MicroPort NeuroTech

T0040046 Rev. B
STN.0.0048

NUMEN™
Coil Embolization System

MicroPort NeuroTech (Shanghai) Co., Ltd.

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NUMEN™ Coil Embolization System

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO THE SALE BY OR ON THE ORDER OF A PHYSICIAN!

⚠ Warnings

- Users of this product have to read and understand this this document and the NUMEN™ FR Detachment System Instructions for Use before use.
- This product should be used by qualified professionals who have received necessary interventional training (especially for interventional radiology) to complete the endovascular procedures.
- The Product is supplied sterile with an ethylene oxide process. Do not use if the sterile barrier is damaged, or if the sterilization validity period has expired.
- The product is for single-use only. Do not reuse, reprocess, or re-sterilize.
- 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.

Device Description

The NUMEN™ Coil Embolization System consists of an implant coil attached to a delivery wire (pusher) within an introducer sheath (Figure 1). The NUMEN™ Coil Embolization System consists of three types of coils: MicroFrame (FR), MicroFill (HL), and MicroFinish (FN). There are a total of 177 model numbers (REF) that vary in shape and dimension. The NUMEN™ Coil Embolization System is designed to be used with separately provided NUMEN™ FR Detachment System.

Key Features:

- NUMEN™ consists of an implantable coil and a delivery wire (pusher).
- NUMEN™ is available in 3 coil types based on the coil primary diameter, coil secondary (loop) diameters and configuration (MicroFrame, MicroFill, and MicroFinish).
- NUMEN™ provides Neurointerventionalists with a range of diameters (1 – 24mm) and lengths (1 –70cm) for a variety of clinical scenarios of aneurysm sizes and morphologies.
- The fluoro-saver marker on the proximal end of the pusher allows physicians to deliver the coil under fluoroscopy in time.
- NUMEN™ 's detachment zone allows for electrolytic detachment in conjunction with NUMEN™FR Detachment System. After deploying coils into the aneurysm, the coils are detached from the delivery wire by NUMEN™ FR Detachment System.

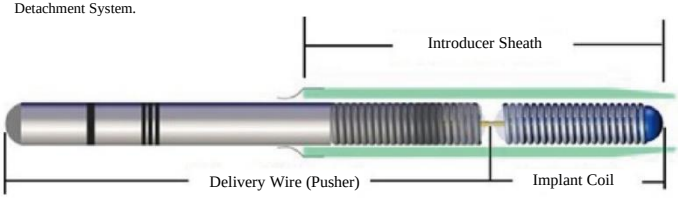


Figure 1. Diagram of NUMEN™ Coil Embolization System

Intended Purpose

NUMEN™ Coil Embolization System is intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular vessels.

Indication for Use

NUMEN™ Coil Embolization system is indicated for endovascular embolization of:

-Intracranial aneurysms

-Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae

Intended User

This product should be used by qualified professionals who have received necessary interventional training (especially for interventional radiology) to complete the endovascular procedures.

Target Population

NUMEN™ Coil Embolization System can be used for patients who are diagnosed with intracranial aneurysms, other neurovascular abnormalities and need coil embolization during percutaneous intervention. No specificity in gender, race or nationality. Efficacy and safety in pediatrics, pregnant women, or children have not been evaluated.

Clinical Benefit

NUMEN™ Coil Embolization System is intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular vessels. Numen coils could prevent the vascular abnormalities from rupturing and bleeding for patients. For aneurysm treating, Numen coils are delivered through catheter to fill the sac of the aneurysm and promote occlusion, which is less invasive versus surgical clipping. The degree of aneurysm occlusion can be evaluated using Raymond-Roy Occlusion Classification (RROC).

