

X-track™ Intracranial Distal Access Catheter

Instructions for Use

CONTENT

Warnings.....	2
Contents.....	2
Device Description	2
Intended Purpose	3
Indication for Use	3
Intended User	3
Target Population	3
Clinical Benefit	3
Contraindications	3
Potential Complications.....	3
Precautions	4
Precautionary Measures	4
Accessories Required for Product Use	4
Operation Procedures	4
Shaping Mandrel.....	5
Introducer	6
Disposal	6
Sterilization	6
Storage Condition	6
Transportation Condition	6
Shelf Life	6
Basic UDI-DI Number	6
Legal Statement	6
After-sales Service	6
Legal Manufacturer	6
After-sales Service Company Information.....	7
European Authorized Representative	7
Symbol Glossary	8

X-track™ Intracranial Distal Access Catheter

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.

Contents

- One intracranial distal access catheter
- One introducer
- One shaping mandrel
- One instructions for use
- One ruler

Device Description

X-track™ Intracranial Distal Access Catheter (hereinafter referred to as “X-track™”) is one single lumen catheter, consisting of inner layer, reinforcement, outer jacket, luer hub and strain relief tubing and provides the introducer, shaping mandrel and ruler as its accessories. It is mainly used for use in facilitating the insertion and guidance of appropriately sized interventional devices into the neurovascular systems. The device is semi-rigid on its proximal end and flexible on its distal end. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy.

Introducer: During surgery, insert the introducer into the hemostatic valve to assist in distal catheter insert a sheath or guide catheter.

Shaping mandrel: During surgery, the doctor will according to the situation of the patient, when steam shaping is performed on the distal end, it is inserted into the inner cavity of the distal catheter head end to provide support and molding.

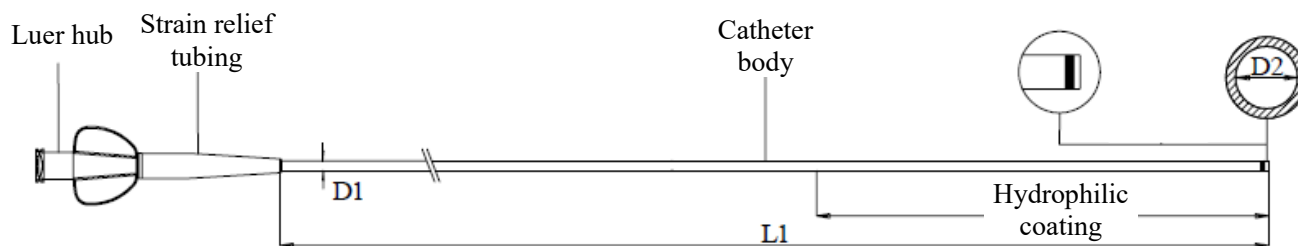


Figure 1. X-track™ Intracranial Distal Access Catheter

Table 1. Specification of X-track™ Intracranial Distal Access Catheter

Specification	Catheter size (French)	Outer diameter D1			Inner diameter D2		Effective length L1 (cm)
		(French)	(inch)	(mm)	(inch)	(mm)	
DC5-115	5F	≤5.5	≤0.072	≤1.84	0.055	1.40	115
DC5-125							125
DC5-135							135

Specification	Catheter size (French)	Outer diameter D1			Inner diameter D2		Effective length L1 (cm)
		(French)	(inch)	(mm)	(inch)	(mm)	
DC6-115	6F	≤6.6	≤0.086	≤2.19	0.070	1.78	115
DC6-125							125
DC6-135							135

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 for Use

X-track™ Intracranial Distal Access Catheter is indicated for use in interventional therapy of neurovascular diseases.

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.

Target 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 populations.

Clinical Benefit

The X-track™ Intracranial Distal Access Catheter has indirect benefits for patients since it facilitates the insertion and guidance of other interventional devices to the distal target site in the neurovascular system in achieving their intended purpose. The clinical benefit of X-track™ catheter also relates to providing patients with a minimally invasive treatment option through facilitating the delivery of interventional devices endovascularly as an alternative to open surgery.

Contraindications

There are no known contraindications.

Potential Complications

They include but are not limited to:

- 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

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.

