Summary of Safety and Clinical Performance

for

VIA™ Microcatheter

SSCP-1103803

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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	VIA Microcatheter
EMDN Code	C0104020202
Medical Device Nomenclature (EMDN)	Peripheral Embolization Catheters and Microcatheters
Device Class	Class III
Basic UDI-DI	08402732VIATR (MVI)
Year when first certificate (CE) was issued for the device	Initial CE Mark of the MicroVention was in 2017.
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-000004449
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August-Schanz-Straße 21 D-60433 Frankfurt am Main Germany
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

Table 1.2 Intended Use

Intended Purpose	
Intended Purpose	VIA 17, 17 Preshaped 45°, 17 Preshaped 90° - The VIA Microcatheter is intended for the introduction of interventional devices (such as WEB device / coils / stents) and infusion of diagnostic agents (such as contrast media) into the neuro and peripheral vasculature. VIA 21, 27, 33 - The VIA Microcatheter is intended for the introduction of interventional devices (such as the WEB device/stents/flow diverters) and infusion of diagnostic agents (such as contrast media) into the neuro and peripheral vasculature.
Indications for Use	VIA 17, 17 Preshaped 45°, 17 Preshaped 90° – The VIA Microcatheter is intended for the introduction of interventional devices (such as WEB device / coils / stents) and infusion of diagnostic agents (such as contrast media) into the neuro and peripheral vasculature. VIA 21, 27, 33 – The VIA Microcatheter is intended for the introduction of interventional devices (such as the WEB device/stents/flow diverters) and infusion of diagnostic agents (such as contrast media) into the neuro and peripheral vasculature.
Target Population	The intended patient population to be treated with the VIA Microcatheter is includes those patients presenting medical conditions requiring temporary occlusion, the delivery of diagnostic agents such as contrast media, and therapeutic agents such as embolization materials, in the peripheral or neurovasculature.
Contraindications and/or Limitations	The VIA Microcatheter is contraindicated for use with liquid embolic materials, such as n-butyl 2-cyanoacrylate or ethylene vinyl alcohol & DMSO (dimethyl sulfoxide).

1.3 Device Description

Table 1.3 Device Description

Device Description

Description of the Device	The VIA Microcatheter is a single lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The physician inserts the catheter into the vein or artery through the skin (percutaneous) using a sheath or guidewire. The device can then be navigated to the treatment site. The distal 100 cm of the catheter contains a hydrophilic coating on the surface which aids navigation and assists with manipulation while in the vasculature. Throughout the procedure the physician can obtain the position of the catheter by the radiopaque marker band using fluoroscopic techniques (VIA 21, 27 and 33 Microcatheters have one radiopaque tip marker band, VIA 17 Microcatheter has 2 radiopaque tip marker band). Diagnostic and interventional devices can be delivered through the lumen of the catheter to the treatment site. The proximal end of the catheter incorporates a standard luer adapter to facilitate attachment of accessories.
Design Characteristics of the Device	The VIA Microcatheter is a sterile single lumen device designed to aid the physician in accessing distal vasculature when used with a guide catheter and steerable guidewire. Variable shaft stiffness ranging from a flexible tip to a semi-rigid proximal section aid the physician in tracking over selectively placed guidewires. The VIA Microcatheter body is constructed with an inner lubricious liner made from polytetrafluoroethylene (PTFE) which assists with delivery of interventional devices, such as neurovascular stents. A stainless steel rolled; flat wire is coiled over the inner liner. A stainless steel rolled, flat wire is braided over the coiled liner from the start of the proximal end and terminates at varied distances from the distal end depending on the model. A single radiopaque marker (for VIA 33, VIA 27, VIA 21) or dual radiopaque markers (VIA 17) positioned at the distal tip facilitates fluoroscopic visualization. This is all covered by an outer layer of varying durometers and lengths of Pebax and Vestamid – distal and proximal, respectively. A polypropylene (PP) hub is attached to the proximal end of the microcatheter over the Vestamid section to facilitate attachment of accessories. A strain relief is placed at the proximal end of the microcatheter and distal end of the hub. The strain relief consist of an inner clear polyolefin heat shrink and an outer white polyolefin heat shrink with the respective VIA size printed on it. The outer surface of the VIA Microcatheter is coated with a hydrophilic coating at 95-105 cm from the distal end to proximal shaft which reduces friction during manipulation in the vessel. The VIA Microcatheters are presented in a Tyvek pouch and are sterile, single-use only and non-pyrogenic. All VIA Microcatheters utilize the same fundamental design, construction, and principal mode of operation. The device diagrams depicted in Figure 1 provides illustrations of the device design and construction.

