Summary of Safety and Clinical Performance

for

BOBBY™ Balloon Guide Catheter

SSCP23-0014

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DOCUMENT CHANGE HISTORY

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

*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	BOBBY Balloon Guide Catheter
EMDN Code	C0104020204
Medical Device Nomenclature (EMDN or GMDN Description)	Global Medical Device Nomenclature System is Code 32584.
Device Class	Class III medical device in accordance with the European Medical Device Regulation 2017/745 Annex VIII Rule 7
Basic UDI-DI	08402732BOBBYBD
Year when first certificate (CE) was issued for the device	CE mark certification (548062) on 03/06/2020.
Legal Manufacturer	
Name & Address	MicroVention, Inc. 35 Enterprise Aliso Viejo, California, 92656 USA
Manufacturer SRN	US-MF-000016658
Authorized Representative	
Name & Address	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye, France
Authorized Representative SRN	FR-MF-000004449
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August –Schanz-Straβe 21 D-60433 Frankfurt am Main
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

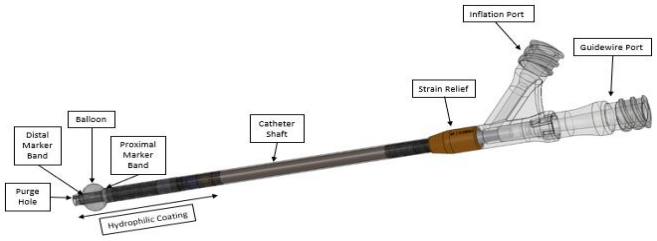
Table 1.2 Intended Use

Intended Purpose	
Intended Purpose	The BOBBY Balloon Guide Catheter is intended for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary occlusion during these and other angiographic procedures. The BOBBY Balloon Guide Catheter is also intended for use as a conduit for Retrieval devices
Indications for Use	The BOBBY Balloon Guide Catheter is intended for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also intended for use as a conduit for retrieval devices.
Target Population	The target patient population for the BOBBY Balloon Guide Catheter is the population of patients who require one of a variety of procedures that involve the use of a balloon guide catheter to facilitate the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems, as well as procedures involving the use of a balloon guide catheter as a conduit for retrieval devices.
Contraindications and/or Limitations	There are no known contraindications for the BOBBY Balloon Guide Catheter

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	The BOBBY Balloon Guide Catheter is a dual lumen catheter with an external hydrophilic coating. The balloon guide catheter incorporates radiopaque markers to facilitate fluoroscopic visualization and indication of the balloon position. The balloon incorporates a distal air-purging system to purge air from the inflation lumen prior to use. The BOBBY Balloon Guide Catheter is intended for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neurovascular systems. The balloon provides temporary occlusion during these and other angiographic procedures. The BOBBY Balloon Guide Catheter is also intended for use as a conduit for Retrieval devices. The BOBBY Balloon Guide Catheter is a co-axial, braid-reinforced, variable stiffness catheter with an external hydrophilic coating. The BOBBY Balloon Guide Catheter incorporates a compliant balloon, radiopaque markers, an air-purging system on the distal end, and a bifurcated luer hub on the proximal end.

Device Description	
	The BOBBY Balloon Guide Catheter has an inner lumen through which a guidewire and catheter can be inserted, and a co-axial outer lumen that is used to inflate and deflate the balloon with a syringe filled with contrast media. A bifurcated luer hub is attached to the proximal end of the balloon guide catheter to provide access to both the inner and outer lumens. In addition, a hydrophilic coating is applied to the distal end of the balloon guide catheter to provide a lubricious outer surface for catheter advancement in the vasculature. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. The balloon incorporates a distal air-purging system to purge air from the inflation lumen prior to use. The balloon catheter also incorporates radiopaque markers to facilitate fluoroscopic visualization and indication of the balloon position. The BOBBY Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on product label. The BOBBY Balloon Guide Catheter is provided individually packaged in a single pouch with a peel away introducer and protective sheaths to prevent kinking. 
Design Characteristics of the Device	The BOBBY Balloon Guide Catheters are dual co-axial lumen (guidewire/catheter lumen and inflation lumen) catheters. Radiopaque markers are included on the distal end for angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation and aspiration. To use the BOBBY Balloon Guide Catheter, a rotating hemostatic valve (RHV) is first attached to the working lumen of the balloon catheter. Then a syringe is connected to the sidearm of the RHV to provide a continuous saline flush line. A catheter with a guidewire is inserted into the inner lumen of the balloon guide catheter, and a peel-away introducer sheath is utilized to insert the balloon guide catheter system through the RHV. The system is then advanced to the desired location in the vasculature using fluoroscopic visualization. The balloon can be inflated for occlusion and deflated for removal or repositioning. The balloon guide catheter can also be used with an aspiration device or a clot retrieval device. The BOBBY Balloon Guide Catheter does not contain latex or PVC material. The BOBBY Balloon Guide Catheter does not incorporate a medicinal