Accessories Required for Product Use

Accessories for performing a procedure to be selected based on the physician’s experiences and preferences:

- long sheath 6F (Connectible RHV) or guiding catheter 8F (the inner diameter should not be less than 0.088 inch/2.23 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/1.12 mm)
- 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

Operation Procedures

Preparation of X-track™ Intracranial Distal Access Catheter

- 1) Check the package to ensure that the product is within the validity period and that the package is not opened or damaged;
- 2) Open the package with standard sterile procedure, flush the hoop with the heparinized saline through the

flushing connector and take out the X-track™ after flushing;

- 3) Check the X-track™ carefully to ensure that there is no damage;
- 4) Use the shaping mandrel to selectively shape the tip of X-track™ on the basis of clinical demand;
- 5) Connect the RHV to the end of the X-track™, connect the one-way stopcock to the side arm of RHV, connect the one-way stopcock with continuous infusion and flush the X-track™ with the heparinized saline;

- **Placement of guiding catheter or sheath**

- 6) Connect the RHV to the guiding catheter or sheath (Connectible RHV) according to standard operating method to prevent blood backflow, and connect the one-way stopcock to the hemostatic valve side arm, flush the guide catheter or sheath with heparinized saline;

- **Delivery of X-track™ Intracranial Distal Access Catheter**

- 7) Select proper guidewire (maximum diameter no more than 0.038 inch) or guiding catheter, insert the guidewire (or guiding catheter with the guidewire) into the X-track™ in accordance with standard operating method and deliver it into the catheter lumen;
- 8) Place the guidewire (or together with the guide catheter) and the distal catheter through the guiding catheter or the long sheath (Connectible RHV), close the RHV appropriately to prevent backflow, but allow the distal catheter to move forward or backward through the RHV. Continue to deliver the X-track™ until it get out of the guiding catheter or sheath (Connectible RHV) and the X-track™ reach to the target artery;

Warning: please carefully use an introducer to assist the catheter into the RHV, otherwise it may cause damage to the tip and the coating of X-track™.

- 9) Remove the guidewire and guiding catheter, connect the RHV to the end of the microcatheter, connect the one-way stopcock to the side arm of RHV, connect the one-way stopcock for continuous infusion and flush the microcatheter with the heparinized saline;
- 10) Insert the microguidewire into the supporting microcatheter, make it come out from the distal end, inset them into the proximal end of X-track™, continue to deliver the X-track™ to the target artery;
- 11) Withdraw the microguidewire and the supporting microcatheter;

Warning: all of the above steps need to be performed under the fluoroscopy.

- **Delivery of treatment device**

- 12) Select proper treatment device (such as retriever and flow diverter) delivery through microcatheter, connect the RHV to the end of the microcatheter, connect the one-way stopcock to the side arm of RHV, connect the one-way stopcock for continuous infusion and flush the microcatheter with the heparinized saline;
- 13) Insert the microguidewire into the microcatheter, make it come out from the distal end, inset them into the proximal end of X-track™ and deliver them to the position;
- 14) Withdraw the microguidewire, insert the treatment device (such as retriever and flow diverter) into the X-track™ intracranial distal access catheter, deliver it to the target artery and release it.
- 15) Retrieval of treatment device deliver system;
- 16) Retrieval of X-track™ Intracranial Distal Access Catheter.

Warning: all of the above steps need to be performed carefully otherwise it may cause damage to the X-track™.

Shaping Mandrel

Note: the shaping mandrel cannot be kept in the catheter; only the steam can be used for shaping; when the tip is damaged, do not use the product.

Shaping method:

- 1) Take the shaping mandrel out of the package and insert it into the tip of X-track™ Intracranial Distal Access Catheter;
- 2) Bend the tip of X-track™ to desired shape;
- 3) Shape with the steam for about 30 seconds;

- 4) When the shaping mandrel becomes cool, take it out from its tip and discard it; do not reuse it;
- 5) Check the shaping tip; if the X-track™ is damaged, do not use it.

Introducer

- 1) Take the introducer out from its packaging bag, insert it into the RHV of sheath or guide catheter;
- 2) Insert the X-track™ through the introducer;
- 3) When the X-track™ has been inserted to the depth of at least 10cm, remove the introducer and continue to deliver the X-track™.

Disposal

After use, devices should be disposed of in accordance with medical waste disposal requirements.

Sterilization

The X-track™ has been sterilized with ethylene oxide. It cannot be re-sterilized for use.

Storage Condition

Store in a dry, clean, well ventilated environment, at room temperature, with no corrosive gases.