Figure 1.1: VIA Microcatheter Diagram

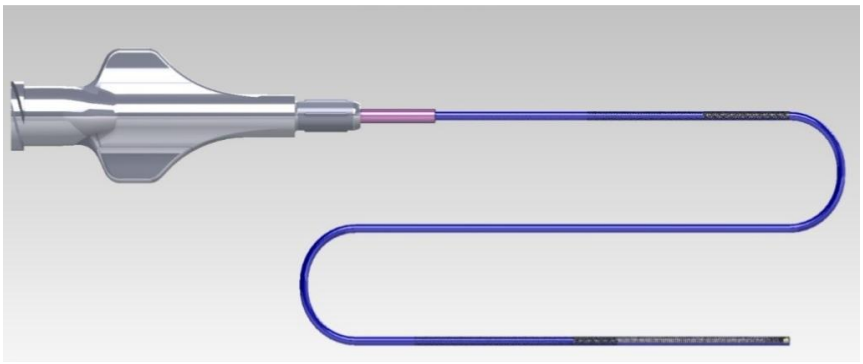

Figure 1.2: Magnified Illustration-Pebax "Cut Away" View of VIA Microcatheter

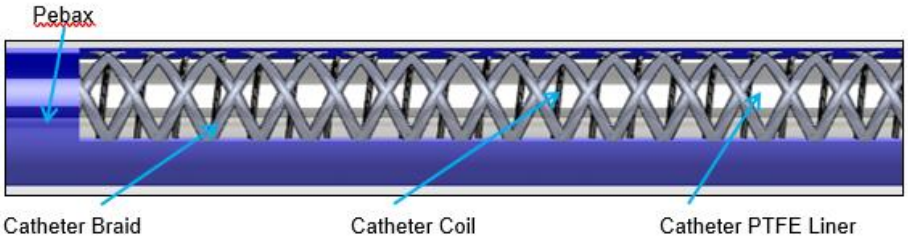

Figure 1.3: Magnified Illustration- Magnified View-VIA Microcatheter Distal Tip

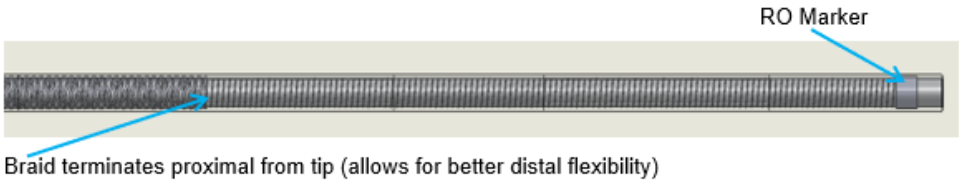

Figure 1.4: Magnified Illustration: Magnified View of VIA 17 Distal Tip

Previous Generations or Variants, if applicable	There are no previous generations.

