Summary of Safety and Clinical Performance
for
Headway ™ and Wedge ™
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: English
B	2024 template update, administrative update, 1 May 2025	☐ Yes ☒ No* Validation language: NA
C	Updated Harmonized Standards table to be aligned with CF-184 Rev V.	☐ Yes ☒ No* Validation language: NA
D	Template and Administrative update 1.1 Device Identification and General Information 1.4 Risks and Warnings 1.5 Summary of the Clinical Evaluation and PMCF 1.6 Possible Diagnostic or Therapeutic Alternatives 1.9 References	☐ Yes ☒ No* Validation language: NA

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

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1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the 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
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	The Headway and Wedge Devices have CE Mark Certification (Headway - 2008, Wedge - 2017, 435827 MRA). Wedge XL received CE mark 2024, under 435827 MDR2017P.
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

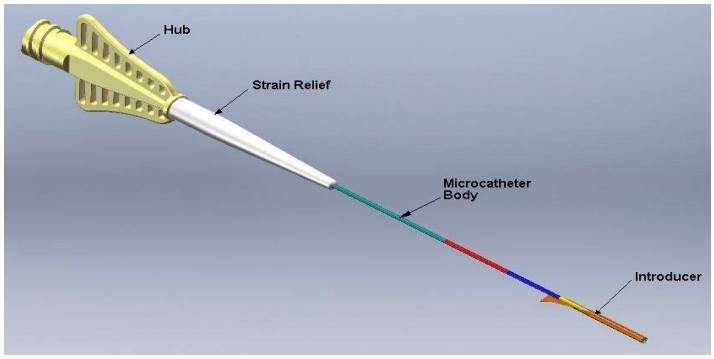
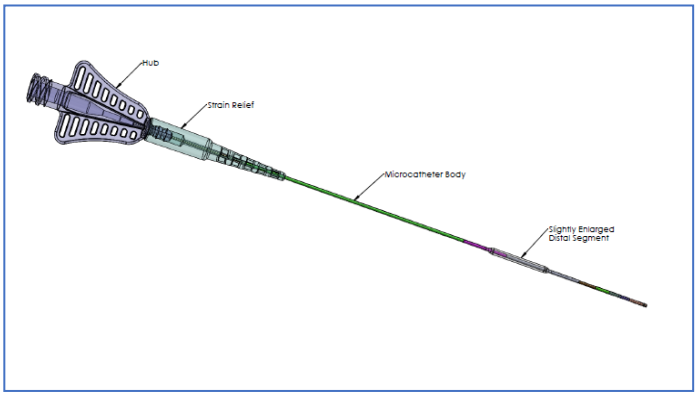
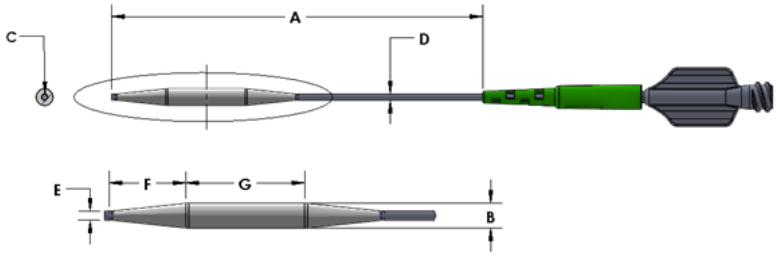
Intended Purpose	
Intended Purpose	Information has been retrieved from IFU100262, IFU100327, IFU100305, IFU212795 and IFU100306. The Headway 17, 17 Adv, 21, 27 Microcatheters are intended for general intravascular use, including the peripheral and neuro vasculature for the infusion of diagnostic, such as contrast media, and therapeutic agents, such as occlusion coils, (IFU100305, IFU212795). 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 Delivery Catheter 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 Delivery Catheter 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 Delivery Catheter 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 Delivery Catheter 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 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. (IFU100262, IFU100327, IFU100305, IFU212795 and IFU100306)

