUR Peripheral Embolization Coil System	MicroVention	The AZUR Peripheral Embolization Coil System is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of 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 AZUR system for embolization procedures as prescribed by a representative from Terumo or a Terumo-authorized distributor.

1.8 Reference to any Harmonized Standards and CS

Standard Number	Edition	Standard Title (equivalent edition)
EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN IEC 60812	2018	Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)
EN 62366-1	2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers

Standard Number	Edition	Standard Title (equivalent edition)
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)
EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
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)
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)
ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less
ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4332	2022	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM F88	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096	2011R2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
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)
EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
EN ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)

Standard Number	Edition	Standard Title (equivalent edition)
EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6	2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
EN ISO 10993-17	2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)
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)
EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
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)
ANSI/AAMI ST72	2019	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
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
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)

Standard Number	Edition	Standard Title (equivalent edition)
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)
ISO 11737-3	2023	Sterilization of health care products - Microbiological methods - Part 3: Bacterial Endotoxin testing
EN ISO 11138-1	2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
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)
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)
EN ISO 14630	2012	Non-active surgical implants - General requirements (ISO 14630:2012)
EN ISO 25539-1	2017	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2017)
EN ISO 25539-2	2020	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2020)
ISO 16428	2005	Implants for surgery – Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices
ASTM F2129	2019a	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
ASTM F3044	2020	Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants
ASTM G16	2013	Standard Guide for Applying Statistics to Analysis of Corrosion Data
ASTM F640	2023	Standard test methods for determining radiopacity for medical use

Standard Number	Edition	Standard Title (equivalent edition)
ASTM F2052	2021	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2119	2007R2013	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2182	2019e2	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213	2017	Standard test method for measurement of magnetically induced torque on passive implants in the magnetic resonance
ASTM F2503	2023e1	Standard practice for marketing medical devices and other items for safety in the magnetic resonance environment

1.9 References

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