LEPU MEDICAL

CE 2797

Balancium™ PTCA Guide Wire

Instruction For Use

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CE-GW-009 Rev. 13 Issued on: 2022-05-17

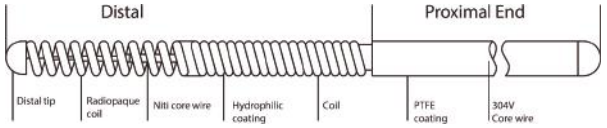
Lepu Medical Technology (Beijing) Co., Ltd.

1.Product Name

General name: PTCA Guide Wire
Trade: Balancium™

2.Device Description

Balancium™ PTCA guide wire provides guidance for interventional devices during angiography and percutaneous coronary intervention.



Guide wire diameter: 0.014 inch;
Guide wire length: 185, 300 cm;
Tip hardness: 0.6, 1, 2 g;
Tip shape: Straight, J;
Distal end structure: Core-to-tip, Shaping ribbon.

3.Intended Purpose

Balancium™ PTCA guide wire is indicated for use in the procedure for angiography to facilitate and localization of the catheter and other intervention devices in coronary arteries.

3.1 Medical indications

The Balancium™ PTCA Guide Wire is used for coronary diseases that need minimally invasive surgery (such as PTCA) treatment to introduce the diagnostic or therapeutic device into target coronary.

3.2 Contraindication

Balancium™ PTCA guide wire is contraindicated for use in cerebrovascular system.

3.3 Intended Patient Populations

This device is suitable for any patients with the above disease or medical condition except for whom with contraindications.

3.4 Intended User

The Balancium™ PTCA Guide Wire should only be used by a physician, who has received the training on angiography and percutaneous coronary intervention (PCI). Before use, the operator should have a full understanding of the using instruction, warnings and precautions.

3.5 Clinical benefit to be expected

1) High success rate of directing a catheter to the desired coronary anatomical location during diagnostic or interventional procedures.
2) Low rate of clinical adverse event.

4. 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

5. Warning

Prior to the procedure, carefully examine the device to verify its proper function and integrity. Failure to abide by the following warnings might result in damage to the vessel, abrasion of the hydrophilic coating, release of the polymeric fragments from the device and/or damage to or breakage/separation of the wire.

- Do not manipulate and/or withdraw the guide wire through a metal device, e.g. a metal entry needle, a metal guide wire introducer. Manipulation and/or withdrawal through a metal device may result in destruction and/or separation of the guide wire.
- Manipulate the guide wire slowly and carefully in the vessel while confirming the behavior and location of the wire tip under X-ray.
- If any resistance is felt or if the tip behavior and/or location seems improper, stop manipulating the guide wire and determine the cause by X-ray. Failure to exercise proper caution may result in bending, kinking and separation of the wire.
- If a retrieving device, e.g. a gripper, will be used, it must be used after the guide wire has been removed out of the patient's vessel.
- Do not bend the guide wire repeatedly at the same point. It may result in deformation, breakage or separation of the wire.
- The safety and effectiveness of the device has not been established or is unknown in vascular regions other than those specifically indicated.

6.Instruction for Use

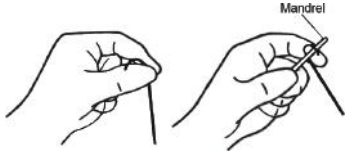
Before use

1) Before taking out the guide wire from the wire dispenser, please inject normal saline with heparin into the hub end of the dispenser to immerse the entire guide wire. Please maintain its moisture for better hydrophilic effect during its usage with other interventional device.
2) Push the exposed sections of the guide wire into the dispenser until the tip and a portion of the core exit the end of the hoop. Then grasp the core of the wire to remove it totally from the dispenser. Avoid damaging the fragile guide wire tip. Do not grasp the tip of the wire while removing it from the dispenser.
3) Once the guide wire is out of the dispenser, please do not re-insert again.

4) The guide wire is fine device, so please operate with careful. Before its usage and during the operation, always examine for any bend, kink, or damage about the guide wire. If any is found, do not continue the operation with the defect.

5) Before the usage, make sure the diamteter of the guide wire matches with the interventional device.

6) If indicated, the guide wire tip may be carefully shaped using standard tip-shaping practices as below:



Carefully wrap the guide wire around the finger or mandrel. But do not use a shaping instrument with a sharp edge.

During operation

Over the Wire System

1) Carefully insert the guide wire through the guide wire lumen hub of intervention device.
2) Advance the guide wire until tip is just proximal to the interventional device tip.
3) If using a guide catheter, engage the guiding catheter and insert the interventional device / guide wire assembly through the hemostatic valve. Advance the system through the guiding catheter until it is just proximal to the tip of the guiding catheter.
4) Tighten the hemostatic valve to create a seal around the interventional device. Make sure the guide wire is free to move.
5) If necessary, connect the guide wire to a torque device.
6) Under X-ray, push the guide wire out of the interventional device, while ensuring that the interventional device is not dislocated. Use the torque device to control the guide wire across the lesion.
7) Also, make sure the guide wire is not dislocated along the path from its insertion into the interventional device to the lesion site.
8) If it is necessary to use different head structure or different type guide wire, observe the movement of guide wire under x-ray vision and carefully remove it.
9) Then, the guide wire can be re-shaped or another new guide wire is used.
10) Re-insert the guide wire following step 1 to step 7.