Device Description	
	substance, animal tissues, or blood products. The BOBBY Balloon Guide Catheter is in contact with the patients' blood and tissues during the procedure. It is a device that is used for a short period of time during the patient's procedure.
Previous Generations or Variants, if applicable	This is the first generation of this product.
Single use – sterilization method	For single use only. The device is sterilized using 100% ethylene oxide (EtO), Ethylene Oxide Sterilization-Cycle 11.
Description of Accessories	The BOBBY Balloon Guide Catheter is packaged with one peel away introducer sheath. The introducer sheath is a simple split-away tube that allows for BOBBY to be more easily inserted through the RHV (rotating hemostatic valve.)
Description of other Devices or Products intended to be used in combination	To use the BOBBY Balloon Guide Catheter, a rotating hemostatic valve (RHV) is first attached to the working lumen of the balloon catheter. Then a syringe is connected to the sidearm of the RHV to provide a continuous saline flush line. A catheter with a guidewire is inserted into the inner lumen of the balloon guide catheter, and a peel-away introducer sheath is utilized to insert the balloon guide catheter system through the RHV. The system is then advanced to the desired location in the vasculature using fluoroscopic visualization. The balloon can be inflated for occlusion and deflated for removal or repositioning. The balloon guide catheter can also be used with an aspiration device or a clot retrieval device to create proximal flow arrest.

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the BOBBY Balloon Guide Catheter 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/bleeding inside the brain
- Embolism
- Ischemia
- Intracerebral/intracranial hemorrhage
- Pseudoaneurysm
- Seizure

- Stroke
- Infection and or fever
- Vessel dissection
- Thrombus formation
- Death
- Anaphylactic shock
- Cardiac arrest/heart attack
- Inflammatory complication
- Myocardial embolism/myocardial infarction
- Tissue necrosis
- Blockage other than target vessel
- Toxic Reaction

1.4.2 Warnings and Precautions

The warnings / precautions for the BOBBY Balloon Guide Catheter are

WARNINGS

- Verify the size of the vessel under fluoroscopy. Ensure that the balloon guide catheter is appropriate for the size of the vessel.
- Do not exceed the maximum recommended inflation volume as balloon rupture may occur.
- The balloon guide catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.
- Viscosity and concentration of contrast may affect balloon inflation and deflation times.
- During preparation, do not deflate the balloon unless the distal tip is submerged in saline or contrast to prevent air from entering balloon.
- Attaching devices other than a syringe to the balloon inflation port may rupture the balloon.
- Do not inflate the balloon with air or any other gas while in the body.
- Improper preparation may introduce air into the system. The presence of air may inhibit proper fluoroscopic visualization.
- For working lumen, do not exceed 300 psi (2068 kPa) maximum recommended infusion pressure. Excess pressure may result in catheter rupture.
- When air-purging the balloon guide catheter, inject fluid slowly otherwise balloon rupture may occur.
- Do not advance the balloon guide catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using fluoroscopic means.
- Always inflate and deflate the balloon while visualizing under fluoroscopy to ensure patient safety.
- 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.
- Do not exceed -28 inHg during aspiration
- 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."

PRECAUTIONS

- Immediately prior to use visually inspect all the sterile barrier systems, that are labeled as sterile. Do not use if breaches in sterile barrier system integrity are evident, such as a damaged pouch.
- After balloon preparation for use and prior to use, re-inflate to nominal volume and inspect for any irregularities or damage. Do not use if any inconsistencies are observed.
- Verify balloon guide catheter compatibility when using other ancillary devices commonly used in intravascular procedures.
- The balloon guide catheter has a lubricious surface and should be hydrated for at least 10 seconds prior to use. Once the balloon guide catheter is hydrated, do not allow it to dry.
- Exercise care in handling the balloon guide catheter to reduce the chance of accidental damage.
- Take precaution when navigating the balloon guide catheter in tortuous vasculature to avoid damage. Avoid advancement or withdrawal against resistance until the cause of resistance is determined.
- Presence of calcifications, irregularities or existing devices may damage the balloon guide catheter and potentially affect its insertion or removal.
- Excessive torque applied to the syringe might result in damage to the hub assembly.
- Exposure to angiographic and fluoroscopic X-ray presents potential risks of alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase.
- Exercise necessary precautions to limit x-ray doses to patients and operators by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.

