Summary of Safety and Clinical Performance

For

Headway and Wedge Microcatheters

SSCP23-0010

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DOCUMENT CHANGE HISTORY

Revision	Date	Description
A		Initial SSCP

*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 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.
Following this information there is a summary intended for patients.

1.1. Device Identification and General Information

Table 1.1 Device Identification and General Information

Device Names	
Device Trade Name	Headway 17, Headway 21, Headway Duo, Wedge, Wedge XL Microcatheters
EMDN Code	C0104020202 Peripheral embolization catheters and microcatheters
Medical Device Nomenclature (EMDN or GMDN Description)	Vascular guide catheter, single use
Device Class	Class III
Basic UDI-DI	08402732HEADWAYWEDGE4N
Year when first certificate (CE) was issued for the device	Headway – 2008 Wedge – 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-000004448
Notified Body	
Name & Address	DQS Medizinprodukte GmbH Team Change Management / Team Aenderungsmeldungen August-Schanz-Str. 21 60433 Frankfurt a. Main Germany
Notified Body Identification Number	0297

1.2. Intended Purpose of the Device

Table 1.2 Intended Use

Intended Purpose	
Intended Purpose / Indications for Use	The 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. The Wedge XL 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. The Headway 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, such as occlusion coils. The Headway Duo Microcatheter is intended for general intravascular use, including the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials. The Headway Duo Microcatheter is intended for neurovascular use, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents that have been cleared or approved for use in the neurovasculature and are compatible with the inner diameter of the Headway Duo Microcatheter.
Target Population	The Headway™ and Wedge™ Microcatheters are intended for general intravascular use, including use in the peripheral and neuro vasculature, are to be used in patients requiring such treatment.
Contraindications and/or Limitations	There are no known contraindications for the Headway™ and Wedge™ Microcatheters.

1.3. Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	The Headway™ and Wedge™ Microcatheters are available in seven types: Headway 17 Advanced Soft, Headway 17 Advanced, Headway 21, Headway 27, Headway Duo, and Wedge and Wedge XL Microcatheters. In this document, the five Headway™ Microcatheters will be grouped together and referred to as "Headway" and the two Wedge™ Microcatheters will be grouped together and referred to as "Wedge," unless noted otherwise. The Headway Microcatheters are single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end

	facilitate fluoroscopic visualization. The outer surface of the Microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the Microcatheter hub is used for the attachment of accessories. The Wedge Microcatheters are single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. Radiopaque markers at the distal end facilitate fluoroscopic visualization. A larger diameter distal segment helps provide stability for navigation. The outer surface of the Wedge Microcatheter is coated with a hydrophilic polymer to increase lubricity; the distal 110 cm outer surface of the Wedge XL Microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the Wedge Microcatheter hub is used for the attachment of accessories.
Design Characteristics of the Device	The principle of operation of the Headway™ and Wedge™ Microcatheters incorporates various design features that allow it to achieve its intended use. A semi-rigid proximal section allows for steerability. Progressively softer durometer distal segments and flexible tip allow for atraumatic navigation through the vasculature. Radiopaque markers allow for fluoroscopic visualization. Hydrophilic polymer coating reduces friction during navigation through the vasculature. A luer fitting on the hub allows for the attachment of accessories. The hub/strain relief provides for kink resistance. Shapeable tip allows the physician to form the optimal shape. The Wedge™ Microcatheter includes an enlarged distal segment that allows for easier navigation through certain parts of the vasculature, such as bifurcations, where a "ledge effect" could occur. Patient contact occurs with the catheter body and coating. The Headway™ and Wedge™ Microcatheters do not incorporate a medicinal substance, animal tissues or blood products.
Previous Generations or Variants, if applicable	Not applicable
Single use – sterilization method	Sterilized Using Ethylene Oxide
Description of Accessories	A luer fitting on the Microcatheter hub is used for the attachment of accessories. A rotating hemostatic valve (RHV) may be attached to the Microcatheter hub and used to facilitate the flushing process. A steam-shaping mandrel accessory is packaged with the Headway and Wedge microcatheters. Wedge XL does not include a steam-shaping mandrel. The steam-shaping mandrel allows the physician to shape the shapeable tip to the optimal shape for the procedure. An introducer sheath is also included to facilitate the introduction of the microcatheter.
Description of other Devices or Products intended to be used in combination	All Headway microcatheters are designed to optimize the performance of LVIS™ and LVIS Jr. Intraluminal Support Devices, FRED™ System flow diverting stents, ERIC™ Retrieval Devices, and embolic coils. Headway microcatheters are also PHIL™ Liquid Embolic System and dimethyl sulfoxide (DMSO) compatible. Wedge and Wedge XL Microcatheters are designed to deliver SOFIA 6F Catheter and SOFIA 88 Catheter, respectively.

1.4. Risks and Warnings

1.4.1. Residual Risks and Undesirable Effects

Hazards associated with the use of the Headway and Wedge 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. Potential hazards associated with the Headway and Wedge Microcatheters include the following:

- Air embolism
- Biological hazard
- Biological hazard – Product becomes contaminated during shipping, distribution, or storage
- Biological hazard – Product is re-used
- Blood Loss - Acute
- Coating length too long or too short
- Embolism due to incompatibility of accessory device due to proper use of product
- Exposed potentially toxic materials
- Foreign body embolism
- Foreign body embolism due to damage to embolic coils (e.g., coated coils) and/or accessories
- Foreign body embolization from luer fitting particulate
- Improper use
- Inability to deliver embolic coil (e.g., “train wreck”)
- Inability to deliver embolic coils or agents or compatible devices
- Inability to deliver therapeutic agents or embolic materials
- Inability to use with accessory devices
- Inadequate radiopacity
- Incompatibility or entrapment with accessory devices
- Incompatible with agents resulting in entrapped catheter
- Increased procedure time. All potential hazards related to procedure
- Insufficient coating
- Jetting causing vascular rupture, dissection, or perforation
- Kink resulting in incompatibility with accessory devices
- Metal parts incompatible with fluoroscopic equipment
- Off Label use
- Product becomes contaminated due to manufacturing environment
- Product becomes contaminated during use
- Product causes vessel damage during navigation through the cerebrovasculature

- Product entrapped in accessory device(s) and unable to remove from patient readily
- Product is not compatible with other devices
- Product kinks due to torquing by user resulting in inability to deliver therapeutic or embolic agents or entrapped accessories
- Product ruptures due to failure from incompatibility with drugs or agents
- Product ruptures due to getting damage by slipping out of packaging track.
- Product separates and a portion remains in the body
- Shape incorrect/not shapeable
- Therapeutic or embolic agents delivered to other than target location
- Thromboembolic embolism
- Thrombus formation on exposed material
- Vessel perforation, dissection, rupture
- Vessel wall irritation
- Wedge separates from the catheter
- Will not mate with accessory devices

1.4.2. Warnings and Precautions

Headway Microcatheters

The warnings / precautions for the Headway Microcatheters are:

Warnings

- The Microcatheter should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.
- The Microcatheter is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if the packaging is breached or damaged.
- The Microcatheter is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose device in accordance with hospital and/or local government policy.
- Inspect the Microcatheter prior to use for any irregularities or damage and discard if any inconsistencies are observed.
- The Microcatheter should be advanced or manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
- Infusion pressure should not exceed 300 psi to avoid potential rupture of the Microcatheter.

