Mogul SP Micro Catheter

WARNINGS

1. Scope

- The product should only be used by healthcare professionals trained in PTCA/PCI and PTA techniques.
- The product should only be used at hospitals where procedures such as emergency coronary artery bypass surgery can be performed promptly.
  [To prepare for complications that may cause disability or life-threatening serious complications.]

CONTRAINDICATIONS/PROHIBITIONS

1. Instructions for Use

(1) Do not reuse
(2) Do not re-sterilize
(3) Do not use the product in combination with drugs containing organic solvents such as alcohol for disinfection, lipid emulsions, drugs containing lipid emulsions, or oil-based contrast media.
[The product may be damaged.]

2. Indicated Patients

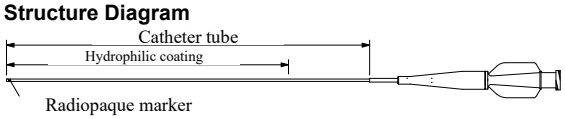
Do not use the product in the following patients.
(1) Patients with serious allergies to drugs required for the procedure, such as contrast media. Patients in conditions so serious that they cannot undergo local anesthesia.
[Life-threatening adverse events may be induced.]
(2) Patients with extremely decreased left ventricular function.
[In compliance with the contraindications for cardiac catheterization.]
(3) Patients with bleeding in the gastrointestinal tract.
[They may experience complications such as nausea and vomiting.]

SHAPE, STRUCTURE, AND PRINCIPLE

1. Configuration

The product consists of a microcatheter body.

2. Structure Diagram



Catheter tube material

- Outer layer: Polyamide, polyurethane
- Inner layer: polytetrafluoroethylene (PTFE)

INTENDED USE OR EFFECTS

The product is used for intravascular diagnosis/treatment to inject contrast media, drugs, and embolic material used in embolization procedures into the target site in the coronary artery and peripheral blood vessels in the abdomen and extremities (excluding cerebrovascular vessels and carotid arteries).
The product is also used to secure a passage for the guidewire and support the passage of the guidewire when performing percutaneous transluminal angioplasty, including percutaneous transluminal coronary angioplasty, in patients with a stenotic lesion in the coronary artery and other blood vessels, where it is difficult to pass the guidewire through (excluding intracranial stenotic and carotid stenotic lesions).

Performance

○ Tensile strength
- Flexible tip
  Basic Type=3N Thinner Type=1N
- Catheter tube
  Basic Type=5N Thinner Type=5N
- Connector joint
  Basic Type=5N Thinner Type=5N

○ Maximum pressure resistance
3447 kPa (500 PSI)
○ Applicable guidewire diameter
0.36 mm (0.014 inch)
○ Coating
Resistance value ≤ 50 gf

USAGE, ETC.

1. Instructions for Use

Preparation

(1) When removing the product from the sterilized packaging, remove it with its protective case en bloc.
(2) Flush the inside of the protective case with heparinized saline from the tip of the protective case using a syringe, etc.
(3) Remove the product from the protective case.
(4) Flush the lumen of the product with heparinized saline using a syringe, etc.
(5) Carefully insert an appropriate guidewire into this product.

Insertion

(1) Insert a guiding catheter appropriate for the product into the target site using the percutaneous introduction method selected. Attach the Y-connector to the connector of the guiding catheter and continue flushing with heparinized saline.
(2) Advance the product along the guidewire to the target site under fluoroscopy.
(3) Once the product has reached the target vascular site, completely remove the guidewire from the product and perform the intended diagnosis and treatment.

Removal

(1) Upon completion of the procedure, insert the guidewire and carefully remove the product.

2. Precautions for Use, etc.

(1) Before use, ensure that the product has no damage or other abnormalities. If the packaging material is damaged or contaminated, or if any abnormality, such as damage, is found in the product, do not use it but replace it with a new product.
[The product may be damaged or broken.]
(2) If resistance is felt when removing the product from the protective case, do not pull it forcibly but flush the inside of the protective case again with heparinized saline.
[The product may become inoperable, damaged, or broken.]
(3) The surface of the product has a hydrophilic coating; it should always be kept moist with heparinized saline.
[The product may become inoperable, damaged, or broken.]
(4) Do not hit the connector excessively during air venting.
[The connector may be damaged.]
(5) Do not perform processing such as opening side holes.
[Such processing may cause unexpected accidents, such as damage to the product.]
(6) Keep the guiding catheter and the inside of the product flushed with heparinized saline.
[Residual contrast media or coagulated blood may impair lubricity.]
(7) Perform intravascular manipulations carefully under high-resolution fluoroscopy.
(8) If any resistance is felt during use, suspend the procedure and identify the cause.
If the cause cannot be identified, remove the product and the guidewire en bloc.
[They may have kinking, bending, or other abnormalities. If the operation is continued forcibly, blood vessels or the product may be damaged.]
(9) If kinking, bending, or other abnormalities are found, immediately suspend the procedure and replace the product with a new one.
[The lumen of this product may become too narrow to insert devices such as a guidewire.]
(10) When operating the product, do not apply excessive local bending.
[Such bending may damage blood vessels or the product.]
(11) Do not abruptly advance the product.
[The blood vessel may be damaged.]
(12) Do not rotate the product.
[The product may be damaged/ruptured.]
(13) Carefully insert/remove the product into/from the stent strut. If any resistance is felt, immediately discontinue use and remove the product and the guidewire en bloc.
[Such bending may damage blood vessels or the product.]
(14) Before injecting a contrast medium, drug, etc., ensure that the product has no nodule formation, kinking, bending, obstruction, or other abnormalities.
[If the product is used with such abnormalities for injection, it may be damaged even when used below the maximum pressure

