Summary of Safety and Clinical Performance

for

ERIC™ Retrieval Device

SSCP1101204

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DOCUMENT CHANGE HISTORY

SSCP Revision	Change 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

Device Names	
Device Trade Name	ERIC Retrieval Device
EMDN Code	C019010
Medical Device Nomenclature (EMDN Description)	Embolus Retriever with Interlinked Cage
Device Class	III
Basic UDI-DI	37015174ERICHX
Year when first certificate (CE) was issued for the device	12 March 2013
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-Straße 21 D-60433 Frankfurt am Main Germany
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

Table 1.2: Intended Use

Intended Purpose	
Intended Purpose	The ERIC Retrieval Device is intended for use in the revascularization of acute ischemic stroke caused by intracranial occlusive vessels in patients.
Indications for Use	The ERIC Retrieval Device is intended for use in the revascularization of acute ischemic stroke caused by intracranial occlusive vessels in patients.
Target Population	The ERIC Retrieval Device is intended for use in patients with acute ischemic stroke caused by intracranial occlusive vessels, who require endovascular revascularization treatment.
Contraindications and/or Limitations	• Patients with known hypersensitivity to nickel-titanium. • Patients with stenosis proximal to the thrombus site that may prevent safe recovery of the ERIC Retrieval Device. • Patients with angiographic evidence of carotid dissection.

1.3 Device Description

Table 1.3: Device Description

Device Description	
Description of the Device	The ERIC Retrieval Device is a resheathable mechanical thrombectomy device for restoring blood flow by removing clots from occlusive vasculature. The ERIC Retrieval Device consists of retrieval spheres that are located on a pusher wire delivery system which requires a Microcatheter. Radiopaque markers provide visualization under fluoroscopic guidance for navigation. The device exit markers on the proximal end of the pusher wire indicate the initiation of fluoroscopic guidance.
Design Characteristics of the Device	The ERIC Retrieval Device is a mechanical thrombectomy device designed to restore blood flow by effectively removing clots from occlusive vasculature in patients suffering patients suffering from acute ischemic stroke. The device consists of a series of nitinol retrieval segments that are located at the distal end of a tapered nitinol delivery wire. The retrieval segments are constructed from laser cut hypo tubes that are expanded, and heat set. Each retrieval segments has two nitinol bands welded inside each end. The retrieval segments are linked together by a flexible connection that consists of a stainless-steel wire with two laser formed ball-ends that connect adjacent retrieval segments. This interconnection design allows each retrieval segment independent rotation. The nitinol core wire is close wound with a tantalum coil that forms the proximal radiopaque marker and is surrounded by a PET tube. The distal end of the device also has a close wound tantalum coil laser welded

Device Description	
	to distal most retrieval segment and polyolefin monofilament resides within this distal coil to provide stretch resistance. To use the ERIC Retrieval Device with pusher diameter of 0.0158", a microcatheter (with a minimum ID of 0.017") is first navigated and advanced through the thrombus. The ERIC device is inserted into the microcatheter where its distal tip is aligned to the distal tip of the microcatheter. Then, the ERIC device is advanced distal to the thrombus so that all retrieval segments are deployed and allowed to expand. The expanded retrieval segments are designed to capture/surround the thrombus as both the ERIC device and microcatheter are retracted as a single unit under guide catheter aspiration. It is resheathable and can be used up to three (3) times. Radiopaque markers (sections of close wound tantalum coil) at the distal and proximal end of the retrieval segment aid in visualization of the device during fluoroscopy. The ERIC device line extension added model sizes that are compatible with 0.021" microcatheters. The diameter on the proximal end of the tapered pusher core wire for these sizes will increase from 0.0158" to 0.0185" to improve pushability. For the ERIC device models with a 0.0185" pusher diameter, these sizes are within the validated range from 3x15mm to 6x44mm. The ERIC line extension models are prepared and used identically to the ERIC devices with pusher diameter of 0.0158".
Previous Generations or Variants, if applicable	ERIC Retrieval Device was CE certified in the year 2013 and has been in the market for 10 years. The fundamental design of ERIC device has not been changed after CE Certifications and the quality of the device has been maintained ever since.
Single use – sterilization method	☒ Electron Beam
Description of Accessories	ERIC Retrieval Device requires a Microcatheter with inner lumen of 0.017 inch or larger.
Description of other Devices or Products intended to be used in combination	Not Applicable

