Shunmei®

CE 2764

Window

INSTRUCTION FOR USE

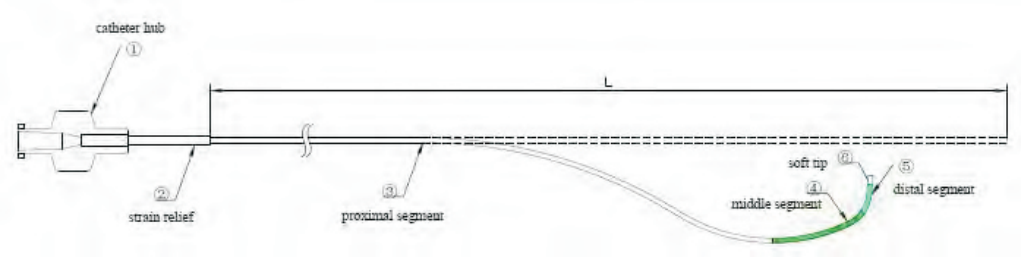
Guiding Catheter

CAUTION

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 Guiding catheter is a sterile, single-use, non-pyrogenic and disposable device that is designed to provide a pathway through which therapeutic and diagnostic devices are introduced. The device consists of catheter hub, strain relief, proximal segment, middle segment, distal segment and soft tip. See figure 1.



1. catheter hub 2.strain relief 3.proximal segment 4.middle segment 5.distal segment 6.soft tip

Figure 1. Structure of Guiding catheter

PACKAGE CONTENTS

1 – Guiding catheter

Note:Catheter length, **diameter**, **models are indicated on the product label**.

INTENDED USE

The Guiding catheter is intended for the purpose of providing a pathway through which therapeutic and diagnostic devices are introduced. The Guiding catheter is intended to be used in the coronary or peripheral vascular system.

CONTRAINDICATIONS

- Patients with an active infection.
- Patients who can't tolerate catheterization.
- Bleeding diathesis (low platelet count, peptic ulcer disease, coagulopathy, etc.)

- Patient noncompliance with procedure and post-PCI instructions and inability to take dual antiplatelet therapy (acetylsalicylic acid [ASA], Plavix, etc.)
- Multiple PCI restenoses
- Pregnancy
- Uncontrolled Hypertension

WARNINGS

- Complications due to the use of this device can cause serious injury or death.
- Manipulate the catheter carefully to avoid the damage of vessels like dissection, perforation and rupture.
- Due to the size of the non-tapered tip, this catheter may occlude smaller vessels. Care must be taken not to completely block flow.
- If resistance is encountered at any time during the withdrawal of the guide wire through the lumen of the Guiding catheter, remember to retrieve the guide wire and Guiding catheter as a whole, in case of damaging the product or vessel walls.
- Be cautious when injecting contrast. Excessive flow can be generated by using little force on the syringe resulting from the catheter's large inner diameter.

PRECAUTIONS

- Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.
- Only physicians who have received appropriate training and are familiar with the principles, clinical applications, side effects and hazards should use this device.
- Do not alter this device.
- Catheter should not be used for long-term applications.
- The device is designed for single use only. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device which could result in patient injury, illness or death. Cleaning, disinfection and resterilization may compromise the essential material and design characteristics of the device leading to device failure.
- Inspect the catheter carefully prior to use to confirm the size, shape and condition of the catheter as suitable for intended procedures.
- The large internal diameter of the catheter permits injection with little force being required on the syringe. Inject slowly whenever attempting to opacify the vessels via this catheter.
- The device is operated under sterile environment.
- Do not use this device if it is out of date.
- Do not use this device if the package is damaged.
- After use, dispose the device according to hospital, administrative or government policies.

POTENTIAL ADVERSE EVENTS

Adverse events or complications associated with the use of the Guiding catheter include, but are not limited to:

- Pain in puncture region
- Vessel or heart dissection, perforation
- Ischemia
- Embolism in the vessel
- Myocardial infraction
- Infection
- Hemorrhage
- Allergic reaction to contrast medium
- Non-fatal MI

COMPLICATIONS

- Stroke
- Death
- Hematoma

HOW SUPPLIED

The Guiding catheter is supplied sterile and non-pyrogenic for single use only.

