MicroPort NeuroTech (Shanghai) Co., Ltd.

Summary of Safety and Clinical Performance:

NeuroHawk™ Thrombectomy Device

Summary of Safety and Clinical Performance according to Medical Device Regulation (MDR) EU 2017/745

Identifier for the SSCP: T0048037

	Name	Title	Signature	Date
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Content

1 Information for the Professional User

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 NeuroHawk Thrombectomy Device. The SSCP is prepared in accordance with the Medical Device Regulation (EU) 2017/745 (MDR) and the document MDCG 2019-9, Rev.1 from March 2022. The SSCP is not intended to replace the instructions for use (IFU) as the main document to ensure the safe use of the NeuroHawk Thrombectomy 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. In addition to this information, there is a summary intended for patients (chapter 2).

1.1 Device Identification and General Information

Device trade name(s) with article numbers	NeuroHawk™ Thrombectomy Device Model: AIS4025, AIS6030
Manufacturer's name and address	MicroPort NeuroTech (Shanghai) Co., Ltd. Building #16, 222 Guangdan Road, Pudong New district, 201318 Shanghai, China
Manufacturer's single registration number (SRN)	CN-MF-000007053
Basic UDI-DI	69586980T0048U4
Medical device nomenclature	GMDN: 61779 Thrombectomy wire-net FDA product code: POL (Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment)
Class of device	Class III medical devices in accordance with Rule 7.3 of Annex VIII of Regulation (EU) 2017/745
Regulatory Status	Initial registration on Eurpoean market
Authorized representative	MicroPort Medical B.V. Paasheuvelweg 25, 1105BP Amsterdam, The Netherlands SRN: NL-AR-000000166
Notified body	DQS Medizinprodukte GmbH (CE 0297)

1.2 Intended Use of the Device

Intended purpose	NeuroHawk™ Thrombectomy Device is intended to restore blood flow of brain vessels by removing thrombus for the treatment of acute ischemic stroke caused by large vessel occlusion.
Indication(s)	The product is indicated for the removal of thrombus in large vessels (including the M1 and M2 segments of the middle cerebral artery, and internal carotid artery) in patients with ischemic stroke within 8 hours of symptom onset so as to restore blood flow.

Targeted population(s)	**Intended user:** This product should be used by qualified professionals who have received the necessary interventional training (especially for interventional radiology) to complete the endovascular procedures. **Patient population:** NeuroHawk™ Thrombectomy Device can be used for patients who are diagnosed with acute ischemic stroke caused by large vessel occlusion (including the M1 and M2 segments of the middle cerebral artery, internal carotid artery) and need thrombectomy. No specificity in gender, race or nationality. Efficacy and safety in pediatrics, pregnant women, or children have not been evaluated.
Contraindications and/or limitations	• Patients with known allergies, resistance, or contraindication to antiplatelet agents, contrast agents, and/or anesthesia. • Known allergy to Nitinol. • Basic condition not suitable for endovascular intervention. • Contraindicated for CT, CTA or MRI. • Angiography suggests that the patient's vascular anatomy is not suitable for endovascular intervention. For example: – Severe intracranial vascular tortuosity – Presence of intracranial vascular stenosis proximal to the obstructed vessel or implanted device that prevents the expansion or safe retrieval of the thrombectomy device – Carotid artery dissection – Other uncommon vascular morphology that may impede device use – Inefficacy of drug therapy for intracranial arterial spasm

1.3 Device Description

1.3.1 Description of the NeuroHawk™ Thrombectomy Device

NeuroHawk™ Thrombectomy Device is an EO-sterilized, single-use device to remove thrombus from occluded artery in large vessels (including the M1 and M2 segments of the middle cerebral artery, internal carotid artery).

It is composed of two parts:

– An introducer sheath to protect the stent system during transport and storage and to introduce the stent system into the matching microcatheter.

– The stent system is composed of a self-expanding stent and a delivery wire. The delivery wire functions to deliver the stent to the target site, and the stent functions to embed and retrieve the thrombus.

There are two models of the thrombectomy device. Before determining that a thrombectomy device is to be used, it is necessary to estimate the diameter of the occluded vessel and the expected length of the occlusion site and to select the appropriate product model and compatible

microcatheter.

The NeuroHawk™ thrombectomy device is supplied sterile for single use only. It is used in acute ischemic strokes caused by large intracranial vessel occlusion. The product adopts the minimally invasive interventional treatment method. Under the supervision of DSA, interventional access is first established by using a puncture sheath, guidewire, catheter, and microcatheter. The thrombectomy stent is then delivered within the microcatheter to the target site by the delivery wire of the thrombectomy device. The self-expandable thrombectomy stent is deployed from the microcatheter within the occluding thrombus, causing the thrombus to be embedded in the mesh of the stent. When it is pulled back, the stent mesh becomes deformed and grabs hold of the thrombus. The stent, together with the thrombus, is retrieved into the catheter and removed from the body. The objective of cerebral blood flow recanalization is thus achieved.

1.3.2 Accessories Required for Product Use

- Microcatheter (inner diameter not less than 0.021 inch);
- Other accessories for performing a procedure to be selected based on the physician's experiences and preferences:
  - Guide catheter or long sheath (inner diameter not less than 0.053 inch);
  - Intermediate Catheters (5F or 6F);
  - Guidewire (outer diameter 0.035 inch, length 150 cm);
  - Micro-guidewire (outer diameter not greater than 0.014 inches, length not less than 185 cm);
  - At least two sets of normal saline or saline-heparin continuous flushing lines;
  - 60 ml syringe;
  - At least two units of rotating hemostasis valves;
  - At least two units of three-way stopcocks;
  - Infusion stand and femoral artery locking device.

1.4 Risk and Warnings

1.4.1 Residual Risks and Undesirable Effects

The risk management of the NeuroHawk™ Thrombectomy Device does not reveal unacceptable

residual risks.

