Summary of Safety and Clinical Performance

for

Low-Profile Visualized Intraluminal Support Device(LVIS™)

SSCP22-0008

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NA

DOCUMENT CHANGE HISTORY

Revision	Date	Description	NB approved/verified
A	22 July 2025	Initial Release	☐Yes ☒ No* Validation language:

*Annual entries must be included. If a revision is not required, an entry stating such must be added.

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1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

This Summary of Safety and Clinical Performance (SSCP) is intended to ZZZprovide 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

<table>
<tr><th colspan="2">Device Names</th></tr>
<tr><td>Device Trade Name</td><td>LVIS Devices (LVIS, LVIS X, LVIS Jr, LVIS Jr X, LVIS EVO, and LVIS EVO X.)</td></tr>
<tr><td>EMDN Code</td><td>P0799</td></tr>
<tr><td>Medical Device Nomenclature (EMDN or GMDN Description)</td><td>Vascular and Cardiac Protheses-Other</td></tr>
<tr><td>Device Class</td><td>III</td></tr>
<tr><td>Basic UDI-DI</td><td>08402732LVISLL</td></tr>
<tr><td>Year when first certificate (CE) was issued for the device</td><td><table><tr><th>Devices</th><th>CE Certification Year</th></tr><tr><td>LVIS and LVIS Jr</td><td>June 2011</td></tr><tr><td>LVIS EVO</td><td>July 2019</td></tr><tr><td>LVIS X/LVIS Jr. X/LVIS EVO X</td><td>May 2020</td></tr></table></td></tr>
<tr><th colspan="2">Legal Manufacturer</th></tr>
<tr><td>Name & Address</td><td>MicroVention, Inc.35 Enterprise
Aliso Viejo, California, 92656 USA</td></tr>
<tr><td>Manufacturer SRN</td><td>US-MF-000016658</td></tr>
<tr><th colspan="2">Authorized Representative</th></tr>
<tr><td>Name & Address</td><td>MicroVention Europe SARL
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye, France</td></tr>
<tr><td>Authorized Representative SRN</td><td>FR-AR-000004448</td></tr>
<tr><th colspan="2">Notified Body</th></tr>
<tr><td>Name & Address</td><td>DQS Medizinprodukte GmbH
D-60433 Frankfurt am Main
Germany</td></tr>
<tr><td>Notified Body Identification Number</td><td>0297</td></tr>
</table>

1.2 Intended Purpose of the Device

Table 1.2 Intended Use

Intended Purpose	
Intended Purpose	The LVIS Devices (implant and delivery device) are designed as stent-assisted coiling (SAC) devices and are intended for use with embolic coils for the treatment of intracranial neurovascular diseases.