Single use – sterilization method	The device is sterilized using 100% ethylene oxide (EtO) gas.
Description of Accessories	The following accessories are intended to be used in combination with the VIA™ Microcatheter: • One (1) straight shaping mandrel to facilitate distal tip shaping. The straight shaping mandrel (stainless steel) facilitates the steam shaping of the microcatheter distal tip into various shapes as desired by the user. • One (1) introducer sheath is provided on the packaging card. It is made of polyether block amide (Pebax). The purpose is to provide support when introducing the distal tip of the catheter into the hemostatic valve. Once the VIA™ Microcatheter distal shaft is placed inside the patient's body, the introducer is removed by peeling it away from the system. Introducer sheath is not intended for use inside the patient's body.
Description of other Devices or Products intended to be used in combination	The VIA 17, VIA 17 Preshaped 45°, and VIA 17 Preshaped 90°, VIA 21, VIA 27, and VIA 33 Microcatheters are intended for the delivery of interventional devices and infusion of diagnostic agents into the neurovascular and peripheral vasculature. They are compatible with a range of endovascular products, including: - **Intrasaccular devices** – such as the Woven EndoBridge™ (WEB™), used for treating wide-necked or bifurcation aneurysms. - **Detachable coils** – including bare platinum, hydrogel-coated, and complex-shaped coils for aneurysm embolization. - **Intracranial stents** – such as LVIS™ and LVIS Jr.™ for stent-assisted coiling procedures. - **Infusates** – including contrast agents, thrombolytics, and vasodilators for imaging or therapeutic use. - **Guidewires** – typically ≤0.014" in diameter, used for navigation through tortuous anatomy. - **Other compatible tools, etc.** – additional endovascular devices meeting dimensional and regulatory compatibility. All products used should be compatible with the microcatheter's specifications and approved for their intended use. Use of incompatible devices may compromise safety or effectiveness.

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the VIA Microcatheters 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:

- Additional procedure / treatment required
- Anaphylaxis
- Aneurysm rupture
- Blockage other than target vessel
- Death
- Hematoma / bleeding inside the brain
- Increased procedure time (< 15 minutes)
- Increased procedure time (> 15 minutes)
- Infection and/or fever
- Inflammatory complication
- Ischemic stroke / Embolic stroke
- Toxic reaction
- Vasospasm
- Vessel / tissue damage

1.4.2 Warnings and Precautions

The warnings / precautions for the VIA Microcatheter are

Warnings

CAUTION: This device should be used only by physicians trained in percutaneous, intravascular, and neurovascular techniques and procedures at medical facilities with the appropriate fluoroscopic equipment.

- The VIA Microcatheter is provided sterile and non-pyrogenic unless the unit package is opened or damaged.

- Do not use if the packaging is damaged. Use before the expiration date noted on the product packaging.

- The VIA Microcatheter is intended for single use only.

- Do not resterilize and/or reuse the device. Reuse and/or resterilization can increase risk of infection, cause a pyrogenic response or other life-threatening complications. Reuse and/or resterilization can degrade product performance, leading to device malfunction. Dispose of all devices in accordance with applicable hospital, administrative and/or local government policy.

- Never advance or withdraw a device against resistance until the cause of the resistance is determined by fluoroscopy. Excessive force against resistance may result in damage to the device or vessel perforation.

- Always monitor infusion rates when using the microcatheter.

- When injecting contrast for angiography, ensure the catheter is not kinked or occluded.

- Do not exceed 300 psi maximum recommended infusion pressure. Excess pressure may result in catheter damage or patient injury.

- Steam shaping may result in improper device delivery and deployment, depending on the degree of shaping and catheter deflection during device delivery.

- Using the VIA Microcatheter with guide catheters smaller than what is recommended may result in damaging the hydrophilic coating.

- The VIA Microcatheter has not been evaluated for use in the pediatric population (<22 yrs of age).

Precautions

- 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.

- The VIA Microcatheter has a lubricious hydrophilic coating on the outside of the catheter. It must be kept hydrated in order to be lubricious. This can be accomplished by attaching a Y-connector to a continuous saline drip.

- High quality, digital subtraction fluoroscopic road mapping, with orthogonal views, is mandatory to achieve correct placement of the microcatheter and embolization device.

