LEPU MEDICAL

CE 2797

Orien™ Guiding Catheter

Instruction For Use

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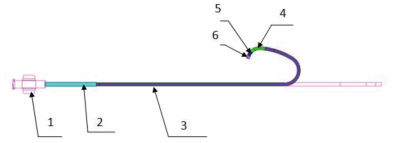
1.Product name

Common Name:Guiding Catheter
Trade Name:Orien

2.Brief introduction on products

This product is a flexible tube with a tube base, a protecting tube, a main body, a distal body (proximal-end and distal-end) and a tip. The main body and the distal tip of the catheter is a composite tube which has three-layers. The inner layer is PTFE, the middle layer is a tightly wound stainless steel braid wire and the outer layer is made of Pebax, PA and Bismuth oxide (as the developer). The central lumen of the catheter is used for the percutaneous, transluminal passage and placement of guidewires, diagnostic and / or therapeutic (interventional) devices within the vascular system.



1.tube base 2.protecting tube 3.main body 4.proximal-end tube 5.distal-end tube 6.tip

3.Specifications of the product

1) Hydrophilic coating: hydrophilic polymer coating further reduces friction to advance catheters more easily into vessels.
2) Outer diameter: 5F (1.67 ± 5% mm), 6F (2.00 ± 5% mm), 7F (2.33 ± 5% mm).
3) Effective length: 1000 ± 5% mm.
4) Inner diameter: 5F (1.40 ± 5% mm), 6F (1.75 ± 5% mm), 7F (2.00 ± 5% mm).
5) Side hole: relief the pressure applied on the guiding catheter when injecting the contrast agent.
6) Various shape of distal end: to meet different position of vessel. Judkins Left (JL), Judkins Curved Left (JCL), Judkins Left (short tip)(JLST), Amplatz Left (AL), Amplatz Left (short tip) (ALST), Femoral Left (FL), Extra Backup (EB), Judkins Right (JR), Judkins Curved Right (JCR), Judkins Right (short tip) (JRST), Amplatz Right (AR), Amplatz Right (short tip) (ARST), Backup Support Right (BSR), ECR Curves (EC),Shepard's Crook Right (SCR), Femoral Right (FR), Femoral Curve Right (FCR), Femoral Right (short tip) (FRST), 3-Dimensional (3D), Champ (CH), El Gamal Bypass (ELG), Internal Mammary (IM), Internal Mammary Cummings (IMC), Left & Right Coronary Bypass (L/RCB), Multi-Purpose (MP), Hockey Stick (HS), Radial Specialty (RS), NOTO, Multi-Aortic-Curves (MAC), Radial Bi-Lateral (RBL), Radial Brachial (RB).
7) Specifications are indicated as follows:
CL Specification + series (+Special requirements, for example, SH

refers to the design with side holes; C refers to the design with coating.For example: for CL6JL35SHC catheter, the outer diameter is 6F, series is JL3.5, designed with side holes and coating.

4. Intended purpose including any clinical claims

4.1 Intended purpose

The disposable guiding catheter is intended to provide an interventional passage to introduce interventional/diagnostic equipment into coronary vascular system.

4.2 Medical indications

The Orien™ Guiding Catheter is indicated for patients who are highly suspected of coronary artery diseases including the following condition: angina, chest pain, arrhythmia, myocardial infarction.

4.3 Patient population

Adult patients who are highly suspected of coronary artery diseases and need further examination or interventional procedure. The safety and efficiency of the product in pregnant women or men intending to father children and the immunocompromised patients have not been established.

4.4 Clinical claims

High success rate of interventional procedure to diagnose or treat patients who are highly suspected of coronary artery diseases.

4.5 Intended users

It should be operated by professional doctors who have received trainings on percutaneous catheter/guiding catheter interventional operation.

5.Contraindications

None known.

6.Instructions

• Open the packing, take out the guiding catheter and confirm that the product packing has not yet been opened and the packing has not been damaged.

Warning:In whatever ways, the damaged/opened product should be replaced with a new one. Damaged/opened product is forbidden to be used.

• Before using the product, wash its lumen with heparinized saline solution.

• Introduce the guiding catheter into the vascular system through percutaneous intervention technology.

• By connecting it to the side arm of the hemostatic valve in the centre of the guiding catheter, set the operation of continuous wash with heparinized saline.

Note: It is suggest that the operation of continuous wash with heparinised saline should be kept between the guiding catheter and any lumen passing through it.

• Under the guidance of X-ray, push the guiding catheter to pass through the guide wire or the introducer until the expected position.

• Before injecting contrast agent or guiding instruments in other blood vessels, take out the guide wire or the introducer.

7.Precautions and Warning

• This device is intended for one time use only.DO NOT resterilize and / or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

• This product should be stored under shady, dry and clean environ ment without any corrosive gas, relative humidity lower than 80% and temperature between 10°C and 30°C.

• Please don't use it if the packing is opened or damaged.

• Use it before the "shelf-life".

• Don't sterilize repeatedly.

• Don't expose it in organic solvent.

• Before using it, identify if the specification, shape and status of the catheter meet requirements of this operation.

• Please interrupt the operation if a strong resistance is met in using it, and don't carry on until the cause of resistance is identified. If not confirm the reason for resistance, pleases remove the catheter.

• Under entanglement condition, twisting the guiding catheter excessively might damage the catheter, and such damage might cause separation of the catheter. If serious entanglement happens during the process of using the guiding catheter, withdraw the entire systems (guiding catheter, guide wire and catheter sheath inducer).

• During the entire process of using the catheter, operations of advancing, operating and withdrawing the catheter all should be carried out under the guidance of X-ray.

