Summary of Safety and Clinical Performance

for

Headway ™ and Wedge ™ Microcatheters

SSCP23-0010

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DOCUMENT CHANGE HISTORY

SSCP Revision	Change Description	NB approved/verified
A	Initial SSCP Release, 11 July 2024	☒Yes ☐ No* Validation language: NA
B	2024 template update, administrative update, 1 May 2025	☐ Yes ☐ No* Validation language: NA

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

TABLE OF CONTENTS

LIST OF TABLES

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	Headway 17, Headway 21, Headway Duo, Wedge, Wedge XL Microcatheters
EMDN Code	C0104020202
Medical Device Nomenclature (EMDN)	Peripheral embolization catheters and microcatheters, Code 17846
Device Class	Class III medical device in accordance with the European Medical Device Regulation 2017/745 Annex VIII Rule 7
Basic UDI-DI	08402732HEADWAYWEDGE4N
Year when first certificate (CE) was issued for the device	Headway - 2008, Wedge - 2017, 435827 MRA
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-AR-000004448
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	Information has been retrieved from IFU100262, IFU100327, IFU100305, IFU212795 and IFU100306. The Headway™ 17, 17 Adv, 21, 27 Microcatheters are intended for general intravascular use, including the peripheral and neuro vasculature for the infusion of diagnostic, such as contrast media, and therapeutic agents, such as occlusion coils, (IFU100305). 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, (IFU100327). 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. (IFU100306). 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, (IFU100262).
Indications for Use	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 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. 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.

Target Population	The Headway™ and Wedge™ Microcatheters are intended for general intravascular use, including use in the peripheral and neuro vasculature, and are to be used in patients requiring such treatment.
Contraindications and/or Limitations	The are no known contraindications for the Headway™ and Wedge™ Microcatheters. (IFU100262, IFU100327, IFU100305, and IFU100306)

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: 1. Headway™ 17 Advanced Soft 2. Headway™ 17 Advanced 3. Headway™ 21 4. Headway™ 27 5. Headway™ Duo 6. Wedge™ 7. Wedge™ XL Microcatheters. Throughout this document, Headway™ Microcatheters will refer to all five types of Headway™ Microcatheters, and Wedge™ Microcatheters will refer to both Wedge™ and Wedge™ XL Microcatheters. As demonstrated in the CER the Wedge™ XL Microcatheter is considered a line-extension of the Wedge™ Microcatheter: The Wedge™ XL Microcatheter can be considered identical to the Wedge™ Microcatheter except for a larger outer diameter. The Headway™ and Wedge™ Microcatheters are designed and intended to deploy embolic materials and other therapeutic agents. The Headway™ and Wedge™ Microcatheters are single lumen catheters with a semi-rigid proximal section with an outer shaft made of Grilamid nylon. The microcatheter transitions to progressively softer durometers and different lengths of Polyether block amide (Pebax). Radiopaque marker bands made of platinum/iridium alloy on the distal tip provide fluoroscopic visualization. The Headway™ products have two radiopaque marker bands, while the Wedge™ Microcatheter has three radiopaque marker bands. The Wedge™ Microcatheter also has a slightly enlarged distal segment, and an atraumatic distal tip made of polyurethane. The Headway™ and Wedge™ Microcatheters are shown Figure 1, Figure 2 and Figure 3. The outer surface of the Headway™ and Wedge™ Microcatheters is coated with a hydrophilic polymer coating to reduce friction during navigation in the vasculature. The Headway™ and Wedge™ Microcatheters have a lubricious inner liner to reduce friction when delivering therapeutic agents. The lubricious inner liner is made from polytetrafluorethylene (PTFE).

A clear nylon hub is attached to the proximal end of the microcatheter. A strain relief made from Pebax is placed at the proximal end of the microcatheter and distal end of the hub. A luer fitting on the microcatheter hub is used for the attachment of accessories. The hub/strain relief provides for the kink resistance from the proximal end. A steam shaping mandrel accessory is packaged with the catheter. An introducer sheath is also included to facilitate the introduction of the microcatheter into the y-connector.

The Wedge™ Microcatheter shares the same basic design and construction as the Headway™ Microcatheters. The Wedge™ Microcatheter has a slightly larger segment on the distal end of the microcatheter intended to reduce the ledge between the outside diameter of the guidewire and the inside lumen of the guide catheter being used in the procedure, creating improved navigation in certain types of vasculature, particularly when navigating past a bifurcation.
The Headway™ and Wedge™ Microcatheters do not incorporate a medicinal substance, animal tissues, or blood products.