- Shaping mandrel is not intended for use inside the body. Ensure shaping mandrel is removed from Microcatheter prior to introduction into the RHV or other accessories.

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.
- Verify Microcatheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- The Microcatheter has a lubricious surface and should be hydrated prior to use.
- Exercise care in handling the Microcatheter to reduce the chance of accidental damage.
- Verify that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the Microcatheter prior to use.
- To reduce the risk of damage or separation of the device, avoid repeated bending at the same point of the Microcatheter.
- Take precaution when manipulating the Microcatheter in tortuous vasculature to avoid damage to the Microcatheter. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

Headway Duo Microcatheters

The warnings / precautions for the Headway Duo Microcatheters are:

Warnings:

- The Microcatheter should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.
- The Microcatheter is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if the packaging is breached or damaged.
- The Microcatheter is intended for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose device in accordance with hospital and/or local government policy.

- Inspect the Microcatheter prior to use for any irregularities or damage and discard if any inconsistencies are observed.
- The Microcatheter should be advanced or manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
- Infusion pressure should not exceed 700 psi to avoid potential rupture of the Microcatheter.
- Shaping mandrel is not intended for use inside the body. Ensure shaping mandrel is removed from Microcatheter prior to introduction into the RHV or other accessories.

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.
- Verify Microcatheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- The Microcatheter has a lubricious surface and should be hydrated prior to use.
- Exercise care in handling the Microcatheter to reduce the chance of accidental damage. With the exception of dimethyl sulfoxide (DMSO), use of organic solvents may damage the Microcatheter and/or coating on the surface.
- Verify that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the Microcatheter prior to use.
- To reduce the risk of damage or separation of the device, avoid repeated bending at the same point of the Microcatheter.
- Take precaution when manipulating the Microcatheter in tortuous vasculature to avoid damage to the Microcatheter. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

Wedge Microcatheters

The warnings / precautions for the Wedge Microcatheters are:

Warnings

- The Wedge Microcatheter should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.

- The Wedge Microcatheter is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if the packaging is breached or damaged.
- The Wedge Microcatheter is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose device in accordance with hospital and/or local government policy.
- Inspect the Wedge Microcatheter prior to use for any irregularities or damage and discard if any inconsistencies are observed.
- The Wedge Microcatheter should be advanced or manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
- Infusion pressure should not exceed 300 psi to avoid potential rupture of the Wedge Microcatheter.
- The shaping mandrel is not intended for use inside the body. Ensure shaping mandrel is removed from Wedge Microcatheter prior to introduction into the RHV or other accessories.

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.
- Verify Wedge Microcatheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- The Wedge Microcatheter has a lubricious surface and should be hydrated prior to use.
- Exercise care in handling the Wedge Microcatheter to reduce the chance of accidental damage.
- Verify that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the Wedge Microcatheter prior to use.
- To reduce the risk of damage or separation of the device, avoid repeated bending at the same point of the Wedge Microcatheter.
- Take precaution when manipulating the Wedge Microcatheter in tortuous vasculature to avoid damage to the Wedge Microcatheter. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

Wedge XL Microcatheters

The warnings / precautions for the Wedge XL Microcatheters are:

Warnings

- The Wedge XL Microcatheter should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.
- The Wedge XL Microcatheter is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if the packaging is breached or damaged.
- The Wedge XL Microcatheter is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose device in accordance with hospital and/or local government policy.
- Inspect the Wedge XL Microcatheter prior to use for any irregularities or damage and discard if any inconsistencies are observed.
- The Wedge XL Microcatheter should be advanced or manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
- Do not torque the Wedge XL Microcatheter.
- Infusion pressure should not exceed 300 psi to avoid potential rupture of the Wedge XL Microcatheter.
- The Introducer Sheath is not intended for use inside the patient body. Ensure that the Introducer Sheath is removed from the Wedge XL Catheter once the distal shaft of the Wedge XL Catheter is placed inside the patient body.
- The Wedge XL Microcatheter has not been evaluated for delivery of stents, retrievers, occlusion coils, liquid embolic agents, including those containing dimethyl sulfoxide (DMSO) or n-butyl cyanoacrylate (n-BCA).
- Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse

Precautions

- Verify Wedge XL Microcatheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- The Wedge XL Microcatheter has a lubricious surface and should be hydrated prior to use.
- Exercise care in handling the Wedge XL Microcatheter to reduce the chance of accidental damage.

- Verify that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the Wedge XL Microcatheter prior to use.
- To reduce the risk of damage or separation of the device, avoid repeated bending at the same point of the Wedge XL Microcatheter.
- Take precaution when manipulating the Wedge XL Microcatheter in tortuous vasculature to avoid damage to the Wedge XL Microcatheter. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.
- Take precaution when advancing the bulb segment of the Wedge XL Microcatheter beyond the distal tip of the guiding catheter. Retraction of the bulb segment of the Wedge XL Microcatheter into the distal tip of the guiding catheter may introduce blood into the guiding catheter lumen.
- Ensure adequate flush is maintained through the guiding catheter lumen whenever the Wedge XL Microcatheter is present.
- 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.
- 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 Headway™ and Wedge™ Microcatheters 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

Potential complications associated with the Wedge XL Microcatheters include:

- 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, and death.
- Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to, alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of occurrence of complications may increase as procedure time and number of procedures increase.
- 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

No field actions or recalls involving the subject devices have been identified.

1.5. Summary of the Clinical Evaluation and PMCF

1.5.1. Clinical Data

Clinical Data from the Scientific Literature

Clinical data from scientific literature included in the clinical evaluation consist of publications identified in the literature that utilize the Headway or Wedge devices. All included publications are listed in **Table 1.4** and summarized in **Table 1.5**.

Table 1.4 References

#	Author	Title
1	[1] El Naamani et al. (2023)	Comparison of Flow-Redirection Endoluminal Device and Pipeline Embolization Device in the Treatment of Intracerebral Aneurysms
2	[2] Ji et al. (2023)	Time correlation of success recanalization for endovascular recanalization of medically refractory non-acute intracranial arterial occlusions
3	[3] Schüngel et al. (2023)	Distal Flow Diversion with Anti-Thrombotically Coated and Bare Metal Low-Profile Flow Diverters—A Comparison
4	[4] Goertz et al. (2022)	Stent-assisted WEB embolization: aneurysm characteristics, outcome and case report of a WEB delivered through a stent
5	[5] Aydin et al. (2022)	Safety, Efficacy, and Durability of Stent-Assisted Coiling Treatment of M2 (Insular) Segment MCA Aneurysms
6	[6] Bhogal et al. (2022)	The Silk Vista Baby–The UK experience
7	[7] Biberoğlu Çelik et al. (2022)	Choroidal and retinal anatomical response following treatment of carotid-ophthalmic aneurysms with flow diverter stents
8	[8] Caton et al. (2022)	Endovascular treatment strategy, technique, and outcomes for dural arteriovenous fistulas of the marginal sinus region.
9	[9] Cheung et al. (2022)	PHIL and Squid Embolization of Cerebral Arteriovenous Malformation: A Retrospective Case Series of 23 Patients

