Summary of Safety and Clinical Performance

for

Traxcess™ Guidewires

SSCP23-0015

MicroVention, Inc.
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DOCUMENT CHANGE HISTORY

Revision	Description	NB approved/verified
A	Initial Release	☐Yes, Validation language: ☒ No*

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

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1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.
Following this information there is a summary intended for patients.

1.1 Device Identification and General Information

Table 1.1: Device Identification and General Information

<table>
<tr><th colspan="2">Device Names</th></tr>
<tr><td>Device Trade Name</td><td>Traxcess 14 Guidewire
Traxcess 14 EX Guidewire
Traxcess 14 SELECT Guidewire
Traxcess 7 Mini Guidewire
Traxcess Docking Wire</td></tr>
<tr><td>EMDN Code</td><td>C04020101
C04020201</td></tr>
<tr><td>Medical Device Nomenclature (EMDN Description)</td><td>Peripheral Vascular Diagnostic Guidewires, Hydrophilic
Peripheral Vascular Therapeutic Guidewires, Hydrophilic</td></tr>
<tr><td>Device Class</td><td>Class III (Guidewires), Class IIa (Docking Wire)</td></tr>
<tr><td>Basic UDI-DI</td><td>08402732TRAXCESS2J</td></tr>
<tr><td>Year when first certificate (CE) was issued for the device</td><td>
<table>
<tr><th>Device Name</th><th>CE Mark Date</th></tr>
<tr><td>Traxcess 14 Guidewire</td><td>21JUL2008</td></tr>
<tr><td>Traxcess 14 EX Guidewire</td><td>01NOV2009</td></tr>
<tr><td>Traxcess 14 SELECT Guidewire</td><td>19JUN2016</td></tr>
<tr><td>Traxcess 7 Mini Guidewire</td><td>24MAR2017</td></tr>
<tr><td>Traxcess Docking Wire</td><td>01NOV2009</td></tr>
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</td></tr>
<tr><th colspan="2">Legal Manufacturer</th></tr>
<tr><td>Name & Address</td><td>MicroVention, Inc.
35 Enterprise
Aliso Viejo, California, 92656 USA</td></tr>
<tr><td>Manufacturer SRN</td><td>US-MF-000016658</td></tr>
<tr><th colspan="2">Authorized Representative</th></tr>
<tr><td>Name & Address</td><td>MicroVention Europe SARL
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye, France</td></tr>
<tr><td>Authorized Representative SRN</td><td>FR-MF-000004448</td></tr>
<tr><th colspan="2">Notified Body</th></tr>
</table>

Device Names	
Name & Address	DQS Medizinprodukte GmbH Team Change Management / Team Aenderungsmeldungen August-Schanz-Str. 21 60433 Frankfurt a. Main Germany
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

Table 1.2: Intended Use

Intended Purpose	
Intended Purpose	**Traxcess 14 Guidewire & Traxcess 14 EX Guidewire:** Traxcess Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries. **Traxcess 14 SELECT Guidewire:** The Traxcess 14 SELECT Guidewire is indicated for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries. **Traxcess 7 Mini Guidewire:** Traxcess 7 Mini Guidewire is indicated for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not indicated for use in coronary arteries. **Traxcess Docking Wire:** The Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The Traxcess Docking Wire can be used with Traxcess guidewires to facilitate the placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.
Indications for Use	**Traxcess 14 Guidewire & Traxcess 14 EX Guidewire:** Traxcess Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries. **Traxcess 14 SELECT Guidewire:** The Traxcess 14 SELECT Guidewire is indicated for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered

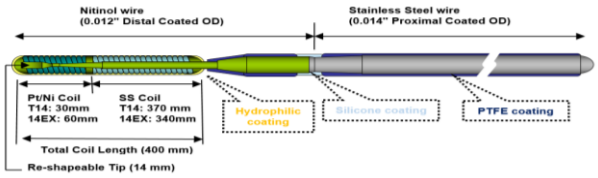
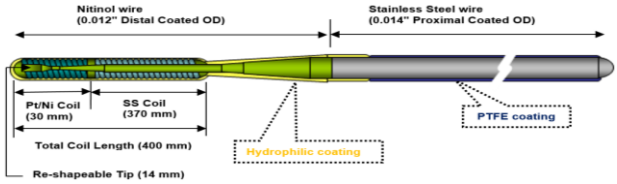
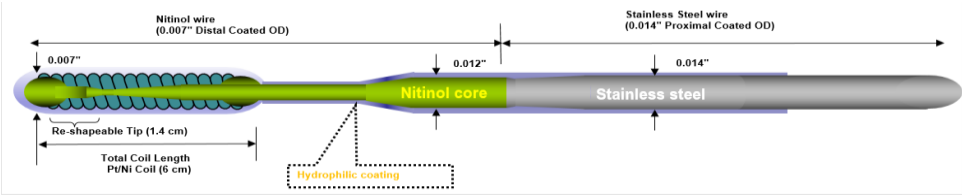
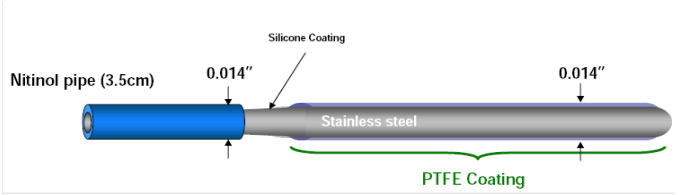
Intended Purpose	
	to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries. **Traxcess 7 Mini Guidewire:** Traxcess 7 Mini Guidewire is indicated for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not indicated for use in coronary arteries. **Traxcess Docking Wire:** The Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The Traxcess Docking Wire can be used with Traxcess guidewires to facilitate the placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.
Target Population	The Traxcess Guidewires are intended for patients who require selective intravascular placement of diagnostic or therapeutic catheters in the neuro and/or peripheral vasculature, in which condition the Traxcess guidewire can be used to facilitate catheter navigation and placement. The Traxcess Docking Wire is used in a condition in which the Traxcess guidewire extension is deemed necessary for facilitating catheter replacement.
Contraindications and/or Limitations	No contraindications are listed for the following Traxcess Guidewire family devices: • Traxcess 14 Guidewire and Traxcess 14 EX Guidewire (IFU100355) • Traxcess 14 SELECT Guidewire (IFU100354) • Traxcess Docking Wire (IFU100357) The following contraindication is listed for the Traxcess 7 Mini Guidewire (IFU100356): • This device is not indicated for use in coronary arteries.

1.3 Device Description

Table 1.3: Device Description

Device Description	
Description of the Device	Traxcess 14 SELECT Guidewire is a 0.014” diameter steerable guidewire consisting of a 0.012” diameter distal coil constructed of radiopaque platinum and stainless steel. The guidewire is coated with a hydrophilic material for lubricity. The distal 14 mm of the coil tip is shapeable. The distal core wire consists of nitinol, and the proximal section is stainless steel. Traxcess 7 Mini Guidewire is a steerable guidewire constructed of radiopaque platinum, Nitinol and stainless steel. The guidewire is coated to provide a lubricious surface. The distal coil tip is shapeable.

Device Description	
	The Traxcess Docking Wire is a 0.014” diameter guidewire attachment consisting of stainless steel and nitinol. The shaft is coated with polytetrafluoroethylene (PTFE) for lubricity. The Traxcess Docking Wire is compatible with the Traxcess guidewire with an extendable proximal end. The Traxcess Docking Wire is used to extend the guidewire for facilitating catheter replacement Traxcess Guidewire is a 0.014” diameter steerable guidewire consisting of a 0.012” diameter distal coil constructed of radiopaque platinum and stainless steel. The coil section is coated with a hydrophilic material for lubricity. The distal 14 mm of the coil tip is shapeable. The distal core wire consists of nitinol, and the proximal section is stainless steel. The proximal shaft section is coated with polytetrafluoroethylene (PTFE).
Design Characteristics of the Device	The Traxcess 14, Traxcess 14 EX and Traxcess 14 SELECT Guidewires consist of a proximal coated 0.014" stainless steel core wire, and a distal coated 0.012" tapered nitinol core wire contained within platinum/nickel and stainless steel coils. The proximal end of the guidewire is tapered in order to connect to the Traxcess Docking Wire. The distal 14 mm of the guidewire can be shaped by the physician. The platinum/nickel and stainless-steel coils are 400 mm in length. The Traxcess 14 and 14 SELECT Guidewires’ distal 30 mm coil section is constructed of platinum/nickel for maximum radiopacity, with the 370 mm balance of the coil is constructed of stainless steel. The Traxcess 14 EX Guidewire distal 60 mm section is constructed of platinum/nickel, with the 340 mm balance is constructed of stainless steel. The Traxcess 14 and Traxcess 14 EX Guidewires consist of PTFE (polytetrafluoroethylene)/silicone and hydrophilic coating on the proximal and distal end of the guidewire, respectively. The Traxcess 14 SELECT Guidewire consists of PTFE (no silicone coating) and hydrophilic coating on the proximal and distal end of the guidewire. The hydrophilic coating on the Traxcess 14 SELECT Guidewire extends up to the proximal stainless-steel section of the guidewire. The PTFE and hydrophilic coating provide lubricity when the guidewire is passed through percutaneous catheters. Traxcess 7 Mini Guidewire consists of a proximal coated 0.014" stainless steel core, and a distal coated 0.007" nitinol core. The distal core is tapered at the distal tip and is contained within platinum/nickel coil. The platinum/nickel coil is 6 cm in length. The distal 1.4 cm of the guidewire is shapeable by the physician. The Traxcess Docking Wire is intended for general intravascular use, including use in the neuro and peripheral vasculature. The docking wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries. The Traxcess Docking Wire is an accessory device used to extend the overall length of Traxcess Guidewires. The wire can be removed when it is not needed. The Traxcess Docking Wire consists of a proximally coated 0.014” stainless steel core with a nitinol pipe (tube) attached at the distal end. The proximal section is coated with PTFE and silicone for lubricity.