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Harms associated with the residual risks identified in the IFU were quantified for the ERIC Retrieval Device in the table below. The analysis includes all the associated data reported in the Scientific literature that are of sufficient scientific validity and relevance to the intended use to suitable access the safety and performace. All the harms are minimized through the use of risk mitigation/control measures and have been evaluated and mitigated.

Table 1.4: Risks associated with the subject device

Harms (Similar Events) identified within IFU	Harms (Similar Events) identified within Scientific Literature (Rate %)	Harms (Similar Events) identified within PMS (Rate %)	Category identified within Risk documentation
Vessel or aneurysm perforation	Yes (0.0% - 4.4%)	No	Yes
Vasospasm	Yes (1.1%)	No	Yes
Hematoma at the site of entry	No	No	Yes
Embolism	Yes (6.5%)	No	Yes
Ischemia	No	Yes (0.01%)	Yes
Intracerebral/Intracranial hemorrhage	Yes (0.0% - 5.6%)	Yes (0.01%)	Yes
Pseudo aneurysm	No	No	No
Seizure	No	No	No
Stroke	Yes (2.1%)	Yes (0.01%)	Yes
Infection	No	No	Yes
Vessel dissection	No	No	Yes
Thrombus formation	No	No	Yes
Death	Yes (2.3% - 30.0%)	No	Yes

1.4.2 Warnings and Precautions

Warnings:

- The ERIC Retrieval Device should only be used by physicians who have received appropriate training in interventional techniques.
- The ERIC Retrieval Device is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.
- Appropriate anti-coagulation and anti-platelet therapy should be administered per standard medical practice.
- Do not advance or withdraw the ERIC Retrieval Device when excessive resistance is observed. Assess the source of resistance using fluoroscopic means. If needed re-sheath the ERIC Retrieval Device into Microcatheter and remove the entire system under aspiration. If resistance is encountered during re-sheathing, stop re-sheathing and remove the entire system under aspiration.
- Position the distal tip marker of Microcatheter just proximal to the retrieval segment after deployment of the ERIC Retrieval Device and maintain the distal tip marker in the same position during withdrawal to reduce risk of device fracture.
- Do not apply excessive force to the distal tip of the ERIC Retrieval Device when cleaning the device for additional retrieval attempts.
- Do not perform more than three (3) retrieval attempts per device.
- Ensure during cleaning of the ERIC Retrieval Device that all foreign components (clot, fibers, etc) are fully removed before reinsertion.

- 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:

- Exercise care in handling the ERIC Retrieval Device to reduce the chance of accidental damage. Use of other organic solvents may damage the ERIC Retrieval Device
- Verify that the inner lumen of Microcatheter is compatible with the ERIC Retrieval Device prior to use.
- Verify ERIC Retrieval Device compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- Use caution when manipulating the ERIC Retrieval Device in tortuous vasculature to avoid damage to the vasculature or the device. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.
- Presence of calcifications, irregularities, or other devices may damage the ERIC Retrieval Device and potentially affect its insertion or removal.
- Maintain saline perfusion between the ERIC Retrieval Device and Microcatheter and Guiding Catheter and Microcatheter to prevent thrombus formation.

1.4.3 Potential Complications / Adverse Effects

The potential complications / adverse effects for the ERIC Retrieval Device are:

- Vessel/Aneurysm Perforation
- Vasospasm
- Hematoma at the site of entry
- Embolism
- Ischemia
- Intracerebral/Intracranial Hemorrhage
- Pseudo aneurysm
- Seizure
- Stroke
- Infection
- Vessel dissection
- Thrombus formation
- Death

1.4.4 Other Aspects of Safety

1.4.4.1 Field Actions

One (1) field action was initiated by MicroVention for the ERIC Retrieval Device for the evaluation period of 01 February 2021 to 31 January 2025.