MicroPort NeuroTech lists the following complications and adverse reactions in the instructions for use:

- Headache
- Fever
- Nausea
- Vomiting
- Pain at puncture site
- Pseudoaneurysm
- Cardiac arrhythmia
- Hypervascularity/hypotension
- Myocardial infarction
- Infection
- Mental confusion
- Embolism
- Intracranial hemorrhage
- Hematoma
- Cerebral ischemia
- Hydrocephalus
- Neurological deficits
- Visual impairment/blindness
- Vascular dissection
- Perforation or rupture of a blood vessel
- Vascular spasm
- Vascular or tissue damage
- Intravascular thrombosis/vascular occlusion
- Adverse drug reactions, allergic reactions, including but not limited to: contrast agents, Nitinol and drugs
- Death

Quantitative data on the occurrence of complications with the NeuroHawk™ Thrombectomy Device can be drawn from the CAPTURE trial conducted by MicroPort NeuroTech. In the CAPTURE trial, the following major safety parameters and their occurrence rate are reported for patients using NeuroHawk with a follow-up of 3 months:

Table 1 Summary of Major Safety Parameters within 3 Months Follow-Up of the CAPTURE Trial (source: Clinical Evaluation Report)

Safety parameters	NeuroHawk group	Solitaire group	P
Perioperative symptomatic Intracranial Hemorrhage (sICH)	8.70%	20.35%	0.012
Perioperative intracranial hemorrhage	25.44%	37.17%	0.057
All-cause mortality within 90 days after	12.07%	17.24%	0.265

Procedure			

All the device-related adverse events of the CAPTURE Trial are quantitatively shown in the Table 2 below:

Table 2 Summary of Device-Related Adverse Events of the CAPTURE Trial (source: Clinical Evaluation Report).

Adverse Event	Device-related Adverse Event of the CAPTURE Trial		
	NeuroHawk group in CAPTURE trial	Solitaire group in CAPTURE trial	P
Basal ganglia hemorrhage	1(0.86%)	1(0.86%)	1.00
Cerebral hemorrhage	6(5.17%)	3(2.59%)	0.499
Intracranial hemorrhage	0 (0%)	1(0.86%)	1.00
Hemorrhagic cerebral infarction	1(0.86%)	1(0.86%)	1.00
Vascular dissection	2(1.72%)	0 (0%)	0.478
Vascular spasm	1(0.86%)	0 (0%)	1.00
Infusion site extravasation	1(0.86%)	0 (0%)	1.00
Arterial Injury	1(0.86%)	1 (0.86%)	1.00
Brain scan abnormalities	4(3.45%)	2 (1.72%)	0.683
Cerebral artery occlusion	1(0.86%)	0 (0%)	1.00

If further quantifiable data are available in the future, this section of the SSCP will be revised to include all relevant data.

1.4.2 Warnings and Precautions

The following warnings and precautions are listed in the instructions for use:

Warning:

- This product has been sterilized by ethylene oxide.
- This product is for single-use only. Do not re-sterilize or reuse.
- Do not use if the packaging is found to have been opened, damaged, or a leak is detected, or the validity period has expired prior to use.
- This Instructions for Use must be read carefully before use.
- This product should be used by qualified professionals who have received necessary interventional training (especially for intracranial thrombectomy) to complete the endovascular procedures.

- The product should not be repositioned in the vessel without complete retrieval into the microcatheter and should be reopened only after complete retrieval into the microcatheter.
- When using this product for thrombus removal, it is recommended, based on the product characteristics, that retrieval attempts for a single thrombectomy stent should be less than or equal to 5, and that the retrieval attempts in the same vessel should be less than or equal to 5 in order to reduce the risk of vascular injury.
- Allergic reactions may occur with the use of this product in people who are allergic to Nitinol.
- After the device has been used, the product and packaging should be disposed of in accordance with the regulations of hospitals, administrative departments and local governments.

Precautions

- Use the product within the sterilization validity period.
- Store the product in dark, clean, and dry environment at room temperature with no corrosive gases.
- Do not expose the product to organic solvents (such as alcohol, etc.).
- Do not use if the inner packaging is found to be damaged.
- Before use, carefully inspect the sterile packaging as well as the system components to ensure that they have not been damaged during transportation. Do not use kinked or damaged components.
- Use the product in combination with a compatible microcatheter.
- The product should be operated under high quality x-ray observation. If resistance is encountered during manipulation, the cause of the resistance needs to be identified before proceeding with the surgical procedure.
- When using this product for thrombus removal, it is recommended, based on the product characteristics, that the number of removals for a single thrombectomy stent should be less than or equal to 5, and that the total number of removals in the same vessel should be less than or equal to 5 in order to reduce the risk of vascular injury.
- Select the appropriate thrombectomy device size so that its diameter after release is as close as possible to the diameter of the occluded vessel. If the wrong thrombectomy device size is selected, incomplete removal or injury to the vessel may occur.
- Care should be taken not to damage the distal end of the stent when introducing the thrombectomy device into the microcatheter from the introducer sheath.

1.4.3 Other Relevant Aspects of Safety

No field safety corrective actions, field safety notices, recalls, or adverse events related to NeuroHawk™ Thrombectomy Device are published. However, in 2023, two complaints about stent deployment failure during the procedural were reported in China. Both complaints were attributed to the excessive hardness of the thrombus and had no apparent causal relationship with the device itself.

1.5 Summary of Clinical Evaluation and Post-Market Clinical Follow-Up (PMCF)

1.5.1 Summary of Clinical Data Related to Equivalent Devices

No clinical data of equivalent devices from other manufacturers were used for the clinical evaluation.

1.5.2 Summary of Clinical Data from Conducted Investigations of the Device

The safety and efficacy of NeuroHawk™ Thrombectomy Device was investigated in the CAPTURE trial. The summary of the trial is given in the following **Table 3**.

Table 3 Summary of the CAPTURE Trial

Title	CAPTURE (A Prospective, Multicenter, Single-blind, and Randomized Controlled Clinical Trial of Thrombectomy Device for the Treatment of Acute Ischemic Stroke)
ClinicalTrials.gov registration number	NCT04995757
Name of investigational medical device	NeuroHawk™ Thrombectomy Device
Study centers	Twenty-three centers in China Coordinating clinical trial site: Changhai Hospital of Shanghai
Time frame	Start date: March 21, 2018 (enrollment of first subject) End date: September 22, 2020
Intended use of the device	NeuroHawk™ thrombectomy device is intended to restore blood flow of brain vessels by removing thrombus for the treatment of acute ischemic stroke caused by large vessel occlusion. It is indicated for the removal of thrombus in large vessels (including the M1 and M2 segments of the middle cerebral artery, internal carotid artery) in patients with ischemic stroke within 8 hours of symptom onset so as to restore blood flow.
Study objective	Evaluate the efficacy and safety of the investigational thrombectomy device in the treatment of acute ischemic stroke by comparing with the efficacy and safety of Solitaire FR (ev3/Medtronic).