Device Description	
	Figure 1: Traxcess **A. Traxcess 14 and 14 EX Guidewires**  **B. Traxcess 14 SELECT Guidewire**  **C. Traxcess 7 Mini Guidewire**  **D. Traxcess Docking Wire** 
Single use – sterilization method	Sterilized using Ethylene Oxide
Description of Accessories	• Torque Device: The torque device may be attached by the physician to the proximal end of the guidewire to facilitate easier rotation / torquing of the guidewire. • Insertion Tool: The insertion tool is essentially a small tube through which the guidewire may be passed. The inserter allows the physician to more easily insert the tip of the

Device Description	
	MicroVention guidewire through catheter Y-connectors and other common off-the-shelf accessory devices. • Shaping Mandrel: The shaping mandrel(s) is provided as a tool for the physician to shape (bend) the distal 14 mm distal tip of the MicroVention guidewire. Shaping the tip may facilitate easier engagement of side branches within the neurovasculature.

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the Traxcess devices 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.

The worldwide unit sales and complaint records for the Traxcess family from 01 November 2020 to 31 October 2024 included a total of 527,790 units shipped with 148 complaint records, for a very low overall complaint rate of 0.028%.

1.4.2 Warnings and Precautions

The Warnings for the Traxcess Guidewire Family are:

Traxcess 14 and 14 EX Guidewires (IFU100355):

- The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.
- The guidewire is provided sterile and non-pyrogenic unless the unit package is opened or damaged.
- The guidewire is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose in accordance with hospital and/or local government policy. Do not use if the packaging is breached or damaged.
- Inspect the guidewire prior to use for any irregularities or damage and discard if noted.
- The guidewire should be manipulated under fluoroscopic guidance. Do not advance or withdraw the guidewire when excessive resistance is met until the cause of resistance is determined. Observe the tip response when turning the guidewire and avoid turning in the same direction more than three times when the tip is stationary. Avoid kinking the tip of the guidewire, as damage to the guidewire might occur.

Traxcess 14 SELECT Guidewire (IFU100354):

- The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.
- The guidewire is provided sterile and non-pyrogenic unless the unit package is opened or damaged.

- The guidewire 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 in accordance with hospital and/or local government policy. Do not use if the packaging is breached or damaged.
- Inspect the guidewire prior to use for any irregularities or damage and discard if noted.
- The guidewire should be manipulated under fluoroscopic guidance. Do not advance or withdraw the guidewire when excessive resistance is met until the cause of resistance is determined. Observe the tip response when turning the guidewire and avoid turning in the same direction more than three times when the tip is stationary. Avoid kinking the tip of the guidewire, as damage to the guidewire might occur.
- 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.

Traxcess 7 Mini Guidewire (IFU100356):

- The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.
- The guidewire is provided sterile and non-pyrogenic unless the unit package is opened or damaged.
- The guidewire 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 in accordance with hospital and/or local government policy. Do not use if the packaging is breached or damaged.
- Inspect the guidewire prior to use for any irregularities or damage and discard if noted.
- The guidewire should be manipulated under fluoroscopic guidance. Do not advance or withdraw the guidewire when excessive resistance is met until the cause of resistance is determined. Observe the tip response when turning the guidewire and avoid turning in the same direction more than three times when the tip is stationary. Avoid kinking the tip of the guidewire, as damage to the guidewire might occur.
- 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.

Traxcess Docking Wire (IFU100357):

- The Traxcess Docking Wire 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 Traxcess Docking Wire is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if package is opened or damaged.
- The Traxcess Docking Wire is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose in accordance with hospital and/or local government policy. Do not use if the packaging is breached or damaged.
- Inspect the Traxcess Docking Wire prior to use for any irregularities or damage and discard if noted.
- The Traxcess Docking Wire cannot be used alone and must be used with the guidewire securely connected.
- Attachment and detachment to and from the guidewire should be done while confirming the position of the guidewire tip and catheter under high resolution fluoroscopy. The unintentional advancement of the wire may result in perforation or damage to the vasculature or other devices.
- Do not bend the Traxcess Docking Wire repeatedly at the same point. This may result in deformation, breakage, or separation of the Traxcess Docking Wire.
- Do not torque or manipulate the Traxcess Docking Wire once it is attached. This may cause the Traxcess Docking Wire to detach from the guidewire.
- Do not insert the Traxcess Docking Wire into the patient (body). This may result in disconnection or breakage of the Traxcess Docking Wire or damage to the vessel.