Table 1.5: ERIC Device Field Actions

Field Action	Date Opened	Origination Source	Title / Description	Status (Open/Closed)
1103961	ERIC Retrieval Device	8/05/2024	The product label states an incorrect expiration date of five (5) years instead of three (3) years which extends beyond their true expiration date. (1370 units impacted).	C24-021 Implementation Phase

1.4.4.2 Corrective and Preventative Action (CAPA)

The CAPA process is conducted under SOP 8.8 Corrective and Prevention Action. During the current review period, two (2) CAPAs were opened or in process that pertained to the ERIC devices. As of the preparation of this document, one CAPA has been closed, 0 are in the Verification of Effectiveness phase, 1 is in the Implement Action Plan phase, and 0 are in the CAPA Root Cause Investigation phase.

Table 1.6: ERIC Device Issues

Type of action	Initiation Date	Scope of the CAPA	Status of the CAPA	Manufacturer Reference number	CAPA description	Root cause	Effectiveness of the CAPA if closed**
Corrective, CAPA20-0001	2/20/2020	Escalation from QAR18-0032 for handling of materials expired or nearing expiration on production floor. (ERIC and V-Trak™) Expired Materials were not promptly identified and removed from the Production floor.	Closed	PD00034, lot R01154896 on the ERIC and V-Trak production lines. D110351-01 Lot# R01168035 prior to use in BR060230 Lot# 200305112.	QAR18-0032 was initiated to address sterile indicators becoming expired on the ERIC and V-Trak* production lines and the issue was addressed with update to the Warehouse inventory management process. Additional gaps were found in the management of material already issued to the production floor. These gaps included: 1. High quantity requested to be issued/FIFO was not followed. 2. No standard process to remove aging	Method – Lack of procedure/ Unclear procedure No procedure for removing/disposing expired and near expiring material in the Cleanroom. MP012 Rev W Section 5.1.1.8-5.1.1.9 not sufficient to avoid using expired materials in Production. MP012 Rev W Section 5.1.1.8 does not define roles and responsibilities for verification of expiration dates clearly Material "IN PROCESS" Production labels do not have a field for expiration date. In cases where Production associates attach these labels to materials there is no visibility of expiration date on the material for the operator to check per	Effective, Closed 4/22/2021

Type of action	Initiation Date	Scope of the CAPA	Status of the CAPA	Manufacturer Reference number	CAPA description	Root cause	Effectiveness of the CAPA if closed**
					(i.e. soon to expire) inventory 3. 3. Artificial expiration date set up in JDE (ERP system for inventory management) These gaps identified a more systemic issue for handling of materials near expiration or already expired on the production floor. The CAPA Review Board held in Feb 2020 made the decision to escalate the investigation to CAPA to address the additional gaps.	MP012 Method – Lack of procedure No procedure for managing/maintaining necessary amount of inventory stored in Production inventory locations and no process for FIFO use of material in Production Man is a contributor factor for failing to follow MP012, Line Clearance.	
Corrective, C24-021	8/16/2024	Build Card and Label Reference contained the incorrect ERIC shelf life	Implementation	ERIC model numbers ER173020-US,	The CF11471J, Build Card and Label	Method: Form CF11471 was released without proper	

Type of action	Initiation Date	Scope of the CAPA	Status of the CAPA	Manufacturer Reference number	CAPA description	Root cause	Effectiveness of the CAPA if closed**
				ER174030-US, and ER176044-US	Reference, contained the incorrect ERIC shelf life of five (5) years instead of three (3) years for the following ERIC model numbers ER173020-US, ER174030-US, and ER176044-US.	review against the shelf-life test report(s).	Open

1.4.4.3 Supplier Corrective Action Reports

Supplier Corrective Action Requests (SCAR) are handled in accordance with the *Supplier Control Process (SOP 7.4)* procedure. During the current review period Two (2) SCARs was opened or in process that pertained to the ERIC devices (Table). All SCARs have been Completed with 100% effectiveness.