Study design	Prospective, multicenter, single-blind and randomized controlled clinical trial with a non-inferiority comparison type, and using the control product of Solitaire FR (ev3/Medtronic).
Effectiveness and safety evaluation	**Efficacy evaluation** • **Primary efficacy indicator** ➢ Successful recanalization rate ✧ "Successful recanalization rate" is defined as the proportion of subjects with mTICI ≥ 2b after thrombectomy. mTICI score is assessed by DSA method 0-3 hours after thrombectomy. • **Secondary efficacy indicator** ➢ Time from start of the procedure to successful recanalization (mTICI 2b or 3) ➢ NIHSS score at 30 ± 6 hours after procedure ➢ mRS score ≤ 2 at 90 ± 14 days after procedure • **Safety evaluation** ➢ Symptomatic intracerebral hemorrhage (sICH) 30 ± 6 hours after procedure ➢ All-cause mortality within 90 days after procedure ➢ All-cause adverse event within 90 days after procedure ➢ AE, SAE related to device, procedure or stroke within 90 days after procedure
Inclusion criteria	Subjects must meet all the following criteria to be enrolled. 1) Presented with clinical symptoms and signs of acute ischemic stroke, diagnosed as acute large vessel (ICA, MCA-M1, MCA-M2) ischemic stroke by imaging. 2) Male or female aged 18 to 80 years (18 and 80 years old inclusive) at the time of signing the informed consent form. 3) Within 6 hours of onset, the subjects start the trial treatment (defined as vascular puncture or incision). 4) Subjects or guardians of the subjects voluntarily sign the informed consent form.
Exclusion criteria	Subjects were excluded if they had any of the following. Including: **Clinical exclusion criteria:** 1) Pre-onset mRS score ≥ 2. 2) Baseline NIHSS score < 2 or > 25. 3) Serious craniocerebral injury with residual neurological deficit within 90 days prior to onset. 4) Neuropsychiatric disorders that could affect neurological function assessment such as dementia treated with cholinesterase inhibitors (e.g., donepezil). 5) Presented with seizures at the time of ischemic stroke leading to diagnostic difficulties and impacting accurate assessment of baseline NIHSS. 6) Known bleeding diatheses, coagulation factor deficiencies; or INR > 3 on anticoagulant testing. 7) Baseline platelet count < 30 * 109/L. 8) Baseline glucose < 50 mg/dL (2.78 mmol/L) or > 400 mg/dL (22.2 mmol/L). 9) Blood creatinine > 3.0 mg/dL (264 μmol/L) in patients with renal failure (note: patients receiving hemodialysis may be treated regardless of blood creatinine level). 10) Serious, persistent elevations in blood pressure (systolic > 185 mmHg or diastolic > 110 mmHg) (note: subjects whose blood pressure remains at an acceptable level on antihypertensive therapy). 11) Known allergy, resistance, or contraindication to one or more of the following: antiplatelet agents, contrast agents, and/or anesthetics. 12) Known allergy to nickel-titanium or other metals constituting a medical device. 13) Not suitable for endovascular intervention or anesthesia.

<table>
<tr><td></td><td>14) History of major procedure within 30 days prior to enrollment.
15) Is participating in any other drug or medical device trial or is likely to participate in any other drug or medical device clinical trial after enrollment in this clinical trial.
16) Infective endocarditis or other serious, active infection.
17) Life expectancy < 6 months.
18) Pregnant or lactating women, or women of childbearing potential admitted to hospital with a positive pregnancy test.
Imaging exclusion criteria:
19) Evidence of the following on cranial CT or MRI:
Ø Mass effect is evident with midline shift.
Ø Intracranial tumors other than small meningiomas.
Ø Evidence of intracranial hemorrhage.
Ø Evidence of flow limitation in internal carotid artery dissection.
Ø Possible intracranial vasculitis.
Ø Possible aortic dissection.
Ø Acute multi-vessel obstruction (e.g. bilateral anterior circulation, anterior circulation and posterior circulation), or clinical evidence of bilateral stroke or multi-site stroke.
20) ASPECTSS ≤ 5.
21) Morphology or lesion that could interfere with the use of the device, including, but not limited to, carotid artery dissection, vasculitis, aortic dissection, aneurysm, or limited vascular access (e.g., serious intracranial vessel tortuosity, serious intracranial vasospasm that is unresponsive to medical therapy, obstruction of device access due to other anatomical or clinical pathology).
22) Acute ischemic stroke in more than 1/3 of the MCA territory showed by cranial CT scan, CTP or DWI images.
23) Acute ischemic stroke involving posterior circulation vessels.
24) Implantation of intracranial vascular stents in the diseased vessel area, hindering safe implantation or movement of the thrombectomy device.</td></tr>
<tr><td>Follow-up</td><td>3 months</td></tr>
<tr><td>Study population</td><td>A total of 239 subjects were randomized into the study, including 118 subjects in the test group and 121 subjects in the control group. 232 subjects were included in the full analysis set (FAS), 115 in the test group and 117 in the control group; 232 subjects were included in the safety set (SS), 116 in the test group and 116 in the control group, of which 1 subject was randomized to the control group and the test group device was used during the second thrombectomy 6 days after procedure, and the safety analysis was based on the test group; 230 subjects were included in the per protocol set (PPS), 114 in the test group and 116 in the control group.

Demographic characteristics (FAS)
<table>
<tr><th>Item</th><th>Indicator</th><th>Total</th><th>Test group</th><th>Control group</th></tr>
<tr><td>Age (years)</td><td>Mean (SD)</td><td>64.12(10.76)</td><td>64.44(10.68)</td><td>63.80(10.88)</td></tr>
<tr><td rowspan="2">Gender</td><td>Male n (%)</td><td>150(64.66%)</td><td>73(63.48%)</td><td>77(65.81%)</td></tr>
<tr><td>Female n (%)</td><td>82(35.34%)</td><td>42(36.52%)</td><td>40(34.19%)</td></tr>
<tr><td>Height (cm)</td><td>Mean (SD)</td><td>167.84(7.66)</td><td>167.32(7.59)</td><td>168.32(7.74)</td></tr>
<tr><td>Body weight (kg)</td><td>Mean (SD)</td><td>69.53(11.92)</td><td>69.35(11.92)</td><td>69.70(11.99)</td></tr>
<tr><td rowspan="2">Smoking history</td><td>Never n (%)</td><td>164(70.69%)</td><td>82(71.30%)</td><td>82(70.09%)</td></tr>
<tr><td>Quitted n (%)</td><td>11(4.74%)</td><td>5(4.35%)</td><td>6(5.13%)</td></tr>
<tr><td>Drinking history</td><td>Never</td><td>184(79.31%)</td><td>87(75.65%)</td><td>97(82.91%)</td></tr>
</table></td></tr>
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	Current medication	Quitted n (%)	5(2.16%)	3(2.61%)	2(1.71%)
		No n (%)	125(53.88%)	57(49.57%)	68(58.12%)
		Yes n (%)	107(46.12%)	58(50.43%)	49(41.88%)
	Medical history	No n (%)	10(4.31%)	5(4.35%)	5(4.27%)
		Yes n (%)	222(95.69%)	110(95.65%)	112(95.73%)

Summary of the study methods

Statistical analysis methods

The demographic data and the general data of disease were statistically described and compared between groups. The concomitant diseases and treatments were described and compared. The quantitative data were statistically described using the mean, median, standard deviation (SD), maximum, minimum, 25 % and 75 % quantiles; the enumeration data or ranked data were presented as frequency and frequency number.