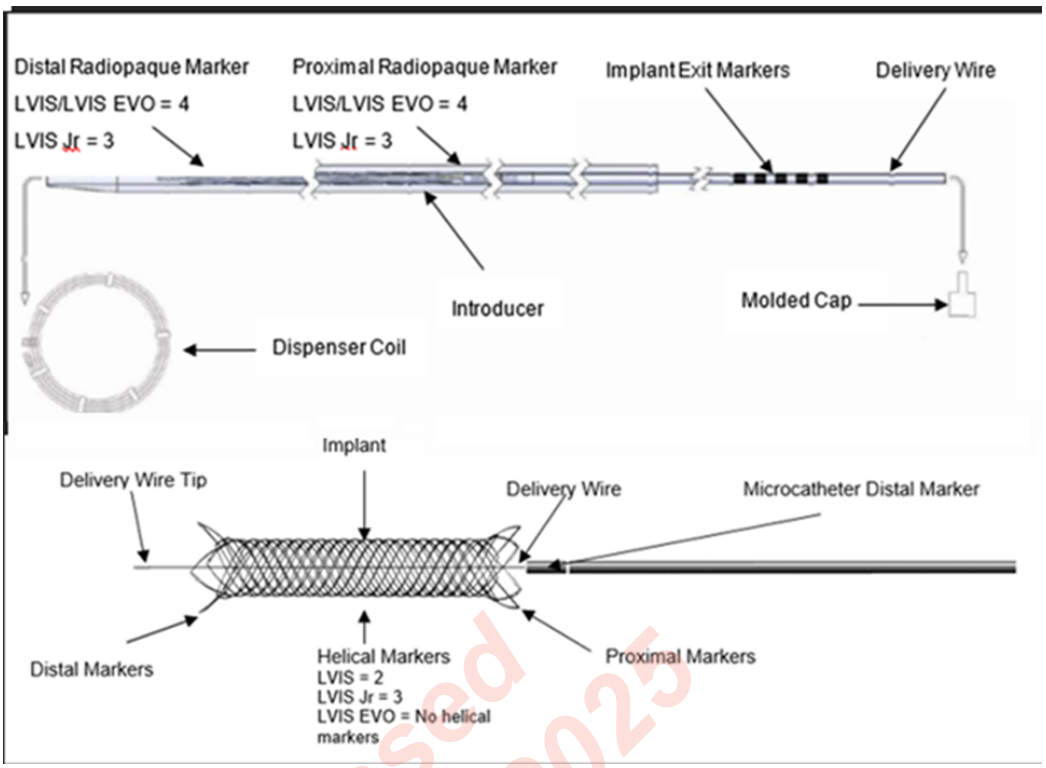
Indications for Use	The LVIS, LVIS Jr, LVIS EVO, LVIS X, LVIS Jr. X and LVIS EVO X devices are intended for use with embolic coils for the treatment of intracranial neurovascular diseases.
Target Population	The LVIS Devices (implant and delivery device) are intended to be used in patients with intracranial aneurysms and other neurovascular diseases, in which endovascular coil embolization is determined to be the treatment modality and coil assist stent is required to provide support to the embolic coils to prevent coil loops from protruding into the parent artery of intracranial aneurysms.
Contraindications and/or Limitations	• Patients in whom anticoagulant, antiplatelet therapy or thrombolytic drugs are contraindicated • Patients with known hypersensitivity to metal, such as nickel-titanium and metal jewelry • Patients with anatomy that does not permit device passage or deployment • Patients with an active bacterial infection • Patients with a pre-existing stent in place at the target aneurysm (LVIS/LVIS EVO/LVIS X/LVIS EVO X devices only)

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	The MicroVention Low-profile Visualized Intraluminal Support (LVIS) device is a self-expanding nickel titanium (LVIS/LVIS X/LVIS Jr./ LVIS Jr.X)/or with platinum core (LVIS EVO and LVIS EVO X). The device consists of: 1. A self-expanding nitinol implant with tantalum radiopaque markers. 2. A delivery system consisting of a delivery pusher and an introducer sheath. Therefore, all references to the LVIS Device throughout this document includes both the nitinol implant and its associated delivery device. *Note- both devices are required to be used together and are specifically designed to work together. The high metal coverage and small pore size of the LVIS stents provide consistent support of coil mass including small finishing coils. The LVIS and LVIS X are deliverable through a 0.021" ID microcatheter whereas the LVIS Jr./LVIS Jr. X/LVIS EVO/LVIS EVO X Device is deliverable through a 0.017" ID microcatheter including the MicroVention Scepter C/XC balloon microcatheter. The nitinol Drawn Filled Tube (DFT) technology with platinum core designed for the LVIS EVO optimizes the device stent visibility. The surface – treated and corresponding surface – untreated LVIS (LVIS/LVIS X, LVIS Jr./LVIS Jr. X and LVIS EVO/LVIS EVO X) Devices utilize the same fundamental design, construction and principal mode of operation. • Self-Expanding Nitinol Implant

Device Description	
	The nitinol implant (LVIS, LVIS Jr., LVIS X, LVIS Jr. X) or nitinol with platinum core (LVIS EVO, LVIS EVO X) has a tubular woven mesh, closed cell structure, with flared ends. The LVIS EVO Device is designed to have short closed flared ends for flexibility in landing zone planning. Two (LVIS, LVIS X) or three (LVIS Jr., LVIS Jr. X) radiopaque tantalum wires are woven into the implant in a helical configuration. In addition, the implant has four (LVIS, LVIS EVO, LVIS EVO X) or three (LVIS Jr., LVIS Jr. X) radiopaque tantalum coil markers at each end to aid in stent placement under fluoroscopy. The LVIS X model series, including LVIS X, LVIS Jr. X, and LVIS EVO X, have additional surface treatment, processed with chemical functionalization using silane compound (3-bromopropyltrimethoxysilane) and poly (MEA-co-APMA). The functional layer is less than 10 nm thick and a reduced advancement/retraction force after the surface treatment has been demonstrated by the functional device testing. There is no change in the design of the braided stent. • Delivery System The delivery system is composed of an introducer and a delivery pusher: The introducer consists of a polymer tube with a tapered end. The introducer is used to protect the stent in the package and facilitates the introduction of the device into the microcatheter hub. The delivery pusher is composed of a mandrel (corewire) tapered proximal to distal. The two proximal markers are used as the delivery mechanism. The proximal end of the stent is located between the two proximal markers. The distal segment of the pusher has three radiopaque markers. The distal-most coil marker is used to indicate the distal end of the delivery wire and also indicates the distal end of the implant when it is fully crimped. Co-axial stainless-steel coils are wound on the outside of the proximal tapered portion of the mandrel to facilitate advancement and retraction of the stent. On the proximal end of the delivery wire, there are fluor-safe marks that indicate when the stent will exit the distal end of the microcatheter, and fluoroscopy must be initiated. The delivery pusher is designed to secure the implant by mechanical means and release the implant at the target lesion.

