



Summary of Safety and Clinical Performance
for
Scepter™ Occlusion Balloon Catheters
SSCP1105554

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

SSCP Revision	Change Description	NB approved/verified
A	Initial release	☒ Yes ☐ No* Validation language: English
B	Annual update in the new template with updates to section 1.4.4, 1.5.3 and 1.5.4. Changed the title of the document to match with Technical documentation. Removed trademark symbol next to the device name after the first mention of the device name 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:
C	Annual update with the following revisions: added device description and undesirable effects from IFU, updated summary of safety and performance data and PMCF activities with no change to benefit/ risk, updated summary of alternative options, references and standards. Minor revisions to re-organize information for clarity throughout.	☐ 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 Scepter C™, Scepter XC™ and Scepter Mini™ Occlusion Balloon Catheters (hereafter referred to as Scepter devices).

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	Scepter C / Scepter XC/ Scepter Mini Occlusion Balloon Catheter
EMDN Code	C0104020202
Medical Device Nomenclature (EMDN)	Peripheral embolization catheters and microcatheters
Device Class	Class III
Basic UDI-DI	08402732SCEPTERKS
Year when first certificate (CE) was issued for the device	Scepter C and XC- 07 June 2011 Scepter Mini - 20 April 2019
Legal Manufacturer	
Name & Address	MicroVention, Inc. 35 Enterprise Aliso Viejo, California, 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-MF-000004448
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August –Schanz-Straße 21 D-60433 Frankfurt am Main

Device Names	
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

Table 1.2 Intended Use

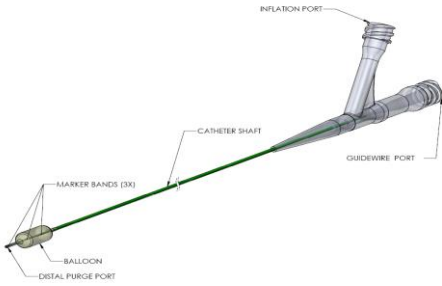
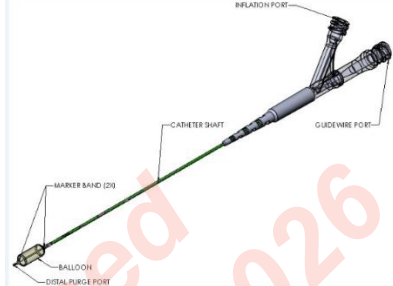
Intended Purpose	
Intended Purpose	The Scepter devices are intended: • For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheters provide temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheters also offer balloon assisted embolization of intracranial aneurysms. • For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents such as embolization materials. - For neurovascular use for the infusion of diagnostic agents such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter C/XC balloon catheter or inner lumen of Scepter Mini balloon catheter.
Indications for Use	The Scepter devices are intended: • For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheters provide temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheters also offer balloon assisted embolization of intracranial aneurysms. • For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents such as embolization materials. • For neurovascular use for the infusion of diagnostic agents such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter C/XC or inner lumen of Scepter Mini.
Target Population	The intended patient population to be treated includes those patients presenting medical conditions requiring temporary occlusion of the blood vessels, the delivery of diagnostic agents such as contrast media to the target site, or therapeutic agents such as embolization materials, into the peripheral or neurovasculature.
Contraindications and/or Limitations	The contradictions for the Scepter devices are: • Not intended for embolectomy or angioplasty procedures

Intended Purpose	
	• Not intended for use in coronary vessels • Not intended for pediatric or neonatal use