Effectiveness analysis

For primary efficacy endpoint, the inter-group difference was compared using the site stratified CMH-x2 test, and the bilateral 95 % confidence interval (CI) of the rate difference P_T-Pc) between two groups was calculated. Meanwhile, 95 % Cl of rates in each group was calculated and the relevant data were listed in a contingency table.

For secondary efficacy endpoints, the inter-group difference was compared using group t test/Wilcoxon rank sum test/ chi-squared test/the exact test according to the distribution of data

Safety analysis

The number and incidence rate of AEs were listed and compared using chi-squared test or the exact test according to the distribution of data. The changes in the results of physical examination and laboratory examination before and after treatment were listed in a crosstab. The changes of vital signs before and after treatment were described and compared between two groups using the suitable statistical methods. The AEs and the abnormal and significant laboratory amination results at the end of treatment were listed separately.

Setting of relevant parameters in the statistical analysis

All statistical tests were bilateral, in which $P \leqslant 0.05$ suggested that the difference was statistically significant (unless otherwise specified).

Handling of missing and abnormal values

Missing data that may occur during the study will be censored at the time of analysis for the primary efficacy indicator in the FAS. Missing data for the primary indicators was handled using the WCCF (Worst Case Carry Forward) strategy.

Deviation

There is one protocol deviation, which is related to the collection of changes of vital signs before and after treatment. This deviation did not affect the results of clinical safety evaluation.

Summary of the results and limitation

Efficacy evaluation:

Primary efficacy endpoint

- **Successful recanalization rate in the two groups:** In the FAS, the successful recanalization rate was 88.70% in the test group and 90.60% in the control

group, and the difference between the two groups (95% confidence interval) is -1.90% (-9.74%, 5.94%); in the PPS, the successful recanalization rate was 89.47% in the test group and 91.38% in the control group, and the difference between the two groups (95% confidence interval) was -1.91% (-9.51%, 5.70%). The results of the FAS and the PPS showed that the lower limit of confidence interval of the difference between the two groups was greater than the non-inferiority margin of -12.5%, suggesting that the successful recanalization rate after thrombectomy with the thrombectomy device in the test group was non-inferior to that with the thrombectomy device in the control group.

Secondary efficacy endpoint

- **Time from the start of procedure to successful recanalization (mTICI 2b or 3) in the two groups:** In the FAS, the time from the start of procedure to successful recanalization [median (quartile)] was 0.98 h (0.60 h - 1.42 h) in the test group and 0.88 h (0.65 h - 1.38 h) in the control group; in the PPS, the time from the start of procedure to successful recanalization [median (quartile)] is 0.98 h (0.60 h - 1.42 h) in the test group and 0.88 h (0.65 h - 1.38 h) in the control group; there was no significant difference between the two groups (FAS: P = 0.772, PPS: P = 0.772). These results suggested that the time from the start of procedure to successful recanalization was comparable between the thrombectomy device in test group and the control group.

- **NIHSS score at 30 ± 6 hours after procedure in the two groups:** In the FAS, the [median (quartile)] NIHSS score at 30 ± 6 hours after procedure was 11.00 (5.00-20.00) in the test group and 12.00 (5.00-23.00) in the control group; in the PPS, the [median (quartile)] NIHSS score at 30 ± 6 hours after procedure was 11.00 (5.00-20.00) in the test group and 11.50 (5.00-23.50) in the control group; there was no significant difference between the two groups (FAS: P = 0.316, PPS: P = 0.319). These results suggested that the NIHSS score at 30 ± 6 hours after procedure was comparable between the thrombectomy device in test group and the control group.

- **mRS score at 90 ± 14 days after procedure in the two groups:** In the FAS, the proportion of subjects with mRS score ⩽ 2 at 90 ± 14 days after procedure was 57.52% in the test group and 58.77% in the control group; in the PPS, the proportion of subjects with mRS score ⩽ 2 at 90 ± 14 days after procedure was 57.52% in the test group and 59.29% in the control group; there was no significant difference between the two groups (FAS: P = 0.849, PPS: P = 0.787). It suggested that the proportion of subjects with mRS score ⩽ 2 at 90 ± 14 days after procedure was comparable between the thrombectomy device in test group and the control group.

Safety evaluation

- **Symptomatic intracranial hemorrhage sICH**: The proportion of subjects who developed symptomatic intracranial hemorrhage (sICH) within 30 ± 6 hours after procedure was 8.70% in the test group and 20.35% in the control group; there was significant difference between the two groups (P = 0.012).