Device Description	
	 The LVIS Device does not incorporate a medicinal substance, animal tissues, or blood products.
Design Characteristics of the Device	The Low-Profile Visualized Intraluminal Support Devices (LVIS Devices) are expandable, braided coil assist stents used for the treatment of intracranial neurovascular diseases. The braided wire construction offers operator a controlled release of the stent implant during deployment for optimal placement. The stent design also allows the braided wire construction to expand to a pre-determined diameter to conform to the vessel wall when released from the delivery system. With the stent-assisted technique, the neurovascular stent is placed across the aneurysm neck, to prevent coil prolapse into the parent vessel bearing the aneurysm. The stent can also serve as a scaffold for neointima deposition across the aneurysm neck. Stenting may allow the operator to more safely achieve a higher packing density of coils. These more thoroughly packed aneurysms are likely better protected against future re-canalization and rupture. These factors are intended to improve the rates of complete aneurysm occlusion and enhance the overall durability of the coiling treatment.
Previous Generations or Variants, if applicable	Design Change History: Only those design changes that may affect safety and performance are addressed. • Description of the Change: Modification of stent braid pattern (Picks per Inch - PPI). • Year of the Change: 27 Jan 2015 • Reason for the change: The increased PPI improved stent opening. *LVIS RD14-001 has a different PPI (picks per inch; another way of describing braiding pattern) from predicate LVIS design, LVIS RD08-001/RD12-025.

Device Description	
Single use – sterilization method	The device a single use device and sterilized by using E-Beam radiation.
Description of Accessories	Other accessories for performing a procedure and NOT supplied; to be selected based on the physician's experience and preferences: • Appropriate-sized Guiding catheter for use with selected microcatheter • Headway® 17 microcatheter or Scepter C® / Scepter XC® Occlusion Balloon • Guidewires • Saline solution/heparin-saline solution continuous flush set • Contrast solution • Rotating Hemostatic Valve (RHV) • Pressurized sterile Infusion solutions – IV stand • Femoral arterial sheath, compatible with delivery guide catheter • Femoral artery access device, sterile needle, guidewire
Description of other Devices or Products intended to be used in combination	The following parts are required to use the LVIS EVO X device: • LVIS EVO X device should be introduced only by means of a Headway® 17 Microcatheter (0.017-inch inner diameter) or Scepter C® / Scepter XC® Occlusion Balloon.

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the LVIS 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 LVIS, LVIS Jr., LVIS EVO, LVIS X, LVIS Jr. X, LVIS EVO X devices are:

- Additional procedure/treatment required
- Anaphylaxis
- Aneurysm rupture/perforation
- Blockage other than target vessel
- Death
- Embolic Stroke
- Hemorrhage (Intracerebral/Intracranial hemorrhage)
- Inability to treat or diagnose patient
- In-complete embolization
- Increased procedure time (< 15 minutes)
- Infection and/or fever Inflammatory complication

- Ischemic stroke
- Ischemic stroke/ Ischemia
- Neurological Deficit
- Non-abrupt headache
- Non-abrupt headache
- Product migration
- Pseudoaneurysm
- Thromboembolic Stroke
- Toxic Reactions
- Undesirable clot formation (embolism/thrombus formation)
- Vessel/tissue damage and/or perforation

1.4.2 Warnings and Precautions

The warnings / precautions for the LVIS, LVIS Jr., LVIS EVO, LVIS X, LVIS Jr. X, LVIS EVO X devices are