1.4.3 Potential Complications / Adverse Effects

The potential complications / adverse effects for the BOBBY Balloon Guide Catheter are

- Vessel or aneurysm perforation
- Vasospasm
- Hematoma/bleeding inside the brain
- Embolism
- Ischemia

- Intracerebral/intracranial hemorrhage
- Pseudoaneurysm
- Seizure
- Stroke
- Infection and or fever
- Vessel dissection
- Thrombus formation
- Death
- Anaphylactic shock
- Cardiac arrest/heart attack
- Inflammatory complication
- Myocardial embolism/myocardial infarction
- Tissue necrosis
- Blockage other than target vessel
- Toxic reaction

1.4.4 Other Aspects of Safety

Data relevant to the clinical safety and performance of the SCEPTER™ devices was collected and evaluated from routine data sources from PMS such as complaints, Corrective and Preventative Action (CAPA), as well as post-market clinical follow-up (PMCF). The data has demonstrated the clinical safety of the subject devices.

- From 01 February 2021 to 28 February 2023, MVI received 53 product complaints concerning the SCEPTER devices, and 2140 units has been sold worldwide, resulting in a complaint rate of 2.48% (53/2140). The complaint rate is defined as the number of complaints per sale for the given period. Of the total units shipped, 510 were in Europe. With 37 complaint records, the complaint rate for Europe was 7.25%.
- No Corrective and Preventive Actions (CAPA) occurred during the evaluation period of 01 April 2019 through 31 March 2023 that pertained to BOBBY Balloon Guide Catheter.
- For the subject device BOBBY Balloon Guide Catheter, the MAUDE database was searched. The search of the MAUDE database identified 11 records for the subject device from 01 February 2020 through 28 February 2023 covered in the PSUR.

  Patient Problems noted were

  - 7 No Clinical Signs, Symptoms or Conditions
  - 3 Vascular Dissection
  - 1 Embolism/Embolus

1.5 Summary of the Clinical Evaluation and PMCF

1.5.1 Equivalent Device Clinical Data

The clinical evaluation for the BOBBY Balloon Guide Catheter includes clinical data from the equivalent device, the SCEPTER Balloon Catheter (MicroVention Inc., Basic UDI-DI: 08402732SCEPTERKS). A systematic review of the scientific literature was performed, and the literature search results demonstrate clinical use of the SCEPTER Occlusion Balloon Catheters for Intracranial Aneurysms, AVFs, AVMs and Ischemic Stroke in 1,495 patients with an average follow up to two years in 28 Retrospective Studies, one (1) Prospective Study, three (3) Journals and six (6) Case Reports/Case Series. As such, the overall quality of the data from the published clinical studies was high. The analysis of the published literature demonstrates clinical performance outcomes Technical or procedural Success of 80 % to 100% and clinical safety outcomes of Thrombosis, Hemorrhage and Ischemic Lesions ranged from 3.6% to 10.7%.

In addition, over the past 5 years the SCEPTER Balloon Catheter had a complaint rate of 1.88%, and a rate of complaints reportable to governmental authorities of 0.02%.

1.5.2 Pre-CE-Mark Clinical Data

No pre-market clinical investigation was conducted for neither the BOBBY Balloon Guide Catheter. Since the BOBBY Balloon Guide Catheter is a legacy device (market since 2020), and its initial CE-marking was based on equivalence, pre-market clinical investigations were not conducted. However, there are currently two ongoing post-market clinical investigations (see section 1.5.5).

1.5.3 Clinical Data

Clinical data sources to evaluate the safety and performance of the BOBBY Balloon Guide Catheter 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. Published clinical data in the CER include literature for the use of the equivalent device in total of 12 retrospective studies. The literature presented demonstrates clinical performance outcomes of technical success from 98.5% to 100% [1,4-6,11,12], and immediate complete occlusion from 58.3% to 94.3% [2-8,10], and clinical safety outcomes with complication rates from 0 to 28.6% [1-4,6-11] of patients. Safety outcomes are for procedures in which the equivalent device was used and not specifically attributed to the equivalent device.

PMS Data Source

- Over that time period, there were a total of 2140 units shipped and 53 complaint records, for an overall complaint rate of 2.48% for the Bobby Balloon Guide Catheter. Over that time period, there were a total of 128,064 units shipped and 1,588 complaint records, for an overall complaint rate of 1.24% for the SCEPTER catheter which is the equivalent device.
- No Escalations or Field Actions were reported in the review period for both the Bobby Balloon Guide Catheter or the equivalent SCEPTER device.
- No Corrective and Preventive Actions (CAPAs) occurred during the evaluation period of 01 April 2019 through 31 March 2023 that pertained to BOBBY Balloon Guide Catheter.
- The FDA MAUDE database identified 11 records for the Bobby Balloon Guide Catheter and 87 reports of the equivalent device i.e., the SCEPTER device, of which all had been identified in the MicroVention complaint system and were reported. Similar device reports identified no novel potential outcomes relevant to the subject device

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

Complications directly associated with use of the equivalent SCEPTER Occlusion Balloon Catheters include Thrombosis (3.6%-7.4%) , Bleeding (3.3%) and Ischemic Lesions (3.3%). The thrombosis rate of the similar devices (HyperForm/HyperGlide and Transform) in the state of the art analysis is Thrombosis at 11.6% , Bleeding at 4.6% and Ischemic Lesion at 2.7%. The rate of adverse events identified for SCEPTER devices are comparatively within acceptable range from the state of the art.