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	The Headway and Wedge 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 Throughout this document, Headway Microcatheters will refer to all five types of Headway Microcatheters, and Wedge Delivery Catheters will refer to both Wedge and Wedge XL Delivery Catheters. As demonstrated in the CER the Wedge XL Delivery Catheter is considered a line-extension of the Wedge Delivery Catheter: The Wedge XL Delivery Catheter can be considered identical to the Wedge Delivery Catheter except for a larger outer diameter. The Headway and Wedge are designed and intended to deploy embolic materials and other therapeutic agents. The Headway and Wedge 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 Delivery Catheter has three radiopaque marker bands. The Wedge Delivery Catheter also has a slightly enlarged distal segment, and an atraumatic distal tip made of polyurethane. The Headway and Wedge are shown Figure 1, Figure 2 and Figure 3. The outer surface of the Headway and Wedge is coated with a hydrophilic polymer coating to reduce friction during navigation in the vasculature. The Headway and Wedge s 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

Device Description	
	catheter. An introducer sheath is also included to facilitate the introduction of the microcatheter into the y-connector. The Wedge Delivery Catheter shares the same basic design and construction as the Headway Microcatheters. The Wedge Delivery Catheter 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 do not incorporate a medicinal substance, animal tissues, or blood products. **Figure 1. Headway Microcatheter Diagram**  **Figure 2. Wedge Delivery Catheter Diagram**  **Figure 3. Wedge XL Delivery Catheter Diagram** 

Device Description	
	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 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 s 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 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 catheter hub and used to facilitate the flushing process. A steam-shaping mandrel accessory is packaged with the Headway and Wedge . 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 intended to be used in combination	The Headway and Wedge 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 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 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 August 2020 to 31 July 2024 include a total of 657,975 units shipped and 1,246 complaint records, for an overall complaint rate of 0.19%.

1.4.2 Warnings and Precautions

The warnings / precautions for the Headway and Wedge 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 Delivery Catheters

The warnings / precautions for the Wedge Delivery Catheters are (IFU100306):

Warnings

- The Wedge Delivery Catheter 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 Delivery Catheter 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 Delivery Catheter 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 Delivery Catheter prior to use for any irregularities or damage and discard if any inconsistencies are observed.
- The Wedge Delivery Catheter 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 Delivery Catheter.
- The shaping mandrel is not intended for use inside the body. Ensure shaping mandrel is removed from Wedge Delivery Catheter 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 Delivery Catheter 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 Delivery Catheter has a lubricious surface and should be hydrated prior to use.
- Exercise care in handling the Wedge Delivery Catheter 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 Delivery Catheter prior to use.
- To reduce the risk of damage or separation of the device, avoid repeated bending at the same point of the Wedge Delivery Catheter.
- Take precautions when manipulating the Wedge Delivery Catheter in tortuous vasculature to avoid damage to the Wedge Delivery Catheter. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

Wedge XL Delivery Catheter

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

Warnings:

- The Wedge XL Delivery Catheter 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 Delivery Catheter 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 Delivery Catheter 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 Delivery Catheter prior to use for any irregularities or damage and discard if any inconsistencies are observed.
- The Wedge XL Delivery Catheter 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 Delivery Catheter.
- Infusion pressure should not exceed 300 psi to avoid potential rupture of the Wedge XL Delivery Catheter.
- 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 Delivery Catheter 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 Delivery Catheter 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 Delivery Catheter has a lubricious surface and should be hydrated prior to use.
- Exercise care in handling the Wedge XL Delivery Catheter 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 Delivery Catheter 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 Delivery Catheter.
- Take precautions when manipulating the Wedge XL Delivery Catheter in tortuous vasculature to avoid damage to the Wedge XL Delivery Catheter. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.
- Take precautions when advancing the bulb segment of the Wedge XL Delivery Catheter beyond the distal tip of the guiding catheter. Retraction of the bulb segment of the Wedge XL Delivery Catheter 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 Delivery Catheter 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 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 August 2020 to 31 July 2024 covered by the PSUR there were no Field Actions involving the Headway and Wedge devices.
The FDA MAUDE system identified 44 MAUDE records for the subject device captured in the MicroVention complaint system. In 30 of the 44 subject device records (68.2%), 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 (30)
- Insufficient Information (3)
- Intracranial Hemorrhage; Rupture (1)
- Hematoma; Intracranial Hemorrhage; Loss of consciousness; Ischemia Stroke (1)
- Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available (1)
- Paralysis; Paresis; Ischemia Stroke (1)
- Foreign Body In Patient; No Clinical Signs, Symptoms or Conditions (3)
- Anaphylactic Shock (1)
- Intracranial Hemorrhage (1)
- Brain Injury (1)
- Foreign Body In Patient (1)

1.5 Summary of the Clinical Evaluation and PMCF

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

However, the devices will be captured within MicroVention's broader post-market real-world evidence activities, including MAESTRO-I (Aneurysm) and MAESTRO-II (Stroke), which collect clinical data on commercially available MicroVention neurovascular treatment devices

used in standard clinical practice. These studies are not specific to the Headway or Wedge Devices and therefore are not presented as device-specific clinical investigations, but they will provide supplemental PMCF information relevant to their use.

1.5.1 Equivalent Device Clinical Data

The Headway Microcatheters serve as an equivalent device for the Wedge Delivery Catheters; as such, clinical data for the Headway microcatheters is relevant to the Wedge Delivery Catheters. Similarly, the Wedge serve as an equivalent device for the Wedge XL. Equivalence has been claimed and established (MicroVention Inc., Basic UDI-DI: 08402732HEADWAYWEDGE4N). The Wedge Delivery Catheter is the equivalent device for the Wedge XL Delivery Catheter. The Wedge Delivery Catheter 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 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 124 published articles were included in the clinical evaluation, comprising 74 retrospective studies, 15 prospective studies, 32 case reports, and 3 case series. The overall quality of the study designs assessed was rated as high.
These clinical results are consistent with the State of the Art, and they support the safety and performance of the Headway and Wedge within their intended indications.

1.5.2 Pre-CE-Mark Clinical Data

There are no pre-market clinical investigations for the Headway and Wedge. As the Headway and Wedge (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

From the methodological and systematic literature search that includes 124 articles were included for analysis [1-212]. Clinical data sources to evaluate the safety and performance of the Headway and Wedge 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 91% 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 27.8 months. The rate of complete embolization ranged up to 100% for a follow-up period range 30.2 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 91% to 100% and complete aneurysm occlusion up to 90% at 27.8 months. In overall, the clinical benefits associated with the use of the Headway/Wedge 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 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 0-15.1%, 0-5% and 0-4.5%. 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 August 2020 to 31 July 2024 include a total of 657,975 units shipped and 1,246 complaint records, for an overall complaint rate of 0.19%. No Field Actions or recalls occurred during this period, and all 6 CAPAs opened were closed with the exception of one that is still in the implementation phase. 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 44 MAUDE records for the subject device captured in the MicroVention complaint system. In 30 of the 44 subject device records (68.2%), 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. 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. Post-market surveillance data show that the Headway and Wedge perform as intended in clinical use. High technical success has been reported in the majority of patients, with very low numbers of reportable complaints and adverse events related to the devices. The data collected is considered sufficient to determine that the Headway and Wedge. achieve the performance intended and is suitable for the intended purpose.

The clinical evaluation included 124 published articles (74 retrospective studies, 15 prospective studies, 32 case reports, and 3 case series), selected through a methodologically sound literature search. The overall study quality was moderate to high.