- **All-cause mortality:** The all-cause mortality within 90 ± 14 days after

	procedure was 12.07% in the test group and 17.24% in the control group; there was no significant difference between the two groups (P = 0.265). ➢ **Adverse events (AEs):** A total of 936 adverse events occurred in 108 subjects in the test group, with an incidence rate of 93.10%; 832 adverse events occurred in 108 subjects in the control group, with an incidence rate of 93.10%; there was no significant difference between the two groups (P = 1.00). ➢ **Thrombectomy device-related AEs:** Eighteen (18) thrombectomy device-related adverse events occurred in 12 subjects in the test group, with an incidence rate of 10.34%; 9 thrombectomy device-related adverse events occurred in 9 subjects in the control group, with an incidence rate of 7.76%; there was no significant difference between the two groups (P = 0.648). ➢ **Procedure-related AEs:** Eighty-three (83) procedure-related adverse events occurred in 40 subjects in the test group, with an incidence rate of 34.48%; 73 procedure-related adverse events occurred in 41 subjects in the control group, with an incidence rate of 35.34%; there was no significant difference between the two groups (P = 1.00). ➢ **Stroke-related AEs:** A total of 291 stroke-related adverse events occurred in 84 subjects in the test group, with an incidence rate of 72.41%; 263 stroke-related adverse events occurred in 82 subjects in the control group, with an incidence rate of 70.69%; there is no significant difference between the two groups (P = 0.884). ➢ **Serious adverse events (SAEs):** Fifty-six (56) serious adverse events occurred in 42 subjects in the test group, with an incidence rate of 36.21%; 52 serious adverse events occurred in 39 subjects in the control group, with an incidence rate of 33.62%; there is no significant difference between the two groups (P = 0.783). ➢ **Thrombectomy device-related SAEs:** Only 1 thrombectomy device-related serious adverse event occurred in 1 subject in the test group, with an incidence rate of 0.86%; 1 thrombectomy device-related serious adverse event occurred in 1 subject in the control group, with an incidence rate of 0.86%; there is no significant difference between the two groups (P = 1.00). ➢ **Procedure-related SAEs:** Eighteen (18) procedure-related serious adverse events occurred in 17 subjects in the test group, with an incidence rate of 14.66%; 25 procedure-related serious adverse events occurred in 22 subjects in the control group, with an incidence rate of 18.97%; there is no significant difference between the two groups (P = 0.483). ➢ **Stroke-related SAEs:** Thirsty-seven (37) stroke-related serious adverse events occurred in 30 subjects in the test group, with an incidence rate of 25.86%; 43 stroke-related serious adverse events occurred in 34 subjects in the control group, with an incidence rate of 29.31%; there is no significant difference between the two groups (P = 0.660). ➢ **Additional safety endpoint- All types of intracranial hemorrhage (ICH)**

	The comparison of All types of intracranial hemorrhage within 30 ± 6 hours after procedure between the two groups showed that the proportion of subjects with intracranial hemorrhage (ICH) within 30 ± 6 hours after procedure was 25.44% in the test group and 37.17% in the control group; there was no significant difference between the two groups (P = 0.057). Moreover, the comparison of PH-1 and PH-2 intracranial hemorrhage within 30 ± 6 hours after procedure between the two groups showed there was no significant difference (PH-1, Test group 10.53%, Control group 12.61%, P = 0.625; PH-2, Test group 2.63%, Control group 3.60%, P = 0.719). **Conclusion** The thrombectomy device manufactured by MicroPort NeuroTech (Shanghai) Co., Ltd. is safe and effective in the treatment of acute ischemic stroke caused by large vessel occlusion, and the efficacy is non-inferior to Solitaire FR (ev3/Medtronic), and the safety is equivalent to Solitaire FR (ev3/Medtronic).

1.5.3 Summary of Clinical Data from Other Sources

1.5.3.1 Clinical Data in the Literature

The CAPTURE trial, was published in a peer-reviewed journal by Zhang Y and colleagues[22] in 2022. This study is the post-hoc analysis of the CAPTURE trial and is conducted by cooperated physician. Details about CAPTURE refer to Chapter 1.5.2.

1.5.3.2 Clinical Data Obtained by PMCF-Measures

No clinical data from conducted PMCF investigations are available.

1.5.3.3 Clinical Data from Medical Device Database

The medical device databases “Manufacturer and User Facility Device Experience (MAUDE) Database” maintained by the United States' Food and Drug Administration was searched for clinical data on the NeuroHawk™ Thrombectomy Device and similar stent retrievers on the market during the preparation of the clinical evaluation report. The search was conducted on Aug. 30, 2023.

For the NeuroHawk™ Thrombectomy Device, no results were identified through the MAUDE search. There were no severe adverse events or malfunctions. Also, MAUDE search for similar stent retriever devices on the US-market (Trevo stent from Stryker Neurovascular and Solitaire stent from Micro Therapeutics) was conducted. The database search yielded records on death and injury with known risks associated with the intravascular interventional procedure, such as hemorrhage, vasoconstriction, dissection, or perforation, as well as device-related malfunctions such as stent break and fracture. The MAUDE database searches listed records with known device- and procedure-related complications. No unknown complications were found.

1.5.4 An Overall Summary of the Clinical Performance and Safety

The NeuroHawk™ Thrombectomy Device belongs to the generic device group, stent retriever devices, which have a long history of safe and efficacious use and are based on well-established technology.

The reviewed clinical literature provides sound evidence that using stent retriever devices in general and the NeuroHawk™ Thrombectomy Device are successful and safe treatment options for acute ischemic stroke (AIS). Reported clinical data on the performance parameters on the treatment with stent retriever device varies, as the treatment of AIS offers various parameters, such as anatomy, patient population, or follow-up duration. The rate of successful recanalization (TICI/mTICI score 2b or 3) immediately after the procedure observed in the CAPTURE trial was 88.70% for the NeuroHawk™ Thrombectomy Device, which is numerically higher than clinical literature reports ranging from 82.82% to 87.64%[1–21]. Based on the performance result, the NeuroHawk™ Thrombectomy Device is shown to be on par with the generic device group. In addition, the rate of good clinical outcome (mRS score≤2) at 90 days after the procedure observed in the CAPTURE trial was 57.52% for the NeuroHawk™ Thrombectomy Device, which is somewhat higher than clinical literature reports ranging from 45.56% to 52.73%[1–21], demonstrating good clinical outcomes. Therefore, the NeuroHawk™ Thrombectomy Device is suitable for its intended use, namely the treatment of acute ischemic stroke.

Thus, it can be concluded that the NeuroHawk™ Thrombectomy Device achieves the performance intended by MicroPort NeuroTech and fulfills the relevant GSPRs for performance.

The clinical evaluation of the NeuroHawk™ Thrombectomy Device is based upon several product-specific documents, including a risk analysis and comprehensive instructions for use, as well as test reports on biological testing, demonstrating fulfillment of the biological requirements. Based on these documents, it was summarized that the procedural and product-specific risks, corresponding warnings, and precautions are adequately provided for the user and offer information on risks associated with the NeuroHawk™ Thrombectomy Device and its clinical application.

The major risks of the NeuroHawk™ Thrombectomy Device include perioperative sICH, perioperative intracranial hemorrhage, all-cause mortality within 90 days after procedure, vessel dissection, vessel perforation and injury, vascular vasospasm, and new territory embolization/vascular occlusion. Clinical data from the CAPTURE trial revealed that the

incidences of the aforementioned safety parameters observed in the NeuroHawk group are comparable to those observed in the Solitaire group, as well as consistent with the data reported in scientific literature[1–21].

The risks described in the literature are consistent with the risks included in the IFU and risk management. Thus, the NeuroHawk™ Thrombectomy Device meets the requirement for safety. Also, no evidence of unduly or unknown risks of the NeuroHawk™ Thrombectomy Device was identified in the clinical evaluation report.