Comparison of Adverse Events across data sources is summarized in the table below.

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 /bleeding inside the brain	No	No
Embolism	No	Yes
Ischemia	Yes	No
Intracerebral/intracranial Hemorrhage	Yes	No
Pseudoaneurysm	No	No
Seizure	No	No
Stroke	No	No
Infection and/or fever	No	No
Vessel Dissection	No	Yes
Thrombus formation	Yes	Yes
Death	No	Yes
Anaphylactic shock	No	No
Cardiac arrest/heart attack	No	No
Inflammatory complication	No	No
Myocardial embolism/myocardial infarction	No	No
Tissue necrosis	No	No
Blockage other than target vessel	No	No
Toxic reaction	No	No
Exposure to angiographic and fluoroscopic X-radiation presents potential risks		
Alopecia	Yes	No
Burns ranging in severity from skin reddening to ulcers	Yes (Scalp Necrosis)	No
Cataracts	No	No
Delayed Neoplasia	No	No

1.5.5 Post-Market Clinical Follow-up

There are two ongoing sponsor-initiated post-market clinical study will be conducted for BOBBY Balloon Guide Catheter. The details are listed in Table 1.4 and Table 1.5.

Table 1.4 STRAIT Study

STRAIT Study	
Official Study Name	BOBBY Balloon Guide Catheter for Endovascular Treatment of Acute Ischemic Stroke (STRAIT)
NCT Number	NCT05361187
Study Type	Observational

STRAIT Study	
Study Status	Recruiting
Enrollment	270
Study Population	Patients suffering from an anterior circulation acute ischemic stroke eligible to mechanical thrombectomy using a BOBBYBalloon Guide Catheter will be screened consecutively by the enrolling center. The patients will be selected in accordance with inclusion and exclusion criteria.
Inclusion Criteria	• Patient is ≥ 18 and ≤ 85 years of age • Informed consent by the patient or legal authorized representative for data collection is obtained • Patient eligible for the mechanical thrombectomy treatment with adjunctive use of the BOBBY BGC • Patient presenting with an anterior circulation large-vessel occlusion of distal internal carotic artery (ICA) through proximal M2 confirmed by computed tomography angiography (CTA), magnetic resonance angiography (MRA), or digital subtraction angiography (DSA). • Core-infarct volume of Alberta Stroke Program Early CT Score (ASPECTS) ≥ 6 based on baseline CT or MR imaging • Treatment initiated (groin puncture) within 8 hours of symptom onset. • Patient with a pre-treatment National Institutes of Health Stroke Scale (NIHSS) score ≥5 • Patient with no personal condition disabling the site to contact him/her at 90 days after procedure
Exclusion Criteria	• Patient has evidence of cerebral ischemia in the posterior circulation • Patient presents severe unilateral or bilateral carotid artery stenosis requiring stent treatment during the procedure • Pregnancy or breastfeeding • Patient presents other serious medical illness (e.g., cancer) with estimated life expectancy of less than 3 months • Patient has a planned procedure that may cause non-compliance with the protocol or confound data interpretation • Patient is already participating in an investigational drug or device trial (change routine care of the patient) • Patient has evidence of intracerebral hemorrhage on initial imaging • Patient has a significant mass effect with midline shift
Interventions	Device: BOBBY Balloon Guide Catheter intended for use in neurovascular procedures, performing or as an adjunctive device The BOBBY Balloon Guide Catheter used during a mechanical thrombectomy procedure (stent retriever alone, contact aspiration alone or stent retriever and contact aspiration) and according to the instruction for use (IFU).
Primary Outcome Measures	The primary endpoint is the proportion of patients with successful reperfusion defined as mTICI≥2b per Core Laboratory evaluation. [Time Frame: 90 days] • Successful reperfusion defined as mTICI≥2b by independent Core Laboratory evaluation.
Secondary Outcome Measures	• Technical success: successful placement of the BOBBY Balloon Guide Catheter at the skull base [Time Frame: 90 days] • BOBBY catheter placement evaluated at predefined segments (cervical, petrous, cavernous, paraclinoid) of the internal carotid artery (ICA) per independent Core Laboratory evaluation