Table 1.7: ERIC Device SCARs

Scar Reference #	Supplier	Date Opened	Issue Description	Source
SCAR-21-0158	Steven Label	4/27/2021	During the receiving inspection process, it was found one bag of PD00574 lot 01215294 and one bag of PD00574 lot 01215302 (Steven Label lot: 11F-741-01) with foreign matter.	Receiving Inspection

1.5 Summary of the Clinical Evaluation and PMCF

The clinical data used to access safety and performance of the ERIC Retrieval Device is summarized below. The data presented include information on the key device related clinical outcome parameters (i.e., the parameters deemed most relevant to establishing the performance and safety of the device). These were selected based on the State of The Art (SOTA) review and input by internal clinicians and other clinical stakeholders. While other outcomes are reported in the clinical data sources, including the known potential device or procedural residual risks and undesirable effects identified in the IFU, they may not have been selected as key outcomes based upon the device-relatedness, prevalence, patient impact, required medical intervention, or frequency of reporting in clinical data source. These data were used to assess the expected clinical benefits of the device.

Table 1.8: Summery of Subject Device Evaluation

Clinical Data Source(s)	Device Specific Clinical Literature

Key Outcome measures used to assess Benefit/Risk	**Performace:**
	• Thrombolysis in Cerebral Infarction (TICI) scores
	  • 2a- minor partial reperfusion
	  • 2b- major partial reperfusion
	  • 3- complete perfusion
	• modified Rankin Scale (mRS)
	  • Score 0: No symptoms
	  • Score 1: No significant disability, despite symptoms, able to perform all usual duties and activities.
	  • Score 2: Slight disability; unable to perform all previous activities but able to look after own affairs without assistance.
	  • Score 3: Moderate disability, requiring some help but able to walk without assistance
	  • Score 4: Moderately severe disability, unable to walk without assistance
	  • Score 5: Severe disability, bedridden, incontinent, and requiring constant care and attention
	  • Score 6: Death.
	Safety:

Clinical Data Source(s)	Device Specific Clinical Literature
	• Adverse Events
Expected Clinical Benefit (When used according to instructions for use and recommended Technique)	Mechanical Thrombectomy is designed to restore blood flow by removing clots from vasculature in patients suffering from Acute Ischemic Stroke (AIS). Endovascular treatment of AIS with the ERIC Retrieval Device can be lifesaving and result in benefits such as restoration of blood flow to previously occluded intracranial vessel segments, improved neurological outcomes immediately post-procedure, and improved functional independence and reduced disability.
Clinical claims (beyond those identified in the intended use and expected clinical benefit).	None

1.5.1 Equivalent Device Clinical Data

Not Applicable- Safety and Performance of ERIC Retrieval device is not based on equivalency. ERIC Retrieval device has robust clinical data of its own to support the safety and performance.

1.5.2 Pre-CE-Mark Clinical Data

There is no Clinical Development Plan for the ERIC Retrieval device because this was approved for CE Mark under the MDD, and no premarket clinical studies were required for market approval. Under EUMDR, there is sufficient clinical data on the ERIC Retrieval device to support safety and performance for its intended use.

1.5.3 Clinical Data

1.5.3.1 Systematic Literature Review

Table 1.9: Scientific Literature Review

Overall Literature search	01 April 2013 to 17 February 2025
Total Included Publications supporting Safety and Performance Conformity	15 publications (672 patients)
Overall follow-up time	30 to 90 days
Patient Population Demographics	All the patients included in the studies were adult patients and the use of ERIC device in pediatric population was not reported.
Key Performace Outcomes	• TICI 2b/3: 40% to 95% achieved major partial to complete reperfusion • mRS (0-2): 50% to 70% achieved slight disability to no symptoms.
Activity Limitations	None

1.5.4 Clinical Performance and Safety

Key outcome parameters such as TICI, mRS were identified across clinical literature and PMCF data sources and were comparable to the State of The Art reported rates. These data indicate that the ERIC Retrieval Device achieves the expected clinical benefit of revascularization of intracranial occlusive vessels.