- If repositioning is required, take special care to retract or to advance the device under fluoroscopy.

- The operator should be aware that microcatheters, in distal blood vessels, may increase the risk of thromboemboli.

- Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors, when possible. The risk of X-ray radiation exposure complications may increase as procedure time and number of procedures increase.

- If removed from the patient, the hydrophilic coating on the VIA Microcatheter should be hydrated with heparinized saline. Do not allow the coating to dry as this may impact the coating safety and performance.

- Avoid pre-soaking devices for long durations when the device is not in use as this may impact the coating safety and performance.

- Avoid wiping the device with dry gauze as this may damage the device coating. Avoid excessive wiping of the coated device.

1.4.3 Potential Complications / Adverse Effects

The potential complications / adverse effects for the VIA Microcatheter are :

Potential Complications

- Hematoma
- aneurysm rupture
- emboli
- vessel/tissue perforation
- blockage other than target vessel
- parent artery occlusion
- hemorrhage
- ischemia

- vasospasm
- anaphylaxis
- inflammatory complication
- infection and/or fever
- vascular thrombosis
- neurological deficits including stroke and death.

Potential X-ray Radiation Exposure Adverse Effects

- Alopecia
- burns ranging in severity from skin reddening to ulcers
- cataracts
- delayed neoplasia
- tissue necrosis
- risks associated with contrast dye

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

1.4.4 Other Aspects of Safety

The total sales over the last 4 years from 01 June 2020 to 31 May 2024 were 32,919 units. A total of 77 complaints (0.61%) were reported for the VIA™ Microcatheter in Europe (including Switzerland and Turkey), and 150 complaints (0.74%) were reported worldwide excluding Europe.

Field Actions are conducted in accordance with the Field Corrective Actions (SOP 8.7) procedure. During the current review period of 01 June 2020 to 31 May 2024 , there was one (1) Field Action involving the VIA Microcatheters.

No Field Safety Notice published by the UK's Medicines & Healthcare products Regulatory Agency (MHRA) was identified as relevant to the subject or similar devices from 01 June 2020 through 31 May 2024.

No Field Corrective Action was found relevant to the subject or similar devices as a result of the medical device vigilance system maintained by Germany's Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) from 01 June 2020 through 31 May 2024.

1.5 Summary of the Clinical Evaluation and PMCF

A Clinical Evaluation of the VIA Microcatheters is continuously updated in conducted in accordance with the requirements in MEDDEV.2.7.1 Revision 4– Guidelines on Medical Devices

– Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies. It includes the following:

- Literature Based Safety Appraisal
- A search of published relevant and available scientific literature was performed to assess the risks and benefits associated with other similar competitive devices
- Performance and Safety - Design Verification and Validation Data Analysis
- Post-Market Surveillance (PMS)

1.5.1 Equivalent Device Clinical Data

The Headway Microcatheter is the equivalent device for the VIA Microcatheter. The Headway Microcatheter is manufactured by MicroVention and is commercially available for general intravascular use in the neuro and peripheral vasculature. The equivalent device is CE Marked with Cert# 435827 (Headway - 2008, Wedge - 2017, 435827 MRA).

Table 1.4: Equivalent Device Description

Aspect	Equivalence Description
Clinical	The VIA™ and Headway™ Microcatheters exhibit comparable clinical characteristics, sharing nearly identical intended purposes and indications for use. While the VIA™ Microcatheter refers to the delivery of interventional devices and the Headway™ specifies therapeutic agents, both support similar procedural applications in neurovascular and peripheral interventions. Patient contact types, anatomical contact sites, and durations are the same for both devices. The target patient populations are equivalent, comprising individuals requiring distal intravascular access for delivery of embolization devices, stents, or therapeutic agents.
Biological	Both microcatheters are constructed using identical or equivalent materials that are in direct contact with human tissues and fluids. The nature and duration of this contact are the same for both devices. Each device has been validated for biocompatibility and undergoes the same sterilization processes, ensuring biological safety and conformity with relevant standards.
Technical	The VIA™ and Headway™ Microcatheters are similar in overall design and intended function, with only minor differences in dimensions such as outer diameter or working length — none of which impact clinical performance or safety. Both devices use comparable polymer blends in the outer catheter construction to achieve flexibility and trackability. Minor differences in internal materials do not compromise device performance or patient safety.