Transportation Condition

The product should be protected from heavy load, direct sunlight, rain or snows during transportation.

Shelf Life

The shelf life of X-track™ is 2 years under the specified storage condition.

Basic UDI-DI Number

X-track™ Basic UDI-Device Identifier Number: 69586980T0047U2

Legal Statement

MicroPort NeuroTech (Shanghai) Co., Ltd. indicates definitely that the X-track™ Intracranial Distal Access Catheter is intended for one-time use only. MicroPort NeuroTech (Shanghai) Co., Ltd. will not be liable for any incidental, special, or consequential loss, damage, or expense resulting, directly or indirectly, from improperly selecting size, inaccurate handling or any other man-caused accident. MicroPort NeuroTech (Shanghai) Co., Ltd. makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the reuse of this catheter. Moreover, MicroPort NeuroTech (Shanghai) Co., Ltd. assumes no responsibility or liability for incidental or consequential damages which may result from such re-use.

Meanwhile, MicroPort NeuroTech (Shanghai) Co., Ltd. assumes no responsibility or liability for any incidental or consequential damages which may result from the following circumstances:

- Any use, dismantling or disposal of the Product not in strict accordance with this Instructions for Use;
- Any intentional acts, gross negligence or non-professional acts of medical personnel;
- Damages caused by Force Majeure or accidents; and
- Other damages not caused due to the quality problems of the product.

This document contains confidential information or proprietary technology of MicroPort NeuroTech (Shanghai) Co., Ltd.

After-sales Service

MicroPort NeuroTech (Shanghai) Co., Ltd. (hereinafter referred to as "MicroPort NeuroTech") takes "provide high quality, high-performance medical products" as the highest business purposes, and warrants that the entire product shall be free of defects in materials and workmanship upon receipt. Contact MicroPort NeuroTech directly with any questions related to the product.

Legal Manufacturer

Company Name: MicroPort NeuroTech (Shanghai) Co., Ltd.

Address: Building #16, 222 Guangdan Road, Pudong New District, 201318 Shanghai, China.

E-mail: Complaints-NeuroTech@microport.com

After-sales Service Company Information

Company Name: MicroPort NeuroTech (Shanghai) Co., Ltd.

Address: Building #16, 222 Guangdan Road, Pudong New District, 201318 Shanghai, China.

Tel: (86)(21) 3895 4600

Tel: (86)(21) 5080 1305

E-mail: Complaints-NeuroTech@microport.com

European Authorized Representative

MicroPort Medical B.V.


Paasheuvelweg 25, 1105BP Amsterdam, The Netherlands

Tel: +31 (0)20 545 0100 ext. 8























Fax: +31 (0)20 545 0109

If any device related serious incident occurs, please inform the Legal Manufacturer and/or European Authorized Representative and the competent authority of the Member State.

All rights reserved by MicroPort NeuroTech (Shanghai) Co., Ltd., and no reproduce without authorization of MicroPort.

“MicroPort” and logo“  ”are the registered trademarks of MicroPort Sinica Co., Ltd., and are authorized to MicroPort NeuroTech (Shanghai) Co., Ltd., any other third-party without permission shall not use them.

Symbol Glossary

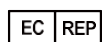
	Date of manufacture		Do not re-use
	Use-by date		Consult instructions for use
	Batch code		Contents 1 Unit
	Catalog number		Manufacturer
	Sterilized using ethylene oxide		Authorized representative in the European Community
	Do not use if package is damaged		Do not re-sterilize
	Keep away from sunlight		Unique device identifier
	Keep dry		CE Mark
	Single sterile barrier system		Medical device
	Caution		Straight tip
	Introducer		Shaping mandrel

More information on this device, including
a Summary of Safety and Clinical Performance,
is available at the websites below:

<https://ec.europa.eu/tools/eudamed>



MicroPort NeuroTech (Shanghai) Co., Ltd.
Building #16, 222 Guangdan Road,
Pudong New District, 201318 Shanghai, China.
Tel: (86)(21)38954600
Fax:(86)(21)50801305
Email: Complaints-NeuroTech@microport.com
Website: www.microportneurosci.com



MicroPort Medical B.V.
Paasheuvelweg 25
1105BP Amsterdam, The Netherlands
Tel: +31 (0)20 545 0100 ext. 8
Fax: +31 (0)20 545 0109



Revision date: 2025-04-25