MRI Safety Information

Non-clinical testing has demonstrated NUMEN™ Coil is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 12,800 G/cm (128 T/m)
- Maximum force product of 231,000,000 G^2/cm (231 T^2/m)
- Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).
- Under the scan conditions defined above, NUMEN™ Coil is expected to produce a maximum temperature rise of less than 2.2 °C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of 1.6 °C (2 W/kg, 1.5 Tesla) 1.7 °C (2 W/kg, 3 Tesla) RF related temperature increase with a background temperature increase of 1.1 °C (2 W/kg, 3Tesla) after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by the device extends approximately 3.14 mm from Numen™ Coil when imaged with a gradient echo pulse sequence and a 3 Tesla MR system. In addition, scanning an aneurysm model with a magnetic resonance angiography (MRA) pulse sequence at 3 T with an echo transit time of 2.4 ms produced a 3.65 mm (length) and 2.20 mm (diameter) artifact. The device may create local field inhomogeneity and susceptibility artifacts during MRA, which may degrade the diagnostic quality to assess effective intracranial aneurysm treatment.

Contraindications

- Patients allergic to platinum-tungsten alloy.

Precautions

- Use the product within the sterilization validity period.
- Product is single-use.
- Store the product in cool, dark, clean, well ventilated, and dry environment with no corrosive gases.
- Do not expose the product to organic solvents (such as alcohol, etc.).
- Do not use the product if the inner packaging is damaged.
- Prior to use, carefully inspect sterile packaging and system components to ensure that they are not damaged during transportation. Do not use kinked or broken components.
- Use the product in combination with a compatible microcatheter.
- Do not advance the delivery pusher with excessive force. In case of excessive resistance during the delivery of the product, the microcatheter/coil system should be withdrawn and checked for damage or kink.
- The damage to the product may result in detachment failure, vascular injury, or unintended movements of microcatheter during the delivery of the product.
- In order to reduce the risk of coil herniation, the diameter of the secondary shape of the first and second implanted coils should not be smaller than the width of the aneurysm neck.
- In order to achieve the coil detachment and reduce the risk of complications of thrombosis, maintain continuous infusion of an appropriate flushing solution
  a. Between femoral sheath and guiding catheter;
  b. Between microcatheter and guiding catheter;
  c. Between microcatheter and guide wire or delivery wire (pusher).
- Continuous flushing is recommended at a rate of one drop per 3-5 seconds through an empty microcatheter. Continuous flushing also reduces the risks of thrombosis forming on the coil detachment zone and adhesion of contrast agents.
- If the size, shape, or length of the product is not suitable, it should be replaced.
- Coil movement, aneurysm rupture, or vessel perforation may occur if the RHV (Rotatable Hemostatic Valve) on the microcatheter is not properly tightened before connecting the coil detachment system.

Precautionary Measures

- Prepare all accessories according to the instructions for use before use.

Complications

Complications and adverse reactions include but are not limited to:

- Arrhythmia;
- Allergic reaction;
- Aneurysm rupture;
- Cerebral infarction;
- Dizziness;
- Headache;
- Epistaxis;
- Fever;
- Fundal haemorrhage;
- Hematoma;
- Hemiplegia;
- Hydrocephalus;
- Infection;
- Inflammatory response;
- Vomiting;
- Coil migration or misplacement
- Limb asthenia;
- Nausea;
- Organ failure;
- Parent artery occlusion;
- Permanent neurological dysfunction (such as impaired vision or hearing);
- Subarachnoid haemorrhage;
- Thrombosis;
- Transient neurological dysfunction;
- Transient ischemic attack;
- Vascular dissection;
- Vasospasm;
- Vessel perforation;
- Neurological deficits incl. stroke and death
- Clot formation

Accessories Required for Product Use

- 5F or 6F puncture sheath;
- 5F or 6F guiding catheter;
- Guidewire (outer diameter: 0.035 inch);
- Microcatheter (inner diameter: ≥ 0.0165 inch, with double RO markers, length: 150 cm);
- Micro-guidewire (outer diameter: ≤ 0.014 inch, length: ≥ 185 cm);
- At least two sets of continuous flushing lines;
- At least two units of RHV (Rotatable Hemostatic Valve);
- At least two units of three-way stopcock;
- NUMEN™FR Detachment System designed for NUMEN™ Coil Embolization System.