No, new emerging issues or risks were identified through an assessment of all available clinical data. The risks for the ERIC Retrieval Device are acceptable when used as intended. The undesirable side effects are acceptable relative to the treatment options and the performance of the device though the therapeutic lifetime.

Table 1.10: Overall Summery of Key Performace outcomes from All included data sources

Data Source	Outcome Measures
Data from Literature Review	• TICI 2b/3: 40% to 95% achieved major partial to complete reperfusion • mRS (0-2): 50% to 70% achieved slight disability to no symptoms.
Data from PMCF Studies	**STABILISE Study:** The study results showed that TICI 2B/3 reperfusion was achieved in 72% of patient population in intervention group compared with 90% in control arm. **ERASER Single Arm Study:** The 90 days data showed good clinical outcome with mRS, 0-2 in 70% of the patients. The recanalization rate (Thrombolysis in Cerebral Infarction 2b/3) was seen in 95% of patient population. **ETI Study:** Higher rate of complete recanalization (mTICI 3) observed in the ERIC device arm (40%). mRS 0–2 or equal to pre-stroke mRS score at 90 days in ERIC device group is 54.9%.
Acceptability of the Benefit Risk Ratio	Based on the review of the benefits and the possible harms from all the data sources, it has been determined that when the ERIC Retrieval Device is utilized according to the intended use, the occurrence of the risks have been reduced as far as possible and the benefits outweigh the possible residual risks over the therapeutic lifetime of the device and are consistent with the state of the art.

1.5.5 Post-Market Clinical Follow-up

1.5.5.1 Manufacture Sponsored Clinical Study- Ongoing

RESTORE Study	
Official Study Name	REal-World Analyses of Stroke - Thrombus Occlusion Retrieval
NCT Number	NCT04451525
Study Type	Observational
Study Status	Recruiting (Estimated to completion Date: December 2025)
Estimated Enrollment	1000

RESTORE Study	
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.
Interventions	Device: MicroVention Mechanical Thrombectomy Devices as first-line treatment
Primary Outcome Measures	1. Current , Submitted on 08 March 2022: Cohort I: Proportion of subjects achieving mTICI ≥ 2b revascularization based on independent core lab assessment [Time Frame: During the procedure] 2. Original, Submitted on 26 June 2020 : Proportion of subjects achieving mTICI ≥ 2b revascularization [Time Frame: During the procedure]
Secondary Outcome Measures	1. Proportion of subjects with good functional outcome defined as mRS ≤ 2 [Time Frame: 90 days] 2. Occurrence of procedure related serious adverse events [Time Frame: During the procedure through study completion at 90 days] 3. Occurrence of sICH within 24 hours [Time Frame: 24 hours post-operative] 4. Occurrence of embolization to new territories (ENT) [Time Frame: During the procedure] 5. Presence of vasospasm involving the accessed vascular tree [Time Frame: During the procedure through 24 hours post-operative] 6. Mortality at day 90 [Time Frame: 90 days post-procedure] 7. Proportion of subjects achieving mTICI ≥ 2b revascularization after first line aspiration treatment [Time Frame: During the procedure] 8. Number of passes to achieve mTICI ≥ 2b revascularization with first line aspiration treatment [Time Frame: During the procedure] 9. Proportion of subjects achieving mTICI ≥ 2b revascularization after first aspiration pass [Time Frame: During the procedure] 10. Time from groin puncture to initial contact of clot with aspiration catheter [Time Frame: During the procedure] 11. Time from groin puncture to achieve mTICI ≥ 2b using first line aspiration treatment [Time Frame: During the procedure] 12. Technical success using the MicroVention BOBBY Balloon Guide Catheter based on successful placement at the target location and successful balloon inflation [Time Frame: During the procedure]
Locations	United States
Results	Not Applicable as the study is in progress

1.5.5.2 Other Clinical Studies- Completed and Ongoing.

There are 3 studies that are Investigator sponsored. These studies have utilized ERIC Retrieval device, and the data is presented in the tables below.

