Shunmei®
Driver

CE 2764

INSTRUCTION FOR USE

Coronary 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 marker. The semi-rigid proximal section transitions to a flexible and soft distal tip to facilitate superselective access of the Microcatheter into the distal vessel and crossing of complex lesions. Stainless steel mid-layer braid construction provides guidewire support for improved pushability. The radiopaque marker at the distal end significantly facilitates 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.

Table 1. 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
1.8F/2.6F	1.05mm(0.041in)	0.36mm (0.014in)
2.6F/2.8F	1.05mm(0.041in)	0.36mm (0.014in)

CONTENT

1- Microcatheter
1- Shaping mandrel
1- Syringe (optional)
1- Y hemostasis valve (optional)

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

INTENDED USE

The product is intended to be percutaneously introduced into blood vessels and support a guide wire in crossing the localized stenotic lesion of the coronary artery while performing PCI (percutaneous coronary intervention) in case the guide wire can hardly cross the lesion, and can be used to exchange one guide wire for another. The product is also intended for injection of radiopaque contrast media for the purpose of angiography.

CONTRAINDICATIONS

• Patients who had previous coronary artery spasm due to possibility of acute coronary occlusion.
• Pregnancy or suspected pregnancy. X-ray could damage fetus.
• Patients in whom CABG(coronary artery bypass graft) is not applicable. Emergent CABG is

required in case of acute ischemic complications.

COMPLICATIONS

Possible complications of PCl include, but are not limited to the following:

• Acute myocardial infarction • Hypotension • Total occlusion of coronary artery • Infection and complications at the puncture site • Coronary artery dissection, perforation, rupture and injury •Coronary artery spasm •Bleeding complications •Arteriovenous fistula• Myocardial ischemia •Bradycardia and palpitation •Unstable angina pectoris •Femoral pseudoaneurysm, aneurysm formation •Arrhythmia inclusive ventricular fibrillation• Coronary embolization, thrombus and occlusion •Allergies to medications• Cerebrovascular disorder • Distal embolization (air, tissue and thrombus)

WARNINGS

• Before surgery, it is necessary to confirm that all devices used in the surgery are in normal condition.

• Carefully handle the product under high resolution fluoroscopy. If any resistance is felt while handling the product, immediately stop the manipulation and find out cause of the resistance in order to avoid damage to blood vessels and separation or breakage of the product.

• Before inserting / withdrawing the product, clean the surface of the guide wire with gauze moistened with saline solution. Advancing / withdrawing the product over a guide wire with residual blood on its surface or a guide wire which is not fully wet may result in separation or breakage of the product.

• Do not torque the product excessively while the distal part of the product crosses the stenosis or is in the stent.

• Take extra care when inserting/withdrawing the product through an opening of the stent struts in order to avoid damage to the product. A scratch by the stent struts may result in separation or breakage of the product.

• Take extra care when exchanging the guide wires leaving the product in the arteries. Carefully insert a guide wire into the product. If any resistance is felt, stop the manipulation and remove the product together with the guide wire in order to avoid separation or breakage of the product.

• Perform appropriate anticoagulant or antiplatelet therapy according to the patient's condition in order to avoid complications, such as thrombotic embolization.

PRECAUTIONS

• This product has been sterilized by ethylene oxide gas. For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.

• Do not apply agents containing organic solvents or oleaginous contrast media in order to avoid breakage of the product.

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

• Do not use the product for lesions in the left main trunk for which no compensation of blood flow by bypass or collateral circulation is available in order to avoid acute coronary occlusion.

• The product must be used by physicians who are well trained in PCI procedures.

• Do not use the product at institutions where an emergent CABG can not be performed in case of severe complications.
• Do not torque the product excessively if it is bent in order to avoid separation or breakage of the product. When the microcatheter is kinked, stop the manipulation immediately.
• Do not soak the product in agents containing organic solvents, such as alcohol for disinfection.Do not clean the product with such agents. Failure to observe this precaution could damage or break the product or cause loss of lubricity.
• The entire procedure must be carried out aseptically.
• Sterile and non-pyrogenic in an unopened and undamaged unit package. Do not use if the unit package or the product have been damaged or soiled.
• The product should be used immediately after opening the package and be disposed of safely and properly after use.
• Do not use a power injector for the purpose of injection of contrast media.
• 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.

DIRECTIONS FOR USE

A. Instructions for use for Microcatheter

1. Preparation

1-1 Carefully remove the product in its holder tube from the package.

1-2 Soak the product in the holder tube in a heparinized saline solution bath.

1-3 Fill the holder with heparinized saline solution through the hub of the holder using a syringe, to thoroughly wet the surface of the product.

Caution: The heparinized saline solution should be injected slowly into the holder so that the product is not driven out of its holder.