Operation Procedures

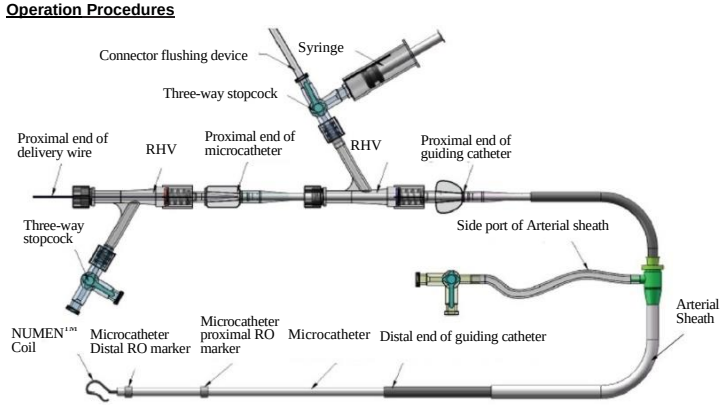


Figure 2. Delivery and Assembly Diagram

Placement of guiding catheter and microcatheter

• Connect the RHV to the guiding catheter, connect the three-way stopcock to the side arm of RHV, connect the continuous flushing device to the three-way stopcock, and then continuously flush the guiding catheter by means of drip infusion;
• Place the guiding catheter into the target vessel with standard method under the guidance of guide wire;
• After shaping the tip of microcatheter as needed, connect the RHV to the microcatheter, connect the three-way stopcock to the side arm of the RHV, connect the continuous flushing device to the three-way stopcock, and then continuously flush the microcatheter with appropriate solution by means of drip infusion;
• Place the microcatheter through guiding catheter into the desired lesion with standard method under the guidance of micro-guide wire.

Preparation of the Product

• Inspect the packaging of the product, and ensure that sterile barrier is not breached;
• Use standard aseptic technique to open the package and remove the product;
• Carefully inspect the product and ensure there is no damage (Figure 3);
• Use a 5 ml syringe to flush the coiled tube with saline through flushing connector (Figure 4);
• Carefully decouple the product from the silicone clamp and remove the product from the packaging hoop (Figure 5).

