Shunmei®
Shun Thros

CE 2764

INSTRUCTION FOR USE

Peripheral Microcatheter

CAUTIONS

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

The Microcatheter consists of catheter hub, strain relief, main body, hydrophilic coating and radiopaque markers.

The catheter tube gradually softens from the proximal end to the distal end. When the proximal end is sufficiently supported, the tapered tip can open the blocked blood vessel, thereby assisting the guide wire to pass through the complicated or calcified blood vessel. The radiopaque markers at the distal end significantly facilitate fluoroscopic visualization. The outer surface of the Microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the Microcatheter hub is used for the attachment of accessories. A shaping mandrel is also included while a syringe and a Y hemostasis valve are optional.

For Microcatheter Kit, it contains a shaping mandrel, a syringe, a Y hemostasis valve and a guidewire.

Table1. Compatibility information

Interface compatibility between the microcatheter and any accessory devices should be carefully considered before use. Consult table below.

Microcatheter OD distal/proximal	Guiding Catheter Min. ID	Guidewire Max. OD
2.2F/2.9F	1.05mm (0.041in)	0.41mm (0.016in)
2.6F/2.9F	1.05mm (0.041in)	0.46mm (0.018in)

Note: In the case of a microcatheter kit, it is recommended to use the guidewire provided.

CONTENTS

Microcatheter Non-kit:

1- Microcatheter

1- Shaping mandrel

1- Syringe(optional)

1- Y hemostasis valve(optional)

Microcatheter Kit:

1- Microcatheter

1- Shaping mandrel

1- Syringe

1- Y hemostasis valve

1- Guidewire

Note: Microcatheter length, OD, ID, models, information of compatible devices and configurations, etc are indicated on the product label.

INTENDED USE

The Microcatheter is intended to provide support to facilitate the placement of guidewires in the peripheral vasculatures, and is also intended to assist in the delivery of contrast media into the peripheral vasculatures.

CONTRAINDICATIONS

Generally, angiography or intervascular therapy is contraindicated for, but not limited to, the patients listed below.

- Patients in the acute phase of myocardial infarction
- Patients with serious arrhythmia
- Patients with serious serum electrolyte imbalance
- Patients who in prior procedures have developed an adverse reaction to the injection of contrast media
- Patients with renal dysfunction
- Patients with coagulopathy or those whose blood has suffered a serious change in coagulation capability for some reasons
- Patients who cannot lie on their back on the operating table because of congestive heart failure or some respiratory disorder
- Patients with mental disease or those who are not expected to lie quietly during angiography
- Patients who are or could be pregnant.(The fetus may be affected by X-rays under fluoroscopy.)
- Any other patients who are judged unsuitable for the procedure by the physician.

WARNINGS

Carefully read and observe all Warnings. Failure to do so may result in life-threatening events in the worst case.

– The device is not intended for use in the coronary vasculature or the neurovasculature.

– Do not modify this product for any reason. Use of a modified product may occur damage to blood vessels and/or accidents.

– When using a Y-connector, excessive tightening to the product with the hemostasis valve and operation with a tightened Y-connector must be avoided. (The device may be damaged.)

– If any resistance or something abnormal is felt in the vessel, do not advance or withdraw the microcatheter system until the cause of resistance is determined through a high resolution fluoroscope and a digital subtraction angiography monitor. Manipulating the catheter and/or the guide wire against resistance may result in damaging the vessel, the catheter or the guidewire. If the situation is not solved, withdraw the entire system of the catheter or the guide wire with the guiding catheter. (Continuing the operation while the cause of the problem is not identified may cause damage to or separation of the catheter or the guidewire, and damage the blood vessel. In the worst case, life-threatening adverse events may occur.)

– The device must always be operated under high-resolution fluoroscopic guidance. Particular attention should be paid when inserting or withdrawing the device into stenotic areas, stent struts, and narrower vessels than the product. (Abrasion may result in damage or separation of the device. This may cause vascular injury and perforation, possibly leading to a life-threatening adverse event.)

– Do not insert the guidewire by force or advance it rapidly when the microcatheter is bent or twisted. Such manipulations may cause breakage or damage of the microcatheter, or perforation of the blood vessel.

– Always advance the guidewire ahead of the microcatheter before attempting any manipulation of the microcatheter. (If the guidewire is not advanced ahead of the microcatheter, the blood vessel may be damaged or perforated, or the microcatheter may be damaged.)

