Shunmei®

CE 2764

INSTRUCTION FOR USE

Peripheral Guidewire

DEVICE DESCRIPTION

Peripheral Guidewire is a sterile, single-use, non-pyrogenic and disposable device. The Peripheral Guidewire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during the intravascular procedures, and the device is intended for peripheral vascular use only. The device consists of 7 parts: Peripheral Guidewire, torquer, insertion tool, Coil tube, Three toggle clips, Soft clip, luer lock. and Insertion tool fixation clamp. According to the different composition of Peripheral Guidewire, the Peripheral Guidewire is divided into four types: Peripheral Guidewire(single core wire) with Polymer Jacket, Peripheral Guidewire (single core wire) without Polymer Jacket, Peripheral guidewire(composite core wire) with Polymer Jacket, Peripheral Guidewire (composite core wire) without Polymer Jacket. Both of the single core wire and composite core wire are made of Stainless steel.

For Peripheral Guidewire (single/ composite core wire) with Polymer Jacket: The guidewire is composed of core wire, proximal coil wire and distal coil wire (which is radiopaque), polymer jacket and hydrophilic coating. core wire is made by 304 stainless steel with PTFE coating, Coil wire's material are 304V stainless steel and platinum nickel alloy, the whole coil wire is covered by polymer jacket made of TPU with tungsten carbide, and with hydrophilic coating on the jacket, the proximal core wire is covered by PTFE coating.

For Peripheral Guidewire (single/ composite core wire) with Polymer Jacket(new models: No.40~No.59): The guidewire is composed of core wire and coil wire(which is radiopaque), polymer jacket and hydrophilic coating. Core wire is made by 304 stainless steel with PTFE coating, Coil wire's material is platinum nickel alloy, the whole coil wire is covered by polymer jacket made of TPU with tungsten carbide, and with hydrophilic coating on the jacket, the proximal core wire is covered by PTFE coating.

For Peripheral Guidewire (single/composite core wire) without Polymer Jacket: The guidewire is composed of core wire, proximal coil wire and distal coil wire (which is radiopaque) and hydrophilic coating. core wire is made by 304 stainless steel with PTFE coating, Coil wire's material are 304V stainless steel and platinum nickel alloy, the whole coil wire is covered by hydrophilic coating on the jacket, the proximal core wire is covered by PTFE coating.

According to the different models and requirements, the accessories of the product are also different and optional. Many specifications are provided to be selected by physician according to clinical condition demand. The length of guidewire have 110cm, 150cm, 180cm, 190cm, 200cm, 235cm and 300cm and the diameter have 0.014in(0.36mm), 0.018in(0.46mm), The tip configurations include straight/tip, Pre-shaped tip.

PACKAGE CONTENTS

1- Peripheral Guidewire

1- Torquer

1- Insertion tool

Note: Guide wire length, diameter, Core wire configurations are indicated on the product label.

INTENDED USE

This Product is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures.This device is intended for peripheral vascular use only.

INDICATIONS

- Peripheral CTO lesion.
- Limb ischaemia or claudication, Rutherford class I-III (grade 1-5) caused by the occluded artery.

CONTRAINDICATIONS

- Guidewires are not intended for use in the cerebral vasculature.
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- Sick sinus syndrome
- Atrioventricular block (grade Ⅱ and above)
- SBP ≤ 90mmHg or cardiogenic shock
- Heart Rate ≤60 bpm
- Pregnancy
- Renal or hepatic failure
- Diabetes
- Cancer
- Allergic to contrast medium

WARNINGS

— Contents supplied Sterile using an ethylene oxide(EO) process. Do not use if sterile barrieria damaged. If damage is found, please contact with the manufacturer.

— For Single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and lead to device failure which, in return, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and /or cause patient infection or cross-infection, including, but not limited to,the transmission of infections disease(s) from one patient to another. Contamination of the device may lead to injury, illness of death of the patient.

— After use,dispose of product and packaging in accordance with hospital, administrative and /or local government policy.

— Note the “Use by date" specified on the package.

PRECAUTIONS

— The patient should be informed about the application risks before the application and the positive and negative effects should be explained.

— The patient should be warned that the application device may have a certain life span that cannot replace the normal tooth, be damaged as a result of strenuous activity or trauma, and may be altered in the future.

— Please read the product manual before use.

— The product is single-used. Do not use again.

— Check the expiration date of the product before use.

— Use should be avoided in patient conditions described in contraindications.

— Allergy and other reactions to the metal material should be considered, tested (if appropriate) before the operation, although they are not frequent.

— Do not use the product in case of foreign matter or impurities in the package or on the product.

— Do not use if the product is damaged.

— Ensuring that the product fulfils the quality control competence.

— Biocompatibility of the product has been demonstrated.

ADVERSE EVENTS

Potential adverse reactions or complications which may result from the improper use of the Peripheral Guidewire include, but are not limited to:

— Air embolism/ Thromboembolism

- Allergic Reaction
- Amputation
- Arteriovenous(AV) Fistula
- Death
- Embolism
- Hematoma
- Hemorrhage
- Infection or Sepsis/Infection
- Myocardial Ischemic and /or Infarction
- Pseudoaneurysm
- Stroke (CVA)/Transient Ischemic Attacks(TIA)
- Thrombus
- Vessel Occlusion
- Vessel Perforation, Dissection, Trauma or Damage
- Vessel Spasm
- Wire Entrapment/Entanglement
- Foreign Body/Wire Fracture

HOW SUPPLIED

Handling

Do not use if the package is opened and /or damaged.Use the device prior to the “Use By” date noted on the product label .Do not use if labeling is incomplete or illegible.