According to risk management, the benefits of the device outweighs the identified risks. It can be concluded that risks which may be associated with the intended use of the NeuroHawk™ Thrombectomy Device constitute acceptable risks when weighed against the benefits to the patient according to the clinical data presented in the scientific literature, the Post-Market Surveillance (PMS) as well as the risk analysis. The main risks are described and documented in detail in the scientific literature, thus being known to the medical expert. Therefore, by complying with all warnings and precautions, the NeuroHawk™ Thrombectomy Device offers an acceptable benefit/risk profile.

The regular PMS data show no adverse event associated with the NeuroHawk™ Thrombectomy Device.

The marketing claims are justified by the technical characteristics, performed preclinical tests, and the clinical literature.

In conclusion, NeuroHawk™ Thrombectomy Device could be shown to be in compliance with the General Safety and Performance Requirements specified by the Medical Device Regulation (MDR) EU 2017/745.

1.5.5 Ongoing or Planned Post-Market Clinical Follow-Up

MicroPort NeuroTech will conduct general PMCF measures, as required in the MDR (systematic literature searches and surveys of databases of competent authorities, as well as monitoring PMS data on clinically relevant data). Due to the nature of the NeuroHawk™ Thrombectomy Device as a part of generic device group utilizing well-established technology, no specific PMCF activities are planned, as the clinical evidence on the devices is considered sufficient.

1.6 Possible Therapeutic Alternatives

Acute treatment for AIS aims to salvage as much of the ischemic region at risk of infarction as possible to save the brain and improve functional outcomes. AIS treatments currently include intravenous thrombolysis with recombinant tissue plasminogen activator (IV-tPA), intra-arterial (IA) thrombolysis via injection of thrombolytic medication directly into the occluded artery, and endovascular procedures. Furthermore, an endovascular procedure alternative to the use of stentretriever thrombectomy is aspiration thrombectomy (aspiration catheter works by sucking thrombus from occluded arteries with an external aspiration pump/a large-volume syringe through a large-bore catheter).

1.7 Suggested Profile and Training for Users

The NeuroHawk^{TM} Thrombectomy Device should be used by qualified professionals who have received the necessary interventional training (especially for interventional radiology) to complete the endovascular procedures.

1.8 Reference to Harmonized Standards and Common Specifications Applied

MicroPort NeuroTech (Shanghai) Co., Ltd. adhered to the following standards, which are listed as harmonized by the European Union, or are the most recent version of the respective standard. No common specification is applicable to the NeuroHawk^{TM} Thrombectomy Device.

Table 4 Standard Adhered to by Microport Neurotech (Shanghai) Co., Ltd

Category	Reference number and date	Title of standard
Product	EN ISO 25539-2:2020*	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2020)
	EN ISO 11070:2014/A1:2018*	Sterile single-use intravascular introducers, dilators, and guidewires - Amendment 1 (ISO 11070:2014/Amd 1:2018)
	EN ISO 10555-1:2013/A1:2017*	Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements - Amendment 1 (ISO 10555-1:2013/Amd 1:2017)
	ASTM F2081-06R22*	Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents
Material	ASTM F2063-18	Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants
	ASTM F2082/F2082M-16	Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery
Usability	EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
Particulate	European Pharmacopoeia	Particulate Contamination: Sub-Visible Particles

Category	Reference number and date	Title of standard
	11 <2.9.19>*	
Microbial	European Pharmacopoeia 11 <2.6.1>	Sterility
	European Pharmacopoeia 11<2.6.14>	Bacterial Endotoxins
EO/ECH residuals	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)
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)
	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 irritation and delayed-type hypersensitivity (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* (ISO10993- 12:2021)
	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation* (ISO 10993-23:2021)
Information provided by manufacturer	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)
Symbols on Label	EN ISO 15223-1: 2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements * (ISO 15223-1:2021)
Packaging Test	ASTM F1886/F1886-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
	ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
	ASTM F1929-15	Standard test methods for detecting seal leaks in porous medical packaging by dye penetration
	EN 868-5:2018	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
	ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials
QMS	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes * (ISO 13485:2016)
Risk Management	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices* (ISO 14971:2019)

Category	Reference number and date	Title of standard
Design Verification and Shelf life	ASTM F3172-15 (2021)	Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Device
	ASTM F 2914-12 (2018)	Standard Guide for Identification of Shelf-life Test Attributes for Endovascular Devices
Package	EN ISO 11607-1: 2020	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
	EN ISO 11607-2: 2020	Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
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 11135:2014	Sterilization of healthcare products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices * (ISO 11135:2014)
	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 medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process * (ISO 11737-2:2019)
	EN ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
	EN ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)
	EN ISO 11138-7:2019	Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results (ISO 11138-7:2019)
	AAMI TIR28:2016	Product adoption and process equivalence for ethylene oxide sterilization.

* This standard is partial referenced.

1.9 Revision History

SSCP revision number	**Date issued**	**Change description**	**Revision validated by the Notified Body**

01	October 30, 2023	First SSCP	☐ Yes Validation Language: ☐ NO

A summary of the safety and clinical performance of the device, intended for patients, is given below.

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2 Information for the Patient

Document revision: 01

Date issued: October 30, 2023

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 information presented below is intended for patients or lay persons. An extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document. The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional if you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace the instructions for use to provide information on the safe use of the device.

2.1 Device Identification and General Information

Device trade name(s)	NeuroHawk™ Thrombectomy Device
Manufacturer's name and address	MicroPort NeuroTech (Shanghai) Co., Ltd. Building #16, 222 Guangdan Road, Pudong New district, 201318 Shanghai, China
Basic UDI-DI	69586980T0048U4
Regulatory Status	Initial registration on European market