– Always hold the connector with one hand and turn the catheter carefully while regularly releasing the accumulated torsion of the catheter. Never turn the catheter continuously while holding the connector with both hands or use any other means to apply force. When releasing the accumulated torsion, be sure to open the hemostatic valve on the Y-connector. Do not turn the catheter in the same direction, either clockwise or counterclockwise, for more than 10 consecutive turns. If resistance is felt while turning the catheter, do not proceed with further rotation even if the 10 turn limit has not been reached. Identify the cause of resistance under fluoroscopy, and take an appropriate action. Never continue the operation without identifying the cause. (Continuing rotation may damage or break the catheter or damage the blood vessels. In the worst case, life-threatening adverse events may occur.)

– This microcatheter is coated with hydrophilic coating. Therefore, the microcatheter is highly lubricious. Always confirm the position of the distal end of this microcatheter by fluoroscopy and manipulate this microcatheter carefully.

– Do not use a power injector to infuse contrast media when the microcatheter is bent or occluded. It may cause damage to the microcatheter such as expansion or breakage.

– Infusion pressure must not exceed nominal pressure indicated on the label(the maximum infusion pressure). Infusion pressure in excess of the maximum may result in microcatheter rupture, possibly resulting in patient injury.

– When infusing contrast media, the device must be operated under high-resolution fluoroscopic guidance, with confirming that the contrast media is being infused from the tip of the device. If the contrast media is not being infused, infusion must be stopped and the device must be replaced with a new one.（If the device lumen is occluded, the device may be dilated, damaged, or ruptured even at not more than the maximum injection pressure (nominal pressure), resulting in a life-threatening adverse event due to spurting contrast media.）

– Do not use guidewires larger than the recommended size. (Resistance may be felt while advancing or withdrawing a guidewire larger than the recommended size, which may cause the catheter to become damaged or break, or the blood vessel to become damaged. In the worst case, life-threatening adverse events may occur.)

– Do not wipe the surface of the microcatheter with gauze or absorbent cotton soaked with alcohols, gluconic acid chlorhexidine aqueous solution, or similar solutions. Otherwise, it may significantly deteriorate the lubricity of the surface of the microcatheter.

– The patient may suffer from subacute thrombosis, vascular complications, or bleeding complications by using this microcatheter. Therefore, it should be well examined if the intervention procedure will be applicable for the patient.

– Repeated insertion and withdrawal of the device may lead to deterioration of the hydrophilic coating. (Continuous use of the device with deteriorated hydrophilic coating may cause vascular damage. This may also increase the risk of trapped tip, resulting in a life-threatening adverse event due to a damage and/or separation of tip.)

– When using many embolic materials, it is recommended to change the microcatheters each time.

– Comply with instructions, precautions, and warnings described in the Instructions for Use supplied with medical devices (Namely, introducer sets, Angiographic catheter, Guiding catheter, Guidewire, Power injector, etc.) that may be used together with the microcatheter.

PRECAUTIONS

– This product is intended for single use only. Do not resterilize and/or reuse.

– Prior to use, carefully examine the unit to verify the sterile package has not been damaged in the shipment. Do not use the product if the package is opened or damaged.

– Prior to use, carefully check all devices to be used for the procedure, including this product, and confirm that their normal function and integrity. Do not use if the product is suspected to be damaged.

– Use by the expiration date indicated on the label of the product package.

– Use immediately after opening the package. After use, discard it as medical waste respecting the disposal policies and infection controls.

– This product must be used under fluoroscopy only by a physician thoroughly trained in percutaneous and intravascular techniques and procedures.

– When inserting the guidewire into the microcatheter which is already placed in the blood vessel, carefully operate the guidewire not to damage the microcatheter at the bend sections.

– Confirm that this microcatheter does not have a kink, knot, torsion, or occlusion before injecting contrast media or other agents. The injection pressure must not exceed the nominal pressure depicted in Label.

– Use the extension tube when contrast media is injected by using power injector.

– Do not use this product for the purposes other than described in the Indications for Use written in this document.

– Select the appropriate size of guiding catheter to use in combination with this microcatheter.

– Do not manipulate the stopcock of the guiding catheter when the microcatheter is inserted in the guiding catheter fitted with a stopcock. It may cause damage of the microcatheter or the guidewire.

– Operate the microcatheter carefully to avoid damage, kinking, or bending, especially when inserting this microcatheter into the guiding catheter.

– Check the patient's condition before the procedure. Provide appropriate anticoagulant therapy if it is necessary.

– Manipulate the microcatheter in the blood vessel very carefully by observing it through a high-definition X-ray fluoroscopy monitor screen. If any resistance is felt, stop the manipulation and identify the cause of the resistance. Continuing the manipulation while the cause of the problem is not identified may cause damage of the blood vessel, or damage or rupture of the microcatheter.