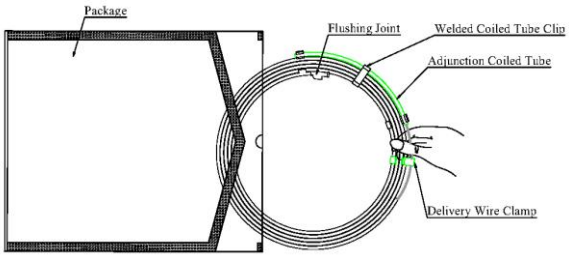


Figure 3. Inspect the coiled tube

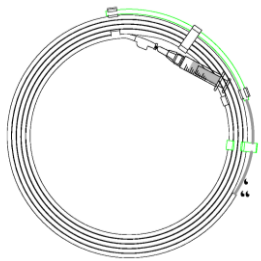


Figure 4. Flush the coiled tube

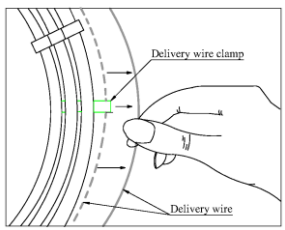


Figure 5. Remove the product

Delivery of the Product

• Inspect the product and ensure that the distal end of the coil is completely inside the introducer sheath and that the proximal end of the delivery wire is free from kink or roughness. Observe the proximal fluoro-saver marks on the delivery wire.
• Loosen the RHV on the microcatheter to ensure that the introducer sheath can be inserted into the RHV.
• Insert the introducer sheath into the RHV but not fully into the microcatheter proximal hub, and tighten the RHV around the introducer sheath.
• Withdraw the clasp between the proximal end of the introducer sheath and the delivery wire, and observe the proximal end of the introducer sheath until there is liquid flowing out.
• Loosen the RHV on the microcatheter again and advance the introducer sheath until it is fully seated within the microcatheter hub, and tighten the RHV but not so tight as to damage the coil during its insertion into the microcatheter;
• Slowly advance the delivery wire so that the coil enters the microcatheter from the introducer sheath, and stop when the proximal end of the delivery wire is less than 5 cm from the proximal end of introducer sheath.
• Loosen the RHV on the microcatheter to remove the introducer sheath from the delivery wire. Put the introducer sheath within the sterile field, and do not discard it before the product is detached.
• Tighten the RHV on the microcatheter enough to advance the delivery wire but not too much to compromise the continuous infusion. Locate the fluoro-safe markers at the proximal end of the delivery wire. Continue to advance the delivery wire into the microcatheter until the fluoro-safe markers approach the RHV. Once the fluoro-saver markers reach the RHV, this indicates the coil is near the exit of the microcatheter tip. At this time fluoroscopic guidance must be initiated. Continue to advance the delivery wire slowly and smoothly under X-ray fluoroscopy so that the coil exits the microcatheter, and carefully place it at the intended position. If the coil is not placed as intended, slowly retract the delivery wire so that the coil retreats into the microcatheter. Reposition the coil by manipulating the delivery wire slowly and smoothly.
• Continue to advance the delivery wire until the proximal edge of RO marker on the delivery wire is flush with the distal edge of the proximal RO marker on the microcatheter forming a shape of "rotated T" (Figure 6). Tighten the RHV on the microcatheter again to ensure that the delivery wire will not move easily.

Warning: Only when liquid flows out from the proximal end of the introducer sheath can the coil continue to be delivered into the microcatheter, so as to prevent gas entering the blood vessel. During the delivery of the coil, the delivery wire should not be rotated to prevent the coil from unintentional detachment, nor be bent to prevent damage to the circuit. After the coil is inserted as intended and the delivery wire is aligned with the microcatheter, ensure that the RHV on the microcatheter has been firmly tightened but not overtightened, so as to prevent damage to the delivery wire.

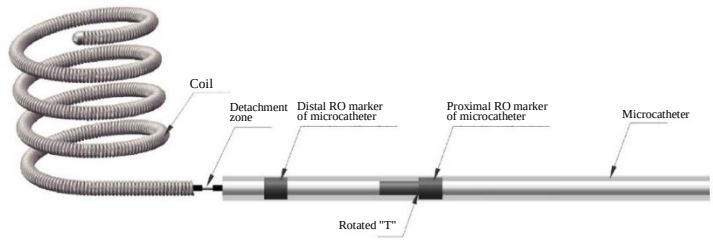


Figure 6. RO marker on the delivery wire is flush with the distal edge of the proximal microcatheter RO marker

Replacement of the Product

• If the shape or size of the coil is not acceptable, the coil may be retracted out of body and be replaced with a more suitable coil to fill the lesion.
• Loosen the RHV on the microcatheter and slowly withdraw the delivery wire to pull the coil back into the microcatheter.
• Continue to withdraw the delivery wire, replace the introducer sheath on the delivery wire from its proximal end, reinsert the introducer sheath into the RHV along the delivery wire, and tighten the RHV.
• Continue to withdraw the delivery wire until the coil is in the introducer sheath entirely, and then withdraw the introducer sheath and delivery wire as a whole from the microcatheter.
• Rinse the withdrawn delivery wire thoroughly to clean up the clot and blood and verify if there is any damage on the delivery wire. After the verification, place the product within the sterile zone for possible later use.

Warning: If repositioning is necessary, take special care to retract and re-deploy the coil under fluoroscopy. Since the coil may be delivered through tortuous vascular pathways, retraction and re-deployement of the coil may cause coil stretch and coil migration.

Detachment of the Coil

• Place of the NUMEN ™ FRDetachment System over the proximal end of the delivery wire.
• When the "Ready" indicator light is on, press the detachment button to detach the coil (Figure 7).
• If the "Detachment Success" indicator light is on and the system sounds a prompt tone, the detachment cycle is complete.
• Slightly pull back the delivery wire under fluoroscopy and ensure that the coil and the delivery wire have completely separated, and then withdraw the delivery wire from the microcatheter.

Warning: Since the coil may not be completely detached after the detachment cycle, it is necessary to pull slightly back on the delivery wire under X-ray fluoroscopy to ensure that the coil does not move or migrate. Coil moving and migration could cause patient harm unintentionally. For the use of the NUMEN ™FR Detachment System, refer to its Instructions for Use.