Rail Type Systems (Bare Wire Technique)

1) Pre-set the guide wire catheter and insert the guide wire introducer via the attached hemostatic valve.
2) Via the guide wire introducer, the distal tip of guide wire can be inserted into the catheter.

3) If a metal guide wire introducer is used, be sure to remove it before withdrawing or further manipulating the wire to avoid damage to the hydrophilic coating.
4) Connect the torque device.
5) Under x-ray, advance the guide wire out of the guiding catheter to the designated blood vessel. Use the torque device to control guide wire across the lesion site.
6) If a different tip configuration or guide wire is indicated, the guide wire may be removed as follows:
   a) Open the hemostatic valve and flush line on the coronary manifold. Slowly withdraw the guide wire while observing guide wire movement under x-ray.
   b) Close the hemostatic valve and coronary manifold flush line.
7) Reshape the guide wire tip according to standard practice or prepare the next guide wire.
8) Re-insert the guide wire following step 2 to step 5.
9) Remove the torque device and the wire guider from the wire.
10) Make sure the guide wire is not dislocated along the path from its insertion into the interventional device to the lesion site.

7.Precautions

1) The device is sterilized with ethylene oxide. Do not use if the package is open or damaged.
2) The device should be used within the period of validity.
3) This device should be used only by physicians trained in angiography and percutaneous Coronary intervention (PCI).
4) Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.
5) Refer to the instructions supplied with any interventional devices to be used in conjuction with Balancium™ guide wire for their intended uses, contraindications, and potential complications.
6) Examine the tip movement under X-ray before manipulating, moving or torqueing the guide wire. Then observe the guide wire under X-ray for tip bucking, which is a sign of resistance.
7) Do not push, auger, withdraw or torque any guide wire that meets resistance.
8) Do not allow the guide wire tip to remain in a prolapsed condition.
9) Do not torque a guide wire if the tip becomes entraped within the vasculature.
10) Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system.

11) Consider that if a secondary wire is placed in bifurcation branch, this wire may need to be retracted prior to stent deployment because there is additional risk that the secondary wire may become entraped between the vessel wall and the stent.

12) Do not expose guide wire to any substance which reacts with coating, such as water, alcohol.

13) Contents supplied STERILE using Ethylene Oxide sterilization process. Do not use if sterile barrier is damaged. If it was already damaged before use, please call you company representative. The device is designed and intended for SINGLE USE ONLY. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing of re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

14) Materials of Radiopaque coil and Ni-Ti core wire contain nickel, which may cause allergic reaction.

15) Before using the product on children, pregnant and breastfeeding women, the benefit/risk ratio need to be considered, for there maybe cobalt above 0.10% w/w in the component.

8.Residual Risks and Undesirable Side-effects

Potential residual risks and undesirable side-effects associated with use of this device include, but not limited to, the following:

- Death
- Myocardial infarction/myocardial embolism
- Hemorrhage or hematoma
- Vessel trauma, perforation and dissection
- Arrhythmia
- Angina/unstable angina
- Thrombosis/Thrombus
- Allergic reaction and infection
- Aneurysm/false aneurysm
- Tissue necrosis
- Stroke including transient ischemic attack, cerebral infarct and embolic stroke
- Acute re-occlusion
- Additional surgical intervention
- Pulmonary embolism/pulmonary infarct
- Guide wire fracture, kinking
- Coating shedding
- Cardiac tamponade/Pericardial effusion

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

9.Storage and Expiry Date

1) During transportation process, the product should be kept away from damp, sunshine, rain, high temperature, stress and impact.
2) It should be stored in shady, dry, well-ventilated clean room with no corrosive gas, relative humidity lower than 80%, and temperature between -10℃ and 40℃.
3) The period of validity is two years when this product is stored under specified conditions.

10. E-IFU

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 Pentium4 and above
	RAM	256M and above
	Hard disk space	20G 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

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.

11. Explanation of Symbols

SYMBOL	DESCRIPTION
REF	CATALOGUE NUMBER
LOT	BATCH CODE
	USE BY
	DO NOT REUSE
	DO NOT USE IF PACKAGE IS DAMAGED
	TEMPERATURE LIMIT
	CAUTION
	CONSULT INSTRUCTIONS FOR USE
	MANUFACTURER
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
MD	MEDICAL DEVICE
UDI	UNIQUE DEVICE IDENTIFIER
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
	COBALT(CAS NO. 7440-48-4) MAY BE PRESENT IN THE DEVICE