#	Author	Title
10	[10] Giurazza et al. (2022)	PHIL® (precipitating hydrophobic injectable liquid): retrospective multicenter experience on 178 patients in peripheral embolizations
11	[11] Goertz et al. (2022)	Safety and Efficacy of the Novel Low-Profile APERIO Hybrid17 for a Treatment of Proximal and Distal Vessel Occlusion in Acute Ischemic Stroke: A Multi-Center Experience
12	[12] Gündoğmuş et al. (2022)	Long-term results and comparison of flow re-direction endoluminal device and pipeline embolization device in endovascular treatment of intracranial carotid aneurysms
13	[13] He et al. (2022)	Perioperative Complications of Transvenous Embolization of Ruptured Intracranial Arteriovenous Malformations
14	[14] Hellstern et al. (2022)	Use of a p64 MW Flow Diverter with Hydrophilic Polymer Coating (HPC) and Prasugrel Single Antiplatelet Therapy for the Treatment of Unruptured Anterior Circulation Aneurysms: Safety Data and Short-term Occlusion Rates
15	[15] Liu et al. (2022)	Overlapping Stents-Assisted Coiling for Vertebral Artery Dissecting Aneurysm: LVIS Stent within Neuroform EZ Stent
16	[16] McDougall et al. (2022)	Safety and efficacy results of the Flow Redirection Endoluminal Device (FRED) stent system in the treatment of intracranial aneurysms: US pivotal trial
17	[17] Liu et al. (2022)	Artificial Intelligence-Assisted Microcatheter Shaping for Intracranial Aneurysm Coiling: A Preliminary Study
18	[18] O'Cearbhaill et al. (2022)	Improving endovascular access to the target vessel for thrombus aspiration –Use of the wedge device to overcome anatomic hurdles.
19	[19] Sayin et al. (2022)	Endovascular treatment of challenging aneurysms with FRED Jr flow diverter stents: a single-center experience
20	[20] Shen et al. (2022)	Initial and mid-term results of LEO Baby stent-assisted coiling of intracranial aneurysms located in small arteries: A single-center experience with 131 consecutive patients
21	[21] Tang et al. (2022)	Braided stents assisted coiling for endovascular management of posterior cerebral artery aneurysms: a preliminary mid-term experience
22	[22] Raz et al. (2022)	Tumor Embolization through Meningohypophyseal and Inferolateral Trunks is Safe and Effective
23	[23] Endo et al. (2022)	Long-term outcomes of Y-stent-assisted coil embolization using Low-profile Visualized Intraluminal Support Junior (LVIS Jr) for intracranial bifurcation aneurysms
24	[24] Okada et al. (2022)	Embolization of Skull Base Meningiomas with Embosphere Microspheres: Factors Predicting Treatment Response and Evaluation of Complications.
25	[25] Rodriguez-Calienes et al. (2022)	Single-center experience with endovascular treatment of cerebral arteriovenous malformations with intent to cure in pediatric patients
26	[26] Sirakov et al. (2022)	Endovascular treatment of wide-necked intracranial aneurysms using the Nautilus Intrasaccular System: initial case series of 41 patients at a single center
27	[27] Tartoushy et al. (2022)	New Endovascular Approaches in Management Of Intracranial Complex Bifurcation Aneurysms Not Amenable To Simple Coiling
28	[28] Vignesh et al. (2022)	Balloon-Assisted Coiling of Intracranial Aneurysms: Technical Details and Evaluation of Local Complications
29	[29] Yatomi et al. (2022)	Outcomes following aneurysmal coil embolization with intentionally shortened low-profile visible intraluminal support stent deployment
30	[30] Davidov et al. (2021)	Feasibility and Efficacy of Low-profile Visual Intraluminal Support Device: A Single Center Five-year Experience
31	[31] Gan et al. (2021)	A single-centre experience and literature review of flow re-directional endoluminal device (FRED) in endovascular treatment of intracranial aneurysms
32	[32] Gavrilovic et al. (2021)	Silk Vista Baby is a safe and technically feasible flow diverting stent for distal aneurysm treatment

#	Author	Title
33	[33] Guenego et al. (2021)	Long-term follow-up of the pCONus device for the treatment of wide-neck bifurcation aneurysms.
34	[34] Martínez-Galdámez et al. (2021)	First multicenter experience using the Silk Vista flow diverter in 60 consecutive intracranial aneurysms: Technical aspects.
35	[35] Rikhtegar et al. (2021)	Effectiveness of very low profile thrombectomy device in primary distal medium vessel occlusion, as rescue therapy after incomplete proximal recanalization or following iatrogenic thromboembolic events
36	[36] Schüngel et al. (2021)	Endovascular Treatment of Intracranial Aneurysms in Small Peripheral Vessel Segments—Efficacy and Intermediate Follow-Up Results of Flow Diversion With the Silk Vista Baby Low-Profile Flow Diverter
37	[37] Vollherbst et al. (2021)	Periprocedural safety and feasibility of the new LVIS EVO device for stent-assisted coiling of intracranial aneurysms: an observational multicenter study
38	[38] Wang et al. (2021)	Comparison of Endovascular Embolization Plus Simultaneous Microsurgical Resection vs. Primary Microsurgical Resection for High-Grade Brain Arteriovenous Malformations.
39	[39] Waqas et al. (2021)	Complete flow control using transient concurrent rapid ventricular pacing or intravenous adenosine and afferent arterial balloon occlusion during transvenous embolization of cerebral arteriovenous malformations: case series.
40	[40] Winters et al. (2021)	First Experience of Three Neurovascular Centers With the p64MW-HPC, a Low-Profile Flow Diverter Designed for Proximal Cerebral Vessels With Antithrombotic Coating
41	[41] Guimaraens et al. (2020)	Efficacy and safety of the dual- layer flow- diverting stent (FRED) for the treatment of intracranial aneurysms.
42	[42] Luecking et al. (2020)	Two-to five-year follow-up of 78 patients after treatment with the flow redirection endoluminal device
43	[43] Ng et al. (2020)	Middle meningeal artery (MMA) embolization as an adjuvant treatment to surgery for symptomatic chronic subdural hematoma (CSDH): A pilot study assessing hematoma volume resorption.
44	[44] Poncyljusz et al. (2020)	Evaluation of the accero stent for stent-assisted coiling of unruptured wide-necked intracranial aneurysm treatment with short-term follow-up
45	[45] Son et al. (2020)	Cerebral aneurysms treated with low-profile visualized intraluminal support device (LVIS Jr) Y-stent constructs: Technical experience with a single microcatheter technique
46	[46] Xue et al. (2020)	Endovascular Treatment of Ruptured Wide-Necked Anterior Communicating Artery Aneurysms Using a Low-Profile Visualized Intraluminal Support (LVIS) Device
47	[47] Yüce and Taşar (2020)	Endovascular treatment of intracranial aneurysms: A single center experience.
48	[48] Zhang et al. (2020)	Incomplete stent apposition of low-profile visualized intraluminal support stents in the treatment of cerebral aneurysms.
49	[49] Fiorella et al. (2019)	The safety and effectiveness of the LVIS stent system for the treatment of wide-necked cerebral aneurysms: Final results of the pivotal US LVIS trial.
50	[50] Goland and Doroszuk (2019)	Transradial approach for endovascular diagnosis and treatment of ruptured cerebral aneurysms: A descriptive study
51	[51] Martínez-Galdámez et al. (2019)	Periprocedural safety and technical outcomes of the new Silk Vista Baby flow diverter for the treatment of intracranial aneurysms: Results from a multicenter experience.
52	[52] Pierot et al. (2019)	SAFE study (Safety and efficacy Analysis of FRED Embolic device in aneurysm treatment): 1-year clinical and anatomical results.
53	[53] Schob et al. (2019)	Flow diversion beyond the Circle of Willis: Endovascular aneurysm treatment in peripheral cerebral arteries employing a novel low-profile flow diverting stent.