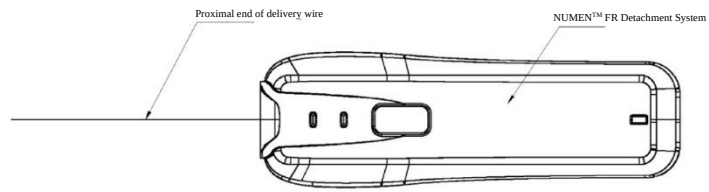


Figure 7. Connection between the delivery wire and NUMEN ™ FR Detachment System

Materials Description

The NUMEN™ Coil Embolization System consists of an implant coil attached to a delivery wire (pusher) within an introducer sheath. Coil composed of a platinum-tungsten alloy The device is made from medical grade polymers, and metals. The devices have undergone successful testing for Biocompatibility to ISO 10993 and have been proven safe for their intended purpose.

Component	Material
Implant coil	Platinum alloy, Polypropylene, UV adhesive, SS 316LVM, Polyimide
Delivery wire (pusher)	Stainless steel 304 and 304V, SS 316LVM, Polyimide, Platinum alloy, Polyester, Epoxy adhesive
Introducer Sheath	Polyethylene

Disposal

Dispose of packaging, delivery wires, introducer sheaths, in accordance with hospital, administrative, and local government policy.
After use, the NUMEN™FR Detachment System (excluding packaging) should be handled and processed as biohazardous material. Dispose of the NUMEN™FR Detachment System unit in accordance with hospital, administrative, and local government policy for the handling, processing, and disposal of biohazardous materials.

Sterilization

The product is sterilized with ethylene oxide and is non-pyrogenic; the product cannot be re-sterilized.

Storage Condition

Store the product at 15-27℃, in dark, clean, well ventilated, and dry environment with no corrosive gases.

Transportation Condition

The product should be protected from stress, direct sunlight, rain or snow during transportation.

Shelf Life

Under conditions consistent with the Storage Conditions, the shelf life of the product is 2 years.

Basic UDI-DI number

NUMEN™ Coil Embolization System Basic UDI-Device Identifier Number: 69586980T0040TL.

Legal Statement

MicroPort NeuroTech (Shanghai) Co., Ltd. indicates definitely that the NUMEN™ Coil Embolization System is intended for single use only. MicroPort NeuroTech (Shanghai) Co., Ltd. will not to 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.

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 purpose, 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/Manufacturing Site

Company Name: MicroPort NeuroTech (Shanghai) Co., Ltd.
Address: Building #16, 222 Guangdan Road, Pudong New District, 201318 Shanghai, China
Manufacturing site: Building #16, 222 Guangdan Road, Pudong New District, 201318 Shanghai, China
E-mail: Complaints-NeuroTech@microport.com

After-sales Service Company Information

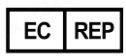
Company Name: MicroPort NeuroTech (Shanghai) Co., Ltd.
Address: Building #16, 222 Guangdan Road, Pudong New District, 201318 Shanghai, China
Manufacturing site: Building #16, 222 Guangdan Road, Pudong New District, 201318 Shanghai, China
Tel: (86)(21)38954600
Fax:(86)(21)50801305
E-mail: Complaints-NeuroTech@microport.com

European Authorized Representative

MicroPort Medical B.V.
Paasheuvelweg 25
1105BP Amsterdam, 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.

Symbol Glossary

	Date of manufacture		Do not re-use
	Use-by date		Consult instructions for use
	Batch code		Contents 1 Unit
	Catalog number		Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Sterilized using ethylene oxide		Non-pyrogenic
	Do not use if package is damaged		MR Conditional
	Keep away from sunlight		Manufacturer
	Keep dry		Authorized representative in the European Community
	Single sterile barrier system		Do not resterilize
	Caution		Patient identification

Revision Date：2023.12

	Patient information website		Health care centre or doctor
	Date		Unique device identifier
	Medical device		CE Mark

MicroPort NeuroTech

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More information on this device, including a Summary of Safety and Clinical Performance, is available at the websites below: https://www.medneurotech.com/181.html
https://ec.europa.eu/tools/eudamed

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

EC REP

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

CE 0297

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