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	Scepter C and Scepter XC Occlusion Balloon Catheters: The Scepter C and Scepter XC Occlusion Balloon Catheters are dual lumen catheters with an external hydrophilic coating. The guidewire lumen is provided for guidewire introduction and delivery of agents. The inflation lumen is used exclusively for the inflation and deflation of the balloon. The guidewire lumen of the balloon catheters is compatible with 0.014 inch or smaller guidewires, and the balloon can be inflated and deflated independently with or without the presence of a guidewire. The balloon catheters are available in different sizes and lengths and incorporate radiopaque markers to facilitate fluoroscopic visualization and indication of the balloon position. The balloon incorporates a distal air-purge hole to purge air from the inflation lumen prior to use. The Scepter C and Scepter XC Occlusion Balloon Catheters are intended for single use only. Do not resterilize or reuse the balloon catheters. After use, dispose of the catheter in accordance with hospital, administrative and/or local government policy. Do not use the balloon catheters if the sterile package is breached or damaged. Scepter Mini Occlusion Balloon Catheter: The Scepter Mini Occlusion Balloon Catheter is a dual lumen catheter with an external hydrophilic coating applied to the distal 100 cm of the device. The guidewire lumen is provided for guidewire introduction and delivery of agents. The inflation lumen is used exclusively for the inflation and deflation of the balloon. The guidewire lumen of the balloon catheter is compatible with 0.008 inch or smaller guidewire, and the balloon can be inflated and deflated independently with or without the presence of a guidewire. The balloon catheter incorporates two radiopaque marker bands to facilitate fluoroscopic visualization and indication of the balloon position. The balloon incorporates a distal air-purge hole to purge air from the inflation lumen prior to use. The Scepter Mini Occlusion Balloon Catheter is intended for single use only. Do not resterilize or reuse the balloon catheter. After use, dispose of the catheter in accordance with hospital, administrative and/or local government policy. Do not use the balloon catheter if the sterile package is breached or damaged. Schematic illustrations of Scepter devices are provided below.

Device Description	
	Figure 1-1: Scepter C, XC Catheter  Figure 1-2: Scepter Mini Catheter 
Design Characteristics of the Device	The Scepter devices achieve their intended use through the following principles of operation. In most cases, a guide sheath is placed in the femoral artery to gain access. Then a guiding catheter and guidewire are placed through the sheath and are used to navigate into the neurovasculature. This guidewire is removed since it is typically an 0.035" or larger outer diameter (OD) select type of wire. The balloon catheter is then advanced over a micro guidewire to the target location for treatment. The balloon can be inflated for occlusion and deflated for removal or repositioning. The balloon's soft, compliant properties allow it to automatically occlude a vessel by expanding to take the shape of the vessel. Diagnostic agents such as contrast media or therapeutic agents such as embolic materials can be delivered through the guidewire lumen. The other lumen is used for balloon inflation/deflation only. Once the treatment is complete, the balloon is deflated and removed from the patient through the guiding catheter. The Scepter Occlusion Balloon Catheters are categorized per ISO 10993-1 as an externally communicating medical device with direct intravascular tissue and circulating blood path contact for a limited patient contact duration (≤ 30 minutes in a typical clinical application, thus < 24 hours per the ISO guideline).
Previous Generations or Variants, if applicable	This is the first generation of these products.

Device Description	
Single use – sterilization method	The device is single use only. The device is sterilized using 100% ethylene oxide (EtO)
Description of Accessories	The Scepter Occlusion Balloon Catheters are packaged with one introducer sheath and one catheter stylet. The introducer sheath is a simple split-away tube that allows for the Scepter balloon catheter to be more easily inserted into a larger guide catheter. The catheter stylet serves to prevent the catheter from being damaged during shipping. It is removed from the catheter before use. The Scepter C and XC are also packaged with a shaping mandrel. The Scepter Mini does not come with a shapeable tip, so a shaping mandrel is not included.
Description of other Devices or Products intended to be used in combination	- Scepter C and XC balloon catheters are compatible with .014" (0.36mm) or smaller guidewires. Scepter Mini balloon catheter is compatible with .008" (0.20mm) or smaller guidewires. Guidewires are not required for inflation of the balloon. - Scepter C, XC, and Mini balloon catheters are compatible with guiding catheters with a minimum inner diameter larger than or equal to 0.053" (1.35mm). The maximum outer diameter of the Scepter Mini balloon catheter is 0.037" (0.94mm). The maximum outer diameter of the Scepter C and Scepter XC balloon catheters is 0.038" (0.97mm). - Scepter C, XC, and Mini balloon catheters are compatible for use with dimethyl sulfoxide (DMSO). Scepter C and Scepter XC balloon catheters have been verified to be compatible for use with diagnostic agents (such as contrast media) and liquid embolic agents (i.e. Onyx Liquid Embolic System). For all other liquid embolics, refer to their Instructions for Use.