– When infusing contrast media, embolization materials or drugs, read carefully the Instructions for Use provided with such contrast media, etc. and comply with instructions, precautions, and warnings to determine compatibility and prevent the microcatheter system damage.

– Because the microcatheter may be advanced into narrow subselective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal.

– The surface of this microcatheter is coated with hydrophilic polymer. Flush the surface and the lumen of the microcatheter continuously with heparinized and sterilized saline during its use to maintain lubricity.

– Do not expose the surface of the microcatheter and the guidewire to alcohols, gluconic acid chlorhexidine aqueous solution, or the like to avoid damage of the hydrophilic polymer coating.

– When inserting or exchanging the microcatheter, flush the lumen of the guiding catheter and the microcatheter system continuously with heparinized and sterilized saline.

– Flush the lumen of the microcatheter sufficiently with heparinized and sterilized saline especially after injecting contrast media.

– Discontinue injection if irregular resistance is felt at the syringe. The microcatheter may be bent or blocked. Excessive pressure may cause expansion and/or rupture of the microcatheter.

– Extensive guidewire manipulation during lengthy procedures and the use of embolic agents may require the exchange the new microcatheters in place of the used microcatheters.

MALFUNCTION, ADVERSE EFFECTS AND COMPLICATIONS

Malfunctions and adverse events may occur from improper use of the product. A serious adverse event may lead to a severe complication or death. Prevent such malfunctions and adverse events from occurring by carefully reading this document and complying with the directions contained in it.

1) Malfunction

If the microcatheter is exposed to excessive force, following malfunctions may occur. Comply with precautions for use described in the above and carefully operate this microcatheter.

- Bend
- Sharp bend
- Torsion
- Separation
- Removal difficulty
- Damage of hydrophilic coating
- Insertion difficulty
- Trap with guidewire

2) Adverse events/Complications

If the complication occurs, appropriate treatment should be performed at the discretion of the physician. Detailed treatment for recovery should be confirmed by the physician in advance.

Possible adverse events/complications include, but are not limited to :

- Bleeding complications
- Ischemic complications
- Peripheral vessel ischemia
- Vasospasm
- Infection or complications at the puncture site
- Allergic reaction
- AV fistula
- Hypotension/Hypertension
- Peripheral arterial embolism (air, tissue, thrombotic) ;
- Peripheral circulatory disorder
- Vessel trauma, such as dissection, perforation, rupture
- Inflammation with embolic material
- Dissecting aneurysm, false aneurysm
- Formation of Hematoma at femoral region/formation of other hematoma

INSTRUCTIONS FOR USE

A. Instructions for use for Microcatheter

1) Take out the holder tube containing the microcatheter from the sterile package.

2) Inject the heparinized and sterilized saline into the holder tube through the flush connector by using a

syringe. Ensure the ejection of heparinized and sterilized saline from distal end of the holder tube to make sure the holder tube is filled with heparized and sterilized saline.

3) Insert a compatible guidewire*(The max. OD of a compatible guidewire is indicated on the label of product package, but in the case of a Microcatheter Kit, use the guidewire provided in the package content.)* through the connector and bring the tip of the guidewire in line with the tip of this microcatheter.

Caution: If the guidewire is inserted through the tip of this microcatheter, care should be taken not to cause any damage to the microcatheter. Also, if the microcatheter is bent or kinked, discontinue its use. If the microcatheter is kinked it may cause severe damage to the patient.

4) Loosen the hemostatic valve of the hemostatic adaptor connected to the guiding catheter and insert this microcatheter.

Caution: Ensure that the hemostatic valve of the hemostatic adaptor is already loosened. A tight hemostatic valve causes resistance during insertion of this microcatheter and may damage the microcatheter.

5) Advance this microcatheter under fluoroscopy until it reaches 2 to 3 cm proximal of the tip of the guiding catheter.

6) Advance this microcatheter under fluoroscopy until it is close to the stenotic area. Advance the guidewire carefully until it passes the target area. Continue advancing the guidewire as distal as possible into the blood vessel, and once it is placed there, check the position by imaging from the guiding catheter. The position of the guidewire must be checked by imaging from multiple angles to confirm that the guidewire is definitely inserted into the target blood vessel.

7) After loosening the hemostatic adaptor, hold the guidewire and guiding catheter firmly. Then advance this microcatheter gradually along the guidewire until the tip has passed through the stenotic area, using the radiopaque markers on the tip of this microcatheter as a guide.

Caution: Procedures inside the blood vessel should be conducted with care, because this microcatheter is hydrophilic coated.