#	Author	Title
54	[54] Wu et al. (2019)	Endovascular treatment of ruptured tiny intracranial aneurysms with low-profile visualized intraluminal support device
55	[55] Ares et al. (2018)	Seeing Is Believing: Headway27 as a Highly Visible and Versatile Microcatheter with Ideal Dimensions for Stroke Thrombectomy.
56	[56] Manzato et al. (2018)	Initial experience with a flow redirection endoluminal device stent—a Brazilian multicenter study.
57	[57] Samaniego et al. (2018)	LVIS Jr device for Y-stent-assisted coil embolization of wide-beck intracranial aneurysms: A multicenter experience.
58	[58] Santillan et al. (2018)	LVIS Jr. stent for treatment of intracranial aneurysms with parent vessel diameter of 2.5mm or less.
59	[59] Su et al. (2018)	225 intracranial aneurysms treated with the Low-profile Visualized Intraluminal Support (LVIS) stent: A single-center retrospective study.
60	[60] Luecking et al. (2017)	FRED Flow Diverter: A Study on Safety and Efficacy in a Consecutive Group of 50 Patients.
61	[61] Möhlenbruch et al. (2017)	Multicenter experience with FRED Jr flow re-direction endoluminal device for intracranial aneurysms in small arteries.
62	[62] Shankar et al. (2017)	Canadian Registry of LVIS Jr for Treatment of Intracranial Aneurysms (CaRLA).
63	[63] Guengo et al. (2021)	Thrombectomy for distal medium vessel occlusion with a new generation of Stentretriever (Tigertriever 13)

Table 1.5 Literature Summary

#	Patient Population	Results	Adverse Events / Complications
[1] El Naamani et al. (2023)	35 patients treated with FRED	6-month complete occlusion = 51.5% Good functional outcome @ 6m = 100%	Periprocedural complications = 0 In-stent stenosis = 15.2% Total minor complications = 14.3% Retreatment = 3.0%
[2] Ji et al. (2023)	69 patients	Technical success = 73.9% Successful reperfusion = 73.9%	Perioperative complications =37.7% Serious complications = 8.7% Dissection = 8.7% Perforation = 1.5% In-stent thrombosis = 1.5% SAH = 10.1% TIA = 5.8% Ischemic stroke =17.4%
[3] Schüngel et al. (2023)	108 patients	OKM A1 = 35.2% OKM A2-A3 = 59.3%	Clinical adverse events = 14.8%
[4] Goertz et al. (2022)	178 intracranial aneurysm patients enrolled; 163 treated by WEB only. 15 patients with wide neck bifurcation aneurysms needed additional stent implantation.	Complete occlusion (immediate) = 48.9% Adequate/complete occlusion (immediate) = 66.3% Complete occlusion (@ 6 mths) = 56.7% Adequate/complete occlusion (@ 6 mths) = 71.9%	Thromboembolic events = 10.1% Hemorrhagic events = 1.7% Ischemic stroke = 1.7% Aneurysm rupture = 0.6% Artery perforation = 0.6% Mortality = 1.1%
[5] Aydin et al. (2022)	61 patients with Wide-Necked Intracranial	Complete occlusion (immediate) = 86.9%	Mortality = 0 Subarachnoid hemorrhage = 1.8%

#	Patient Population	Results	Adverse Events / Complications
	Bifurcation Aneurysms	Complete occlusion (final) = 89.1% mRS 0-2 = 100% Retreatment = 1.8%	Periprocedural complications = 11.5%
[6] Bhogal et al. (2022)	60 patients with 61 aneurysms	mRS 0-2 = 93%	Clinical complications = 6.7% Aneurysm rupture = 1.7% Mortality = 5.1%
[7] Biberoğlu Çelik et al. (2022)	35 patients (70 eyes) with flow diverter stent endovascular treatment of ophthalmic segment aneurysms.	Technical success = 100%	Permanent visual damage = 0
[8] Caton et al. (2022)	29 FMR-AVF were identified in 28 patients	Technical success = 100% Complete obliteration = 100%	Mortality = 0 Arterial rupture = 3.6% Additional procedure needed = 6.3% New occlusion = 3.6%
[9] Cheung et al. (2022)	23 patients with 34 endovascular embolization sessions	Technical success = 100% mRS 0-3 @3-6 mths = 80%	Mortality = 0 Femoral artery dissection = 4.3%
[10] Giurazza et al. (2022)	178 patients with 190 embolizations	Technical success = 94.7% Clinical success = 92.1%	Complication rate = 7.4% Non-target embolizations = 3.2% Post-embolization syndrome = 1.6% Parenchymal infarctions = 1.6%
[11] Goertz et al. (2022)	71 patients with acute proximal and distal vessel occlusions	TICI ≥2b = 92.7% mRS 0-2 (discharge) = 50.7% 90-day mRS 0-2 = 69% (29/42) Rescue treatment = 2.8%	Embolism in new territory = 1.4% Parenchymal hematoma = 0 SAH = 6.3% sICH @ 24 hr = 2.8% Mortality = 17.4% Procedure-related mortality = 0
[12] Gündoğmuş et al. (2022)	83 patients 99 with intracranial aneurysms	6-month occlusion = 82.7% 12-month occlusion = 82.7%	In-stent thrombosis = 6% Hemorrhagic event = 2.4% Aneurysm rupture = 1.2% Artery occlusion = 2.4% Mortality = 4.8%
[13] He et al. (2022)	27 patients with ruptured intracranial arteriovenous malformations	Complete disappearance = 88%	Perioperative complications = 25.9% Interoperative hemorrhage = 11.1% Mortality = 3.7%
[14] Hellstern et al. (2022)	102 patients with 132 intracranial aneurysms	Technical success = 100% 4m occlusion = 72.6% 9m occlusion = 83.8% mRS 0-2 = 94.1%	Artery dissection = 0.98% Periprocedural hemorrhagic complications = 0 Periprocedural thromboembolic complications = 0 Delayed complications: Neurological deficits = 5.8%
[15] Liu et al. (2022)	18 patients	Technical success = 94.4% Immediate adequate / complete occlusion = 77.8% 3-9m adequate / complete occlusion = 100% mRS 0-2 = 94.4%	In-stent thrombosis = 5.6%