resistance.]

(15) When injecting a contrast medium, agent, etc., check that it outflows from the tip. If no outflow is observed, the product may have abnormalities such as kinking and bending. Immediately discontinue injection and replace it with a new product.
Do not perform opening operations using pressurization or a guidewire.
[The product may be damaged or broken.]

(16) If any abnormality, such as leakage and clogging, is observed during use, discontinue using the product and replace it with a new one.

(17) Do not force in an embolic material such as a coil when increased resistance is felt while inserting it.
[Forcibly inserting it may cause damage.]

(18) When using a parent catheter with an infusion stopcock, never operate the stopcock while inserting the product.
[The product or guidewire may be damaged.]

(19) If any resistance is felt when removing the guidewire, do not remove the guidewire but pull the product back to a position where the resistance is reduced.
[Forcible removal may damage the product.]

(20) If resistance is felt when removing the product, do not try to pull it out forcibly; pull it out carefully.
[Forceful removal may cause the product to be severed and remain in the blood vessel.]

(21) When disposing of the product, treat it as medical waste and take measures to prevent the spread of infection.
[Incorrect disposal may lead to infection.]

PRECAUTIONS

1. Important Precautions

- For the procedure, anticoagulant or antiplatelet therapy appropriate for the patient's condition should be performed.
- Do not use the product in areas other than coronary arteries and peripheral blood vessels in the abdomen and extremities.
  [Safety for use outside the specifications for the dedicated design has not been confirmed.]
- When injecting a drug or contrast medium into the product, be sure to use it under the maximum pressure resistance (indicated on the label).
  [Injection exceeding the maximum pressure resistance may cause damage.]

2. Serious Malfunctions

The following malfunctions may occur with the use of the product.

- Kinking or breaking of the catheter shaft
- Breaking of the catheter shaft
- Rupturing of the catheter shaft
- Difficulty in removing the catheter and guidewire
- Poor maneuverability or inability to manipulate the guidewire
- Damage to the connector
- Difficulty in injecting drugs and contrast media

3. Serious Adverse Events

The following adverse events may occur with the use of the product. However, adverse events are not limited to those listed below.

- Bleeding/hematoma
- Infection
- Unstable angina pectoris
- Coronary embolism/occlusion
- Aortic dissection
- Air embolism
- Coronary artery spasm
- Hypotension (severe hypotension)
- Pseudoaneurysm
- Arterial embolism/occlusion
- Vascular dissection
- Acute myocardial infarction
- Bleeding complication
- Peripheral embolism
- Myocardial ischemia
- Renal failure
- Cerebral infarction
- Arrhythmia
- Puncture site hemorrhage
- Endovascular thrombosis
- Arteriovenous fistula
- Vascular injury
- Device partially remaining in blood vessels due to device damage
- Allergic reaction to contrast media

4. Use during Pregnancy, Delivery or Lactation and Pediatric Use

For the use of the product in pregnant or possibly pregnant patients, the influence of X-ray on fetus should be considered.

STORAGE METHOD AND SHELF LIFE

1. Precautions for Storage

- Store the product, avoiding high temperature, high humidity, direct sunlight, and wetting.
- Store the product in a safe and stable environment, avoiding tilting, vibration, and shock (including during transportation).

2. Expiration Date

See the expiration date section on the package label (based on self-certification).

3. Sterilization Method

The product is sterilized by exposure to ethylene oxide gas (EtO) and is not intended for re-sterilization.

MANUFACTURING SITE

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SYMBOLS

	Catalogue Number
	Batch code
	Use-by date
	Date of manufacture
	See instructions for use
	Sterilized using ethylene oxide
	Do not resterilize
	Do not re-use
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Manufacturer

15th May , 2024 / Rev.1 / GM118 / L03820001X