8) When removing this microcatheter, loosen the hemostatic valve of the hemostatic adaptor. Remove this microcatheter while keeping the guidewire stable in the blood vessel. (When this microcatheter is removed, check the position of the guidewire under fluoroscopy. Also, if any resistance is felt during the removal of this microcatheter, remove all devices including the parent microcatheter and the guidewire.) After removal of this microcatheter, tighten the hemostatic valve of the hemostatic adaptor.

B. Instructions for use for Shaping mandrel

If desired, the tip of the Microcatheter may be steam shaped using the shaping mandrel provided.

1) Insert the shaping mandrel into the distal lumen of the Microcatheter and gently shape to the desired angle.

2) Hold Microcatheter tip/shaping mandrel assembly approximately 25.4mm(1 inch) or no closer than 25.4mm(1 inch) from a steam source for approximately 30 seconds to form shape(Fig. 1). Multiple shaping is not recommended.

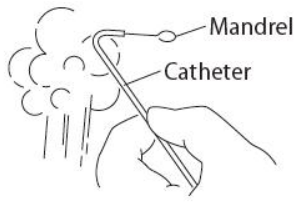


Fig. 1

3) Immediately place Microcatheter tip/shaping mandrel assembly into heparinized saline to set the shape.

4) Carefully remove shaping mandrel from Microcatheter and discard.

Warning:

• Do not rub or bend the catheter tip with too small radius, pinch by forceps or tweezers, which may result in the damage of the surface coating, collapse of the catheter shaft and/or deformation of catheter.

• Positioning the catheter tip closer than 2 cm from the steam source may result in the damage of the surface coating or the tip of the catheter.

• Excessively re-shaping the catheter may damage the surface coating or the tip of the catheter.

• When shaping with steam, take care not to burn yourself.

• Shaping mandrel is not intended for use inside the body. Do not insert the enclosed shaping mandrel into the patient's body.

• Do not stretch the catheter tip tightly or bend excessively when shaping it not with enclosed shaping mandrel but with your fingers. It may result in collapse of the catheter shaft and/or deformation of the catheter.

• When removing the shaping mandrel, support the distal end of the Microcatheter with the fingers and slowly pull out the shaping mandrel.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages and intended for single use only. Sterile if package is unopened or undamaged.

STORAGE

- Store the product under controlled room temperature and in a clean, dry and dark place to avoid extended exposure to water, sunlight, extreme temperatures and high humidity. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.
- Storage environment should be rat-proof and moth-proof in order to keep the integrity of package.
- Keep it from contacting corrosion gas.
- Storage temperature: 0 °C to 40 °C, Storage humidity: ≤ 80%

PRODUCT IDENTIFICATION AND MODEL

- Product identification: See label information,include product name, pattern of Microcatheter tip shape.
- Model:

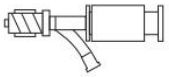
Microcatheter	Models	Catheter OD distal/proximal	Models	Microcatheter	Models

Shun Thros 2.2F	MCS105-22S	Shun Thros 2.6F	MCS105-26S	Shun Thros 2.6F	MCK15026S-18200S-3
	MCS125-22S		MCS125-26S		
	MCS150-22S		MCS150-26S		
	MCS105-22A		MCS105-26A		MCK15026S-18200S-6
	MCS125-22A		MCS125-26A		
	MCS150-22A		MCS150-26A		
	MCS105-22SA		MCS105-26SA		MCK15026S-18300S-3
	MCS125-22SA		MCS125-26SA		
	MCS150-22SA		MCS150-26SA		
	MCS105-22AA		MCS105-26AA		MCK15026S-18300S-6
	MCS125-22AA		MCS125-26AA		
	MCS150-22AA		MCS150-26AA		

Note: Models that contain the letters MCK are kits.

DIFINITIONS

	**Caution**		**Keep dry**
	**Batch code**		**Do not use if package is damaged.**
	**Do not re-sterilize**		**Do not re-use**
	**Use by date**		**Date of manufacture**
	**Sterilized by ethylene oxide**		**Consult instructions for use**
	**Catalogue number**		**Keep away from sunlight**
	**Manufacturer**		**Authorized representative of European Community**
	**Inner diameter of Microcatheter**		**The nominal pressure of Microcatheter**
	**The minimum inner diameter of Guiding catheter**		**Shaping mandrel**
	**Contents in preliminary package**		**Syringe**

	**Unit**		**Y Hemostasis valve**
	**Temperature limit**		**Non-pyrogenic**
	**CE Marking**	2764	**Notified Body ID number**
	Guidewire		**Fragile item**

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