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the Scepter devices 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. The overall residual risk is deemed acceptable and the benefit from using the device outweighs the overall residual risk.

Undesirable effects are addressed in the IFU as potential complications, which include but are not limited to:

- Vessel or Aneurysm perforation
- Vasospasm
- Hematoma at the site of entry
- Embolism

- Ischemia
- Intracerebral/intracranial hemorrhage
- Pseudoaneurysm
- Seizure
- Stroke
- Infection
- Vessel dissection
- Thrombus formation
- Death

Exposure to angiographic and fluoroscopic X-radiation presents potential risks of alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase.

1.4.2 Warnings and Precautions

WARNINGS

The following Warnings are relevant to the Scepter Occlusion Balloon Catheters:

- Verify the size of the vessel under fluoroscopy. Ensure that the balloon catheter is appropriate for the size of the vessel.
- Do not exceed the maximum recommended inflation volume, as balloon rupture may occur.
- The balloon catheter has been tested for compatibility or use with Onyx™ Liquid Embolic System and DMSO. For all other liquid embolics, refer to their Instructions For Use.
- The balloon catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.
- Viscosity and concentration of contrast will affect balloon inflation and deflation times.
- During preparation, do not deflate the balloon unless the distal tip is submerged in saline or contrast to prevent air from entering the balloon.
- Do not attach any high-pressure devices to the balloon inflation port, as this may rupture the balloon.
- Do not inflate the balloon with air or any other gas while in the body.
- Do not inflate the balloon with air or any other gas while in the body.
- Improper preparation may introduce air into the system. The presence of air may inhibit proper fluoroscopic visualization.

- Excessive pressure higher than 700 PSI (4826kPa, 47.6atm) may cause leakage or rupture of the balloon catheter guidewire lumen.
- When air-purging the balloon catheter, inject fluid slowly; otherwise balloon rupture may occur.
- If back-loading the balloon catheter over a guidewire, ensure the distal tip of the balloon catheter is not damaged.
- Do not over-tighten the RHV around the balloon catheter. Over-tightening damages the catheter shaft and delays balloon inflation and deflation.
- Do not advance the balloon catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using fluoroscopic means.
- Always inflate and deflate the balloon while visualizing under fluoroscopy to ensure patient safety.
- n-BCA (n-butyl cyanoacrylate) and solutions containing ethyl esters of iodized fatty acids of poppy seed oil are not compatible with the balloon.
- 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.

The following additional Warnings are specific to the Scepter C and Scepter XC Occlusion Balloon Catheters:

- If backloading the balloon catheter over a guidewire, ensure the distal tip of the balloon catheter is not damaged.
- The shaping mandrel is not intended for use inside the body. Ensure the shaping mandrel is removed from the balloon catheter prior to introduction into the RHV or other accessories.

The following additional Warning is specific to the Scepter Mini Occlusion Balloon Catheter:

- Do not use click activated flow control switch such as FloSwitch™ with the balloon catheter.

PRECAUTIONS

The following Precautions are relevant to the Scepter Occlusion Balloon Catheters:

- Immediately prior to use, visually inspect all the sterile barrier systems that are labeled as sterile. Do not use if breaches in sterile barrier system integrity are evident, such as a damaged pouch.