STORAGE

- Store the Guiding catheter in a clean, cool, dry and dark place to avoid extended exposure to light and moisture.
- 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%

INSTRUCTIONS FOR USE

1. Remove the device from package and ensure the integrity and usability before use.
   Warning:Do not use a guiding catheter that has been damaged in any way. If damage is detected, replace with an undamaged guiding catheter.
2. Flush the Guiding catheter with sterile saline solution. Flush the dilator if it is necessary.
3. Interventional angiography
   1) Puncture blood vessel with an introducer needle. A guide wire used for puncture is then advanced through lumen of the introducer needle, and then the introducer needle is withdrawn.
   2) Introducer sheath with dilator will be passed over the puncture guide wire into vessel, and after that remove the dilator and puncture guide wire.
   3) Guide wire for Angiographic catheter is advanced through the lumen of catheter under to approximately 5cm beyond the catheter's soft tip under the function of hemostasis valve and then guide wire is inserted alone into the artery and Angiographic catheter is advanced into introducer sheath to reach the desired vessel over guide wire with development under the fluoroscopy.
   4) Withdraw the Angiographic guide wire and contrast media are injected for angiography.
   5) After the procedure is completed, draw the catheter back from the site. Insert the guide wire into the catheter until it extends slightly beyond the distal end of the catheter. Carefully remove the catheter and guide wire together.
4. Interventional operation
   1) Through the guide wire, the Guiding catheter is placed into the vascular system, under the X-ray, the position of the catheter tip is located, and the Guiding catheter is pushed to the desired position.
   2) While applying sheathless catheterization, remove the sheath first and leave the guide wire in the vessel, then advance the Guiding catheter and the dilator into the vessel through the guide wire.
   3) Remove the guide wire and the dilator if it is necessary.
   4) Guiding the catheter for other vascular instruments, such as Balloon Dilation catheter, PTCA guide wire, Micro-catheter, Stent and so on, for vascular interventional therapy.
   5) The Guiding catheter should be manipulated only under fluoroscopic observation and address the vascular site selected.

Product identification and Model

- Product identification: See label information,include product name, pattern of Catheter tip shape.
- Model: Tip shape : JL3.5, JL4.0, JL4.5, JL5.0, JR3.5, JR4.0, AL0.75, AL1.0, AL2.0, AR1.0, AR2.0, XB3.0, XB4.0, JL3.0, JL3.5 LT, JL3.5 ST, JL4.0 LT, JL4.0 ST, JL4.5 LT, JL4.5 ST, JL5.0 LT, JL6.0, JCL3.5, JCL4.0, XB3.0 LT, XB3.5, XB3.5 LT, XB4.0 LT, XB4.5, XBC3.0, XBC3.5, XBC3.5 LT, XBC4.0, XBLAD3.0, XBLAD3.5,XBLAD3.5 LT, XBLAD4.0, XBLAD4.5, AL1.0 LT, AL1.0 ST, AL1.5, AL2.0 LT, AL3.0, AL3.0 LT, JR3.5 LT, JR4.0 LT, JR4.0 ST, JR4.5 ST, JR5.0 LT, 3DRC, 3DRC LT, AR1.0 LT, AR2.0 LT, RBL4, RBL4.5, RBL5, CAS2, CAS3, SON1, BL(Tilon), RB, Barbeau, 3D LIMA 90, IM Barbeau, JFL, JFR, MPA1 LT, MPA1, MPA2, MPB1, H-STICK, H-STICK LT, LCB, LCB LT, RCB, IM, IM LT, JL2.0 LT, JL5.0 ST, JR1.0, JR2.0, JR3.5 ST, JR4.5, JR5.0, JR5.0 ST, JR6.0, AL R1.2, AL0.75 ST, AL1.5 ST, AL2.0 ST, AL3.0 ST, AR3.0, XB2.0, XB2.5, XB2.75, XB3.25, XB3.75, XBC2.5, XBC2.75, XBC3.25, XBC3.75, XBC4.5, XBLAD3.5 LT, XBR1.0, XBR2.0, XBRCA, JCL4.5, JCL5.0, JCR3.5, JCR4.0, JCV, JFL LT, JFL ST, JFR LT, JFR ST, DA75, DA90, Barbeau LT, CBL, Contra1, MPC, MPD, NR4.0, RB LT, RCV, RCV1, RDC, RRAD5.0, RRAD6.0, RRAD6.0 XB, SCR3.5, SCR4.0, SCR5.0, STR, VER, CAS1, SON2

-Sizes: Diameter: 5F, 6F, 7F, 8F, 9F, 10F; Length: 55cm, 90cm,95cm, 98cm, 100cm, 110cm,125cm.

PATIENT POPULATION

The populations include adults and children with the age range from 5-80 years old.

DEFINITIONS

	Caution		Keep dry
LOT	Batch code		Non-pyrogenic
	Do not re-sterilize		Do not use if package is damaged.
	Use by date		Do not re-use
STERILE EO	Sterilized by ethylene oxide		Date of manufacture
REF	Catalogue number		Consult instructions for use
	Manufacturer		Keep away from sunlight
	Temperature limit	EC REP	Authorized representative of European Community
CE	CE Marking	2764	Notified Body ID number

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File No.:SM-IFU-GC-001 ,A.5

Effective Date: 2021.05.10