Post-Market Clinical Studies
STABILISE Study

Post-Market Clinical Studies	
Official Study Name	Evaluation of stroke thrombectomy including patients where IV thrombolysis is contraindicated or has failed: a randomized trial of two novel thrombectomy devices
NCT Number	ISRCTN 15698516
Study Type	Interventional, randomized
Study Status	Completed (01 Nov 2014 – 30 Apr 2019)
Enrollment	66 Participates (45 stroke patients assigned into ERIC device /SOFIA™ arm, 21 assigned into control arm)
Study Population	Adults aged at least 50 diagnosed with a stroke caused by a blocked artery (acute ischaemic stroke)
Inclusion Criteria	1. Clinical diagnosis of acute ischaemic stroke 2. Male or nonpregnant female at least 50 years of age 3. Clinically significant neurological deficit and NIHSS score 10 or greater 4. Enrolment, randomization and procedure commencement (groin puncture) possible within 90 minutes of the imaging (CT/CTA) confirmed diagnosis of LVO (AND maximum 5h after stroke onset anterior circulation, 8.5h for posterior circulation). 5. Occlusion of the MCA trunk, MCA bifurcation or intracranial internal carotid artery (including carotidT) M1 or =2 proximal M2 branches; intracranial vertebral/basilar/P1 PCA demonstrated on CTA, MRA, or DSA 6. Interventional device delivery (guide catheter placed in target artery beyond aortic arch and angio obtained) can be achieved within 6 hours of onset of the stroke (9h for posterior circulation occlusions) 7. Consent of patient or assent of appropriate representative 8. Independent prior to the stroke (estimated mRS 02) 9. Expected to be able to be followed up at 12 months
Exclusion Criteria	1. CT evidence of ICH, or evidence of extensive established hypodensity on CT(defined as >1/3 MCA territory or ASPECTS score =7). In posterior circulation strokes pcASPECTS <7 or >1/3 of territory 2. Clinical history suggestive of subarachnoid haemorrhage even if CT normal. 3. Eligible for an academic “treatment policy” (i.e. phase III trial) RCT of stroke thrombectomy in that institution & willing to be randomized into such 4. Vascular access contraindications e.g. bilateral femoral bypass surgery, tight ipsilateral carotid or vertebral stenosis (if judged not readily amenable to acute intervention by Interventional Neuroradiologist [INR] who would carry out the procedure), unsuitable proximal vascular anatomy likely to render endovascular catheterization difficult, unsafe or impossible (as judged by INR who would carry out the procedure) 5. Extracranial: chronic/atherosclerotic ipsilateral ICA or dominant vertebral artery occlusion 6. Alternative intracranial pathology potentially responsible for the new symptoms 7. Medical comorbidities which would preclude safe cerebral vessel catheterization or which are expected to limit life expectancy to <3 months (e.g. severe cardiac, renal or hepatic failure, significant coagulopathy, metastatic malignancy) 8. Known allergy to radiological contrast 9. Absolute contraindication to MRI

Post-Market Clinical Studies	
Interventions	Device: ERIC Retrieval Device
Primary Outcome Measures	Safety and efficacy of novel thrombectomy device, based on the angiographic run at the end of the procedure via independent core lab adjudication of reperfusion (modified Thrombolysis in Cerebral Infarction (mTICI) scale)
Secondary Outcome Measures	1. Safety – intracranial haemorrhage at 24 hours, others will be throughout the follow up period 2. Feasibility – at day 1, 90 and 180 3. Neurological recovery – mRS at day 90 and 365 4. Early major neurological improvement – at 72 hours 5. Sustained recanalization – 24h 6. Days spent at home – 90 days 7. Mortality – 365 days 8. Collateral score on CTA & clinical outcome – 365 days 9. MRI marker of procedural risk – 24 hours
Locations	United Kingdom
Sponsor(s)	Newcastle upon Tyne Hospitals NHS Foundation Trust
Results	Sixty-six patients were enrolled. TICI 2B/3 reperfusion was achieved in 72% in intervention compared with 90% in control arm on intention to treat (ITT) analysis (P=0.2) and 78% compared with 86% on per protocol analysis (P=0.7). Functional independence at 90 days was 40% (intervention) compared with 43% (control) on ITT analysis (P=1.0). sICH rates were low at 0% and 5%, respectively (P=0.3). The 30-day mortality was 9% intervention compared with 14% control (P=0.7).
ERASER Study	
Official Study Name	ERASER: ERIC Acute Stroke Recanalization
NCT Number	NCT02534701
Study Type	Interventional
Study Status	Completed (May 2015 – July 2017)
Enrollment	81 Participates
Study Population	Patients over 18 years old with acute ischemic stroke
Inclusion Criteria	1. Acute ischemic stroke with NIHSS score of 8-25 2. CTP/ MRP <4.5h after symptom onset completed 3. CTA/ MRA confirms M1-occlusion 4. Groin puncture estimated <6h after stroke onset 5. Intended usage of ERIC as first device in combination with SOFIA Distal Access - Catheter (secondary bail-out with other devices allowed)
Exclusion Criteria	1. MCA >1/3 abnormal in DWI or CBV (ASPECTS ≤ 7, >100 mL) 2. Pre stroke mRS ≥ 2 3. Necessity of ipsilateral internal carotid artery (ICA) angioplasty 4. Age > 18 years