Precautions for the Traxcess Guidewire Family as referenced in the IFUs are as follows:

Traxcess 14 Guidewire and Traxcess 14 EX Guidewire (IFU100355):

- Verify guidewire compatibility when using other ancillary devices commonly used in intravascular procedure. Physician must be familiar with percutaneous, intravascular technique and possible complications associated with the procedure.
- The guidewire has a lubricious surface and distal platinum coil section should be hydrated prior to use.
- Exercise care in handling the guidewire to reduce the chance of accidental damage. Do not expose the guidewire surface to organic solvents such as alcohol or medications, which might damage the guidewire coatings and/or cause the guidewire to lose lubricity.
- Verify that the inner diameter of any diagnostic or therapeutic catheter to be used with the guidewire is compatible with the outer diameter of the guidewire prior to use.
- Avoid repeated bending at the same point in order to avoid damage or separation of the guidewire.
- Take precaution when manipulating the guidewire in tortuous vasculature to avoid damage to the guidewire.

Traxcess 14 SELECT Guidewire (IFU100354):

- Verify guidewire compatibility when using other ancillary devices commonly used in intravascular procedure. Physician must be familiar with percutaneous, intravascular technique and possible complications associated with the procedure.
- The guidewire has a lubricious surface and should be hydrated prior to use.

- Exercise care in handling the guidewire to reduce the chance of accidental damage. Do not expose the guidewire surface to organic solvents such as alcohol or medications, which might damage the guidewire coatings and/or cause the guidewire to lose lubricity.
- Verify that the inner diameter of any diagnostic or therapeutic catheter to be used with the guidewire is compatible with the outer diameter of the guidewire prior to use.
- Avoid repeated bending at the same point in order to avoid damage or separation of the guidewire.
- Take precaution inserting or withdrawing the guidewire through metal introducer to avoid damage to guidewire as this may lead to potential shearing of the coating on the guidewire.
- Take precaution when manipulating the guidewire in tortuous vasculature to avoid damage to the guidewire.
- Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.

Traxcess 7 Mini Guidewire (IFU100356):

- Verify guidewire compatibility when using other ancillary devices commonly used in intravascular procedure. Physician must be familiar with percutaneous, intravascular technique and possible complications associated with the procedure.
- The guidewire has a lubricious surface and the entire wire should be hydrated for at least 30 seconds prior to use.
- Exercise care in handling the guidewire to reduce the chance of accidental damage. Do not expose the guidewire surface to organic solvents such as alcohol or medications, which might damage the guidewire coatings and/or cause the guidewire to lose lubricity.
- Verify that the inner diameter of any diagnostic or therapeutic catheter to be used with the guidewire is compatible with the outer diameter of the guidewire prior to use.
- Avoid repeated bending at the same point in order to avoid damage or separation of the guidewire.
- Take precaution inserting or withdrawing the guidewire through metal introducer to avoid damage to guidewire as this may lead to potential shearing of the coating on the guidewire.
- Take precaution when manipulating the guidewire in tortuous vasculature to avoid damage to the guidewire.

Traxcess Docking Wire (IFU100357):

- Verify Traxcess Docking Wire compatibility when using other ancillary devices commonly used in intravascular procedure. The physician must be familiar with percutaneous, intravascular technique and possible complications associated with the procedure.
- Exercise care in handling the Traxcess Docking Wire to reduce the chance of accidental damage. Do not expose the Traxcess Docking Wire surface to organic solvents such as alcohol or medications, which may damage the coating and/or cause loss of lubricity.
- Verify that the inner diameter of any diagnostic or therapeutic catheter to be used with the Traxcess Docking Wire is compatible with the outer diameter prior to use.

Cautions

Cautions for the Traxcess Guidewire Family referenced in the IFU's are provided below:

Traxcess 14 Guidewire and Traxcess 14 EX Guidewire (IFU100355)
Traxcess 14 SELECT Guidewire (IFU100354)
Traxcess 7 Mini Guidewire (IFU100356)
Traxcess Docking Wire (IFU100357)

Rx-Only: Federal law (USA) restricts this device to sale by or on the order of a physician.