- Should unusual resistance be felt at any time during access or removal, the introducer/guide catheter/microcatheter and LVIS device should be removed as a single unit. Applying excessive force during delivery or retrieval of the LVIS device can potentially result in loss or damage to the device and delivery components.
- The LVIS device should only be used by physicians trained in endovascular interventional neuroradiology, radiology, neurosurgery or interventional neurology for the treatment of intracranial aneurysms or other vascular lesions.
- It is imperative to use the LVIS device with compatible microcatheters. If repeated friction is encountered during LVIS device delivery, verify microcatheter is not kinked or in extremely tortuous anatomy. Confirm that the microcatheter does not ovalize. Confirm that there is an adequate sterile flush solution.
- Do not reposition the LVIS device in the parent vessel without fully retrieving the device. The LVIS device MUST be retrieved into the microcatheter and re-deployed at the desired target location or removed completely from the patient.
- Do not attempt to re-position the LVIS implant after detachment.
- Do not shape the tip of the delivery wire.
- Do not torque the delivery wire while advancing or retracting the LVIS Jr. X device. A torque device should not be used (LVIS Jr X only)

The Precautions:

- This product should only be used by experienced physicians who have completed endovascular training in the use of the LVIS device for angiographic, percutaneous

neurointerventional and peripheral vascular procedures as prescribed as prescribed by a representative from MicroVention-Terumo or a MicroVention-authorized distributor.

- The LVIS device is provided sterile 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.
- Carefully inspect the sterile package and the LVIS device prior to use to verify that neither has been damaged during shipment. Do not use kinked or damaged components, or if the packaging is damaged.
- See the product label for the device shelf life. Do not use the device beyond the labeled use by date.
- Exercise caution when crossing the deployed/detached LVIS device with adjunctive devices such as guidewires, catheters, microcatheters or balloon catheters to avoid disrupting the device geometry and device placement.

1.4.3 Potential Complications / Adverse Effects

The potential complications / adverse effects for the LVIS, LVIS Jr., LVIS EVO, LVIS X, LVIS Jr. X, LVIS EVO X devices are:

- Hematoma at the puncture site
- Perforation or dissection of the vessel(s)
- Intravascular spasm
- Hemorrhaging
- Rupture or perforation of aneurysm
- Coil herniation
- Device migration
- Neurologic insufficiencies including stroke and death
- Ischemia
- Vascular occlusion
- Vessel stenosis
- Incomplete aneurysm occlusion
- Pseudoaneurysm formation
- Distal Embolization
- Headache
- Infection
- Reaction to contrast agents including severe allergic reactions and renal failure

1.4.4 Other Aspects of Safety

Corrective and Preventive Action

A summary of all Corrective and Preventive Actions (CAPA) occurring during the evaluation period of 01 May 2020 to 30 April 2024 is listed in Table below. Of the three (3) CAPAs, one (1) has been closed, one (1) is in the investigation phase, and one (1) is in the implementation phase.

Corrective Action: CAPAC22-0006

Initiation Date: March 3, 2022
Scope: LVIS EVO
Status: Closed
Manufacturer Reference Number: CAPAC22-0006

This CAPA was initiated following a retrospective review of vigilance reports conducted by the Field Assurance team in Q4 of 2021. The review determined that 12 MedWatch reports were required for six LVIS EVO complaints. The issue related to the lack of defined methodology in Work Instruction WI8.3.2 Rev. E (U.S. Medical Device Reporting, Section 5.3.1 and Appendix 1) for determining device similarity to an approved product, even though the criteria themselves were clearly stated.

Root Cause:
While the criteria for determining product similarity were well defined, the work instruction did not include a clear process for executing the determination steps.

Effectiveness of CAPA:
The corrective action has been completed and deemed effective.

Corrective Action: CAPAC24-002

Initiation Date: March 20, 2024
Scope: LVIS, LVIS EVO, LVIS Jr
Status: Under Investigation
Manufacturer Reference Number: CAPAC24-002

This CAPA is currently under investigation. Between May 2023 and February 2024, nine complaints were reported involving stent pusher separation issues across the LVIS product line, including LVIS, LVIS EVO, and LVIS Jr. The specific failure modes cited were "Delivery Wire Detached/Separated" (ST3) and "Delivery System Tip Separation" (ST27).

Root Cause:
Still under investigation.

Effectiveness of CAPA:
Not applicable at this time, as the CAPA has not yet been closed.

Corrective Action: CAPAC24-001

Initiation Date: March 4, 2024
Scope: LVIS Jr, LVIS EVO
Status: Implementation
Manufacturer Reference Number: CAPAC24-001

This corrective action addresses seven complaints received from February 2023 through January 2024 related to improper stent loading orientation for the LVIS and LVIS EVO systems.