- After balloon preparation for use and prior to use, re-inflate to nominal volume and inspect for any irregularities or damage. Do not use if any inconsistencies are observed.
- Verify balloon catheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physicians must be familiar with percutaneous and intravascular techniques and possible complications associated with the procedure.
- The balloon catheter has a lubricious surface and should be hydrated for at least 30 seconds prior to use. Once the balloon catheter is hydrated, do not allow it to dry.
- Exercise care in handling the balloon catheter to reduce the chance of accidental damage. With the exception of dimethyl sulfoxide (DMSO), use of other organic solvents may damage the balloon catheter and/or coating on the surface.
- DMSO-based embolization materials should only be used in accordance with their neurovascular approved intended use. Verify that the diameter of any guidewire or accessory used is compatible with the inner diameter of the balloon catheter prior to use.
- Take precautions when manipulating the balloon catheter in tortuous vasculature to avoid damage. Avoid advancement or withdrawal against resistance until the cause of resistance is determined.
- Presence of calcifications, irregularities or existing devices may damage the balloon catheter and potentially affect its insertion or removal.
- Always verify proper balloon vessel occlusion prior to and during embolic material delivery.
- Excessive torque applied to the syringe might result in damage to the Scepter hub assembly.
- Exercise necessary precautions to limit X-radiation doses to patients and operators by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.

The following additional Precautions are specific to the Scepter C and Scepter XC Occlusion Balloon Catheters:

- Protect the balloon when tip steam shaping or purge hole sealing of the balloon catheter as it may affect the integrity of the balloon material.
- Sealing the purge hole prior to embolic material delivery may provide assistance during use.

- Continuing negative aspiration after the balloon is fully deflated will result in blood entering the balloon and will reduce fluoroscopic visibility.

There are no additional Precautions specific to the Mini Occlusion Balloon Catheter.

1.4.3 Potential Complications / Adverse Effects

The potential complications for the Scepter Occlusion Balloon Catheters, per the Instructions for Use, state that potential complications include, but are not limited to:

- Vessel or Aneurysm perforation
- Vasospasm
- Hematoma at the site of entry
- Embolism
- Ischemia
- Intracerebral/intracranial hemorrhage
- Pseudoaneurysm
- Seizure
- Stroke
- Infection
- Vessel dissection
- Thrombus formation
- Death

Exposure to angiographic and fluoroscopic X-radiation presents potential risks of alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase.

1.4.4 Other Aspects of Safety

None. There were no field safety actions during the review period for the Scepter Occlusion Balloon Catheters.

1.5 Summary of the Clinical Evaluation and PMCF

A clinical evaluation of the Scepter devices 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 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 Scepter Occlusion Balloon Catheters.

1.5.1 Equivalent Device Clinical Data

Equivalency is not claimed in the clinical evaluation for the Scepter devices.

1.5.2 Pre-CE-Mark Clinical Data

There were no pre-market clinical investigations conducted for the Scepter devices.

1.5.3 Clinical Data

Clinical data sources to evaluate the safety and performance of the Scepter devices included published peer-reviewed clinical literature and post market surveillance data, which are also the general post market clinical follow-up activities for this device. There were no post-market clinical studies conducted for the Scepter devices.

Clinical evidence was identified, collected and appraised from published peer reviewed literature obtained via a systematic search for the Scepter Occlusion Balloon Catheters. The clinical literature review identified 63 publications with clinical data for the Scepter devices, comprising 26 retrospective studies, 8 case series, and 29 case reports. The Scepter devices were used in 882 patients for treatment of aneurysms, both ruptured and unruptured; arteriovenous malformations; and various arteriovenous fistulae. There were also 29 articles that reported Scepter devices in off label uses based on the IFU, primarily pediatrics and angioplasty.

From this clinical literature, technical or procedural success averaged 95.8%, and immediate complete occlusion, after the Scepter devices facilitated primary treatment, averaged 82.0%, which was comparable to the standard of care. Further, the reported complications/ rates for procedures in which the Scepter devices were used were comparable to the standard of care, and no new risks were identified.

1.5.4 Clinical Performance and Safety

The clinical safety data collected from published literature and post-market surveillance demonstrate the overall safety of the Scepter devices. The literature review demonstrated acceptable clinical safety outcomes with no new risks found. The post-market surveillance data demonstrates low rates of reportable complaints. The data collected is sufficient to determine that the Scepter devices do 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 from published literature and post-market surveillance demonstrates the overall performance of the Scepter devices. The literature review demonstrated acceptable clinical performance outcomes, shown in high technical success rates

for the device, which is supported by the post-market surveillance showing no new unanticipated, emerging, or unacceptable risks. The data collected is sufficient to determine that the Scepter devices achieve the performance intended and are suitable for the intended purpose.