1.4.3 Potential Complications / Adverse Effects

The potential complications / adverse effects for the Traxcess Guidewires and the Traxcess Docking Wire include but are not limited to (IFU100355, IFU100354, IFU100356, IFU100357):

- vessel or aneurysm perforation,
- vasospasm,
- hematoma at the site of entry,
- embolism,
- ischemia,
- intracerebral/intracranial hemorrhage,
- pseudoaneurysm,
- seizure,
- stroke,
- infection,
- death
- thrombus formation
- additional procedure/treatment required, and
- inability to treat or diagnose patient.

The potential complications / adverse effects related to angiographic and fluoroscopic X-ray radiation doses in association with the use of fluoroscopy for the Traxcess Guidewires include but are not limited to:

- alopecia,
- burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia.

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. No field actions or recalls were initiated by MicroVention for the Traxcess Guidewire Family during the evaluation period of 01 November 2020 to 31 October 2024.

A search was conducted on the user experience of the Traxcess Guidewires using the US Food and Drug Administration's MAUDE Database. The database contains all adverse events reported worldwide for devices marketed in the United States. The MAUDE search criteria included all reports in the database for the evaluation period of 01 November 2020 to 31 October 2024. The search produced 26 records. A summary of the search results is provided in **Table** .

These 26 reported Traxcess Guidewire device issues showed an overall low rate of 0.004926% out of 527,790 units that were shipped. 24 of these reports showed " no clinical signs, symptoms or conditions. 1 report of foreign body in patient and 1 report of inflammation was observed (0.000189%), **Table** .

Table 1.4 : MAUDE Database Device/ Malfunction Results

Reported Device problem	Subject Device	Similar Devices		
		Synchro Select Guidewire	Transend Guidewire	Glidewire
Death	0	1	0	1
Injury	7	50	9	25
Malfunction	19	147	59	18
Total MAUDE Records	26	198	68	44

1.5 Summary of the Clinical Evaluation and PMCF

The Traxcess Guidewire family devices have long been on the market since the CE Mark in 2008. Clinical data accumulated for evaluation of the intended use demonstrated the safety and performance of the subject devices and acceptability of identified risks. There are no pre-market clinical investigations conducted for the Traxcess Guidewire family devices. There are no post-market clinical investigations conducted for the Traxcess Guidewire family devices. There are no non-MV sponsored clinical studies conducted for the Traxcess Guidewire family devices.

1.5.1 Equivalent Device Clinical

Equivalency is not claimed in the clinical evaluation for the Traxcess Guidewire family devices.

1.5.2 Pre-CE-Mark Clinical Data

There is no Clinical Development Plan for the Traxcess Guidewire family devices because this was approved for CE Mark under the MDD, and no premarket clinical studies were required for market approval. Under EU MDR, there is sufficient clinical data on the Traxcess Guidewire family devices to support safety and performance for its intended use.

1.5.3 Clinical Data

Clinical data for the Traxcess Guidewire family devices was obtained from the below mentioned publications, **Error! Reference source not found.**.

Clinical Data from Post-Market Surveillance

MicroVention has an historical complaint rate for the Traxcess family of devices of approximately 0.03 to 0.04%, of which only about 10-20% are reportable to governmental authorities.

1.5.4 Clinical Performance and Safety

The Traxcess Guidewire devices are not a primary therapeutic device on which the treatment outcomes of safety can be based. However, success and benefits of using the Traxcess Guidewire devices, especially when compared against the risks and complications associated with the conditions that require endovascular treatment, are substantial. Benefits associated with use of the Traxcess Guidewire Family include

Relevant clinical data was extracted and analyzed to reach conclusions about the safety and performance of the Traxcess guidewire including its clinical benefits. The high-level data from different sources and comparison to the acceptability criteria that is set up in the State of The Art is summarized in this section.

Scientific Literature Data Source

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 rates was 75% to 100%. Clinical success ranged from 91% to 100% for the Traxcess device. The performance parameters in the State of the Art were comparable for common standard of care i.e. technical success ranged from 47.4% to 100% and clinical success ranged from 44.9% to 83%. Complete immediate occlusion for the device under evaluation ranged from 67% to 100% and was comparable with the SOTA which was reported to be 90.7%. Complete occlusion for the device under evaluation ranged from 6 to 46.5 months from 42% to 98.8% which was comparable to the SOTA which ranged from 86% to 97.6%. In the State Of The Art the mRS score which was immediate was in the range of 40.1% to 86.2% which was comparable to the device under evaluation which was 70% to 100%. Long term follow up in the SOTA for the mRS score i.e. 0-2 ranged from 90 days to 36 months and the range was reported as 29.2% to 86.6% when compared to the device under evaluation which ranged from 90 days up to 6 months i.e. 27% to 100%,. In overall, the clinical benefits associated with the use of the Traxcess guidewire are deemed acceptable as compared to the state of the art for the indications of use of this device.