Root Cause:
The issue was attributed to incomplete and unclear instructions in multiple manufacturing and quality system documents, including MP11555, MP12162, and QS022 (LVIS D). These documentation deficiencies contributed to procedural errors during device assembly or preparation.

Effectiveness of CAPA:
To be determined; the CAPA is currently in the implementation phase.

Field Actions and Recalls

Field Actions are conducted in accordance with the Field Corrective Actions (SOP 8.7) procedure. During the time period covered by this PSUR (01 May 2020 to 30 April 2024) there were no Field Actions involving the LVIS family of devices.

1.5 Summary of the Clinical Evaluation and PMCF

1.5.1 Equivalent Device Clinical Data

Equivalency is not claimed in the clinical evaluation for the LVIS Devices.

1.5.2 Pre-CE-Mark Clinical Data

There were no pre-market clinical studies conducted for the LVIS Devices.

1.5.3 Clinical Data

Clinical data from scientific literature

A total of 77 publications on the use of LVIS devices were included in previous clinical evaluations report. From the additional systematic literature search, 16 additional publications were identified

for the period i.e., 01 May 2021 to 30 April 2025 resulting in a total of 93 publications on the use of LVIS devices.

Clinical Data from Post-Market Surveillance

For the evaluation period of 01 May 2020 to 30 April 2024, 97,722 units of the LVIS Devices been sold worldwide and received 1,461 product complaints concerning the LVIS Devices, resulting in a complaint rate of 1.49%. Of these complaints, 157 were considered reportable to EU authorities for a reportable complaint rate of 0.16%. There were zero reported complaints/adverse events, field actions or recalls pertinent to the LVIS Devices in BfArM, MHRA and EUDAMED.

1.5.4 Clinical Performance and Safety

The literature search detailed in this report presents relevant clinical data from the scientific literature for the LVIS Devices. The literature search was performed with high methodological quality, scientific validity, and relevance to the fields of use.

A total of 93 studies evaluating the clinical efficacy and safety of LVIS devices were included in the analysis. Of the 93 articles, there was one (1) randomized controlled study, 80 retrospective studies, one (1) case control study and 12 case series. The literature search results demonstrated clinical use of the LVIS Device for the treatment of intracranial neurovascular diseases in 7897 patients.

Technical success was reported in 56 articles ranging from 92%-100%, with 47 of them reporting a 100% success rate. Four (4) of these studies reported the 100% technical success rate with the LVIS device for >200 patients (Long, 2024; Jiang, 2022; Su, 2018; Xue, 2020). The study that reported a 92% technical success rate used a balloon-assisted stent deployment technique, which reflects challenges with deployment rather than device failure, as all patients ultimately received successful stent placement (Mosimann, 2024). Another study reported 93.2% success due to incomplete stent opening in tortuous or calcified vessels, again reflecting anatomical complexity rather than device malfunction (Vollherbst, 2021). These findings support consistently high technical success rates for the LVIS Device family. Variations were attributed to procedural complexity, reinforcing the reliability and effectiveness of the devices when used as intended.

Angiographic occlusion rate is a factor to measure successful embolization of aneurysms. Immediate angiographic results were graded using the Modified Raymond-Roy Classification (mRRC) and the Raymond–Roy occlusion classification (RROC).

Immediate complete occlusion was reported in 56 articles. Two (2) articles reported 100% immediate occlusion, and 44 articles reported immediate complete occlusion ranging from 40.6%-97% (Ponculijusz, 2020; Sirakov, 2020). The rest of the 10 articles reported a very low immediate complete occlusion rate either because they are case reports, or because they have a high near-

complete occlusion rate but low complete occlusion rate. (Wang, 2017; Aihara, 2021; Okuma, 2021; Turner, 2013; Feng, 2016; Zhu, 2017; Wallace, 2019; Kadziolka, 2013).

The modified Rankin scale (mRS) is a commonly used scale to assess clinical outcome and measures functional independence instead of performance of specific tasks. The modified Rankin Scale (mRS) scores range from 0 to 6: 0 indicates no symptoms; 1–2 reflect slight disability but independence; 3–5 indicate increasing levels of disability and dependence; and 6 represents death.