STORAGE

- Store the product at room temperature and 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 °C to 40 °C.
- Storage humidity: ≤ 80%.

INSTRUCTIONS FOR USE

1. Check before use

a. Before use, please carefully check and confirm that all devices and packaging are not damaged.

b. Before use, please make sure that the guide wire is compatible with other interventional devices that need to be used.

2. Preparation before use

a. Select the most suitable guide wire for the lesion and remove coil tube containing the guide wire from the sterilized pouch.

b. Release the proximal end of the guide wire from the tail soft clip and slowly pull it through the coil tube.

c. When the distal end of the guide wire exceeds 5-6cm of the holder, if necessary ,shape the distal tip in accordance with the standard practice, When shaping the distal end, use minimum force as possible so that the coil is not damage.Especially, the polymer jacket of the guide wire with plastic covered -type distal end is very delicate against damage.Pay careful attention not to damage the polymer when shaping the distal tip.Inspect the coil and guide wire for damaged after shaping and before using.

3. Procedures for insertion

• Over-the-wire system

a. Insert the distal end of the guide wire carefully into the guide wire lumen of the interventional device.

b. Advance the guide wire carefully until its tip is just proximal to the the interventional device tip.

c. Engage the guiding catheter (if used) and insert the interventional device system (with guide wire) into the Y connector.

d. Advance the interventional device system through the guiding catheter until its tip is just proximal to the distal tip of the guiding catheter.

e. Tighten the Y-Hemostasis valve component to create a seal around the interventional device. Ensure the guidewire movement is still permitted.

f. Check to ensure that the guide wire moves smoothly.

g. Attach a torquer to the guidewire if necessary.

h. Advance the guide wire under fluoroscopy to pass through the lesion Confirm by angiography that the guide wire has passed through the target lesion.

i. Observe the movement of guide wire in blood vessels. Before the guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque without observing corresponding movement of the tip.Otherwise,vessel trauma may occur .

j. Do not use in areas of vessels that are not or cannot be visualized.

k. Advance the interventional device until the lesion is reached while preventing the guide wire from moving. Ensure that the distal tip and its position in the vessel are visible during interventional device manipulations.

• Rapid exchange system

a. Engage the guiding catheter.

b. Insert the insertion tool into the Y connector of the guiding catheter.

c. Carefully insert the guide wire distal tip into the insertion tool.

d. Advance the guide wire through the guiding catheter under fluoroscopy until the distal tip of the guide wire is just proximal to the tip of the guiding catheter.

e. Attach a torquer to the guidewire, if necessary.

f. Advance the guide wire under fluoroscopy. to pass through the lesion.Confirm by angiography that the guide wire had passed through the target lesion.

g. Observe the guide wire movement in the vessels.Before the guide wire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque a guide wire without observing corresponding movement of the tip.Otherwise,vessel trauma may occur.

h. Do not use in areas of vessels that are not or cannot be visualized.

i. Remove the guide wire torquer and the insertion tool.

j. Track the interventional device over the guidewire while preventing the guide wire from moving,and advance until the the lesion is reached.Ensure that the distal tip and its position in the vessel are visible during interventional device manipulations.

4. Procedures to change the guide wire

• Over-the-wire system

a. Slowly remove the guide wire while monitoring the guide wire movement under fluoroscopy

b. Insert the next guide wire in accordance with the direction in this 'Instruction for use' section

Special instructions for hydrophilic coated guide wire

• Warning

a. Avoid abrasion and hydrophilic coating peeling.

b. Do not use metal sleeve or sharp guide tools, otherwise the hydrophilic coating will be damaged.

• Preparation before use

a. Flush the whole coil tube with heparinized saline before removing the guide wire .Repeat injection if difficult removal of the wire occurs.

b. After Removing the guide wire, please check whether it is damaged.

c. If the guide wire surface is dry, the hydrophilic coated guide wire can be lubricated by wetting the guide wire surface with .heparinized saline

d. Before inserting the guide wire to the interventional device use heparinized saline to completely wetting it.

e. After removing the guide wire from the body, wipe it with a gauze soaked in heparinized saline and keep it moist.

Product identification and Model

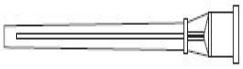
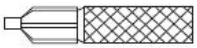
- Product identification: See label information,include product name, pattern of guide wire tip shape.

- Specification information:

Product Name	**Core Wire Type**	**Specification**		
		Wire Coating Material Coating	**Tip Stlffnees**	**Tip Shape**
Peripheral Guidewire	Single	- Polymer Jacket &Hydrophilic - Hydrophilic	1g, 3g, 4g, 6g,8g, 12g, 20g, 30g,40g	Straight Tip -Angled Tip
	Composite	- Polymer Jacket &Hydrophilic - Hydrophilic	3g, 4g, 7.5g,12g	Straight Tip - Pre-shaped Tip

DIFINITIONS

	**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**
	**Fragile items**		**Authorized representative of European Community**
	**Straight**		**Pre-shaped/ Angled**
	**Insertion tool**		**Torquer**
	**CE mark and NB ID Number**		



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