It should be noted that complications reported in the literature may not be directly related to or caused by the subject device.. The Traxcess guidewire is used separately or in conjunction with a microcatheter to access vascular locations that could otherwise not be accessed and is not the primary device involved in the treatment of the primary condition. Overall common complications included aneurysm rupture; 0% to 1.8%, vessel dissection 0% to 12.5%, bleeding; 1% to 4.4%; emboli; 0% to 5% and thrombosis; 0% to 7.1%, . These rates were aligned with the state of the

art benchmarks.. All complications are identified in the risk documentation and are deemed acceptable.

1.5.5 Post-Market Clinical Follow-up

PMS Data Source

• The worldwide unit sales and complaint records for the Traxcess guidewire from 01 November 2020 to 31 October 2024 reported a total of 527,790 units shipped and 148 complaint records, for an overall low complaint rate of 0.028%.

• During the time period covered by this PSUR there were zero (0) Field Actions involving the Traxcess guidewire

• During the current review period, two (2) CAPAs has been closed and one (1) is in Effectiveness Check. For further details pertaining to each CAPA.

• The FDA MAUDE system identified 26 MAUDE records for the subject device captured in the MicroVention complaint system. In 24 of the 26 subject device records (0.004547%), there were 'no clinical signs, symptoms or conditions' reported.

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

Treatment option for vascular disease varies widely depending on the location and type of vascular issue and may include one of more of several combinations that include:

1. Medical Management: Treatment for thrombosis/embolisms can include thrombolytics drugs, such as tissue plasminogen activator (t-PA), which may be administered systemically through an IV [59].
2. Lifestyle modifications
3. Surgical approaches such as open or laparoscopic surgery are more directed treatment options that can be used to ligate ruptured blood vessels or malformations. In contrast, endovascular surgery is a minimally invasive surgical option to deliver interventional therapies for vascular disease from within the vascular system[59, 60]. Endovascular surgery can be used to either stop or restore blood flow in the target vessels through the deployment of devices such as coils, stents, flow diverters, and embolism retrieval procedures.

Endovascular surgery involves creating an entry incision along a major vessel (e.g., femoral or radial artery) through which a catheter can be placed extending from the entry site to the target vasculature [61]. Interventional therapies can then be delivered through the catheter [60, 62, 63]. The placement of the catheter requires the use of a the Seldinger Technique [64]. This technique requires 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 slide over the guidewire into the lumen of the vessel. The guidewire is subsequently removed. For accessing surgical locations farther from the entry site, such as in neurovascular procedures, the guidewire can continue to be advanced through the vascular anatomy. Once the guidewire reaches the target location, the catheter can be slid over the entire length of the guidewire. The intended clinical benefit of the use of guidewires is to provide surgical access for endovascular procedures.

Guidewires have been in use and widely accepted as a means to provide access to the neuro and peripheral vasculature[60]. Guidewires are a standard component in the armamentarium of interventional therapy and are used separately or in conjunction with microcatheters to access vascular locations that could otherwise not be accessed. These interventions include treatment for aneurysms through the endovascular implantation of coils, or treatment for embolisms by delivery of endovascular embolism retrieval devices.

The systematic literature reviews have identified numerous articles pertaining to the current knowledge/state of the art of endovascular treatment (EVT). It is believed that a guidewire is utilized in EVT when appropriate. This would include the intended use of the subject device. That is, to facilitate the selective placement of diagnostic or therapeutic catheters in general intravascular use, including neurovascular and peripheral vasculature. The following recent publications confirm the use of endovascular treatments, with the use of a guidewire when appropriate, as state of the art treatment. Guidewires are also utilized in various treatments of the coronary arteries, though treatment of those arteries is not indicated for the subject device of this clinical evaluation.

Alexander at al. (2021) discuss the epidemiology, clinical presentation, imaging findings, classification considerations, and treatment options for cerebral arteriovenous fistulae (AVF)[65]. For high-risk lesions, treatment is always indicated, with complete obliteration the primary goal. Embolization is the first-line therapy when intervention is indicated, and a number of endovascular treatment options are possible. Standard treatment to reach the lesion needing treatment is through standard procedures, utilizing a guidewire when appropriate.

Chen et al. (2020) provide a contemporary and comprehensive discussion of the natural history, pathobiology, and interventions for brain arteriovenous malformations (AVM). They evaluate multicenter prospective and retrospective studies describing AVM natural history and treatment outcomes from the recent literature [66]. Treatment of ruptured AVMs is deemed acceptable if the patient is determined high risk of recurrent hemorrhage with the balance between the estimated cumulative lifetime hemorrhage risk and the risk of intervention often the major determinant for treatment. The authors describe the use of embolization/endovascular intervention to treat AVMs.