#	Patient Population	Results	Adverse Events / Complications
[16] McDougall et al. (2022)	145 patients	Technical success = 100% Complete occlusion = 62.9% Adequate / complete occlusion = 80%	30d major stroke = 4.1% 1y major stroke (ipsilateral) = 2.1% 1y neurological death = 0.7% 30d mortality = 0 Retreatment = 5.7%
[17] Liu et al. (2022)	24 patients with 30 intracranial aneurysms	Technical success = 100% mRS 0-2 (at discharge) = 100% RR I = 73.3% RR II = 26.7%	Details not provided
[18] O'Cearbhaill et al. (2022)	38 patients that received endovascular thrombectomy.	Technical success = 97.4% Clinical success = 97.4%	Groin hematoma = 3.7% Additional device needed = 2.6% Complications related to device = 0
[19] Sayin et al. (2022)	25 patients with 31 aneurysms treated with FRED Jr	Technical success = 100% Complete/adequate occlusion = 93.7% mRS 0-1 = 96%	In-stent thrombosis = 8% Vasospasm = 4% Delayed rupture = 4% Second stent deployed = 4%
[20] Shen et al. (2022)	131 patients with aneurysms arising from small parent arteries treated with Leo Baby stent-assisted coiling.	Technical success = 100% Complete occlusion (immediate) = 82.2% Complete occlusion (@ 6 mths) = 96.2% mRS 0-2 = 91.6%	Thromboembolic complications = 9.6% Hemorrhagic complication = 0.7% In-stent stenosis = 10.4% Mortality = 4.6% Procedure-related mortality = 0
[21] Tang et al. (2022)	28 PCE aneurysms in 28 patients	Complete occlusion (immediate) = 46.4% Adequate/complete occlusion (immediate) = 60.7% Adequate/complete occlusion (@ follow-up) = 79.2% mRS 0-2 = 96.4%	Hemorrhagic complication = 3.6% Mortality = 3.6%
[22] Raz et al. (2022)	14 patients in whom tumor embolization was performed using the meningohypophyseal or inferolateral trunk.	% of Tumors embolized = 79%	Morbidity = 0 Mortality = 0
[23] Endo et al. (2022)	21 patients with 22 intracranial bifurcation aneurysms.	Technical Success = 100% Complete occlusion (immediate) = 59.1% Adequate/complete occlusion = 68.2% Complete occlusion (1 yr) = 81.8% Adequate/complete occlusion (1 yr) = 95.5%	Aneurysm rupture = 4.5% SAH = 4.5% In-stent thrombus = 4.5% Ischemic stroke = 4.8% Mortality = 0
[24] Okada et al. (2022)	143 vessels from 80 patients with skull base meningiomas	Technical success = 100% Reductions in tumor lesions = 68.8%	Neurological complications (permanent) = 3.7% Peritumoral edema = 1.3% Hemorrhage = 0 Ischemic stroke = 0
[25]	120 embolizations were performed in	Immediate obliteration = 58%	Technical complications = 15% Microperforations = 10.8%

#	Patient Population	Results	Adverse Events / Complications
Rodriguez-Calienes et al. (2022)	69 patients with cerebral arteriovenous malformations.		Microcatheter fracture = 4.2%
[26] Sirakov et al. (2022)	41 patients with 41 aneurysms	Technical success = 100% Immediate occlusion = 73.1% 3-6m complete occlusion = 94.5% 3-6m mRS 0 = 94.5%	Minor stroke = 2.4% Procedure related mortality = 0 Mortality (all cause) = 7.3%
[27] Tartoushy et al. (2022)	32 patients with intracranial complex bifurcation aneurysms	Technical success = 100% Complete occlusion = 93.1% (27/29) 90-day mRS 0-2 = 96.6% (28/29)	Hematoma = 3.1% Neurological deficit = 6.2% Mortality = 3.1%
[28] Vignesh et al. (2022)	198 aneurysms treated with balloon-assisted coiling	Technical success = 98.5%	Thromboembolism complication = 14.1% Arterial dissection = 0.5% Aneurysm rupture = 4.5% Coil migration = 5.6% Mortality = 1.6%
[29] Yatomi et al. (2022)	130 patients with 131 aneurysms	Immediate adequate / complete occlusion = 71.5% Follow-up adequate / complete occlusion = 90.9%	Ischemic complications = 0.76% Hemorrhagic complications = 3.8%
[30] Davidov et al. (2022)	74 patients with 74 intracranial aneurysms.	Complete occlusion (immediate) = 83.5% Adequate/complete occlusion (immediate) = 87.6% Complete occlusion (follow-up) = 89.0% Adequate/complete occlusion (follow-up) = 90.4%	In-stent thrombus = 4.1% Artery perforation = 2.7% Aneurysm rupture = 1.4% Mortality = 2.7%
[31] Gan et al. (2021)	21 patients with 25 aneurysms	Complete occlusion @ 6m = 68% Adequate / complete occlusion @ 6m = 88% Complete occlusion @ 1y = 76% Adequate / complete occlusion @ 1y = 88%	Hemorrhagic complication = 4% Thromboembolic complication = 8% Mortality = 0
[32] Gavrilovic et al. (2021)	18 patients with 22 aneurysms	mRS 0 = 77.8% adequate/complete occlusion @ 3m = 86.7% adequate/complete occlusion @ 6m = 92.3%	Mortality = 0 Side-branch occlusion = 5.6% In-stent thrombosis = 5.6%
[33] Guenego et al. (2021)	43 patients with 43 wide-neck bifurcation aneurysms	Technical success = 100% Adequate/complete occlusion after procedure = 95% Adequate/complete occlusion at final follow-up = 86% In stent stenosis = 0 Post-operative neurological deficit = 0	Mortality = 0 Interoperative rupture = 0 complications related to device = 0 Vasospasm = 0 Arterial rupture = 0 Temporary occlusion = 2.3% Retreatment = 9.3%
[34] Martínez-Galdámez et al. (2021)	57 patients with 60 intracranial aneurysms	Technical success = 91% Clinical success = 92%	Mortality = 0 Neurological deterioration = 1.8% Aneurysm rupture = 0 Aneurysm dissection = 0 Thromboembolic events = 5.3%

#	Patient Population	Results	Adverse Events / Complications
			Recapture and repositioning of device = 31.6% Hemorrhagic complication = 1.8% Stroke = 1.8%
[35] Rikhtegar et al. (2021)	115 patients	eTICI 2b/3 = 74.8%	Hemorrhagic complication = 6.9% sICH = 1.7% In-hospital mortality = 18.1%
[36] Schüngel et al. (2021)	44 patients with 47 aneurysms	Clinical success = 98% @ 8 mths Clinical success 1st follow-up = 80%	Aneurysm rupture = 2.3% Branch occlusion = 4.6% Vasospasm = 4.6% SAH = 2.3% Morbidity @ 90-days = 4.6%
[37] Vollherbst et al. (2021)	57 patients with 59 aneurysms	Technical Success = 100% Immediate complete occlusion = 54.2% Immediate adequate occlusion = 10.2%	Thrombus formation = 5.1% TIA = 3.4% Stroke = 3.4%
[38] Wang et al. (2021)	38 cases with brain arteriovenous malformations (AVMs)	Technical success = 100% 90-day mRS 0-2 = 75%	Mortality = 5.3% Post-operative hemorrhage = 7.9% CNS infection = 15.8% Respiratory Infection = 2.6% Seizure = 2.6%
[39] Waqas et al. (2021)	12 patients treated for transvenous AVM embolization	Complete embolization = 83.3% Complete obliteration = 100% mRS 0-2 @ 6 months = 91.7%	complications related to device = 0 mortality = 8.3% hemorrhagic complications = 16.7%
[40] Winters et al. (2021)	32 patients with 33 aneurysms	Technical success = 100% Reduction in aneurysm size = 26.1% Separation from parent vessel = 65.2%	Thromboembolic complication = 6.3% Hemorrhagic complication = 3.1% Delayed aneurysm rupture = 3.1%
[41] Guimaraens et al. (2020)	150 patients with 185 aneurysms	Adequate/complete occlusion = 84.6% mRS 0-1 = 97.8%	Major complications = 6.5% Subarachnoid hemorrhage = 1.1% Cerebral hemorrhage = 0.5% Stroke = 1.1% TIA – 0.5% arterial dissection = 1.1% arterial occlusion = 1.1% intra-stent stenosis = 1.6% mortality = 0.5%
[42] Luecking et al. (2020)	78 patients with intracranial aneurysms.	Complete occlusion = 90.5% Adequate occlusion = 5.4%	Retreatment = 1.3% Perforation = 1.3% Morbidity = 3.8%
[43] Ng et al. (2020)	21 patients treated for hematoma with embolization	Technical success = 95.2% Hematoma reabsorption = 52.6ml Surgical reoperation = 4.8% Mortality = 0	Seizure = 4.8% Surgical rescue treatment = 4.8%
[44] Poncyljusz et al. (2020)	17 patients with 18 aneurysms	Technical Success = 100% Immediate complete occlusion = 76.5% Immediate occlusion adequate / complete = 100% Immediate occlusion follow-up = 88.2%	Stent perforation = 5.6% SAH = 5.6%