Clinical outcome mRS (0-2) was reported in 52 articles. Of them, 14 articles reported a 100% rate of good clinical outcomes (Feng, 2016; Wang, 2017; Wallace, 2019; Poncyljusz, 2020; Ge, 2016; Zhang, 2016; Feng, 2015; Gupta, 2017; Park, 2019; Wu, 2023; Boddu, 2019; Oishi, 2020; Samaniego, 2016; Sirakov, 2020). Furthermore, 50 articles reported clinical outcome mRS (0-2) ranging from 70.8%-99.2% at a follow up from immediate post-operation to 29.6 months. The two (2) articles reported low mRS (0-2) score either because they are case reports or low enrolled patient numbers (Aihara, 2021; Okuma, 2021).

The above-listed studies are serving the purpose of PMCF studies to provide sufficient data to demonstrate or confirm the medium/long-term safety and performance of the LVIS Devices, and to identify possible residual risks that may impact the benefit/risk ratio. In this case, the purpose of PMCF has already been met.

Of the 711 number of references found in the database searches, 19 cited uses of the Subject Device in a manner that is not consistent with the intended use as defined by the manufacturer. These references were excluded per the pre-determined exclusion criteria and not used in the evaluation of safety and performance for the subject device. The review of these references is to ensure there is no misuse of the subject device.

1.5.5 Post-Market Clinical Follow-up

1.5.5.1 Completed Post-Market Clinical Investigations

A total of 15 post market studies were conducted for LVIS or/with LVIS Jr devices in patients with intracranial aneurysms. Of them, seven (7) were Microvention sponsored studies and eight (8) were investigator sponsored studies.

1.5.5.2 Planned/Ongoing/Unknown Status Post-Market Clinical Investigations

A total of 8 ongoing/unknown status studies were conducted for LVIS devices in patients with intracranial aneurysms. Of them, three (3) were Microvention sponsored studies and the other five (5) were investigator sponsored studies.

The above-listed studies are serving the purpose of PMCF studies to provide sufficient data to demonstrate or confirm the medium/long-term safety and performance of the LVIS Devices, and to identify possible residual risks that may impact the benefit/risk ratio. In this case, the purpose of PMCF has already been met.

1.6 Possible Diagnostic or Therapeutic Alternatives

This newer treatment approach is reported to achieve approximately 80% occlusion rates, with a 10% recurrence and 10% retreatment rate (Lee et al., 2022a). It offers the benefit of sparing surrounding perforators and does not require antiplatelet therapy post-procedure.

However, its use is limited by certain aneurysm-specific factors, such as tortuous vascular anatomy (e.g., anterior communicating artery aneurysms) that can make device navigation difficult. Intrasaccular flow disruptors are especially indicated for wide-necked aneurysms, bifurcation aneurysms, and sidewall aneurysms that are unsuitable for coiling, BAC, or SAC.

1.6.1 Available Technologies

The neurovascular stents approved for stent-assisted coiling, such as those listed in the table below. Similar Devices are well established medical devices with numerous types and styles available from a variety of manufacturers. A few examples of the neurovascular stents approved for stent-assisted coiling similar to the LVIS devices.

Table 1.4 Similar Devices

Similar Device	Manufacturer	Intended Use
Neuroform Atlas Stent System	Stryker	The Neuroform Atlas Stent System is indicated for use with neurovascular embolization coils in the anterior circulation of the neurovasculature for the endovascular treatment of patients ≥ 18 years of age with saccular wide-necked (neck width ≥ 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of ≥ 2.0 mm and ≤ 4.5 mm.
Solitaire AB	Medtronic	The SOLITAIRE AB Neurovascular Remodeling Device is designed for use as an adjunctive device in the treatment of intracranial aneurysms.

1.7 Suggested Profile and Training for Users

The LVIS Devices (implant and delivery device) are only to be used by physicians trained in endovascular angiographic, percutaneous neurointerventional and peripheral vascular procedures

as prescribed by a representative from MicroVention-Terumo or a MicroVention-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)
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)
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 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

Standard Number	Edition	Standard Title (equivalent edition)
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)
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

Standard Number	Edition	Standard Title (equivalent edition)
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)
ISO 11737-3	2023	Sterilization of health care products - Microbiological methods - Part 3: Bacterial Endotoxin testing
EN ISO 11137-1	2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006/Amd 2:2018)
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)
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 G16	2013R2019	Standard Guide for Applying Statistics to Analysis of Corrosion Data
ASTM F2081	2006R2022	Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents
ASTM F2477	2023	Standard Test Method for in vitro Pulsatile Durability Testing of Vascular stents
ASTM F640	2023	Standard test methods for determining radiopacity for medical use
ASTM F2052	2021	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

Standard Number	Edition	Standard Title (equivalent edition)
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

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