MicroPort NeuroTech (Shanghai) Co., Ltd.

Summary of Safety and Clinical Performance:

X-track™ Intracranial Distal Access Catheter

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

Identifier for the SSCP: T0047008

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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 X-track™ Intracranial Distal Access Catheter. The SSCP is prepared in accordance with the Medical Device Regulation (EU) 2017/745 (MDR) and the document MDCG 2019-9, Rev.1. The SSCP is not intended to replace the instructions for use (IFU) as the main document to ensure the safe use of the X-track™ Intracranial Distal Access Catheter, 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	X-track™ Intracranial Distal Access Catheter Model: DC5-115, DC5-125, DC5-135, DC6-115, DC6-125, DC6-135
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	69586980T0047U2
Medical device nomenclature	GMDN: 17846 Vascular Guide-Catheter, Single Use EMDN: N010401, PERIPHERAL NERVOUS SYSTEM CATHETERS AND KITS. FDA product code: QJP (Catheter, Percutaneous, Neurovasculature)
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 European 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	X-track™ Intracranial Distal Access Catheter is intended for use in facilitating the insertion and guidance of appropriately sized interventional devices into the neurovascular system.
Indication(s)	X-track™ Intracranial Distal Access Catheter is indicated for use in interventional therapy of neurovascular diseases.
Targeted population(s)	**Intended user:** X-track™ Intracranial Distal Access Catheter should be used by professional physicians who have received necessary training and are qualified in the field of neurovascular interventional therapy. **Patient population:** X-track™ Intracranial Distal Access Catheter is intended to be used in patients with neurovascular diseases that require interventional therapy. The safety and efficacy of this device have not been established in pregnant or breastfeeding women, or in pediatric patients.
Contraindications and/or limitations	There are no known contraindications.

1.3 Device Description

1.3.1 Description of the X-track™ Intracranial Distal Access Catheter

The X-track™ Intracranial Distal Access Catheter is a non-tapered, single-lumen, flexible catheter, which is constituted by a hub, a strain relief tubing and a catheter body. The distal segment of catheter body is steam shapeable and is designed with an external hydrophilic coating to reduce friction during use. The catheter includes a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end allowing attachments of accessories. X-track Catheter is packaged with a shaping mandrel, an introducer and a ruler. The X-track Catheter is provided sterile, and intended for single use only.

There are six models of the X-track. Before determining that a X-track is to be used, it is necessary to estimate the diameter of the target vessel and the expected position of lesions and to select the appropriate product model and compatible devices.

X-track™ Intracranial Distal Access Catheter is a single-use medical device, intended to deliver interventional devices into the neurovascular system during minimally invasive procedures. Under the dynamic monitoring of DSA (Digital Subtraction Angiography), with the aid of a

puncture needle, sheath or guiding catheter connecting with hemostasis valve, and guidewire, X-track can be introduced into the intracranial circulation through an access point to the femoral artery. Once positioned in the targeted vessel, X-track catheter functions as a working channel through which smaller devices, like microcatheters, may be introduced into the brain.

The shaping mandrel is used by the physician to shape the catheter tip to accommodate different vessels. The function of introducer is to facilitate the introduction of the catheter into the sheath or the guiding catheter though hemostasis valve.

The product is an auxiliary instrument for neurointerventional surgery, which is used to provide access for treatment devices and has no therapeutic effect itself.

1.3.2 Accessories Required for Product Use

- Long sheath 6F (Connectible RHV) or guiding catheter 8F (the inner diameter should not be less than 0.88 inch/2.33 mm)
- Guidewire (maximum guidewire diameter 0.038 inch/0.97 mm)
- Microguidewire (maximum microguidewire diameter 0.038 inch/0.97 mm)
- Microcatheter (maximum microcatheter diameter 3.4F/1.12mm)
- 60 ml syringe
- At least two sets of normal saline or saline-heparin continuous flushing lines
- 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 X-track™ Intracranial Distal Access Catheter does not reveal unacceptable residual risks.