#	Patient Population	Results	Adverse Events / Complications
		90-day mRS 0-2 = 100%	
[45] Son et al. (2020)	17 patients with 18 aneurysms	Technical Success = 100% Clinical Success = 94.4% Immediate occlusion adequate / complete = 61.1% Follow-up occlusion adequate / complete = 83.3% mRS 0-2 = 100%	Retreatment = 5.6% Post-procedure stroke = 11.1% Delayed stroke = 5.6% Mortality = 0
[46] Xue et al. (2020)	31 patients with intracranial aneurysms	Technical Success = 100% Complete occlusion = 87.1% Adequate/complete occlusion = 93.6% mRS 0-2 = 83.9% Long term occlusion = 96.1%	Severe cerebral vasospasm = 6.5% Mortality = 6.5% Thrombolic event = 3.2% Aneurysm bleeding = 3.2% Additional device needed = 3.2% Additional treatment needed = 3.2%
[47] Yüce and Taşar (2020)	37 patients treated with intracranial aneurysms	Technical success = 86.4%	Vasospasm = 10.8% Mortality = 10.8% Additional treatment needed = 2.7% Tissue damage = 2.7%
[48] Zhang et al. (2020)	303 patients with cerebral aneurysms	Good outcomes = 91.4%	Aneurysm perforation = 4.6% Thromboembolic events = 12.9%
[49] Fiorella et al. (2019)	153 patients with wide-necked cerebral aneurysms	Technical success = 97.3% Complete occlusion at 12 months = 79.1% Artery stenosis ≥50% = 0 Retreatment = <3.9% (reported as <5%)	Stroke complications = 9.2% Major stroke at 30 days = 2.6% Minor stroke at 30 days = 3.9% Mortality at 30 days = 2% Major ipsilateral stroke at 30 days – 12 months = 2% Neurologic death >30 days = 1.4%
[50] Goland and Doroszuk (2019)	59 patients with 61 aneurysms	Technical success = 100%	None reported
[51] Martínez-Galdámez et al. (2019)	41 patients with 43 intracranial aneurysms	Technical success = 100% Complete occlusion = 18.6% Adequate occlusion = 11.6%	Vasospasm = 4.7% Artery perforation = 2.3% Aneurysm rupture = 0 Infection = 2.3%
[52] Pierot et al. (2019)	103 patients with intracranial aneurysms.	Technical success = 95.1% Additional devices used = 24.4% Complete occlusion = 61.1% Adequate occlusion @ 6 months = 82.1% Retreatment = 2.2%	Aneurysm rupture = 1.9% Arterial perforation = 1% Hemorrhagic complications = 1% Mortality = 1.9% Thromboembolic complications = 6.8%
[53] Schob et al. (2019)	25 patients with 27 intracranial aneurysms	Technical success = 100% Complete occlusion = 63%	Procedure related complications = 0 Mortality = 0 Additional device needed = 11.1% Hemorrhagic complications = 0
[54] Wu et al. (2019)	32 patients with intracranial aneurysms	Technical success = 100% Complete occlusion = 40.6% Adequate/complete occlusion = 78.1% Complete occlusion at follow-up = 82.1% mRS 0-1 = 96.9%	Mortality = 0 Ruptures = 0 Thromboembolic events = 0 Asymptomatic stenosis = 3.6% Hemorrhagic complications = 0

#	Patient Population	Results	Adverse Events / Complications
[55] Ares et al. (2018)	50 patients treated with manual aspiration thrombectomy	Technical success = 100% mRS 0-2 = 48%	Device related complications = 0 Dissection = 0 Perforation by device = 0 Perforation by microwire = 2.0% Additional device needed = 0
[56] Manzato et al. (2018)	28 patients with 38 intracranial aneurysms	Technical success = 100% Complete aneurysm obliteration at 6 months = 79%	Mortality = 0 Thrombosis complication = 7.1% Neurologic deterioration = 7.1%
[57] Samaniego et al. (2018)	30 patients treated with intracranial aneurysms	Technical success = 100% Complete obliteration = 89.6% mRS 0-2 = 86.7%	Stroke = 3.3% Mortality = 10% In-stent thrombosis = 3.3%
[58] Santillan et al. (2018)	35 patients with 35 intracranial aneurysms	Technical success = 100% Complete occlusion = 72.4% mRS 0-2 = 97.1%	Vessel dissection = 0 Aneurysm rupture = 2.8% In-stent thrombosis = 11.4% In-stent stenosis = 3.4% Neurological morbidity = 2.9% Mortality = 0
[59] Su et al. (2018)	218 patients with 225 intracranial aneurysms	Technical success = 100% Adequate/complete occlusion = 98.2% mRS 0-2 = 97.5%	Vessel perforation = 0.5% Hemorrhagic complication = 0.5% In-stent thrombosis = 1.4% Mortality = 0.9%
[60] Luecking et al. (2017)	50 patients with 52 intracranial aneurysms	Technical success = 100% Complete occlusion = 72.3% Adequate/complete occlusion 87.2%	Device related complications = 0 Mortality = 0 Additional device used = 4%
[61] Möhlenbruch et al. (2017)	42 patients with 47 intracranial aneurysms	Technical success = 100% Adequate/complete occlusion = 66% at 1 month (27/41), 78% at 6 months (21/27), and 100% at 12 months (11/11)	Device related complications = 0 Mortality = 0 Stroke = 4.8% TIA = 2.4%
[62] Shankar et al. (2017)	100 patients with saccular aneurysms	Technical success = 100%	Mortality = 1% Aneurysm rupture = 1% Permanent neurological deficits = 3% Stroke = 2%
[63] Guengo et al. (2021)	16 patients with 17 distal, medium vessel occlusions.	Technical success = 100% mTICI ≥2b = 94% 90-day mRS 0-2 = 65%	sACH = 29% Mortality = 6% Vasospasm = 17% Minor bleed = 6%

Clinical Data from Post-Market Surveillance

MicroVention has an historical complaint rate for the Headway/Wedge family of devices of approximately 0.16%, of which only about 1% are reportable to governmental authorities.

1.5.2. Clinical Performance and Safety

Neurovascular lesions, such as intracranial aneurysms, can cause potential injury or death if left untreated. Endovascular interventions to treat these conditions require access to the desired vascular site of treatment using access devices, including microcatheters. The Headway™ and Wedge™ Microcatheters are intended for the introduction of interventional devices and infusion of diagnostic agents into the neuro and peripheral vasculature, and as such, allows access to the vascular site of interest.

Successful treatment of conditions avoids some risks and complications associated with these conditions. Either the Headway™ or Wedge™ Microcatheters used as an access device is not a primary therapeutic device on which the treatment outcomes of safety can be based. However, success and benefits of using either microcatheter in association with a primary treatment device, such as the endovascular coils, especially when compared against the risks and complications associated with the conditions that necessitate treatment, are substantial. Among various endovascular treatments that utilize the subject devices, the utilization of a Headway™ or Wedge™ Microcatheter in this treatment has been widely investigated and accepted as a safe and effective method.