Post-Market Clinical Studies	
Interventions	ERIC and SOFIA Devices ERIC device in combination with SOFIA Distal Access Catheter
Primary Outcome Measures	VOST (volume of saved tissue) = VPIv- VMT [Time Frame: 30 h] volume of saved tissue (VOST) as difference of the brain volume with an infarct risk of >50%, based on a prediction- algorithm trained in a historical cohort treated with IV tPA (VPIv) and the actual infarct volume
Secondary Outcome Measures	1. mRS≤2 [Time Frame: 90 days]: neurological outcomes (mRS≤2) 2. NIHSS score improvement ≥10 from baseline [Time Frame: 90 days]: neurological outcomes (NIHSS score improvement ≥10 from baseline)
Locations	Germany, Switzerland,
Sponsor(s)	Universitätsklinikum Hamburg-Eppendorf
Results	Eighty-one patients were enrolled. The median patient age was 71 years (interquartile range, 61-77). National Institutes of Health Stroke Scale score was 14 (interquartile range, 12-18). The actual infarct volume was smaller than predicted by the intravenous tPA therapy model, with a median volume of saved tissue of 50 mL (interquartile range, 19-103; P<0.0001). Good clinical outcome (modified Rankin Scale, 0-2 at 90 days) was observed in 48 out of 69 (70%). The recanalization rate (Thrombolysis in Cerebral Infarction 2b/3) was 95%.
ETIS Study	
Official Study Name	Endovascular treatment in ischemic stroke follow-up evaluation (ETIS)
NCT Number	NCT03776877
Study Type	Observational
Study Status	Estimated completion in December 2022 (Study has passed its completion date and status has not been verified in more than two years)
Enrollment	250 Participates for ERIC device arm (total ETIS participants: 4000)
Study Population	Patients over 18 years old with acute ischemic stroke
Inclusion Criteria	• Age 18 and older (i.e., candidates must have had their 18th birthday) • Neuroimaging demonstrates acute ischemic stroke with large vessel proximal with the use of neuro-thrombectomy devices intended to restore blood flow • No upper or lower limits of the neurological severity at baseline (NIHSS). • With or without intravenous thrombolysis • Oral informed consent (patient and/or trustworthy person)
Exclusion Criteria	• Pregnant or breast-feeding women • Patient benefiting from a legal protection • Non-membership of a national insurance scheme
Interventions	Trevo®, Solitaire™ , ERIC device
Primary Outcome Measures	Rate of complication when ERIC device was used as 1st line treatment defined as perforation or dissection or emboli in new territory.