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

- Allergic reaction

- Vasospasm
- Vascular dissection
- Vessel perforation
- Distal embolization
- Intracranial hemorrhage
- Ischemia
- Pseudoaneurysm
- Pain and tender
- Hematoma at access site
- Infection
- Acute obstruction
- Air embolism
- Neural defects including shock and death

Quantitative data on the occurrence of complications with the X-track™ Intracranial Distal Access Catheter can be drawn from the clinical study of X-track conducted by MicroPort NeuroTech. In this study, the following major safety parameters and their occurrence rate are reported for patients using X-track:

Table 1 Summary of Major Safety Parameters of the X-track Clinical Study

(Source: Clinical Evaluation Report)

Safety Parameters	Device-related Adverse Events of the X-track Clinical Study
Vasospasm	0.9%
Distal embolization	0.0%
Intracranial hemorrhage	0.0%
Infection	0.0%
Neural defects including shock and death	0.0%

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/Precautions/Precaution Measures

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

- Warnings
  - This Instructions for Use must be read carefully before use.
  - This product has been sterilized by ethylene oxide. Do not use if the package is opened, damaged or leaky.
  - This product is intended for single use only. Do not resterilize or reuse.
  - Use the product prior to “Use by” date.
  - This product should only be used by qualified physicians who have received appropriate training in interventional techniques.
  - After use, this product and its package should be discarded in accordance with regulations of the hospital, administrative department and/or local government.
- Precautions
  - Use the product prior to the “Use by” date;
  - Store the product in the dry and cool place, away from light and corrosive gases;
  - Keep it away from any organic solvents (such as alcohol, etc);
  - Do not use the product if the inner package is damaged;
  - Do not use the product if the product is kinked, deformed or damaged;
  - When used in conjunction with other devices, refer to the Accessories Required for Product Use section for detailed compatibility information. Device compatibility should be confirmed by consulting the labeling provided with the X-track™ catheter as well as with the devices.
  - When the catheter goes into human body, it is forbidden to move the catheter until its tip is visible under the fluoroscopy;
  - Do not torque the catheter during the procedure;
  - When the X-track™ is obstructed, it is required to replace it with a new one or get it out

to find out the cause for obstruction;

- When it is difficult to deliver the vascular disease diagnosis device or interventional treatment device due to resistance, do not attempt to advance and withdraw it until the cause for resistance is found;
- Do not exceed maximum recommended infusion pressure of 2070kPa (300psi). Too high pressure may damage catheter or hurt the patient.
- This product contains hydrophilic coating, which poses a risk of peeling off and may cause occurrence of adverse events.
- This product is not available for power injection.

➢ Precautionary Measures

- Ensure the compatibility between the interventional devices and catheter before using;
- Prepare all accessories and reagents in accordance with the instructions for use before using;
- Keep the hydrophilic coating of the X-track™ wet and glossy.

1.4.3 Other Relevant Aspects of Safety

No recalls, field safety corrective actions (FSCAs), or reportable adverse events related to the X-track™ Intracranial Distal Access Catheter happened.

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 the X-track™ Intracranial Distal Access Catheter was investigated in the X-track clinical study. The summary of the study is given in the following **Table 2**.

Table 2 Summary of the X-track Clinical Study

Title	Clinical Study on the Safety and Efficacy of X-track for Neurological Intervention in China
Name of investigational medical device	X-track™ Intracranial Distal Access Catheter
Study centers	six centers in China
Time frame	Start date: December 7, 2023 (enrollment of first subject) End date: March 1, 2024
Intended use of the device	X-track™ Intracranial Distal Access Catheter is intended for use in facilitating the insertion and guidance of appropriately sized interventional devices into the neurovascular system. It is indicated for use in interventional therapy of neurovascular diseases.
Study objective	To evaluate the safety and effectiveness of Intracranial Distal Access Catheter in neurointerventional therapy.
Study design	Prospective/retrospective, multicenter, single-arm clinical study
Effectiveness and safety evaluation	**Effectiveness evaluation** • **Primary effectiveness endpoint** ➢ Technical success rate ✧ "Technical success rate" is defined as the proportion of subjects where Intracranial Distal Access Catheter can reach the expected position to successfully deliver the device and meet the treatment needs. • **Secondary efficacy indicator** ➢ Catheter delivery success rate ✧ "Catheter delivery success rate" is defined as the proportion of Intracranial Distal Access Catheter where Intracranial Distal Access Catheter can reach the expected position to successfully deliver the device and meet the treatment needs. ➢ Device operation performance, including device compatibility, supporting capability, and pushing resistance • **Safety evaluation** ➢ Incidence of device-related adverse events ➢ Incidence of device-related serious adverse events
Inclusion criteria	• **Subject selection of retrospective study** Patients must meet all of the following criteria to be enrolled: 1) Age = 18–80 years old. 2) Patients with mechanical thrombectomy for acute ischemic stroke, treatment of intracranial aneurysms and other ischemic and hemorrhagic diseases, requiring the use of Intracranial Distal Access Catheter to complete the operation (such as poor vascular access conditions, lesions located in secondary or higher branches of cerebral vessels, inability of conventional guiding catheters in place and providing effective support; Treatment with flow-diverter devices, covered stents, etc.).