• Care must be taken in using it so as to avoid damage caused to the vascular system where the guiding catheter passes through. As small blood vessels might be blocked by the guiding catheter, care must be taken so as to avoid complete blocking-up of blood flow.

• For guiding catheters with large lumens, force imposed to the injector when injecting is smaller.

• During transportation, the product should be protected from becoming damp, solarization, high temperature, great pressure and shock.
• The Guiding Catheter contains metal, do not use with any inappropriate (e.g. MRI).

8.Complications

It should be operated by professional doctors who have received trainings on percutaneous catheter/guiding catheter interventional operation and should not be executed by doctors who are not familiar with possible complications. Complications might be caused during the operation or any time after that.

Possible complications include, but not limited to:
• Bleeding
• Infection
• Bradycardia
• Inflammation
• Allergy
• Limited access site intimal tear
• Occlusion
• Bruises
• Edema
• Air embolism
• Myocardial infarction
• Unstable angina
• Secondary procedure
• Death
• Perforation
• Haemothorax
• Arterio–venous fistula
• Arteriorrhexis
• Pseudoaneurysm
• Target vessel revascularization
• Dissection
• Spasm
• Thrombosis
• Transient ischemic attack
• Coronary artery bypass graft
• Hematoma
• Ischemia
• Laceration
• Fall of blood pressure

If there is any serious incident that has occurred in relation to the device, please report it to the manufacturer and the competent authority in your locale. For information of competent authority, please visit: https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

9.Facility requirement

The procedure is typically conducted in a catheterization lab and the following equipment is recommended to be prepared to support the procedure or foreseeable emergencies:
a) Gloves and gowns
b) Special X-ray machine for cardiovascular system examination
c) High-resolution see-through phosphor screen
d) Blood pressure monitor system
e) X-ray protective equipment
f) Multi-channel physiological recorder
g) Ambulance equipment
h) High pressure syringe
i) Operating table
j) Irrigation tray
k) Catheter examination table

10. Connecting Parts

When used, has such as below devices to be used in combination with this product:
• Sheath
• Guide wire
• Manifold
• Balloon catheter
• Stent

The sheath builds a channel between the skin and blood vessel. The guide wire enters the blood vessel from the sheath introducer and plays a directing role. The guiding catheter is delivered to the target location along the guide wire. The manifold is connected with the guiding catheter for injection of heparin or contrast medium. The balloon catheter or stent is delivered to the target location along the guide wire through the guiding catheter.
The selection of sheath mainly takes the inner diameter, the outer diameter, the length of the sheath, the size of the blood vessels of the patient and the instrument for introduction with the blood vessel into consideration.
The diameter of sheath that is recommended by the instrument for introduction is generally selected.
The selection of guide wire mainly takes the inner diameter of the guiding catheter and the diameter of the guide wire into consideration, and the diameter of the guide wire shall allow the guiding catheter to be introduced.
The selection of balloon catheter and stent shall take their outer diameters and inner diameter of the guiding catheter into consideration, which means the balloon catheter and stent can get through the guiding catheter is the main embodiment of their joint use. The maximum diameter of folded balloon and stent suggested is smaller than 1mm.

The selection of manifold mainly takes the connector size into consideration, and it shall meet the requirements of ISO 594-1 and ISO 594-2.

11.Removal and disposal of the product

The removal and disposal of the product should only be performed by physicians who have received adequate training, conforming to ISO 12891-1 and local laws and regulations.

12. eIFU

Software and hardware requirements needed to display the instructions for use in electronic form are shown as:
Computer:

Configuration item		Requirements
Hardware configuration	CPU	Intel Pentium 4 and above
	RAM	256 M and above
	Hard disk space	20 G and above
Systems platform		Windows platform (compatible with Windows XP, Windows 7, Windows 8 & 8.1, Windows 10, compatible with 32-bit &64-bit)
Required software		Adobe Acrobat Reader or pdf reader software of the same type

Mobile phone:

Configuration item	Requirements
System platform	Android 4.0 and above or IOS 5.0 and above
Required software	Adobe Acrobat Reader or pdf reader software of the same type

eIFU Indicator The exact same pdf version e-IFU can also be found on the website of Lepu

Medical: https://en.lepumedical.com/e-ifu/
If you can not download it on the website, please contact the manufacturer:
Tel: +86-10-80120666
Fax: +86-10-80120600
Note:
When the manufacturer's instruction for use is updated, it will be uploaded timely. For it is difficult to trace to every end user to inform the change, so we advise the customer to browse and check it regularly.

13. Summary of Safety and Clinical Performance (SSCP)

The summary of safety and performance for the device is available on the website of Eudamed: https://ec.europa.eu/tools/eudamed

EXPLANATION OF SYMBOLS

SYMBOL	DESCRIPTION
REF	CATALOGUE NUMBER
LOT	BATCH CODE
	USE-BY DATE
STERILE EO	STERILIZED USING ETHYLENE OXIDE
	DO NOT RE-USE
	DO NOT USE IF PACKAGE IS DAMAGED
30°C 10°C	TEMPERATURE LIMIT FOR STORAGE AND HANDLING
	CAUTION
	CONSULT INSTRUCTIONS FOR USE
	MANUFACTURER
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
STERILIZE	DO NOT RESTERILIZE
STERILE EO	SINGLE STERILE BARRIER SYSTEM AND STERILIZED USING ETHYLENE OXIDE
STERILE EO	SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE AND STERILIZED USING ETHYLENE OXIDE
eIFU Indicator	ELECTRONIC INSTRUCTIONS FOR USE
MD	MEDICAL DEVICE
UDI	UNIQUE DEVICE IDENTIFIER
	KEEP AWAY FROM SUNLIGHT
	KEEP DRY
	DATE OF MANUFACTURE
	HUMIDITY LIMITATION FOR STORAGE AND HANDLING