Herpich et al. (2020) discuss the management of AIS as described in the recent literature. They conclude that appropriate treatment of ischemic stroke is essential in the reduction of mortality and morbidity. This appropriate treatment includes modern endovascular treatment, with modern endovascular treatment more than doubling the odds of a better functional outcome compared to standard therapy alone [67].

Hou et al. (2020) discuss targeted endovascular treatment for ruptured brain AVMs and conclude that endovascular treatment plays a very important role [68]. The authors state that EVT may improve the natural history of ruptured brain AVMs to a level similar to that of unruptured brain AVMs, with a significant reduction in hemorrhage risk.

Kim, Moore and Alfahad (2021) discuss endovascular recanalization of peripheral arterial chronic total occlusions. In particular, they described using the stiff or sharp end of a guidewire to break the hard calcified occlusion cap, and once the cap is broken, the guidewire is used as usual to assist with balloon angioplasty and/or stenting [69].

Majeed et al. (2021) review the types of stents typically used in common practice, indications, contraindications, equipment, techniques, personnel, tools, and devices used for angioplasty and percutaneous intervention. The authors list a guidewire as necessary equipment for the procedure and describe its usage[70].

Pelz et al. (2021) review interventional neuroradiology in cerebrovascular disorders including aneurysms, stroke, brain arteriovenous malformations, dural arteriovenous fistulae, and atherosclerotic disease. The authors describe a number of endovascular techniques as standard of care. These procedures require a guidewire as an accessory device[71].

Rutledge et al. (2021) discuss treatment of brain AVMs, including endovascular embolization [72]. Brain AVMs are associated with excess long-term morbidity and mortality, even when unruptured. Therefore, treatment is warranted.

Vlisides and Moore (2021) discuss stroke in surgical patients, including screening methods for the detection of postoperative cerebral ischemia and how multidisciplinary collaborations, including endovascular interventions, should be considered to improve patient outcomes. The authors state that new studies support endovascular intervention for large-vessel occlusion, even with prolonged time between stroke onset and clinical recognition. This makes identification of new neurologic symptoms critical in surgical patients, who may be candidates for endovascular intervention [73].

In addition, Wassélius et al. (2022) [74] describe the current SOTA of endovascular treatment of AIS, stating the need for a microwire (guidewire) to help initiate the process. The authors state "Currently used techniques for mechanical thrombectomy are stent retriever thrombectomy and contact aspiration….Stent retriever thrombectomy is performed by passing through/on the side of the clot with a microcatheter and microwire. Next, the microwire is exchanged for a stent retriever, which is expanded across the clot as the microcatheter is retracted. The stent retriever is then retracted while deployed, most often with simultaneous flow arrest in the internal carotid artery by a balloon-guide catheter, and reversal of the flow by brisk aspiration in the balloon-guide catheter…."

Additional recent publications reinforce the use of guidewires in treating disorders/issues involving the peripheral vasculature. Takenaka and Kudo (2022) [75] Tse et al. (2022) [76] evaluated the use of guidewires in biliary cannulation; Tse et al. (2022) stated that guidewire-assisted cannulation probably reduces the risk of pancreatitis compared to contrast-assisted

cannulation [76]. Hawes (2022) also stated that standard cannulation techniques usually succeed when performing endoscopic retrograde cholangiopancreatography to treat issues of the bile and pancreatic ducts, particularly when utilizing the wire-guided technique [77]. Op den Winkel (2021) also discussed the importance of guidewires during endoscopic retrograde cholangiography [78], as did Tsou et al. (2022) [79]. In addition, Zhu et al. (2022) described the use of guidewires to place tubes when the use of decompressive gastrostomy tubes are not feasible in patients with advanced malignant bowel obstructions [80]; Zhong et al. (2022) discussed the coaxial guidewire technique for adrenal vein sampling when treating various endocrine disorders [81]; Nakama et al. (2022) describe the need for guidewires in the endovascular therapy of complex femoropopliteal lesions [82]; and Wu et al. (2022) describe the need for guidewires in endovascular stent placement for treatment of malignant Superior Vena Cava Syndrome [83].

Numerous recent articles describe the use of guidewires in treating issues associated with the cardiovascular system. Though the subject device is not indicated for use in the coronary arteries, the recent literature does emphasize the necessity of guidewires in all types of endovascular treatments.