Figure 1. Headway™ Microcatheter Diagram

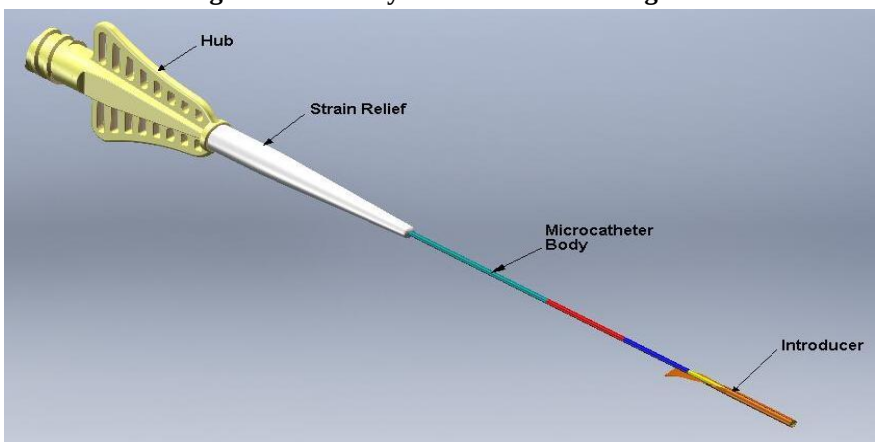


Figure 2. Wedge™ Microcatheter Diagram

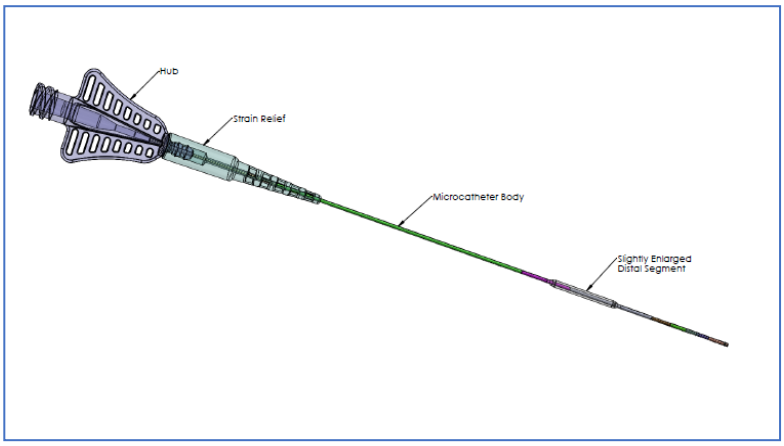
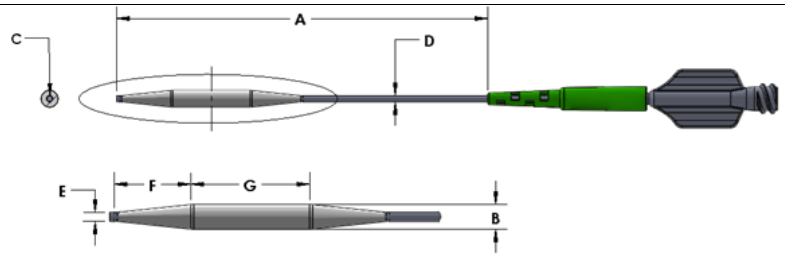


Figure 3. Wedge™ XL Microcatheter Diagram

	 *A, working length; B, bulb diameter; C, inner diameter; D, Diameter (outer), proximal; E, diameter (outer), distal; F, distal market band distance; G, bulb marker band distance.*
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. A 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™ 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. The Headway™ and Wedge™ Microcatheters does not incorporate a medicinal substance, animal tissues, or blood products. Patient contact occurs with catheter body and coating.
Previous Generations or Variants, if applicable	This is the first generation of this product. There are no previous generations. Not applicable.
Single use – sterilization method	The Headway™ and Wedge™ Microcatheters are a single use / disposable device with limited contact with circulating blood (less than or equal to 24 hours). The device is sterilized using 100% ethylene oxide (EtO), Ethylene Oxide Sterilization - Cycle 11
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 into the y-connector.
Description of other Devices or Products	The Headway™ and Wedge™ Microcatheters are intended to treat conditions requiring the access intravascular infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils. This includes use in directly

intended to be used in combination	or indirectly advancing devices such as guidewires, microcatheters, coils, stents, and balloons to treat a wide variety of vascular conditions. They are used in general vasculature including the peripheral and neuro vasculature.