1.5.2 Pre-CE-Mark Clinical Data

There are no pre-market clinical investigations for the VIA Microcatheters. As the VIA Microcatheter is a legacy device (marketed since 2012) and as the initial CE-marking was based on equivalence, pre-market clinical investigations were not conducted.

1.5.3 Clinical Data

Post-Market Clinical Studies

Currently, there are no ongoing post-market clinical investigations for the VIA Microcatheter. Through the years, sufficient clinical evidence including clinical literature data and clinical experience data have been collected and evaluated for the VIA Microcatheters, and as no significant changes to the product have been proposed, there is no need to conduct additional post-market clinical investigations.

Published Peer-reviewed Clinical Literature

The literature search presents relevant clinical data from the scientific literature for the VIA Microcatheter. The literature search was performed with high methodological quality, scientific validity, and relevance to the fields of use. Clinical data from scientific literature included in the clinical evaluation consist of publications identified in the literature searches that are relevant. (Galyfos, 2021; Ghaith, 2023; Lauzier, 2022; Li, 2021; Martinez-Perez, 2021; Perini, 2021; Sattari, 2023; Shao, 2019; Sun, 2020; Van Schaik, 2021; Wang, 2021; Kwon, 2021; Lefevre, 2022; Zhang, 2023; Arslan, 2021; Corpus-Gutierrez, 2025)

The VIA Microcatheter for the introduction of interventional devices and infusion of diagnostic agents into the neuro and peripheral vasculature in over 3,300 patients. The clinical benefit has been demonstrated across 39 studies, showing high technical and procedural success rates (90–100%) and high rates of clinical success (adequate or complete occlusion). The VIA Microcatheter achieved high technical success, with 2 studies reporting 100% success and 3 studies reporting 90–99.9% success. Clinical success, defined as adequate or complete aneurysm occlusion, was achieved between 90–99.9% in 7 studies and between 70–89.9% in 7 additional studies. Studies evaluating procedures for intracranial aneurysms reported complete or near-complete aneurysm occlusion rates between 76% and 84%, which aligned with State of the Art (SOTA) literature reporting occlusion rates greater than 72%. (Hecker, 2023; Cagnazzo, 2020; Fiorella, 2020; Li-Mei, 2018; Adeeb, 2022; Huang, 2022)

Favorable functional outcomes, defined as modified Rankin Scale (mRS) scores of 0–2 at 90 days, were achieved in approximately 70% to 90% of patients, which is consistent with or slightly below the >85% benchmark identified from SOTA for similar procedures.

Of the studies cited, none used the subject device in a manner that is not consistent with the intended use as defined by the manufacturer. The review of these references is to ensure there is no misuse of the subject device. Articles cited that the subject device was used safety and performed as the physician intended, OR device did not perform as the physician intended.

Post-Market Surveillance. In accordance with this procedure, the process should obtain relevant new production and post-production information in order to evaluate any potential early warning signs of design and quality problems, emerging issues, or safety signals, and to assign action items as necessary throughout the lifetime of the medical device.

The post-market surveillance (PMS) for VIA Microcatheter includes internal, external, and market-based sources of active data analysis as defined in the PMS procedure. PMS data will be provided for the last 4 years from 01 June 2020 to 31 May 2024. Additional information on these events is provided below.