Recently, Kayali et al. (2022) and D'Onofrio et al. (2022) described the use of guidewires in the endovascular treatment and/or replacement of the aortic arch [84, 85]. Johansen et al. (2022) described the difficult left ventricular lead placement in cardiac resynchronization therapy. The authors stated that the main principle in interventional cardiac resynchronization therapy is to add better support for delivery of the left ventricular lead through dedicated inner catheters that also allows more flexibility with the use of more guidewires and better imaging with direct venography in the target vein [86].

Aksu et al. (2022) review the cardioneuroablation technique. The authors discuss the necessary equipment for this technique, including the use of a guidewire as the initial vascular device [87]. Ben Ali et al. (2022) mention the use of coronary guidewires in the treatment of tricuspid valve disease [88]. And Kumar and Janapati (2022) review the use of guidewires in microcatheter use in interventional cardiology [89].

Although the evaluation of guidewires was not the direct focus of the cited publications, they demonstrate that the use of endovascular treatments, including the utilization of guidewires when appropriate, are maintained in current medical practice and thus state of the art in facilitating the selective placement of diagnostic or therapeutic catheters in general intravascular use, including neurovascular and peripheral vasculature. No new risks with the use of guidewires were identified in this review.

Guidewire access and navigation through vascular anatomy to a target vessel or vascular lesion is an initial step in endovascular procedure, preceding to catheter deployment of a primary interventional device, or to perform a diagnostic function via the guided catheter. Therefore, there is no treatment options and the associated benefits or risks for an initial guidewire access and navigation. Endovascular treatment options are for the primary diagnostic or interventional devices and catheters to deliver the primary devices.

Table 1.5: Treatment Options Benefits and Risks

Treatment Option	Pro/Benefit	Con/Risks
Lifestyle modification in vascular disease	Easy to manage in the early stages to aid in reducing symptoms or progression of the disease [90].	Some may require medical management along with lifestyle management[90].
Medical management	Medical management includes cholesterol reduction, antiplatelet therapy, anticoagulation, peripheral vasodilators, blood pressure control, exercise therapy, and smoking cessation, all of which have the capacity to reduce mortality, symptoms, and complications. [59, 90]	Side effects of the pharmacologic treatment. Treatment for thrombosis / embolisms, can include thrombolytic drugs, such as intravenous tissue plasminogen activator (t-PA), however, intravenous thrombolysis can have limited reperfusion in some anatomic locations as well as having a narrow therapeutic window (for example, ≤4.5 h after onset in acute ischemic stroke
Surgical approaches including endovascular interventions	Some of the neuro-endovascular treatments include surgical clipping, endovascular thrombectomy, angioplasty and stenting, coiling, device placement for aneurysms, flow diverters, tumor embolization that imply the benefits of guidewire utilization. The benefit of these minimally invasive surgical options result in better results in terms of mortality, re-bleeding, and retreatments. Temporary devices are used that are removed once the procedure is completed and shorten procedure duration and hospital stay with faster recovery time, significant improvement in functional outcome. Embolization significantly reduces the size of the lesion, permitting surgical or radio surgical resection of the embolized lesion. Low rates of temporary and permanent morbidity were observed after embolization. [65-89, 91, 92]	These treatments carry additional risks related to vascular access, catheter placement, direct vessel injury, and each procedure poses risks depending on the type of device such like aneurysm rupture, arterial dissection, stroke, hemorrhage, thromboembolism, and micro-embolism.

1.6.2 Available Technologies

Guidewires are well established medical devices with numerous types and styles available from a variety of manufacturers. Examples of guidewires similar to the Traxcess devices are listed in Table.

Table 1.6: Similar Devices

Device	Manufacturer	Intended Purpose
Synchro®	Stryker	The Synchro® Neuro Guidewire series is intended for neurovascular use. It can be used to selectively introduce and position catheters and other interventional devices within the neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.
Transend™	Stryker	The Transend Guidewire is intended for general intravascular use, including neuro and peripheral vasculature. The guidewires can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. These devices are not intended for use in coronary arteries. A torque device (pin vise) is included with the guidewires to facilitate directional manipulation of the guidewires.
Glidewire®	Terumo	The Glidewire is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedure.

1.7 Suggested Profile and Training for Users

These devices are not to be used by unqualified personnel. It is essential that the surgeon and operating room staff are fully conversant with the appropriate surgical technique and associated accessories.

1.8 Reference to any Harmonized Standards and CS

List of the Harmonized Standards are shown in Table.

Table 1.7: Harmonized Standards

Standard Number	Edition	Standard Title (equivalent edition)
EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN IEC 60812	2018	Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)
EN 62366-1	2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)
ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers

Standard Number	Edition	Standard Title (equivalent edition)
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 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 F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
EN ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)

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 11070	2014/A1:2018	Sterile single-use intravascular introducers, dilators and guidewires (ISO 11070:2014/Amd 1:2018)
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

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