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.

Risks associated with the subject device include the following:

- 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

They are also mentioned in IFU100262, IFU100327, IFU100305, IFU212795 and IFU100306.

The worldwide unit sales and complaint records for the Headway™ and Wedge™ from 01 July 2019 to 30 June 2023 include a total of 591,724 units shipped and 1,202 complaint records, for an overall complaint rate of 0.20%.

1.4.2 Warnings and Precautions

The warnings / precautions for the Headway™ and Wedge™ Microcatheters are as mentioned in IFU100262, IFU100327, IFU100305, IFU212795 and IFU100306:

Headway™ Microcatheters

The warnings / precautions for the Headway™ Microcatheters are (IFU100305, IFU212795):

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 it 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 of the 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, which are labeled as sterile. Do not use it 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 precautions 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 (IFU100327):

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 it 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 of the 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, which are labeled as sterile. Do not use it 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 precautions 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 (IFU100306):

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 it 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 of the 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, which are labeled as sterile. Do not use it 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 precautions 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 Microcatheter

The warnings / precautions for the Wedge™ XL Microcatheters are (IFU100262):

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. Visually inspect all the sterile barrier systems, which are labeled as sterile, immediately prior to use. Do not use if breaches in sterile barrier system integrity are evident, such as pouch is damaged, open. The Wedge™ XL Microcatheter is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose of the 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 events.

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 precautions 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 precautions 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 are mentioned in IFU100262, IFU100327, IFU100305, IFU212795 and IFU100306.

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

Field Actions are conducted in accordance with the Field Corrective Actions (SOP 8.7) procedure. During the time period 01 July 2019 to 30 June 2023 covered by the PSUR there were no Field Actions involving the Headway™ and Wedge™ devices.

The FDA MAUDE system identified 26 MAUDE records for the subject device captured in the MicroVention complaint system. In 11 of the 26 subject device records (42.3%), there were 'no clinical signs, symptoms or conditions' reported. The adverse events / complications occurring with the subject device were:

- No Clinical Signs, Symptoms or Conditions (11)
- Insufficient Information (3)
- No Consequences Or Impact To Patient (2)
- Intracranial Hemorrhage; Rupture (1)
- Perforation of Vessels (1)
- Hematoma; Intracranial Hemorrhage; Loss of consciousness; Ischemia Stroke (1)
- Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available (1)
- Hemorrhage, Cerebral; Rupture (1)
- Paralysis; Paresis; Ischemia Stroke (1)
- Vascular Dissection (1)
- Foreign Body In Patient; No Clinical Signs, Symptoms or Conditions (1)
- Anaphylactic Shock (1)
- Intracranial Hemorrhage (1)

1.5 Summary of the Clinical Evaluation and PMCF

There are no pre-market clinical investigations for the Headway™ and Wedge™ Microcatheters. As the Headway™ and Wedge™ Microcatheters (with the exception of the Wedge™ XL device) are legacy devices (marketed since 2008 and 2017, respectively) and as the initial CE-marking was based on equivalence, pre-market clinical investigations were not conducted.

Regarding Wedge™ XL , no clinical investigations necessary as it is a line extension to the Wedge™(the equivalent device). Clinical data from the Wedge™ will be used to support the Wedge™ XL.

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

1.5.1 Equivalent Device Clinical Data

The Headway™ Microcatheters serve as an equivalent device for the Wedge™ Microcatheters; as such, clinical data for the Headway™ microcatheters is relevant to the Wedge™ microcatheters. Similarly, the Wedge™ Microcatheters serve as an equivalent device for the Wedge™ XL microcatheters. Equivalence has been claimed and established (MicroVention Inc., Basic UDI-DI: 08402732HEADWAYWEDGE4N).

The Wedge™ Microcatheter is the equivalent device for the Wedge™ XL Microcatheter. The Wedge™ Microcatheter is manufactured by MicroVention and is commercially available for general intravascular use, including the peripheral and neuro vasculature, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents. The publications included in the Clinical evaluation report were from the Headway™ Microcatheters.