<table>
<tr><th>Title</th><th>Clinical Study on the Safety and Efficacy of X-track for Neurological Intervention in China</th></tr>
<tr><td></td><td>• Subject selection of prospective study
Patients must meet all of the following criteria to be enrolled:
1) Age = 18–80 years old.
2) Patients with mechanical thrombectomy for acute ischemic stroke, treatment of intracranial aneurysms and other ischemic and hemorrhagic diseases, requiring the use of Intracranial Distal Access Catheter to complete the operation (such as poor vascular access conditions, lesions located in secondary or higher branches of cerebral vessels, inability of conventional guiding catheters in place and providing effective support. Treatment with flow diverter device, covered stent, etc.).
3) Patients agree to participate in the study and sign the informed consent form.</td></tr>
<tr><td>Exclusion criteria</td><td>Patients are excluded if they have any of the following:
(1) Intracranial Distal Access Catheter is used during the interventional therapy of non-neurovascular diseases, such as peripheral vascular and coronary artery diseases.
(2) Interventional procedure is performed with other distal catheters or devices with the same function before using Intracranial Distal Access Catheter.
(3) Ordinary guiding catheters can be used to establish access to complete the procedure without the use of Intracranial Distal Access Catheter.</td></tr>
<tr><td>Follow-up</td><td>At discharge</td></tr>
<tr><td>Study population</td><td>A total of 114 subjects were enrolled in the study. All the subjects were included in the full analysis set (FAS) and the safety set (SS).
<table>
<tr><th>Item</th><th>Indicator</th><th>Value</th></tr>
<tr><td>Age (years)</td><td>Mean (SD)</td><td>62.4 (12.59)</td></tr>
<tr><td rowspan="2">Gender</td><td>Male n (%)</td><td>66 (57.9%)</td></tr>
<tr><td>Female n (%)</td><td>48 (42.1%)</td></tr>
<tr><td>Height (cm)</td><td>Mean (SD)</td><td>164.1 (7.71)</td></tr>
<tr><td rowspan="4">Diseases</td><td>Acute cerebral infarction n (%)</td><td>60 (52.6%)</td></tr>
<tr><td>Intracranial aneurysms n (%)</td><td>47 (41.2%)</td></tr>
<tr><td>Carotid cavernous fistula n (%)</td><td>0</td></tr>
<tr><td>Cerebral arteriovenous malformation n (%)</td><td>3 (2.6%)</td></tr>
<tr><td></td><td>Other diseases</td><td>4 (3.5%)</td></tr>
</table></td></tr>
<tr><td>Summary of the results and limitation</td><td>Effectiveness evaluation:
Primary effectiveness endpoint
➢ Technical success rate: In the main analysis of FAS, all the 114 subjects achieved technical success, with a technical success rate of 100% and a 95% confidence interval of 100% (96.8%, 100%). The lower limit of 95% confidence interval (96.8%) is greater than 90% (target value), and the test product is considered effective.

