

INSTRUCTION FOR USE

Neural 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 is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end 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.

Table 1. Compatibility information

Interface compatibility between the microcatheter and any accessory devices, or diagnostic, therapeutic agents should be carefully considered before use. Consult table below.

Microcatheter Name	Microcatheter OD distal/proximal	Guiding Catheter Min. ID	Guidewire Max. OD	Coil Max. Size
Shun Captain 1.7	1.7F/2.4F	1.42mm (0.056in)	0.014in. (0.36mm)	≤ 0.014in. (0.36mm)
Shun Captain 2.0	2.0F/2.5F	1.42mm (0.056in)	0.018in. (0.46mm)	≤ 0.018in. (0.46mm)
Shun Captain 2.6	2.6F/3.1F	1.42mm (0.056in)	0.018in. (0.46mm)	≤ 0.018in. (0.46mm)

The Microcatheter is also compatible for use with dimethyl sulfoxide (DMSO).

CONTENTS

- 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 Microcatheter is intended for use in the neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.

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.

COMPLICATIONS

Potential complications include, but are not limited to:

vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudoaneurysm, seizure, stroke, infection, vessel dissection, thrombus formation, and death.

WARNINGS

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

- The Microcatheter is not intended for use in the coronary vasculature or the peripheral vasculature.
- The Microcatheter should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.
- The Microcatheter is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if the packaging is breached or damaged.
- The Microcatheter is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose device in accordance with hospital and/or local government policy.
- Inspect the Microcatheter prior to use for any irregularities or damage and discard if any inconsistencies are observed.

- The Microcatheter should be advanced or manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
- Infusion pressure should not exceed 300 psi to avoid potential rupture of the Microcatheter.
- Shaping mandrel is not intended for use inside the body. Ensure shaping mandrel is removed from Microcatheter prior to introduction into the hemostasis valve or other accessories.

PRECAUTIONS

- Verify Microcatheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- The Microcatheter has a lubricious surface and should be hydrated prior to use.
- Exercise care in handling the Microcatheter to reduce the chance of accidental damage.
- Verify that the diameter of any guidewire or accessory device that is used is compatible with the inner diameter of the Microcatheter prior to use.
- To reduce the risk of damage or separation of the device, avoid repeated bending at the same point of the Microcatheter.
- Take precaution when manipulating the Microcatheter in tortuous vasculature to avoid damage to the Microcatheter. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

PREPARATION FOR USE

Before removing the Microcatheter, fully hydrate the hydrophilic segment of the device by flushing heparinized saline through the dispenser tube using a syringe attached to the dispenser tube hub.

To remove the Microcatheter from the dispenser tube, gently pull the hub out from the dispenser tube. Remove the Microcatheter by pulling it from the dispenser tube. If resistance is met, repeat the flushing procedure until the Microcatheter is well hydrated and can be easily removed from the dispenser tube. Inspect the Microcatheter thoroughly to ensure it is not damaged. Do not allow Microcatheter to dry prior to introduction into the guiding catheter.

Steam Shaping

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.

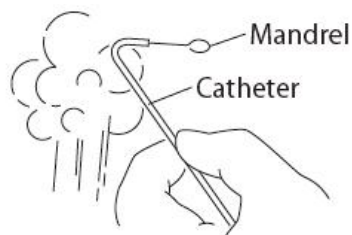


Fig. 1

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.

DIRECTIONS FOR USE

1. Prior to use, flush the Microcatheter lumen thoroughly with heparinized saline to prime the Microcatheter and provide smooth movement of the guidewire within the Microcatheter. A hemostasis valve may be attached to the Microcatheter hub and used to facilitate the flushing process.
2. Carefully insert the distal section of the guidewire into the Microcatheter hub. A guidewire insertion tool may be used to facilitate insertion of the guidewire distal tip through a hemostasis valve and into the Microcatheter hub. Advance the guidewire until the distal tip is near the distal end of the Microcatheter. Gently tighten the hemostasis valve to maintain position.
3. Slip the torque device over the proximal end of the guidewire to the desired location. Secure the torque device in place by tightening the rotating knob. The torque device may be repositioned by loosening and retightening the rotating knob.
4. A guiding catheter is placed into the appropriate vessel and the Microcatheter/guidewire assembly is then advanced through the guiding catheter to the target vessel or vascular lesion. Set up a continuous flush of heparinized

saline by connecting hemostasis valves with pressurized flush solution lines to the hub of the guiding catheter and Microcatheter.

5. Loosen the guiding catheter hemostasis valve and introduce the Microcatheter/guidewire into the guiding catheter using the introducer sheath. Carefully advance the Microcatheter/guidewire to the guiding catheter distal tip. After the Microcatheter/guidewire reaches the tip of the guiding catheter, remove the introducer from the Microcatheter shaft by retracting the introducer from the hemostasis valve and peeling off the introducer. During navigation in the vasculature, advance the guidewire a short distance, then advance the Microcatheter over the guidewire and repeat until the desired site is reached. The proximal portion of the Microcatheter does not have the hydrophilic surface and may encounter resistance when this section is advanced through the hemostasis valve.
6. Once the desired location has been reached, the guidewire is removed from the Microcatheter. The diagnostic or therapeutic agent(s) are then prepared for delivery through the Microcatheter. **Warning:** Do not exceed the maximum recommended infusion pressure of 300 psi.

Microcatheter	Microcatheter ID	Dead Space
Shun Captain 1.7 150cm	0.43mm (0.017in.)	0.41 cc
Shun Captain 2.0 150 cm	0.53mm (0.021in.)	0.49 cc
Shun Captain 2.0 156 cm		0.55 cc
Shun Captain 2.6 150 cm	0.69mm (0.027in.)	0.79 cc
Shun Captain 2.6 156 cm		0.83 cc

Note: The dead space of the catheter will vary due to the manufacturing tolerance, and the dead space described above is for reference only.

7. Between uses, rinse the Microcatheter in a basin of heparinized saline and wipe it gently with sterile, wet gauze and place in a basin of heparinized saline or a flushed dispenser tube to keep the hydrophilic surface wet until use.

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%

MATERIALS

The Microcatheter does not contain latex or PVC materials.















PRODUCT IDENTIFICATION AND MODEL








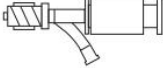



- Product identification: See label information, include product name, dimensions, pattern of Microcatheter tip shape.

- Model:

Microcatheter	Models	
Shun Captain 1.7	MCS150-17S	MCS150-17SA
	MCS150-17A45	MCS150-17A45A
	MCS150-17A90	MCS150-17A90A
	MCS150-17J	MCS150-17JA
Shun Captain 2.0	MCS150-20S	
	MCS156-20S	
	MCS150-20SA	
	MCS156-20SA	
Shun Captain 2.6	MCS150-26SY	
	MCS156-26S	
	MCS150-26SAY	
	MCS156-26SA	

DEFINITIONS

	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



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