Shunmei®

CE 2764

INSTRUCTION FOR USE

Conveyor

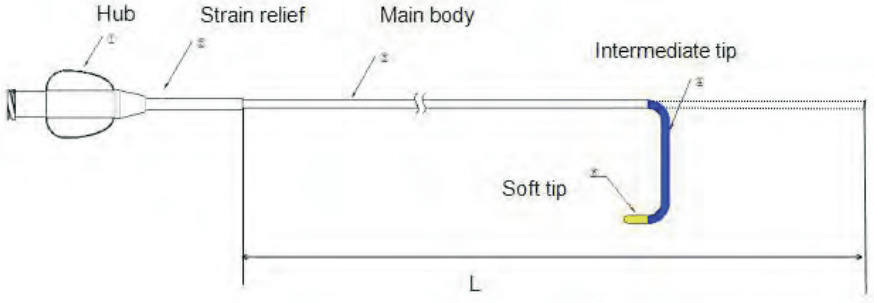
Angiographic Catheter

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 Angiographic Catheter is a sterile, single-use, non-pyrogenic and disposable device that is designed to provide a pathway for delivering contrast media to selected sites in the vascular system. This device consists of catheter hub, strain relief, main body, intermediate tip and soft tip, see Figure 1.



1. Hub 2. Strain relief 3. Main body 4. Intermediate tip 5. Soft tip

Figure 1 Structure of Angiographic Catheter

PACKAGE CONTENTS

1 – Angiographic Catheter

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

INTENDEDUSE/INDICATION

Angiographic Catheter is intended for use in angiographic procedures to deliver radiopaque media to selected sites in the vascular system.

INTENDED USER

- Cardiologists, or doctors who specialize in the heart, especially for coronary artery angiography;
- For more advanced P.A.D, a vascular specialist may be involved. This is a doctor who specializes in treating blood vessel diseases and conditions.

CONTRAINDICATIONS

- Acute phase of myocardial infarction
- A serious heart failure.
- A serious arrhythmia.
- A serious systemic infection or fever
- A serious disease other than coronary disease.
- A serious serum electrolyte imbalance.
- An allergy to or reaction from the contrast medium
- Renal dysfunction
- Blood coagulopathies
- Some respiratory disorders
- Mental disease
- Pregnancy

POTENTIAL ADVERSE EVENTS

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

- Arterial embolism or obstruction
- Artery dissection
- Artery injury
- Acute myocardial infarction
- Unstable angina pectoris
- False aneurysm
- Ventricular fibrillation/arrhythmia
- Artery perforation
- Arteriovenous fistula
- Spasm
- Vascular thrombosis
- Distal embolism
- Infection and pain at the puncture site
- Hematoma
- Bradycardia
- Hemorrhage
- Stroke
- Kidney damage
- Low blood pressure

WARNINGS

Failure to observe these warnings may result in damage to the vessel, damage to or breakage/separation of the catheter that may necessitate retrieval.

- Do not heat or bend the catheter tip, which may result damage to the catheter.
- Consider the use of systemic heparinization to prevent or reduce the possibility of thrombus formation on the surface of the catheter.
- Never advance the guide wire briskly and/or force it into the catheter when the catheter is bent or twisted. This may cause breakage/separation of the catheter, resulting in damage to the vessel.
- Before starting infusion, verify that the catheter has not been kinked and/or blocked. Failure to abide by this warning may cause the catheter to break/rupture/separate, resulting in damage to the vessel.

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 used by surgeons 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.

- For single patient use only. Do not reuse, reprocess or resterilize this product. 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.
- Select the catheter of optimal tip shape and size, take into account the site in which it is to be advanced to, as well as the patient's anatomy.
- The device is operated under sterile condition and only at hospitals.
- Do not expose the product to organic solvent, for example, alcohol.
- Do not use the contrast media which incorporates the component of Ethiodol, Lipiodol or some kind of agents. The contrast media should be injected at 37℃
- Do not exceed the maximum permissible injection pressure.
- 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.

HOW SUPPLIED

The Angiographic Catheter is supplied sterile and non-pyrogenic for single use only.

STORAGE

- Store the Angiographic 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 temperatureq: C0 to 40℃
- Storage humidity: 80%

INSTRUCTIONS FOR USE

1. Carefully open the sterile pouch and gently remove the catheter from the package. Flush it by injecting heparinized saline solution through the catheter hub using a syringe.

Caution:employ an aseptic technique during removal from the package and use.

2. Insert a guide wire of appropriate size into the catheter through its hub and advance the wire to approximately 5cm beyond the catheter's distal tip.

3. Gain access to the artery by using a percutaneous or cut down technique.

Caution: consider the use of systemic heparinization.

4. Insert the guide wire alone into the artery. Then proceed to advance the catheter into the artery over the guide wire.

Caution: to avoid damage to the catheter after it has been advanced into the vessel, manipulate the guide wire carefully, particularly when negotiating a bend in the catheter and/or when passing through the catheter's tip.

5. Manipulate the catheter slowly and carefully in the artery.

6. When the catheter tip has reached the branch of the desired vessel, remove the guide wire through the catheter.

7. While confirming the location of the catheter tip under fluoroscopy, advance the catheter to the desired site and perform angiography.

8. 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.

Product identification and Model

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

Effective Length: 40cm, 65cm, 80cm, 90cm, 100cm, 110cm,125cm.

Catheter OD: 4Fr, 5Fr, 6Fr

Angiographic catheter according to structure, can be classified into models of JL1.5, JL2.0,JL2.5, JL3.0, JL3.5, JL4, JL4.5, JL5,JL6, JR1.5,JR2.0, JR2.5, JR3.0, JR3.5, JR4, JR4.5, JR5, JR6,TIG, PIG(S), PIG145 , PIG155 , AL0.75, AL1, AL1.5, AL2,AL3,AL4, AR1.0, AR2.0, AR3.0, XB3.5, Barbeau, EGB1, RB, C1, C2, C3, CHG2.5, CHG-B, CHG-C, DAV, FC3, H1, H2, H3, HN5, JB1, JB2, KMP, LEV1, MIK, MPA1, MPA2, MPA3, MPA, MPB, PIG, RBT, RC1, RC2, RDC, RH, RIM, RLG, RS, SHK1.0, SIM1, SIM2, SIM3, TEGT, VANSCHIE1, VANSCHIE2, VANSCHIE3, VANSCHIE4, VANSCHIE5, VERT, VS, VS1, VS2, VS3, VTK, WNBG, YASHIRO, AR-JP, AR-R5, AR-RC, BLK, BP-JL, BP-JR, IM, IM-JP type, IM-Round tip, IMShort tip, MP2.5, MP3.0, MP3.5, MP4.0, ST, TIGII 3.5, TIGII 4.0, TIG4.5, TIGII 5.0.TIGI 3.5,TIGI 4.0,TIGI 4.5,TIGI 5.0, JCL 3.5, JCL 4.0, ARMOD, AR1MOD, AR2MOD, MPB1,MPB2, SRC, 3DRC,SON1, SON1.5, SON2, CAS1, CAS2, CAS3, RBL4.0, RBL4.5, RBL5.0, RBMP, RCB, LCB, 3D LIMA, SIM4, STR, H5, H6 Nt1, NT2, NT3, NT4, NT5, BS1, BS2, BS3, BER, Hocky Stick, MANI, HK0.8, HK1.0, SHK 0.8, OS 1, OS 2, J-Curve 0.6, J-Curve 1.1, J-Curve 1.4, RUC

DIFINITIONS

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

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