35 of the reference papers reported 100% technical success, which implies the subject devices performed as indicated. In addition, nine additional papers reported technical success >85%. It should be noted that not all included papers stated a technical success rate, but it can be implied that, based on other included data, technical success was substantial.

For the Headway and Wedge devices, adverse events rates reported in the included published literature are listed in the Literature Summary Table. Listed harms may be a result of more than one hazard (source of harm). There were no new harms identified in the published literature that were not already considered through the risk management process.

Again, it should be stressed that it is difficult to determine if an adverse event is due to the catheter device or another device utilized in the procedure. However, it should be noted that almost all, if not all, published harms were not directly linked to the Headway or Wedge device and were most likely a complication of the overall procedure, which involved a number of devices other than the subject device. Recall that the subject device is an accessory device and only utilized as part of an overall more involved treatment procedure.

1.5.3. Post-Market Clinical Follow-up

No Post-Market Clinical Follow-up activities or studies have been initiated or completed for the Headway or Wedge Microcatheter devices.

1.6. Possible Diagnostic or Therapeutic Alternatives

1.6.1. Treatment Options and Interventions

Current treatment options for vascular diseases include one or a combination of the following: lifestyle modification, medical management, and/or surgical approaches including endovascular

interventions. The location and type of the vascular issue and the patient circumstances in each case dictate whether one treatment approach may be favored over another.

In cases where lifestyle modification alone is not successful in reducing symptoms or progression of the disease, the use of medication in conjunction with lifestyle modification may be recommended. Statin therapy is by far the most well-recognized cholesterol-lowering therapy in the management of cardiovascular and peripheral vascular disease. Other medical management includes antiplatelet therapy, anticoagulation, vasodilators and antihypertensive therapy. Treatment for thrombosis / embolisms, can include thrombolytic drugs, such as intravenous tissue plasminogen activator (t-PA), however, intravenous thrombolysis can have limited reperfusion in some anatomic locations as well as having a narrow therapeutic window (for example, ≤4.5 h after onset in acute ischemic stroke (AIS)).

Open or laparoscopic surgery are more direct treatment options that can be used to ligate ruptured blood vessels or malformations. The risk for open surgery includes restenosis, infection, and long recovery time. If a patient is a candidate for either open or laparoscopic surgery, the less invasive option is the current standard of care.

Endovascular surgery is a minimally invasive surgical option that delivers interventional therapies for vascular disease from within the vascular system. Endovascular surgery can be used to either inhibit or restore blood flow in the target vessels through the use of devices such as coils, stents, stent retrievers (stentrievers) and flow diverters. In treatment of AIS, endovascular mechanical thrombectomy techniques combined with chemical thrombolysis are routinely utilized.

Endovascular surgery is initiated with the placement of a catheter through a major vessel (e.g., femoral or radial artery), passing from an entry incision site in the skin to the target vasculature. Interventional therapies can then be delivered through the catheter. The placement of the catheter requires the use of the Seldinger Technique. This technique involves an initial puncture of the artery with a hollow needle, followed by the introduction of a guidewire through the needle. The needle is then removed, and a catheter is tracked over the guidewire into the lumen of the vessel. The guidewire can then be subsequently removed.

In endovascular procedures, both guide catheters and microcatheters, such as the subject devices of this clinical evaluation, are used to advance interventional and diagnostic devices (e.g., guidewires, microcatheters, coils, stents, balloons, or chemical agents), through the vasculature from the entry site to or nearly to the surgical location. Guide catheters are large diameter catheters (5-7F) that provide support and lubricity for the passage of additional devices, sometimes accommodating multiple devices simultaneously, through vascular anatomy. In contrast, the small diameter of a microcatheter (1-3F) together with its steerability, trackability, and flexibility, allows for navigation through narrow tortuous vessels for the distal placement of balloons, flow diverters, coil, and other embolic or diagnostic agent.

Treatment of coronary chronic total occlusions has advanced greatly since its advent in the late 1970s through the development of dedicated wires and microcatheters, the improved skills of

highly experienced operators and the adoption of new sophisticated strategies to guide procedural planning. The contemporary procedural success rate is 80-90% with a reduction in complications.

In addition, the treatment or peripheral vasculature issues has also greatly benefited from the progress with microcatheters. Embolization is routinely performed in many clinical situations including arterial/venous bleeding, vascular/lymphatic malformations, visceral/renal aneurysms, endoleaks, variceal diseases, pre-surgical treatments, oncological treatments, and benign/hypertrophic nodules/organs. Each of these treatments could not be done without the use of a microcatheter. Embolic agents can be released using standard four or five French catheters but often using coaxial microcatheters, particularly in case of tortuous, distal, and/or small caliber vessels. TransArterial ChemoEmbolization (TACE) treatment, meaning TACE performed selectively with a microcatheter positioned as close as possible to the tumor, has been demonstrated to improve outcomes, maximizing the anti-tumoral effect and minimizing the collateral damages of the surrounding tissue/organs.

1.6.2. Available Technologies

Microcatheters are well established medical devices with numerous types and styles available from a variety of manufacturers. Examples of microcatheters similar to the Headway and Wedge Microcatheters are listed in Table 1.6.

Table 1.6 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 neuro vasculature.

1.7. Suggested Profile and Training for Users

The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the Instructions for Use prior to using the Headway/Wedge device product.

1.8. Reference to any Harmonized Standards and CS

A listing of the standards and common specifications, as listed in the CER, is shown in **Table 1.7**.

Table 1.7 Standards and Guidance Documents

Standard / Guidance No.	Compliance	Standard / Guidance Name	Edition
Quality System			
EN ISO 20417	Full	"Terminology, Symbols and Information Supplied with Devices."	2021
EN 62366-1	Full	Medical devices – Part 1: Application of usability engineering to medical devices	2020
EN ISO 13485	Full	Particular requirement for application of ISO 9001	2016 / A11:2021
EN ISO 14971	Full	Medical Device – Application of Risk Management to medical devices	2019 + A11:2021
EN ISO 14155	Full	Clinical investigation of medical devices for human subjects -- Good clinical practice	2011 / AC:2020
EN ISO 14644-1	Full	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness	2015 / Reaffirmation:2021
ISO 14644-2	Full	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	2015 / Reaffirmation: 2021
EN ISO 14644-3	Full	Cleanrooms and associated controlled environments -- Part 3: Test methods	2020
ISO TR 20416	Full	Medical devices – Post-market surveillance for manufacturers	2020
Packaging, Labeling, and Sterilization			
EN ISO 11070	Full	Sterile, single-use intravascular introducers, dilators and guidewires	2014 / A1:2018
ASTM 1980	Full	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2021
EN 556-1	Full	Sterilization of medical devices – Requirements for medical devices to be designated as "STERILE" – Part 1: Requirements for terminally sterilized medical devices.	2001 / Reaffirmation 2016
EN 556-2	Full	Sterilization of medical devices – Requirements for medical devices to be designated as "STERILE" – Part 2: Requirements for aseptically processed medical devices.	2015
EN ISO 10555-1	Full	Sterile, Single-Use Intravascular Catheters - Part 1: General Requirements	2013+A1:2017
EN ISO 11135-1	Full	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)	2020
EN ISO 80369-7	Full	Small-bore connectors for liquids and gases in healthcare applications. Connectors for intravascular or hypodermic applications	2021
EN ISO 80369-20	Full	Small-bore connectors for liquids and gases in healthcare applications. Part 20: Common test methods	2015
EN ISO 11607-1	Full	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	2020
EN ISO 11607-2	Full	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)	2020
EN ISO 11737-1	Full	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products.	2018/A1:2021