STRAIT Study	
	• Near complete reperfusion defined as mTICI≥2c [Time Frame: 90 days] • mTICI evaluation per independent Core Lab members • Patients with modified First Pass Effect observed (mFPE: mTICI≥2b after one pass) [Time Frame: 90 days] • mTICI result after first pass evaluated by independent Core Lab members • Patients with functional outcome at 90 days post-procedure defined by mRS [Time Frame: 90 days] • modified Ranking Scale (mRS) assessment and questionnaire at 90 days follow up visit • Mortality at 24 hours and 90 days [Time Frame: 24 hours and 90 days] • Serious adverse event evaluation validated by clinical event committee • Safety evaluation device malfunction [Time Frame: 90 days] • Device related adverse event evaluation and follow up, validated by clinical event committee • Neurological deterioration events at 24h post procedure [Time Frame: 24 hours] • NIHSS evaluation by questionnaire to assess worsening of condition compared to baseline • Procedure related events [Time Frame: 24 hours] • Procedure related events and outcome evaluation validated • Occurrence of new territory embolization [Time Frame: 24 hours] • Assessment by independent Core Lab members of DSA or MRA at the end of the procedure and at 24 hours • Occurrence of symptomatic intracranial hemorrhage (sICH) within 24 hours [Time Frame: 24 hours] • procedure imaging assessment of imaging
Locations	Germany, Switzerland
Sponsor(s)	MicroVention-Terumo, Inc.

Table 1.5 RESTORE Study

RESTORE Study	
Official Study Name	REal-World Analyses of Stroke - Thrombus Occlusion REtrieval
NCT Number	NCT04451525
Study Type	Registry
Study Start (Actual)	2020-07-15
Primary Completion (Estimated)	2025-12
Study Completion (Estimated)	2025-12
Study Status	Recruiting/ Ongoing

RESTORE Study	
Enrollment	1000
Study Population	Adults with acute ischemic stroke in the cerebral circulation who will be treated with mechanical thrombectomy at the direction of the treating physician.
Inclusion Criteria **Exclusion criteria for Cohort I and Cohort II**	**Cohort I:** **Inclusion Criteria:** 1. Patient is ≥ 21 and ≤ 85 years of age. 2. Patient has a pre-morbid mRS ≤ 1. 3. Neuroimaging (CT/CTA and/or MR/MRA collected at no more than 90 minutes prior to groin puncture) demonstrates large vessel proximal occlusion (distal ICA through MCA bifurcation). 4. Patient has an NIHSS score ≥ 5 at time of intervention. 5. Symptom onset is within 8 hours of when groin puncture can be achieved. 6. Patient will undergo treatment via femoral access and the decision to use femoral access has been made by the treating physician outside the context of the RESTORE study and prior to study enrollment. 7. Patient will be treated using the direct aspiration as first line treatment technique and the decision to use this technique and the study device has been made by the treating physician outside the context of the RESTORE study and prior to study enrollment. 8. Patient or patient's legally authorized representative (LAR) has provided written informed consent. 9. Patient is considered by the treating physician to be available for and able to complete all follow-up visits with a trained site investigator. **Exclusion Criteria:** 1. Inability to obtain written informed consent. 2. Patient is < 21 or > 85 years of age. 3. Patient has a pre-morbid mRS ≥ 2. 4. More than 8 hours have passed since symptom onset. 5. Severe unilateral or bilateral carotid artery stenosis or dissection requiring stent treatment. 6. Presence of a pre-existing large territory infarction. 7. Absent femoral pulses or other condition preventing femoral access. 8. Patient has vascular anatomy/tortuosity or other vascular disease preventing access to the target occlusion or that will likely result in unstable access. 9. Patient is pregnant. 10. Known or suspected pre-existing/chronic large vessel occlusion in the symptomatic territory. 11. Patient has known, untreatable hypersensitivity to contrast dye, iodine or any component of the treatment device that cannot be medically controlled. 12. The intracranial occlusion is suspected to be chronic based on past imaging, clinical history, or clinical judgment. 13. Patient has a severe or life-threatening comorbidity that could confound study results, or that will render the procedure unlikely to benefit the patient. 14. Patient is unable to complete scheduled follow-up assessments due to comorbidities, geographical limitations, or a life expectancy of less than 3 months. 15. Patient is enrolled in another device or drug study in which participation could confound study results.