Literature search results demonstrate clinical use of the Headway™ and Wedge™ Microcatheters to facilitate distal vascular access, delivery of embolization materials, and infusion of diagnostic or therapeutic agents in patients with a variety of neurovascular and peripheral vascular conditions. The clinical evidence was identified, collected, and appraised from published peer-reviewed literature. The literature search was performed using a sound methodological process, and the relevant data are mainly associated with the use of Headway™ Microcatheters for the treatment of intracranial aneurysms, in addition to other medical conditions.

A total of 89 published articles were included in the clinical evaluation, comprising 59 retrospective studies, 12 prospective studies, 16 case reports, and 2 case series. The overall quality of the study designs assessed was rated as moderate to high.

These clinical results are consistent with the State of the Art, and they support the safety and performance of the Headway™ and Wedge™ Microcatheters within their intended indications.

1.5.2 Pre-CE-Mark Clinical Data

There are no pre-market clinical investigations for the Headway™ and Wedge™ Microcatheters. As the Headway™ and Wedge™ Microcatheters (with the exception of the Wedge™ XL device) are legacy devices (marketed since 2008 and 2017, respectively) and as the initial CE-marking was based on equivalence, pre-market clinical investigations were not conducted.

Regarding Wedge™ XL , no clinical investigations necessary as it is a line extension to the Wedge™(the equivalent device). Clinical data from the Wedge™ will be used to support the Wedge™ XL.

1.5.3 Clinical Data

See section Error! Reference source not found. from the methodological and systematic literature search that includes 89 articles, [1-89]. Clinical data sources to evaluate the safety and performance of the Headway™ and Wedge™ microcatheter was collected from the following reputable data sources.

Published Peer-reviewed Clinical Literature

The literature search detailed in the clinical evaluation report (CER) presents relevant clinical studies in the published literature.

The common clinical benefits found in the literature are technical or procedural success, rates of complete embolization and mRS. The range of technical or procedural success rate is 97.4% to 100%. In the SOTA the mRS score of 0-1 was reported at 2 years in comparison to the devices under evaluation which was reported as 0-1 at 27.4 months.The rate of complete embolization ranged up to 81.8% for a follow-up period range 45.3 months.

The performance parameters identified in the systematic literature review are similar to the parameters in the State of the Art for the common standard of care i.e., technical success of 98.5% to 100% and complete aneurysm occlusion up to 90% at 30.6 months. In overall, the clinical benefits associated with the use of the Headway/Wedge microcatheters are deemed acceptable as compared to the state of the art for the indications of use of this device.

Complications cited in the published literature were collected and detailed in the Clinical Evaluation report per publication. It should be noted that complications reported in the literature may not be directly related to or cause by the subject device. The Headway and Wedge Microcatheters are access devices, and not the primary device involved in the treatment of the primary condition.

Overall common complications included hemorrhage, aneurysm rupture and hematoma and ranged from 0-10.4%, 0-4.8% and 0-5%. Complications cited in the published literature were collected and detailed in the Clinical evaluation report for each publication. All the complications are all identified in the risk documentation, and they are deemed acceptable.

Safety outcomes are for procedures in which the equivalent device was used and not specifically attributed to the equivalent device.

PMS Data Source

The worldwide unit sales and complaint records for the Headway™ and Wedge™ from 01 July 2019 to 30 June 2023 include a total of 591,724 units shipped and 1,202 complaint records, for an overall complaint rate of 0.20%. No Field Actions or recalls occurred during this period, and all 11 CAPAs opened were closed.

During the time period covered by this PSUR there were zero (0) Field Actions involving Headway™ and Wedge™

During the current review period, eleven (11) CAPAs were opened or in process that pertained to Headway™ and Wedge. All CAPAs have been closed

The FDA MAUDE system identified 26 MAUDE records for the subject device captured in the MicroVention complaint system. In 11 of the 26 subject device records (42.3%), there were ‘no clinical signs, symptoms or conditions’ reported.

1.5.4 Clinical Performance and Safety

The clinical performance data presented in this document, collected from published literature, post-market clinical studies, and post-market surveillance, demonstrates the overall performance of the Headway™ and Wedge Microcatheters. The literature review demonstrated acceptable clinical performance outcomes, shown in high technical success rates and lower complication rates associate with the use of the subject device. The post-market surveillance data demonstrates acceptable overall clinical performance through the high Headway™ and Wedge Microcatheters. technical success in the vast majority of the patients that the Headway™ and Wedge Microcatheters. were used for treatment, as evidenced by the extremely low rates of vigilance reportable complaints and adverse events that are attributable to the subject devices. The data collected is considered sufficient to determine that the Headway™ and Wedge Microcatheters. achieve the performance intended and is suitable for the intended purpose.