1-4 Carefully take the product out of the holder.

Caution: Do not bend the product at the edge of the holder. The product may break or separate.

2. Insertion of the product

2-1 Prime the product with heparinized saline solution through the catheter hub in order to remove air inside.

2-2 Insert a guide wire (O.D. 0.014" (0.36 mm) or smaller) into the catheter hub and advance tip of the wire to the end of the catheter.

Caution: Take care not to damage the product, when a guide wire is inserted from its distal end.

2-3 Open the hemostasis valve of the Y connector attached to the guiding catheter and insert the product into the valve.

Caution: Make sure that the hemostasis valve is open enough for insertion of the product. If not, the valve may cause resistance.

2-4 Advance the distal end of the product to 2-3cm proximal to the end of the guiding catheter under high resolution fluoroscopy.

Caution: Carefully insert the product into the guiding catheter with other devices in it. The other devices may be forced into the guiding catheter, which may result in damaging blood vessels.

2-5 Advance the guide wire into the target coronary artery and place the distal tip of the wire to the

extreme periphery of the coronary artery under high resolution fluoroscopy. Inject a radiopaque dye in order to make sure that the guide wire crosses the stenosis. Perform the angiogram from multiple angles in order to make sure that the guide wire is placed at the target vessel.

2-6 Securely fix position of the guide wire and the guiding catheter and slowly advance the distal end of the product bit at a time over the guide wire until the radiopaque marker crosses the stenosis.

Caution:

▪ Carefully handle the product inside coronary arteries because of its hydrophilic coating.

▪ Do not insert the product into small vessels, which have smaller inner diameter than outer diameter of the product.

▪ The product can be inserted into severely tortuous vessels but only at the physician's discretion.

▪ Do not torque the product if it is or seems stuck in order to avoid separation or breakage of the product.

2-7 In case injection of contrast media is required, withdraw the guide wire and inject the contrast media from the catheter hub with a syringe.

Caution: Slowly inject a small amount of contrast media and observe the flow from the distal end of the product to ensure the lumen is maintained. When the product is occluded, it may result in deformation or damage of the product.

3. Removal of the product

3-1 Open the hemostasis valve.

3-2 Withdraw the product along the guide wire leaving the guide wire inside the vessel.

3-3 Close the hemostasis valve after removing the product.

Caution:

▪ Confirm position of the guide wire under fluoroscopy when the product is removed.

▪ Remove the product, the guide wire and the guiding catheter altogether if any resistance is felt while withdrawing the product.

▪ Rinse residual blood on the surface of the product in a heparinized saline solution bath.When it is difficult to remove the residual blood, carefully wipe the surface with gauze moistened with heparinized saline solution. Flush the inner lumen of the product in order to remove residual blood inside the lumen.

▪ Carefully handle the product not to kink it. If it gets kinked, stop using it. Using the kinked product may result in separation or breakage of the product.

▪ Take care when re-inserting an angled guide wire into the product which remains in the coronary artery. Just before the tip of the guide wire protrudes from the tip of the product, stop advancing the guide wire and carefully withdraw the product so that the tip of the guide wire gradually protrudes from the product under high resolution fluoroscopy.The tip of the guide wire may spring out of the tip of the product, which may result in damage to blood vessels.

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.

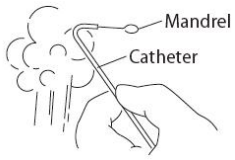

Fig. 1

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℃ to 40℃, Storage humidity: ≤ 80%

PRODUCT IDENTIFICATION AND MODEL

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

- Model:

Microcatheter	Models	Microcatheter	Models
Driver 1.8F	MCS130-18S	Driver 2.6F	MCS125-26SX
	MCS150-18S		MCS150-26SX
	MCS130-18SA		MCS125-26SAX
	MCS150-18SA		MCS150-26SAX

DIFINITIONS

	Caution		**Keep dry**
LOT	**Batch code**		**Do not use if package is damaged.**
	Do not re-sterilize		**Do not re-use**
	Use by date		**Date of manufacture**
STERILE EO	**Sterilized by ethylene oxide**		**Consult instructions for use**
REF	**Catalogue number**		**Keep away from sunlight**
	Manufacturer	EC REP	**Authorized representative of European Community**
	Inner diameter of Microcatheter		**The nominal pressure of Microcatheter**
GC	**The minimum inner diameter of Guiding catheter**		**Shaping mandrel**
Contents	**Contents in preliminary package**		**Syringe**
1	**Unit**		**Y Hemostasis valve**
40℃ 0℃	**Temperature limit**		**Non-pyrogenic**
CE	**CE Marking**	2764	**Notified Body ID number**

	Guidewire		**Fragile item**

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