The clinical safety and performance outcomes for Scepter Occlusion Balloon Catheters were comparable to the standard of care and the benefit-risk ratio of these devices is acceptable.

1.5.5 Post-Market Clinical Follow-up

Post market clinical follow-up (PMCF) activities include ongoing review of the published clinical literature and PMS data for the Scepter Occlusion Balloon Catheters. Additional clinical data may be obtained from an observational registry. The PMCF data will be evaluated for safety, performance and benefit/ risk of the device as it is available.

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

Balloon catheters can be used in the peripheral and neuro vasculature where temporary occlusion is desired, or for the infusion of diagnostic agents; they are mostly used in the neurovasculature. Usage is to facilitate treatment or diagnosis of medical conditions, primarily intracranial aneurysm, arteriovenous malformation, and arteriovenous fistula. The ability to access or reach the treatment site is critical to the success of the primary intervention. Various access sites, including transradial, tranfemoral, brachial, and direct carotid puncture, may be used. Once access is obtained, various primary therapeutic devices may be used to treat intracranial or peripheral aneurysms, or other vascular anomalies, including arteriovenous malformations (AVM) or arteriovenous fistulae.

Balloon occlusion catheters are standard of care medical devices with various types and styles available from different manufacturers. Balloon catheters are used to assist in the primary treatment interventions for aneurysm, AVM, and AVF. For example, during endovascular coiling to treat an aneurysm, the balloon is inflated across the aneurysm neck during placement of coils, and a balloon catheter can also be used to provide temporary occlusion of the parent artery if there is aneurysm rupture during coiling (Campos, 2020).

1.6.2 Available Technologies

The **Table 1.4** lists similar devices for the Scepter Occlusion Balloon Catheters. Balloons have become more compliant over time and the similar devices listed below as well as the Scepter

Occlusion Balloon Catheters are commonly used; the similar devices are all single lumen balloons while the Scepter Occlusion Balloon Catheters are dual lumen.

Table 1.4 Similar Devices

Device	Manufacturer	Intended Purpose
HyperForm™ HyperGlide™ Occlusion Balloon Catheter	Medtronic	The HyperForm™ and HyperGlide™ occlusion balloon catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow; the occlusion balloon catheters may also be used in balloon-assisted embolization of intracranial aneurysms and treatment of vasospasm.
Transform™ Occlusion Balloon Catheter	Stryker	The Stryker Neurovascular TransForm Occlusion Balloon Catheters are indicated for use in the neuro and peripheral vasculature to temporarily stop or control blood flow and for balloon assisted embolization of intracranial aneurysms.

1.7 Suggested Profile and Training for Users

Physicians must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

1.8 Reference to any Harmonized Standards and CS

The Scepter devices were designed, developed, and tested following the standards and guidance documents listed in the table below.

Table 1-5 Relevant Standards

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)
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)
EN ISO 14155	2020/A11:2024	Clinical investigation of medical devices for human subjects - Good clinical practice
ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers
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

Standard Number	Edition	Standard Title (equivalent edition)
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 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
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 10993-23	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)
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)

Standard Number	Edition	Standard Title (equivalent edition)
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 10555-1	2013A1:2017	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements (ISO 10555-1:2013A1:2017)
EN ISO 10555-4	2013	Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters (ISO 10555-4:2013)
EN ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)
EN ISO 80369-20	2015	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (ISO 80369-20:2015)
ASTM F640	2023	Standard test methods for determining radiopacity for medical use
ANSI T564	2021	Transparent Chart for the Estimation of Defect Size

1.9 References Cited

CAMPOS, J. K., LIEN, B. V., WANG, A. S., LIN, L. M. 2020. Advances in endovascular aneurysm management: Coiling and adjunctive devices. *Stroke and Vascular Neurology*, 14–21.