The clinical evaluation included 89 published articles (59 retrospective studies, 12 prospective studies, 16 case reports, and 2 case series), selected through a methodologically sound literature search. The overall study quality was moderate to high.

The Headway™ and Wedge™ Microcatheters provide clinical benefits by facilitating distal vascular access, enabling effective delivery of embolization materials and therapeutic agents, and achieving successful endovascular outcomes. These benefits directly support the device claims in the IFU and promotional materials. Clinical performance outcomes demonstrated high to complete technical or procedural success rates of **97.4% to 100%**, and complete embolization rates up to **81.8%** during follow-up periods of up to **45.3 months**. These results are consistent with the State of the Art.

The adverse events reported in the data sources are identified in the IFUs by the manufacturer and are deemed acceptable. The benefit-risk assessment concludes that the benefits outweigh the risks, with high procedural success rates and acceptable complication rates, including hemorrhage (0–10.4%), aneurysm rupture (0–4.8%), and hematoma (0–5%). No new risks were identified. Complications cited in the published literature were collected and detailed in the Clinical evaluation report for each publication. All the complications are all identified in the risk documentation, and they are deemed acceptable. Comparison of Adverse Events across data sources is summarized in the table below.

Table 1.4: Comparison of Adverse Events across all data sources

Adverse Events/Residual Risk identified within IFU	Adverse Events (Similar Events) identified within Scientific Literature	Adverse Events (Similar Events) identified within PMS
vessel or aneurysm perforation	Yes	No
vasospasm	Yes	No
hematoma at the site of entry	Yes	Yes
embolism	Yes	No

Adverse Events/Residual Risk identified within IFU	Adverse Events (Similar Events) identified within Scientific Literature	Adverse Events (Similar Events) identified within PMS
ischemia	Yes	
intracerebral/intracranial hemorrhage	Yes	Yes
pseudoaneurysm	No	No
seizure	No	No
stroke	Yes	Yes
infection	No	No
vessel dissection	Yes	Yes
thrombus formation	Yes	No
death	Yes	No

Overall, the Headway™ and Wedge™ Microcatheters are safe and effective when used as intended.

1.5.5 Post-Market Clinical Follow-up

Currently, there are no ongoing or planned post-market clinical investigations for the Headway™ and Wedge™ Microcatheters. 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 Headway™ and Wedge™ Microcatheters 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

1.6.1 Treatment Options and Interventions

Lifestyle Modification

Lifestyle modification is the first-line approach for managing vascular diseases [90, 91]. It focuses on reducing symptoms and slowing disease progression through interventions such as diet, exercise, and smoking cessation. While lifestyle changes are often effective for early-stage disease, some patients may eventually require additional medical therapies if symptoms persist or disease progresses [90, 91].

Medical Management

Medical therapy complements lifestyle changes to further reduce vascular disease burden. Statins remain the primary cholesterol-lowering agents in the management of cardiovascular and peripheral vascular diseases. Additional pharmacological therapies include antiplatelet agents, anticoagulants, vasodilators, antihypertensive medications, and smoking cessation support [90]. These treatments improve mortality rates, reduce symptoms, and lower complication risks. In thrombotic and embolic disease, intravenous thrombolytic therapy such as tissue plasminogen activator (t-PA) may be used; however, thrombolysis alone has limitations, including reduced reperfusion success in certain anatomical locations and a narrow therapeutic window (≤4.5 hours after symptom onset in acute ischemic stroke (AIS)) [92, 93]. The combination of thrombolysis with mechanical thrombectomy is now the standard of care for AIS, significantly improving reperfusion outcomes according to the 2019 AHA/ASA guidelines [128]. Despite their benefits, pharmacologic treatments carry potential side effects and risks, including bleeding, thrombosis, and systemic complications.

Surgical Approaches, Including Endovascular Interventions

When medical management is insufficient, surgical interventions may be required. Open or laparoscopic surgery may be performed to ligate ruptured vessels or resect vascular malformations; however, these approaches carry risks such as restenosis, infection, and prolonged recovery [91]. Whenever feasible, minimally invasive endovascular approaches are preferred, consistent with guidance from the Society for Vascular Surgery (SVS) and the European Society of Vascular Surgery (ESVS) [129].