Standard / Guidance No.	Compliance	Standard / Guidance Name	Edition
Quality System			
EN ISO 15223-1	Full	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied - General requirements	2021
		Biocompatibility	
EN ISO 10993-1	Full	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)	2020
EN ISO 10993-3	Full	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2003)	2014
EN ISO 10993-4	Full	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amend 1:2006)	2017
EN ISO 10993-5	Full	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2017
EN ISO 10993-6	Full	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)	2016
EN ISO 10993-10	Full	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	2021
EN ISO 10993-11	Full	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)	2018
EN ISO 10993-12	Full	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)	2021
EN ISO 10993-16	Full	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachable (ISO 10993-16:2010)	2017
EN ISO 10993-17	Full	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	2009
EN ISO 10993-18	Full	Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)	2020
EN ISO 10993-23	Full	Biological evaluation of medical devices - Part 23: Tests for irritation	2021
ASTM F2475	Full	Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	2020
ASTM F748	Full	Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices	2016
Product Specific			
ISTA 3A	Full	ISTA (International Safe Transit Association) Procedure 3A – Performance Tests for Packaged-Products for Parcel Delivery System 150 lbs. (70 kg) or Less	2018
ASTM F640	Full	Standard test methods for determining radiopacity for medical use	2020
EN 1618	Full	Catheters other than intravascular catheters. Test methods for common properties	1997
MDD & MDR			
MEDDEV 2.7/1	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies		
MDR	European Medical Device Regulation (MDR) 2017/745		

Standard / Guidance No.	Compliance	Standard / Guidance Name	Edition
Quality System			
Council Directive 93/42/EEC as amended by 2007/47/EC	Medical Device Directive (MDD) concerning medical devices		
MDCG 2019-9	Summary of safety and clinical performance		
MDCG 2020-5	Clinical Evaluation – Equivalence		
MDCG 2020-6	Regulation (EU) 2017/745: clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/386/EEC		
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template		
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template		

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1.10. Validation History

SSCP Revision	Date Issued	Change Description	NB Validation
A	TBD	Initial SSCP	☒Yes ☐ No* Validation language: English
			☐ Yes ☐ No*

			Validation language:

*only applicable for class IIa or some IIb implantable devices for which the SSCP is not yet validated by the NB

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2. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

[Patient version]

Document Revision: A
Date Issued:

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 information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

2.1. Device Identification and General Information

Table 2.1 Device Identification and General Information

Device Names	
Device Trade Name	Headway 17, Headway 21, Headway Duo, Wedge, Wedge XL Microcatheters
Device Class	Class III
Basic UDI-DI	08402732HEADWAYWEDGE4N
Year when first certificate (CE) was issued	Headway – 2008 Wedge – 2017
Legal Manufacturer	
Name & Address	MicroVention, Inc. 35 Enterprise Aliso Viejo, California, 92656 USA
Authorized Representative	
Name & Address	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye, France
Notified Body	
Name & Address	DQS Medizinprodukte GmbH Team Change Management / Team Aenderungsmeldungen August-Schanz-Str. 21 60433 Frankfurt a. Main Germany

2.2. Intended Use of the Device

Table 2.2 Intended Use

Intended Use	
Intended Purpose Indications for Use	The Headway and Wedge Microcatheters (small flexible tubes) are intended for general use in blood vessels, for the placement of materials or other devices to treat disease.
Intended Patient Group(s)	The Headway or Wedge devices are used in patients who require that flexible tubes be placed into their blood vessels in order to place additional devices or drugs for treatments.
Contraindications and/or Limitations	There are no known reasons not to use the device.

2.3. Device Description

Table 2.3 Device Description

Device Description	
Description of the Device	The Headway and Wedge Microcatheters are small flexible tubes (microcatheters) that can be placed in a blood vessel to access other areas of the blood vessel that need treatment. Medicines are even smaller devices can be delivered to the area that needs treatment by having them go through the Headway or Wedge device.
Materials or substances in contact with the patient's tissues	The outside coating of the small flexible tube may be in contact with the patient's blood. The tube is coated with a material to allow easy movement through the blood.
Description of how device achieves its intended mode of action	When access to a blood vessel is necessary to deliver a device or drug, a flexible tube needs to be placed into the blood vessel. The small flexible tube is moved through the vessel to the area where the other device or drug is needed. That area of the blood vessel can then receive the necessary treatment.
Description of Accessories	A connector (luer) on the tube end is used for the attachment of accessories. A shut-off valve (rotating hemostatic valve) may be attached to the tube end and used to add other materials into the tube.

2.4. Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed. Steps have been taken to lessen or remove possible risks associated with the use of the catheters.

Treatment into blood vessels does have some remaining risks. These risks include:

- A hole made in a blood vessel

- Sudden narrowing of a blood vessel
- Blood clot at the site where the wire is inserted
- A blockage in a blood vessel
- Reduced blood supply to an area of the head or body
- Blood leaking into a tissue due to a hole in a blood vessel
- Damage to a blood vessel wall
- A sudden uncontrolled disturbance in the brain
- Reduced or blocked blood flow to the brain
- Infection
- Death
- A blockage/clot in a blood vessel

Warnings and precautions associated with the catheters include:

- The device should only be used by trained doctors.
- The guidewire should not be used if the package has been opened or damaged.
- The guidewire is for single-use only.

2.5. Summary of Clinical Evaluation and Post-Market Clinical Follow-up

Catheters are used with other devices to treat the patient, with the outcome due to the overall procedure, and not due to any individual device. The use of the catheter as part of the overall procedure provides the benefit to the patient.

- Clinical background of the device
  The Headway device have been available for use in patients since 2008, and the Wedge devices have been available for use in patients since 2017. They have a proven record of safety and successful performance since that time.

- The clinical evidence for the CE-marking
  Clinical evidence for the safety and performance of the Headway and Wedge devices comes from the published scientific literature. The recent literature describes the successful use of the device in over 4000 patients treated for different reasons.

- Safety
  The manufacturer continuously collects information concerning the safety and performance of the device, and studies that information for any new risks or hazards. Steps are taken to remove any possible risks and to make sure the device still provides benefits to the patient.
  The manufacturer continuously studies data for the device and makes sure the benefits of the use of the device are better for the patient than any possible risk.

2.6. Possible Diagnostic or Therapeutic Alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

Treatment option for blood vessel disease varies widely. Treatments can include treatments with drugs or with surgery. A procedure that enters through a blood vessel is less involved than brain surgery, for example.
A procedure that enters through a blood vessel involves using a special tool needed to make an entry incision along a major blood vessel through which a flexible tube (catheter) can be placed extending from the entry site to the target location within the blood vessel. Treatments or other devices can then be delivered through the tube. The use of these flexible tubes is necessary for the delivery of the medicine or other treatment device to the area where treatment is needed.
Catheters for this type of treatment are made by a number of companies. Please discuss with your healthcare provider options for different devices.

2.7. Suggested Training for Users

The device should only be used by physicians who are familiar with use of catheters in blood vessels in the head and body.