Secondary effectiveness endpoints
➢ Catheter delivery success rate: 115 catheters were successfully delivered in 114 subjects, with the delivery success rate of 100% and a 95% confidence interval of (96.8%, 100%).</td></tr>
</table>

Title	Clinical Study on the Safety and Efficacy of X-track for Neurological Intervention in China
	➢ **Device operation performance:** All catheters were compatible with the device. Among the 115 catheters, 101 (87.8%) had excellent supporting capacity, 14 (12.2%) had good supporting capacity, and there were no catheters with poor supporting capacity. 114 (99.1%) catheters had excellent pushing resistance, 1 (0.9%) catheter had good pushing resistance, and there were no catheters with poor pushing resistance. **Safety evaluation:** ➢ **Incidence of device-related adverse events:** Among 114 subjects, 25 (21.9%) subjects had 27 adverse events, of which 1 (0.9%) had 1 adverse event related to Intracranial Distal Access Catheter (vasospasm), and 20 (17.5%) had 20 adverse events related to procedure. ➢ **Incidence of device-related serious adverse events:** Among 114 subjects, 7 (6.1%) subjects had 7 serious adverse events, none of which were related to Intracranial Distal Access Catheter. **Device defect:** 1 (0.9%) subject had 1 (0.9%) device rupture, which did not result in any AE. **Conclusion** The Intracranial Distal Access Catheter has good effectiveness and safety, meeting the requirements of clinical application.

1.5.3 Summary of Clinical Data from Other Sources

1.5.3.1 Clinical Data in the Literature

No clinical data of X-track in the literature are available.

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 X-track™ Intracranial Distal Access Catheter and similar distal access catheters on the market during the preparation of the clinical evaluation report. The search was conducted on March 10, 2024.

For the X-track™ Intracranial Distal Access Catheter, no results were identified through the

MAUDE search. There were no severe adverse events or malfunctions. Also, MAUDE search for similar distal access catheters on the US-market (Sofia™ Distal Access Catheter from Microvention and Navien™ Intracranial Support Catheter 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 vasoconstriction, hemorrhage/ bleeding/ rupture, obstruction/ occlusion, vascular dissection, thrombosis/ thrombus/ thromboembolism as well as device-related malfunctions such as break and bent. 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 X-track™ Intracranial Distal Access Catheter belongs to the generic device group, vascular guide-catheter, 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 distal access catheter in general and the X-track™ Intracranial Distal Access Catheter is efficacious and safe for facilitating the endovascular treatment of the neurovascular diseases. It is recognized as an essential device for delivering drugs and devices to the targeted lesions.

Reported clinical data on the performance parameters of the distal access catheters varies due to various pathology and patient population. The success rate of positioning at the intended target in the X-track clinical study is 100.0%, which is numerically higher than or equal to the data from the literature review, which ranges from 75.3% to 100.0% [1-22]. Based on the performance result, the X-track™ Intracranial Distal Access Catheter is shown to be on par with the generic device group. Therefore, the X-track™ Intracranial Distal Access Catheter is suitable for its intended use, namely facilitating the insertion and guidance of approximately sized interventional devices into the neurovascular system. Thus, it can be concluded that the X-track™ Intracranial Distal Access Catheter achieves the performance intended by MicroPort NeuroTech and fulfills the relevant GSPRs for performance.

The clinical evaluation of the X-track™ Intracranial Distal Access Catheter 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 X-track™ Intracranial Distal Access Catheter and its clinical application.

The major risks of the X-track™ Intracranial Distal Access Catheter include vasospasm, vessel dissection, vessel rupture or perforation, and arterial embolization. Clinical data from the X-track clinical study revealed that the incidences of the aforementioned safety parameters observed in the X-track are consistent with the data reported in scientific literature [1-23].

The risks described in the literature are consistent with the risks included in the IFU and risk management. Thus, the X-track™ Intracranial Distal Access Catheter meets the requirement for safety. Also, no evidence of unduly or unknown risks of the X-track™ Intracranial Distal Access Catheter 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 X-track™ Intracranial Distal Access Catheter 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 X-track™ Intracranial Distal Access Catheter offers an acceptable benefit/risk profile.

The regular PMS data show no adverse event associated with the X-track™ Intracranial Distal Access Catheter.

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

In conclusion, X-track™ Intracranial Distal Access Catheter 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 X-track™ Intracranial Distal Access

Catheter 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

The current treatment options for treating neurovascular diseases generally include endovascular therapy, surgical intervention, risk factor management, medical therapy, and special therapy for specific diseases. Patient characteristics and the features of the lesions typically determine the choice of which option to pursue.

1.7 Suggested Profile and Training for Users

The X-track™ Intracranial Distal Access Catheter 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 X-track™ Intracranial Distal Access Catheter.