Endovascular surgery, performed from within the vascular system [94-96], has become the preferred strategy for treating cerebrovascular, peripheral, and coronary vascular conditions in alignment with CIRSE Standards of Practice [130]. These procedures employ devices such as coils, stents, stent retrievers, and flow diverters to inhibit or restore blood flow. In AIS, endovascular mechanical thrombectomy combined with thrombolytic therapy has demonstrated superior outcomes [128].

Endovascular procedures typically begin with catheterization through a major vessel (e.g., femoral or radial artery) [97], following the Seldinger Technique, allowing for the delivery of interventional therapies [94, 98-102]. Guide catheters and microcatheters, including the subject devices evaluated herein, are essential for advancing diagnostic and therapeutic devices such as guidewires, coils, balloons, and embolic agents to or near the target lesion. Microcatheters, due to their small diameter (1–3F), flexibility, and steerability, enable navigation through tortuous distal vessels [99, 107, 109-119], facilitating precise embolic or therapeutic delivery. Their critical role in complex neurovascular and peripheral interventions, particularly selective embolization, is recognized by the Society of NeuroInterventional Surgery (SNIS) and the World Federation of Interventional and Therapeutic Neuroradiology (WFITN) [131].

Endovascular procedures encompass neurovascular interventions such as surgical clipping, thrombectomy, angioplasty and stenting, coil embolization, placement of woven EndoBridge (WEB) devices, flow diversion, tumor embolization, and treatment of arteriovenous malformations (AVMs) and dural arteriovenous fistulas (dAVFs). These minimally invasive techniques are associated with lower mortality, faster recovery, fewer complications, and improved functional outcomes compared to open surgery. Embolization significantly reduces lesion size, facilitates surgical or radiosurgical resection, and is associated with low rates of both temporary and permanent morbidity. Microsurgical approaches to AVMs achieve up to 95.5% complete obliteration. However, procedural risks remain and include vascular access complications, direct vessel injury, aneurysm rupture, arterial dissection, hemorrhage, stroke, thromboembolism, and micro-embolism.

In oncology, Transarterial Chemoembolization (TACE) relies heavily on microcatheters for selective drug delivery, maximizing therapeutic effects while minimizing collateral damage, in accordance with Society of Interventional Radiology (SIR) guidelines for embolization and TACE procedures [132].

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 1.4.

Table 1.5 Similar Devices

Device	Manufacturer	Intended Use
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 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 Headway™ and Wedge™ Microcatheters are 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 1.6 Harmonized Standards and CS

Standards	Edition	Standard Title
Quality System		
EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
Risk Management		
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)
Usability		
EN ISO 62366-1	2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
Clinical		
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)
Post Market Surveillance		
ISO/TR 20416	2020	Medical devices – Post market surveillance for manufacturers
Labeling		
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)

Standards	Edition	Standard Title
EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
Packaging		
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)
Shelf Life & Stability		
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
Biocompatibility		
EN ISO 10993-1	2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management

Standards	Edition	Standard Title
		process (ISO 10993-1:2018, including corrected version 2018-10)
EN ISO 10993-3	2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
EN ISO 10993-4	2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5	2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-6	2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
EN ISO 10993-10	2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitization (ISO 10993-10:2021)
EN ISO 10993-11	2018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-23	2021	Biological evaluation of medical devices – Part 23: Tests for irritation (ISO 10993-23:2021)
Manufacturing (Environmental Controls)		
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
Sterilization		

Standards	Edition	Standard Title
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 ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
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
Biological Indicators		
EN ISO 11138-1	2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
Steam / Autoclave / Moist Heat		
EN ISO 17665-1	2006	Sterilization of health care products - Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)
Device Specific		
Implants		
EN ISO 14630	2012	Non-active surgical implants - General requirements (ISO 14630:2012)
Catheters		
EN ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)

Standards	Edition	Standard Title
MRI		
ASTM F2182	2019e2	Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging
ASTM F2052	2021	Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment
ASTM F2503	2023e1	Standard practice for marketing medical devices and other items for safety in the magnetic resonance environment
ASTM F2213	2017	Standard test method for measurement of magnetically induced torque on passive implants in the magnetic resonance
ASTM F2119	2007R2013	Standard test method for evaluation of MR image artifacts from passive implants

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