Table 1.5: Complaints and Complaint Rates 01 June 2020 to 31 May 2024

Device	Geographical Region	Complaint Type / Rate	Year Range	Grand Total
VIA Microcatheter	Europe (including Switzerland and Turkey)	77 (0.61%)	01 June 2020 to 31 May 2024	77 (0.61%)
VIA Microcatheter	Worldwide (excluding Europe)	150 (0.74%)	01 June 2020 to 31 May 2024	150 (0.74%)

The VIA Microcatheters have maintained an historical complaint rate of <1% based on the number of units shipped worldwide. Five events resulted in patient deaths due to artery or aneurysm rupture. The (Manufacturer and User Facility Device Experience) MAUDE search criteria included all reports in the database for the evaluation period from 01 June 2020 through 31 May 2024. The search produced 32 records.

There are no planned or on-going post-market clinical studies conducted for the VIA Microcatheter.

1.5.4 Clinical Performance and Safety

The available clinical evidence demonstrates that the VIA Microcatheter provides safe and effective access and delivery during neurovascular procedures, with outcomes consistent with the current standard of care. The device achieved high technical success rates (85–100%), effective aneurysm occlusion (70–100%, with multiple studies exceeding 90%), and favorable functional outcomes, with modified Rankin Scale (mRS) scores of 0–2 reported in approximately 80–100% of patients. These clinical results are comparable to, or better than, those of similar devices used in the same anatomical territory.

These outcomes support the manufacturer's claims of optimized device delivery, controlled deployment, enhanced navigability, and reliable compatibility with adjunctive devices, as outlined

in the IFU and promotional materials describing features such as the PTFE Polytetrafluoroethylene) liner, flat braid construction, radiopaque markers, and balanced shaft transitions.

The benefit-risk profile of the VIA Microcatheter is favorable, with risks well-characterized and effectively mitigated through device design, labeling, and clinical use. The evaluation of undesirable side effects revealed complication rates within acceptable limits for neurovascular access devices, including mortality (0.0–5.0%), thromboembolic events (up to 15.0%), ischemic complications (0.6–10.3%), and procedural complications (1.1–14.3%). No unexpected adverse events were identified.

Overall, the clinical performance and safety data support the continued use of the VIA Microcatheter for its intended indications and confirm its alignment with the current state of the art in neurovascular access technology.

1.5.5 Post-Market Clinical Follow-up

Currently, there are no ongoing or planned post-market clinical investigations for the VIA Microcatheter. Sufficient clinical evidence, including published literature and clinical experience data, has been collected and evaluated, and no significant product changes have occurred that would necessitate new clinical studies.

The most recent Post-Market Clinical Follow-up Plan (PMCFP) for the VIA Microcatheter consists of continuous post-market surveillance activities, including analysis of complaint data, adverse event reports, and a systematic review of scientific literature. No prospective post-market clinical studies are planned.

No emerging risks, new complications, or unexpected device failures have been identified through post-market surveillance or the literature review during the most recent evaluation period. The clinical performance and safety profile remain consistent with the State of the Art and the previously identified risk profile.

1.6 Possible Diagnostic or Therapeutic Alternatives

These treatment modalities represent established standards of care for various neurovascular and peripheral vascular conditions and include conservative, pharmacologic, and open surgical approaches. While effective in appropriate clinical scenarios, these options are not dependent on microcatheter-based techniques. Current therapeutic alternatives and standards of care are outlined in the Table 1.6.