Table 3 Standard Adhered to by Microport Neurotech (Shanghai) Co., Ltd

Reference number and date	Title of standard
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN ISO 10555-1:2023	Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO 10555-1:2023)
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 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
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

Reference number and date	Title of standard
	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)
EN ISO 10993-7:2008/A1:2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993 - 7:2008/Amd 1:2019)
EN ISO 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)
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)
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)
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019, Corrected version 2020-06)
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
EN ISO 11607-1: 2020/ A1: 2023	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems - Amendment 1: Application of risk management (ISO 11607-1:2019/ Amd1: 2023)
EN ISO 11607-2: 2020/ A1: 2023	Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing and assembly processes - Amendment 1: Application of risk management (ISO 11607-2:2019/ Amd1: 2023)
EN 556-1:2024	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

Reference number and date	Title of standard
	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)

1.9 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
01	July 17, 2024	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: 02

Date issued: June 12, 2025

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)	X-track™ Intracranial Distal Access Catheter
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 X-track™ Intracranial Distal Access Catheter is intended for delivering therapeutic devices into the nerve (neurovascular) vessels.
Indication(s)	The X-track™ Intracranial Distal Access Catheter is indicated for use in the interventional treatment (a minimally invasive procedure by using devices that pass through blood vessels to diagnose and treat vascular diseases and conditions rather than using open surgery) of neurovascular diseases.
Intended patient groups	The device can be used for patients who are diagnosed with neurovascular diseases that is suitable for interventional treatment.
Contraindications and/or limitations	There are no known contraindications.

2.3 Device Description

2.3.1 Description of the X-track™ Intracranial Distal Access Catheter

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

- A hub: To allow attachments of accessories
- A strain relief tubing: To provide kink resistance for the proximal end
- A catheter body: To establish access to the neurovascular vessels and deliver therapeutic devices to the intended target. (The distal segment of catheter body is steam shapeable and is designed with an external hydrophilic coating to reduce friction during use. Also, the distal end of the catheter has a radiopaque marker for angiographic visualization.)

Other accessories include an introducer to facilitate the introduction of the catheter into the sheath or the guiding catheter, a stainless-steel shaping mandrel used by physicians for catheter tip steam-shaping, and a ruler used by physicians to compare the distal bend angle after steam-shaping.

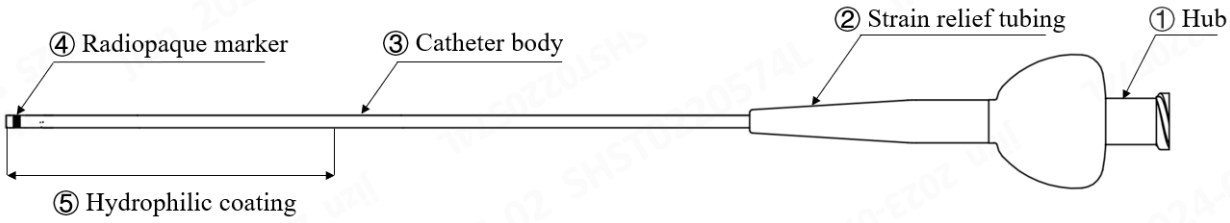

Figure 1 Illustration of the X-track Catheter

2.3.2 Mode of Action

An endovascular procedure is performed through a small incision in the puncture site, where access into the femoral artery is gained with a plastic sheath. Through the sheath, the thin tube ('distal access catheter') is introduced and then through the arteries to the intended target under real-time x-ray guidance. After that, a smaller catheter is then pushed through the main catheter, and then tracked to the targeted lesion. Through the microcatheter, therapeutic devices are delivered and deployed to treat the targeted lesions. Thus, the goal of facilitating the treatment of neurovascular diseases is achieved.

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 product does not reveal unacceptable residual risks.