2.2 Intended Use of the Device

Intended purpose	The NeuroHawk™ thrombectomy device is intended to clear clot from the blocked brain vessels, thereby restoring blood flow. It is used in the treatment of acute ischemic stroke caused by the blockage of large blood vessels.
Indication(s)	The NeuroHawk™ thrombectomy device is indicated for the removal of clots from large vessels, such as the M1 and M2 segments of the middle brain artery and the neck artery (internal carotid artery), in patients with ischemic stroke within eight hours of first experiencing symptoms.
Intended patient groups	The device can be used for patients who are diagnosed with acute ischemic stroke caused by large vessel blockage (occlusion), including the M1 and M2 segments of the middle brain artery and the neck artery (internal carotid artery), and requiring thrombectomy. No specificity in gender, race, or nationality. Efficacy and safety in pediatrics, pregnant women, or children have not been evaluated.
Contraindications and/or limitations	• Patients with known allergies, resistance, or contraindication to drugs what prevent blood clots (antiplatelet agents), contrast agents, and/or sedatives (anesthesia). • Known allergy to Nitinol. • Basic condition not suitable for operation inside the blood vessel (endovascular

	intervention). • Contraindicated for medical imaging, including CT, CTA, or MRI. • Medical imaging to examine blood vessels (angiography) suggests that the patient's vessel structure (vascular anatomy) is not suitable for operation inside the blood vessel (endovascular intervention). For example: – Significant bends or twists of the blood vessels in the brain (intracranial vascular tortuosity) – Presence of brain vessel narrowing (intracranial vascular stenosis) near (proximal to) the blocked (obstructed) vessel or implanted device that prevents the expansion or safe removal (retrieval) of the thrombectomy device – Dissection of the carotid artery, a neck artery that supplies blood to the head and brain – Other uncommon vessel shape (vascular morphology) that may affect (impede) device use – Inefficacy of drug therapy for tightening or narrowing of brain blood vessels (intracranial arterial spasm)

2.3 Device Description

2.3.1 Description of the NeuroHawk™ Thrombectomy Device

The system is a sterile, single-use device. It is composed of two parts (Figure 1):

– An introducer sheath.

To protect the stent system during transport and storage and to introduce the stent system into the matching microcatheter.

– The stent system.

It is composed of a self-expanding stent (Figure 1) and a delivery wire (Figure 1). The delivery wire is used to deliver the stent to the target lesion, and the stent is used to capture (embed) and remove (retrieve) the clot (thrombus).

Figure 1 Illustration of the Stent System

2.3.2 Mode of Action

A small catheter is inserted into the patient's artery. It is navigated to the site of the lesion. The physician determines the size and type of the stent to use. Then, the stent is delivered through the small catheter to the site of the lesion. The stent is attached to a delivery wire. As it travels across the lesion area, the stent temporarily expands and captures the clot within the blocked brain vessel. Next, the clot and stent are put back together with the small catheter and taken out of the body. Thus, the goal of recovering brain blood flow is accomplished.

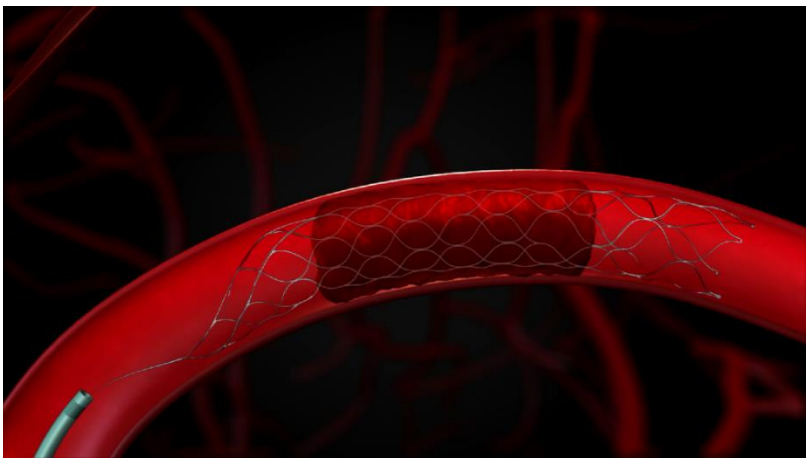

Figure 2 Exemplary Stent Deployment during Interventional Procedure

2.3.3 Accessories Required for Product Use

For the clinical procedure, the following accessories are required: microcatheter, guiding catheter or long sheath, intermediate catheters, guide wires, micro-guidewire, flushing lines, 60 ml syringe, rotating hemostatic valves, three-way stopcock, as well as infusion stand, and femoral artery locking device.

2.4 Risk and Warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

2.4.1 Residual Risks and Undesirable Effects

The manufacturer employed a risk management system according to the ISO (International Organization for Standardization) 14971:2019, which is the industry standard. The risk management of the system does not reveal unacceptable residual risks.

MicroPort NeuroTech lists the following complications and adverse reactions in the instructions for Use:

- Headache
- Fever
- Nausea
- Vomiting
- Pain at puncture site
- Formation of localized vessel bulge (Pseudoaneurysm)
- Unsteady heart rate (Cardiac arrhythmia)
- Low blood vessel pressure (Hypervascularity/hypotension)
- Heart tissue damage or death due to restriction in blood supply (Myocardial infarction)
- Infection
- Mental confusion
- Vessel closure due to blood clotting consisting of air or foreign body or plaque or clotted blood (Embolism)
- Bleeding within the brain region (Intracranial hemorrhage)
- Localized bruise (Hematoma)
- Temporary period of symptoms similar to those of a stroke (Cerebral ischemia)
- Accumulation of fluid within the brain (Hydrocephalus)
- Neurological deficits
- Visual impairment/blindness
- Splitting open of the vessel (Vascular dissection)
- Tearing open of the vessel (Vascular perforation)
- Contraction of the blood vessel (Vasospasm)
- Vascular or tissue damage
- Blood clot formation (Intravascular thrombosis/vascular occlusion)
- Adverse drug reactions, allergic reactions, including but not limited to: contrast agents, Nitinol, and drugs
- Death

Quantitative data on the occurrence of complications with the NeuroHawk™ Thrombectomy Device can be drawn from the CAPTURE trial conducted by MicroPort NeuroTech. In the CAPTURE trial, the following major safety parameters and all device-related adverse events with their occurrence rate are reported for patients using NeuroHawk with a follow-up of 3 months:

Table 5 Summary of Major Safety Parameters within 3 Months Follow-Up of the CAPTURE Trial (source: Clinical Evaluation Report).

Safety parameters	NeuroHawk group	Solitaire group	P
Perioperative symptomatic Intracranial Hemorrhage (sICH)	8.70%	20.35%	0.012
Perioperative intracranial hemorrhage	25.44%	37.17%	0.057
All-cause mortality within 90 days after Procedure	12.07%	17.24%	0.265

All the device-related adverse events of the CAPTURE Trial are quantitatively shown in the Table 6 below:

Table 6 Summary of Device-Related Adverse Events of the CAPTURE Trial (source: Clinical Evaluation Report).