Post-Market Clinical Studies	
Secondary Outcome Measures	Angiography and Clinic: • mTICI≥2b after 1st line treatment • mTICI≥2b at end of procedure • Fist pass effect (mTICI3) • modified first pass effect (mTICI2b-3) • Time for recanalization (from punction to mTICI 2b-3) • Rate mRS 0-2 at 90 days • Rate mRS 0-1 at 90 days • Rate mortality at 90 days Safety: • Rate of ICH at 24hrs • Rate of symptomatic ICH at 24hrs (increase of at least 4points of NIHSS) • Rate of patients with at least 1 complication during procédure
Locations	France
Sponsor(s)	Foch hospital/ETIS (Endovascular Treatment in Ischemic Stroke) Study Group
Results	The published study data from the currently ongoing ETIS Registry, including a total of 1230 patients (206 patients were treated with ERIC device as first line and 1024 treated with other commercial standard SR), demonstrated that the clinical and radiological results in patients treated with first-line ERIC device were equivalent to conventional Stent Retrievals (SRs), with a higher rate of complete recanalization (mTICI 3) observed in the ERIC device arm (40%) over the SR arm (25.4%), and comparable mRS 0–2 or equal to pre-stroke mRS at 90 days between the two groups (ERIC device: 54.9% vs. SRs: 49.1%). Comparable safety outcomes, shown as 90-day all-cause mortality (2.3%) and procedural complication (2.7%) were noted in the two groups.

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

AIS caused by intracranial occlusive vessels can be treated utilizing several therapeutic options, including the target treatment option (associated with the device in scope) as described in the table below. Cerebral Catheterization technique is gold standard treatment for AIS when no surgical treatment and other surgical treatments have failed to adequately treat the occlusion.

Table 1.11: Treatment options

Treatment Option	Pro/Benefit	Con/Risks	Notes
Thrombolytic Drugs (e.g., IV-tPA)	reduces death, reduces disability, or improve neurological function/independence	Complications (angioedema and symptomatic intracranial hemorrhage) Contraindicated in prior/recent hemorrhage AIS patients	Time limit use, Low recanalization rate
Stent Retrievers (SR)	reduces death, reduces disability, or improve neurological function/independence	SR Mechanical thrombectomy carries procedural /periprocedural risks such as sICH, dissection, and death.	No significant difference was seen in safety and effectiveness between the thrombo-aspiration approach and stent-retrieval thrombectomy for treating people with AIS. Furthermore, the combined group did not show any obvious advantage over either intervention applied alone.
Aspiration	reduces death, reduces disability, or improve neurological function/independence	Aspiration thrombectomy carries procedural /periprocedural risks such as sICH, dissection, and death.	
Combination of SR and Aspiration	reduces death, reduces disability, or improve neurological function/independence	SR and CA combination carries procedural /periprocedural risks such as sICH, dissection, and death.	

1.6.2 Available Technologies

Table 1.12: Similar Devices

Device	Manufacturer	Intended Purpose
Trevo XP ProVue Retriever (Stryker)	Stryker	The TREVO extractor is indicated for restoring blood flow in the neurovascular system by thrombectomy in the treatment of acute ischemic stroke to reduce disability in patients with persistent proximal anterior circulation, large vessel occlusion and smaller infarcts, and who have initially received intravenous tissue plasminogen activator (IV t-PA). Endovascular treatment with this device should begin within 6 hours of the onset of symptoms

Device	Manufacturer	Intended Purpose
Solitaire FR Revascularization Device	Medtronic	Solitaire Flow Restoration (FR) Revascularization Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

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

Table 1.13: Harmonized Standards

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 to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
Packaging		
EN ISO 11607-1	2020/A11:2022	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)

Standards	Edition	Standard Title
EN ISO 11607-2	2020/A11:2022	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming sealing and assembly processes. (ISO 11607-2:2019)
ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less
ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F88	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096	2011R2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
Shelf Life & Stability		
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
Biocompatibility		
EN ISO 10993-1	2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management 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 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		

Standards	Edition	Standard Title
EN 556-1	2001/AC:2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE"- 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)
Gamma or E-Beam Radiation		
EN ISO 11137-1	2015/A2:2019	Sterilization of health care products - Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006/Amd 2:2018)
EN ISO 11137-2	2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
Device Specific		
Catheters		
EN ISO 10555-1	2013A1:2017	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements (ISO 10555-1:2013A1:2017)
EN ISO 10555-4	2013	Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation 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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