The Headway and Wedge 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 technical or procedural success rates of 91% 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 (0–15.1%), aneurysm rupture (0–5%), and hematoma (0–4.5%). 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 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 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. Sufficient clinical evidence, including published literature and clinical 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 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.

It should be noted that these devices will be captured within MicroVention's broader post-market real-world evidence activities, including MAESTRO-I (Aneurysm) and MAESTRO-II (Stroke), which collect clinical data on commercially available MicroVention neurovascular treatment devices used in standard clinical practice. These studies are not specific to the Headway or Wedge Devices and therefore are not presented as device-specific clinical investigations, but they will provide supplemental PMCF information relevant to their use.

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:

1. Lifestyle modification

2. Medical management and/or
3. Surgical approaches, including endovascular interventions. The location and type of the vascular issue and the patient's circumstances in each case dictate whether one treatment approach may be favored over another.

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].

Medication Management

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 [90, 91]. Statin therapy is by far the most well-recognized cholesterol-lowering therapy in the management of cardiovascular and peripheral vascular disease. 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. If lipid goals are not achieved with statin therapy alone, additional lipid-lowering agents such as ezetimibe, PCSK9 inhibitors, bempedoic acid, or inclisiran may be used in accordance with current clinical guidelines [133, 134].

Other medical management includes antiplatelet agents, anticoagulants, vasodilators, antihypertensive medications, and smoking cessation support [90]. Recent guidelines also support the selective use of low-dose anticoagulation combined with antiplatelet therapy, such as rivaroxaban 2.5 mg twice daily plus aspirin, in patients at high ischemic risk and low bleeding risk, particularly in peripheral artery disease [135].

Treatment for thrombosis or embolisms can include thrombolytic drugs, such as intravenous tissue plasminogen activator (t-PA). However, thrombolysis can have limited reperfusion in certain anatomical locations as well as having a narrow therapeutic window (for example, ≤4.5 hours after onset in acute ischemic stroke (AIS)) [92, 93].

Surgical Interventions

Open or laparoscopic surgery is a more direct treatment option that can be used to ligate ruptured vessels or resect vascular malformations. The risks for open surgery include restenosis, infection, and prolonged recovery [91]. 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 diseases from within the vascular system [94-96]. Endovascular approaches are used to treat issues with the neuro, peripheral, and coronary vascular. Published studies and guideline statements confirm the benefit from mechanical thrombectomy in appropriately selected patients up to 24 hours from symptom onset, including those with large infarct cores, further consolidating endovascular thrombectomy as the preferred treatment strategy for large vessel occlusion stroke [136-138].

Endovascular surgery is initiated with placement of the catheter through a major vessel (e.g., femoral or radial artery), passing from an entry incision site in the skin to the target vasculature [97]. Interventional therapies can then be delivered through the catheter [94, 98-102]. 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 [103].

In endovascular procedures, both the 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. and embolic agents to or near the target lesion. 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 [104-108]. 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, coils and other embolic or diagnostic agents [99, 107, 109-119]. Lee et al specifically discuss the double microcatheter technique as an alternative to treat intracranial aneurysms with complex configurations, not amenable to simple coiling, such as a wide neck aneurysm or those with vital vessels branching from the fundus [118]. Endovascular treatment with and without carotid artery stenting (CAS) was comparable with regard to functional outcomes. CAS during EVT might be a feasible option to treat the extracranial internal carotid artery (ICA) stenosis, but randomized studies are warranted to prove non-inferiority or superiority [63]. Recent multicenter registry and observational data have reported mixed safety and functional outcomes for emergent CAS during thrombectomy in tandem lesions, and a randomized trial (CASES) is underway to compare immediate versus deferred CAS, highlighting that the optimal role of acute CAS remains unresolved [144-146].