Adverse Event	Device-related Adverse Event of the CAPTURE Trial		
	NeuroHawk group in CAPTURE trial	Solitaire group in CAPTURE trial	P
Basal ganglia hemorrhage	1(0.86%)	1(0.86%)	1.00
Cerebral hemorrhage	6(5.17%)	3(2.59%)	0.499
Intracranial hemorrhage	0 (0%)	1(0.86%)	1.00
Hemorrhagic cerebral infarction	1(0.86%)	1(0.86%)	1.00
Vascular dissection	2(1.72%)	0 (0%)	0.478
Vascular spasm	1(0.86%)	0 (0%)	1.00
Infusion site extravasation	1(0.86%)	0 (0%)	1.00
Arterial Injury	1(0.86%)	1(0.86%)	1.00
Brain scan abnormalities	4(3.45%)	2(1.72%)	0.683
Cerebral artery occlusion	1(0.86%)	0 (0%)	1.00

If further quantifiable data are available in the future, this section of the SSCP will be revised to include all relevant data.

2.4.2 Warnings and Precautions

The manufacturer lists warnings and precautions in the instructions for use. This ensures a safe and successful implantation of the device.

Warning:

- This product has been sterilized by ethylene oxide.
- This product is for single-use only. Do not re-sterilize or reuse.
- Do not use if the packaging is found to have been opened, damaged, or a leak is detected, or the validity period has expired prior to use.
- This Instructions for Use must be read carefully before use.
- This product should be used by qualified professionals who have received necessary interventional training (especially for intracranial thrombectomy) to complete the endovascular procedures.
- The product should not be repositioned in the vessel without complete retrieval into the microcatheter and should be reopened only after complete retrieval into the microcatheter.
- When using this product for thrombus removal, it is recommended, based on the product characteristics, that retrieval attempts for a single thrombectomy stent should be less than or equal to 5, and that the retrieval attempts in the same vessel should be less than or equal to 5 in order to reduce the risk of vascular injury.
- Allergic reactions may occur with the use of this product in people who are allergic to Nitinol.
- After the device has been used, the product and packaging should be disposed of in accordance with the regulations of hospitals, administrative departments and local governments.

Precautions

- Use the product within the sterilization validity period.
- Store the product in dark, clean, and dry environment at room temperature with no corrosive gases.
- Do not expose the product to organic solvents (such as alcohol, etc.).
- Do not use if the inner packaging is found to be damaged.
- Before use, carefully inspect the sterile packaging as well as the system components to ensure that they have not been damaged during transportation. Do not use kinked or damaged components.
- Use the product in combination with a compatible microcatheter.
- The product should be operated under high quality x-ray observation. If resistance is encountered during manipulation, the cause of the resistance needs to be identified before proceeding with the surgical procedure.

- When using this product for thrombus removal, it is recommended, based on the product characteristics, that the number of removals for a single thrombectomy stent should be less than or equal to 5, and that the total number of removals in the same vessel should be less than or equal to 5 in order to reduce the risk of vascular injury.
- Select the appropriate thrombectomy device size so that its diameter after release is as close as possible to the diameter of the occluded vessel. If the wrong thrombectomy device size is selected, incomplete removal or injury to the vessel may occur.
- Care should be taken not to damage the distal end of the stent when introducing the thrombectomy device into the microcatheter from the introducer sheath.

2.4.3 Other Relevant Aspects of Safety

No field safety corrective actions, field safety notices, recalls, or adverse events related to NeuroHawk™ Thrombectomy Device are published. However, in 2023, two complaints about stent deployment failure during the procedure were reported in China. Both complaints were attributed to the excessive hardness of the clot (thrombus) and had no clear causal relationship with the device itself.

2.5 Summary of Clinical Evaluation and Post-Market Clinical Follow-Up (PMCF)

The NeuroHawk™ Thrombectomy Device from MicroPort NeuroTech is a medical device designed to remove clots from the blocked brain vessels in the treatment of acute ischemic stroke. The materials of the device manufactured have been used for several decades for medical devices and have good biocompatibility.

The NeuroHawk™ Thrombectomy Device has a proven track record of safety and performance. This track record is summarized in the clinical evaluation report, a document evaluating the clinical safety and performance of the device, which is crucial for CE-marking. Safety and performance are evaluated based on clinical data. In the case of the NeuroHawk™ Thrombectomy Device, the clinical data comprise a clinical study conducted by the manufacturer, publications in scientific journals on comparable devices, and surveillance of the device after marketing (Post-Market Surveillance) and will be detailed in the following.

The scientific literature on devices comparable to the NeuroHawk™ Thrombectomy Device (part of the so-called generic device group) comprises studies and investigations conducted by practitioners and scientists.

In summary, the published literature concludes that similar devices (generic device group) have a good safety profile and offer the performance for a good treatment result, as intended by the manufacturer of the device. The clinical study on the NeuroHawk™ Thrombectomy Device collected data on the safety and performance of the device, which were compared to the generic device group in the clinical evaluation report. It was shown that the treatment with the NeuroHawk™ Thrombectomy Device was also safe and efficacious, and the device offers a benefit to the patient. Therefore, the NeuroHawk™ Thrombectomy Device meets the requirement for performance, a prerequisite for CE-marking according to the current European legislation on medical devices.

The safety of the treatment of acute ischemic stroke by the NeuroHawk™ Thrombectomy Device was assessed in the clinical evaluation through the review of several product-specific documents, including a risk analysis and comprehensive instructions for use, as well as test reports on biological testing. From this review, it can be concluded that the device fulfills the biological requirements.

Based on these documents, it can be summarized that the procedural and product-specific risks, corresponding warnings, and precautions are adequately provided for the user and offer information on risks associated with the NeuroHawk™ Thrombectomy Device. Thus, the device meets the requirement for safety, a prerequisite for CE-marking according to the current European legislation on medical devices. Potential risks of the device are acceptable residual risks for the patient. The main risks are described and documented in detail in the scientific literature, thus being known to the medical expert.

2.6 Possible Therapeutic Alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional, who can take into account your individual situation.

Currently, intravenous (IV) or intra-arterial (IA) thrombolysis and operation inside the blocked blood vessel (endovascular treatment) are used to treat an acute ischemic stroke caused by a blockage in a large blood vessel. Intravenous or intra-arterial (IA) thrombolysis refers to the administration of a clot-dissolving medication through a vein or blocked artery. In addition to stent thrombectomy, aspiration thrombectomy is an alternative therapy performed from inside the vessel (endovascular treatment). Aspiration thrombectomy operates by using an external pump or a large syringe to suction the clot from the blocked artery through a larger catheter.

2.7 Suggested Profile and Training for User

The system should be used by qualified professionals who have received the necessary training (especially for interventional radiology) to complete the operation inside the blocked blood vessel (endovascular procedure).

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