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

- Allergic reaction
- Contraction of the blood vessel (Vasospasm)
- Splitting open of the vessel (Vascular dissection)
- Tearing open of the vessel (Vessel perforation)
- Movement of the clot into a previously uninvolved portion of the cerebral vasculature or further downstream in the affected vessel (Distal embolization)
- Bleeding within the brain region (Intracranial hemorrhage)
- Restriction in blood supply (Ischemia)
- Formation of localized vessel bulge (Pseudoaneurysm)
- Pain and tender
- Localized bruise due to puncture (Hematoma at access site)
- Infection
- Acute blockage in a blood vessel (Acute obstruction)
- Entry of air into the blood vessel (Air embolism)

- Neural defects including shock and death

Data on how often (quantitative data) these risks occur with the X-track™ Intracranial Distal Access Catheter can be drawn from the clinical study of X-track conducted by MicroPort NeuroTech. In this study, the following major safety parameters and their occurrence rate are reported for patients using X-track:

Table 4 Summary of Major Safety Parameters of the X-track Clinical Study (Source: Clinical Evaluation Report)

Safety Parameters	Device-related Adverse Events of the X-track Clinical Study
Vasospasm	0.9%
Distal embolization	0.0%
Intracranial hemorrhage	0.0%
Infection	0.0%
Neural defects including shock and death	0.0%

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 use of the device.

➢ Warnings

- This Instructions for Use must be read carefully before use.
- This product has been sterilized by ethylene oxide. Do not use if the package is opened, damaged or leaky.
- This product is intended for single use only. Do not resterilize or reuse.
- Use the product prior to “Use by” date.
- This product should only be used by qualified physicians who have received appropriate training in interventional techniques.
- After use, this product and its package should be discarded in accordance with regulations

of the hospital, administrative department and/or local government.

- Precautions

  - Use the product prior to the “Use by” date;
  - Store the product in the dry and cool place, away from light and corrosive gases;
  - Keep it away from any organic solvents (such as alcohol, etc);
  - Do not use the product if the inner package is damaged;
  - Do not use the product if the product is kinked, deformed or damaged;
  - When used in conjunction with other devices, refer to the Accessories Required for Product Use section for detailed compatibility information. Device compatibility should be confirmed by consulting the labeling provided with the X-track™ catheter as well as with the devices.
  - When the catheter goes into human body, it is forbidden to move the catheter until its tip is visible under the fluoroscopy;
  - Do not torque the catheter during the procedure;
  - When the X-track™ is obstructed, it is required to replace it with a new one or get it out to find out the cause for obstruction;
  - When it is difficult to deliver the vascular disease diagnosis device or interventional treatment device due to resistance, do not attempt to advance and withdraw it until the cause for resistance is found;
  - Do not exceed maximum recommended infusion pressure of 2070kPa (300psi). Too high pressure may damage catheter or hurt the patient.
  - This product contains hydrophilic coating, which poses a risk of peeling off and may cause occurrence of adverse events.
  - This product is not available for power injection.

- Precautionary Measures

  - Ensure the compatibility between the interventional devices and catheter before using;
  - Prepare all accessories and reagents in accordance with the instructions for use before using;

- Keep the hydrophilic coating of the X-track™ wet and glossy.

2.4.3 Other Relevant Aspects of Safety

No recalls, field safety corrective actions (FSCAs), or reportable adverse events related to the X-track™ Intracranial Distal Access Catheter happened.

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

The X-track™ Intracranial Distal Access Catheter from MicroPort NeuroTech is a medical device designed to provide a platform to deliver devices. The materials of the device manufactured have been used for several decades for medical devices and have good biocompatibility.

The X-track™ Intracranial Distal Access Catheter 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 X-track™ Intracranial Distal Access Catheter, 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 X-track™ Intracranial Distal Access Catheter (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 and performance profile, as intended by the manufacturer of the device. The clinical study on the X-track™ Intracranial Distal Access Catheter 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 X-track™ Intracranial Distal Access Catheter is used safely and efficaciously for facilitating the endovascular treatment, and the device offers a benefit to the patient. Therefore, the X-track™ Intracranial Distal Access Catheter meets the requirement for performance, a prerequisite for CE-marking according to the current European legislation on medical devices.

The safety of the X-track™ Intracranial Distal Access Catheter 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 X-track™ Intracranial Distal Access Catheter. 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.

The current treatment options for treating neurovascular diseases generally include procedures done inside the blood vessels (endovascular treatment), open surgery, risk factor management, medical therapy, and special therapy for specific diseases. Risk factor management typically involves lowering blood lipid levels or blood pressure, as well as lifestyle management, such as regular exercise and smoking cessation. Medical therapy commonly includes intravenous delivery of drugs and the use of oral medications. The choice of which option to pursue is typically determined by your characteristics and your lesions' feature.

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 in the endovascular procedure.

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