1.6.1 Treatment Options and Interventions

Table 1.6: Treatment and Intervention Options

Treatment Option	Pro/Benefit	Con/Risks	Notes
Surgical Treatment			
Intracranial–Intracranial Bypass (Brown, 2025)	For aneurysms not amenable to conventional microsurgical clipping or endovascular intervention, IC–IC bypass offers a viable surgical alternative. Procedure presents high aneurysm obliteration rate and preservation of parent arteries.	The procedure carries a permanent morbidity rate of 8.1% and requires advanced microsurgical expertise for precise anastomosis, with potential risks including graft occlusion and limited patient eligibility due to anatomical or clinical constraints.	Typically reserved for complex, fusiform, giant, or previously treated aneurysms not amenable to endovascular techniques
Supra Orbital Keyhole surgery (Abdulateef, 2023)	SOK was introduced as an alternative approach for clipping the 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.	Non-Available

Treatment Option	Pro/Benefit	Con/Risks	Notes
Surgical Clipping (Shao, 2019; Abdulateef 2023)	Surgical clipping is a 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 IAs 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 study found that surgical clipping resulted in a lower rate of treatment failure—defined as incomplete occlusion, aneurysm rupture during follow-up, or residual aneurysm at one year—compared to endovascular methods. 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.
Pharmacological Intervention			
Intravenous Thrombolytics (e.g., Alteplase) (Germans, 2023)	Dissolve clots to restore cerebral blood flow in acute ischemic stroke. Proven efficacy when administered within 4.5 hours of symptom onset.	Increased risk of intracranial hemorrhage; contraindicated in certain conditions. Symptomatic Intracerebral Hemorrhage (sICH) Incidence: 6.4% in patients receiving alteplase vs. 0.4% with placebo.	Thrombolytic agents like alteplase can restore cerebral blood flow in acute ischemic stroke if given within 4.5 hours, but carry a risk of symptomatic intracerebral hemorrhage (6.4% vs. 0.4% with placebo). Anticoagulants help prevent embolic strokes in patients with atrial fibrillation or cardioembolic sources, though bleeding risks and monitoring requirements must be considered.
Anticoagulants (e.g., Warfarin, Direct Oral	Manage stroke risk in patients with atrial fibrillation or other cardioembolic sources. Effective in preventing	Bleeding risks, need for monitoring (especially with warfarin).	

Treatment Option	Pro/Benefit	Con/Risks	Notes
Anticoagulants) (Ferreira, 2024)	embolic strokes; the choice of agent depends on patient-specific factors.		
Conservative Intervention			
Watchful waiting (Ferreira, 2024)	No risk of procedure-related complications such as vessel perforation, thromboembolism, or device failure. Watchful waiting may be appropriate for: Small (<7 mm) anterior circulation aneurysms Asymptomatic patients with no history of SAH Patients with high procedural risk or limited life expectancy	Annual rupture risk may increase over time or with aneurysm growth. Some aneurysms grow or change morphology over time, making later treatment technically more difficult or riskier.	Watchful waiting avoids procedural risks and may be suitable for small, asymptomatic aneurysms or high-risk patients. However, rupture risk can increase over time, and aneurysm growth may complicate future treatment.

1.6.2 Available Technologies

Access catheters such as VIA Microcatheter, are well-established medical devices with numerous types and styles available from a variety of manufacturers. List of similar devices are summarized in Table 1.7.

Table 1.7: Similar Devices

Device	Manufacturer	Intended Purpose
Echelon Microcatheter	Medtronic	The Echelon Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.
Excelsior® XT-17	Stryker	Stryker Neurovascular's Excelsior XT-17 Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary, and neurovascular systems.
Headway/Wedge Microcatheter	MicroVention	The Headway/Wedge Microcatheter is intended for general intravascular use, including the peripheral and neuro vasculature

		for the infusion of diagnostic agents, such as contrast media, and therapeutic agents.

1.7 Suggested Profile and Training for Users

The VIA Microcatheter is intended for use only by physicians trained and experienced in endovascular procedures. Users should have appropriate education and hands-on experience with catheter-based vascular access techniques, microcatheter navigation, and embolization procedures involving neurovascular or peripheral vasculature.

1.8 Reference to any Harmonized Standards and CS

Table 1.8: Harmonized Standards & CS

Standards	Edition	Standard Title
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 ISO 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/A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11607-2	2020/A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
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
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 10993-10	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 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/A1:2021)
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 11138-1	2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
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