RESTORE Study	
	16. Imaging (CT or MR) exclusion criteria: ○ Presence of intracerebral hemorrhage as evidenced on initial imaging ○ Ischemic changes in the posterior circulation territories (including the vertebra-basilar and posterior cerebral arteries) ○ Significant mass effect with midline shift ○ Evidence of intracranial tumor ○ Baseline ischemic core lesion >50 cc ○ Involvement of > 1/3 of the middle cerebral artery territory ○ ASPECTS <6 (hemispheric sulcal effacement and/or loss of grey-white differentiation alone are not contraindications for treatment) **Cohort II:** **Inclusion Criteria:** 1. Neuroimaging (CT/CTA and/or MR/MRA) demonstrates intracranial vessel occlusion. 2. Symptom onset is within 24 hours of when arterial access puncture can be achieved. 3. Patient will be treated using an FDA-cleared/approved and market-released MicroVention mechanical thrombectomy device as the initial, primary treatment device and the decision to use this device has been made by the treating physician outside the context of the RESTORE study and prior to study enrollment. Note: For the purposes of this protocol, ancillary/accessory devices such as balloon guide catheters and other access devices are not considered primary treatment devices. Further, devices used for rescue following attempt of a different primary treatment device are not considered initial primary treatment devices. 4. Patient or patient's legally authorized representative (LAR) has provided written informed consent within 48 hours of procedure. **Exclusion Criteria:** 1. Inability to obtain written informed consent within 48 hours of procedure. 2. Patient is enrolled in another device or drug study in which participation could confound study results.
Interventions	MicroVention Mechanical Thrombectomy Devices as first-line treatment
Outcome Measures	To collect real-world evidence allowing assessment of functional, imaging, and safety outcomes of MicroVention market-released acute ischemic stroke devices when used at the direction of the treating physician
Results	No results are available to report in this annual update of the Clinical Evaluation report
Locations	United States
Sponsor(s)	Microvention-Terumo, Inc.

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

Treatment for acute ischemic stroke is aimed at restoring blood flow and reperfusing ischemic tissue, halting progression of infarction, and preventing recurrence.[13,14] Restoration is achieved using a thrombolytic drug or by intervention with endovascular treatment (EVT), or both. Approximately 25% of all ischemic stroke patients are eligible for medical thrombolysis, and 10- 12% are eligible for EVT due to the critical time window. The number of patients who can benefit from these treatments continues to increase as new studies demonstrate that not just time since stroke onset but also collateral circulation influences outcome.[15]

Thrombolytic Drugs

Treatment options for AIS include intravenous thrombolysis using recombined tissue plasminogen activator (tPA), intra-arterial (IA) thrombolysis using urokinase, or a combination of IV and IA fibrinolysis. IV-tPA is proven to be effective in improving functional outcomes after ischemic stroke up to 4.5 hours after symptom onset. The US Food and Drug Administration (FDA) has only approved tPA for use within 3 hours of stroke onset, but regulatory agencies in most other countries, including those in the European Union, have approved its administration within 4.5 hours of stroke onset.[14] The FDA approval was based upon the results of the 1995 National Institute of Neurological Disorders and Stroke (NINDS) tPA trial. This trial was able to show a significant improvement in functional outcome at 90 days when tPA was given 3 hours of symptom onset. The European Cooperative Acute Stroke Studies (ECASS-III) evaluating the efficacy of IV alteplase within 3 and 4.5 hours after symptom onset and pooled analysis of multiple trials testing IV alteplase within various time windows support the value of IV thrombolysis up to 4.5 hours after symptom onset.[16] Although tPA remains the mainstay of AIS therapy, it has several limitations, including a short half-life, low recanalization rate of 30-40% for proximal occlusions and of <5% for distal ICA occlusion.[17] Other thrombolytic drugs, like Tenecteplase, have been tested in AIS patients, which may lead to FDA approval for AIS.[18]

The use of IV-tPA in AIS related to large vessel occlusion (LVO), however, has shown low recanalization rates and poor clinical outcomes. These patients are less likely to experience quick recanalization, due to poor IV thrombolysis.[17] Also, the use of IV-tPA may delay the time to initiating thrombectomy and may result in thrombus migration. The use of IV-tPA may also increase the risk of intracranial hemorrhage (ICH), especially in patients taking antiplatelet drugs.

Endovascular Treatment

Although IV-tPA has been shown to be effective, its effectiveness may diminish with more proximal or larger occlusions. The low success of tPA to achieve recanalization of LVO prompted development of endovascular treatments. This was possible due to technological advances in endovascular surgery with better catheters to enable more distal access and better

stent retrievers to safely remove the thrombi from brain vessels. The benefit of endovascular mechanical thrombectomy (EMT) for AIS caused by emergent LVO in the anterior circulation has been uniformly reported by randomized controlled trials (RCTs) and meta-analyses. The mechanical thrombectomy devices to remove blood clots from a large cerebral artery and to restore blood flow are mostly of 2 types: Stent retrievers and aspiration catheters. Both techniques can be used in conjunction with a proximal flow control by balloon guide catheters temporally inflated in the parent vessel. The main goal of mechanical thrombectomy is to remove the embolism while limiting the creation of adverse downstream emboli in new-initially unaffected-territories. The benefits of endovascular treatment are regularly observed irrespective of a patient's age, their NIH Stroke Scale (NIHSS) score, or whether they received intravenous thrombolysis. Compared to medical therapy with tPA alone, patients who received EVT were more likely to have a good functional outcome (mRS 0-2, mRS 0-1, and mRS 0-3), without an increased rate of symptomatic intracerebral hemorrhage or mortality. The advances in AIS treatment with EVT have demonstrated significant reduction in stroke morbidity and mortality.