Some of the neuro-endovascular treatments include 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). Guidelines and scientific advisories have expanded the indications for endovascular therapy in acute ischemic stroke, including large core infarcts and basilar artery occlusions, reinforcing endovascular approaches as standard of care in carefully selected patients [136, 139, 140]. Recent updates in stroke and neurointerventional guidelines emphasize the use of balloon guide catheters, distal access catheters, and low profile microcatheters to improve first pass reperfusion and procedural safety in large vessel occlusion and posterior circulation stroke [197, 198].

Treatment of coronary chronic total occlusions has advanced greatly since its advent in the late 1970's 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 [121]. The contemporary procedural success rate is 80-90% with a reduction in complications [121]. Recent reviews confirm that experienced centers now routinely achieve CTO PCI success rates of approximately 85 to 90 percent with low rates of major complications, largely due to refined antegrade and retrograde techniques and dedicated crossing equipment [147, 148]. One such example is depicted in a review by Hou et al. in 2022. Hou et al. discussed the endovascular treatment (EVT) of the anterior inferior cerebellar artery and stated that only a slim microcatheter can navigate along this artery. Therefore, though EVT is the preferred treatment, many EVT techniques cannot be applied [149].

In addition, the treatment of 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 [123,150]. 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 the case of tortuous, distal, and/or small caliber vessels.

Published studies in interventional oncology and peripheral embolization describe advanced microcatheter designs, including steerable and reflux-control microcatheters, which improve super selective catheterization and reduce non-target embolization during drug-eluting bead TACE and other embolization procedures [86-88]. Trans Arterial Chemo Embolization (TACE) treatment, is 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 damage of the surrounding tissue/organs [143]. Recent comprehensive reviews reaffirm TACE as a first line locoregional therapy for intermediate stage hepatocellular carcinoma and highlight technical advancements such as balloon-occluded TACE and highly selective microcatheter positioning to optimize tumor response [152].

Intra-arterial chemotherapy, a form of targeted drug therapy that involves direct administration of chemotherapy drugs via the ophthalmic artery, has also been shown to improve global salvage rates for refractory retinoblastoma [126]. Emerging literature similarly supports super selective microcatheter techniques for other organ specific intra-arterial therapies and combined embolization plus ablation strategies, reflecting the central role of microcatheter technology in modern interventional oncology [151]

In interventional oncology, embolic agents can be used in association with drugs in chemoembolization or in association with percutaneous ablations in combined treatments to enhance therapeutic efficacy. Recent reviews also describe the integration of microcatheter based embolization with yttrium 90 radioembolization, pressure-enabled delivery systems, and imageable microspheres, further underscoring how advances in embolic agents and delivery microcatheters are expanding the therapeutic envelope of minimally invasive cancer treatment [151, 152].

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 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 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

Standard Number	Edition	Standard Title (equivalent edition)
EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

Standard Number	Edition	Standard Title (equivalent edition)
EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN IEC 60812	2018	Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)
EN 62366-1	2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)
ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers
EN ISO 15223-1	2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
EN ISO 11607-1	2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019/Amd 1:2023)
EN ISO 11607-2	2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019/Amd 1:2023)
ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less
ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4332	2022	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM F88	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096	2011R2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
EN ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)

Standard Number	Edition	Standard Title (equivalent edition)
EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
EN ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
ANSI/AAMI ST72	2019	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
EN 556-1	2001/AC:2006	Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices
EN ISO 11737-1	2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018/Amd 1:2021)
EN ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
ISO 11737-3	2023	Sterilization of health care products - Microbiological methods - Part 3: Bacterial Endotoxin testing
EN ISO 11138-1	2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
EN ISO 11135	2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014/Amd 1:2018)
EN ISO 10993-7	2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008/Amd 1:2019)
EN ISO 10555-1	2013A1:2017	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements (ISO 10555-1:2013A1:2017)
EN ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)
EN ISO 80369-20	2015	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (ISO 80369-20:2015)
ASTM F640	2023	Standard test methods for determining radiopacity for medical use
ANSI T564	2021	Transparent Chart for the Estimation of Defect Size

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