Stent Retrievers

Stent retrievers are self-expandable wire mesh tubes delivered by a microcatheter, intended to remove the clot that is trapped and withdrawn by pulling.[19] The use of stent retrievers to perform mechanical thrombectomy has become a rapidly emerging therapy for the treatment of AIS.[20] Six RCTs (MR CLEAN, EXTEND-IA, ESCAPE, REVASCAT, SWIFT PRIME and THRACE) confirmed the benefits of using endovascular thrombectomy on the clinical outcome of patients with stroke with LVO.[21] The use of stent retrievers in the trials led to recanalization rates of between 59% and 88%. The trials showed also that the likelihood of a good outcome increased with better recanalization. The highest recanalization rates were achieved in SWIFT PRIME (88%) and EXTEND-IA (86%), correlating with the high rates of good clinical outcomes (mRS [0-2]) seen in these trials (60% and 71%, respectively). The lowest recanalization rate was in MR CLEAN at 59% with a favorable clinical outcome occurring in only 33% of the patients.[22] All 6 trials provided strong evidence to support the use of thrombectomy that is initiated within 6h of stroke onset, prompting worldwide changes in the guidelines for management of acute stroke by endovascular treatment.[19,23] The recent publication of the Wake-Up and Late Presenting Strokes Undergoing Neurointervention with Trevo® (DAWN)/Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke (DEFUSE 3) trials extended the time window to patients with strokes in this study and those presenting beyond 6 hours from symptoms' onset up to 16-24 hours from last time seen well.[19]

Aspiration

Despite the impressive results of the stent retrievers with successful recanalization, there are some vessel occlusions and thrombi that are resistant to this technique even after repeated recanalization attempts. These vessel occlusions include cases of terminal ICA occlusions. Moreover "hard" thrombi in other locations, such as the MCA, can also be resistant to the stent retriever technique. For these cases, direct aspiration of the thrombus can be used as an

alternative technique.[22] Mechanical thrombectomy with aspiration, uses large bore aspiration catheters guided to the proximal end of the clot put under negative pressure using an electric pump or manual suction with a syringe to retrieve the clot (the thrombus is either aspirated through the catheter or stuck at the tip and retrieved with the aspiration catheter).[19] During aspiration thrombectomy, aspiration catheters are placed through a guide catheter and advanced coaxially over a microcatheter or microwire to the occluded vessel. The microcatheter or microwire is advanced through the clot, and the aspiration catheter is advanced into the proximal clot. The microwire and microcatheter are then removed, and suction is applied manually with a large-volume syringe or an aspiration pump.[25] Current generations of distal aspiration catheters have better trackability and flexibility and have been shown to be safe and effective with treatment results comparable to but not superior to stent retriever thrombectomy with the benefit of lower procedural costs [26].

Combination of stent retriever and direct aspiration

There are attempts to enhance the rate of successful recanalization through a combination of stent retriever thrombectomy and direct clot aspiration. The first is called the "switching strategy," which involves switching from forced arterial suction thrombectomy (FAST) using the Penumbra® reperfusion catheter to Solitaire™ stent thrombectomy, and this has been suggested to provide better angiographic outcomes than a one technique-only strategy. Another is called "SOLUMBRA" technique, which involves the combination of stent retrievers and large-bore aspiration catheters. The stent retriever is removed under concurrent aspiration to minimize clot fragmentation and potential distal vessel occlusion.[20]

Acute Ischemic Stroke Treatment with vs. without Using Balloon Guide Catheters

Multiple studies have suggested that using balloon guide catheters improves the clinical outcomes of the endovascular treatment (i.e., stent retriever, aspiration, combination of stent and aspiration) on the acute ischemic stroke, when compared to those treatments without using balloon guide catheters.

Using Balloon Guide Catheters with stent retrievers

Kim et al. [30] evaluated efficacy of combining balloon guiding catheter stent retrieval for anterior circulation ischemic stroke, which resulted in increased TICI 3 reperfusion (68.4% vs. 28.8%; $p<0.01$) and better clinical outcomes (mRS at 3 months ≤2) rate (59.6% vs. 33.9%; $p=0.005$). Zaidat et al. [31] compared the rates of early revascularization success and good clinical outcomes in patients with acute ischemic stroke with balloon guide catheter versus conventional guide catheter. The balloon guide catheter group had a higher first-pass effect[b] (212/443 [48%]) versus conventional guide catheter (16/62 [26%]; P=0.001) [31].

Using Balloon Guide Catheters with aspiration

Lee et al. [29] evaluated the use of balloon guide catheter in thrombus aspiration, concluding it significantly decreased the risk of distal embolization with less frequent cases in the balloon guide catheter group (5/73, 6.8% vs. 21/66, 31.8%; OR, 6.3; 95% CI, 2.2–18.0; P < 0.001).

Using Balloon Guide Catheters with combination of stent retriever and direct aspiration

There have been studies that show the improvement in stroke treatment with vs. without using balloon guide catheters. Velasco et al. [32] observed that the effectiveness of mechanical thrombectomy with stent retrievers in acute ischemic stroke in the anterior circulation in terms of angiographic results and procedure duration was improved when performed in combination with the balloon guide catheter. Successful recanalization with the balloon guide catheter was achieved in 89.2% of thrombectomies (91 of 102) versus 67.9% (55 of 81) achieved with the non–balloon guide catheter (P = .0004) [32]. A systematic review and meta-analysis of the literature by Brinjikji et al. [33] suggested that balloon guide catheters use during stent retrieval for acute ischemic stroke is associated with superior clinical and angiographic outcomes. Compared with the non-balloon guide catheter group, patients treated with balloon guide catheters had higher odds of first-pass recanalization (OR 2.05, 95% CI 1.65 to 2.55), TICI 3 (OR 2.13, 95% CI 1.43 to 3.17), TICI 2b/3

(OR 1.54, 95% CI 1.21 to 1.97), and mRS 0–2 (OR 1.84, 95% CI 1.52 to 2.22). The balloon guide catheter-treated patients also had lower odds of mortality (OR 0.52, 95% CI 0.37 to 0.73) compared with the non-balloon guide catheters patients [33].

1.6.2 Available Technologies

Balloon Guide Catheters are well established medical devices with numerous types and styles available from a variety of manufacturers. A few examples of Balloon Guide Catheters similar to BOBBY Balloon Guide Catheter are listed in Table 1.7.

BOBBY Balloon Guide Catheter are well established medical devices with numerous types and styles available from a variety of manufacturers. Examples of Balloon Guide Catheters similar to BOBBY Balloon Guide Catheter are listed in Table 1.6.

Table 1.6 Similar Devices

Device	Manufacturer	Intended Purpose
HyperForm™/HyperGlide™ Occlusion Balloon Catheters	Medtronic	The HyperForm and HyperGlide occlusion balloon catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow; the occlusion balloon catheters may also be used in balloon-assisted embolization of intracranial aneurysms.

FlowGate2 Balloon Guide Catheter	Stryker	FlowGate2™ Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

1.7 Suggested Profile and Training for Users

This device should be used only by physicians with neuro or peripheral interventional training and a thorough knowledge of the vascular pathology to be treated, vascular architecture, angiographic techniques, and super-selective embolization techniques.

1.8 Reference to any Harmonized Standards and CS

Standards	Edition	Standard Title
Quality System		
EN ISO 13485	2016 / A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
Risk Management		
EN ISO 14971	2019 / A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN IEC 60812	2018	Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)
Usability		
EN ISO 62366-1	2015/A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices (IEC 62366- 1:2015/A1:2020)
Clinical		
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects -- Good clinical practice (ISO 14155:2020)
Post Market Surveillance		
ISO/TR 20416	2020	Medical Devices-Post Market Surveillance for Manufacturers
Labeling		
EN ISO 15223-1	2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN ISO 20417	2021	Medical devices - Information supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
Packaging		
EN ISO 11607-1	2020/A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	2020/A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)

Standards	Edition	Standard Title
ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 150 lbs. (70 kg) or Less
ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F88	2023	Standard Test Method for Seal strength of Flexible Barrier Material
ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096	2011R2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
Shelf Life & Stability		
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
Biocompatibility		
EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management 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)
Manufacturing (Environmental Controls)		
EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
EN ISO 14644-2	2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
ANSI/AAMI ST72	2019	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
Sterilization		
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)
Biological Indicators		

Standards	Edition	Standard Title
-EN ISO 11138-1	2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
Ethylene Oxide		
EN ISO 11135	2014 / A1:2019	Sterilization of health care products — Ethylene oxide — Requirements for 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)
Device Specific		
Catheters		
EN ISO 10555-1	2013/A1: 2017	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements (ISO 10555-1:2013A1:2017)
EN ISO 10555-4	2013	Intravenous catheters – Sterile and single use catheters – Part 4: Balloon dilation catheters (ISO 10555-4:2013)
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)

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