Shunmei®

CE 2764

INSTRUCTION FOR USE

PTCA Guide Wire

CAUTIONS

This device should be used only by physicians who Specializing in cardiovascular ,such as intervention cardiologist and cardiothoracic surgeon.

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 PTCA Guide Wire is supplied sterile, non-pyrogenic and are intended for single use. The device is a steerable guide wire available in several lengths and diameters. The distal tip is shapeable or, as an option, a angled tip is available for some wire families. Refer to the product label for product specifications (e.g., wire length, diameter, distal tip and length of tip radiopacity).

PACKAGE CONTENTS

1 – PTCA Guide wire

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

INTENDED USE

The PTCA Guide Wire is intended to facilitate the placement and exchange of balloon catheters or other interventional devices during Percutaneous Transluminal Coronary Angioplasty (PTCA) or other intravascular interventional procedures.

CONTRAINDICATIONS

- Patients who had previous coronary artery spasm.
- Pregnant patients or patients who may be pregnant.
- Patients who, because of their condition are contraindicated for surgical operation.
- Lesions that follow the bypass constructed less than one month ago or the false aneurysm.
- Patient who are contraindicated for anti-platelet or anti-coagulation treatment.

- Patient who has a critical allergy to contrast media.
- Patient with cancer or chemotherapy.

WARNINGS

- This device is designed and intended for single use only. Do not resterilize, reprocess or reuse.
- Do not use the guide wire after the expiration date indicated on the label. Discard any guide wire that exceeds the expiration date.
- Observe guide wire movement in the vessels. Before a 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. In addition, during catheter manipulations, ensure that the distal guide wire tip is visible.
- Torquing a guide wire against resistance may cause guide wire damage and / or guide wire tip separation. Always advance or withdraw the guide wire slowly. Never push, auger, withdraw or torque a guide wire, which meets resistance. Resistance may be felt and / or observed under fluoroscopy by noting any buckling of the guide wire tip. If guide wire tip prolapse is observed or used for positioning, do not allow the tip to remain in a prolapsed condition; otherwise, damage to the guide wire may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.
- If the guide wire tip becomes entrapped within the vasculature, Do not torque the guide wire.
- Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system. Perform exchanges slowly to prevent air entry and/or trauma.
- When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guide wire exit of the device. Use the radiopaque marker of the interventional device to confirm position.

PRECAUTIONS

- The PTCA Guide Wire should be used by, or under the order of a physician, who is well trained in manipulation and observation of guide wires under high resolution fluoroscopy.
- The PTCA Guide Wire has been sterilized by ethylene oxide gas. For single use only. Do not reuse, reprocess or resterilize.
- The entire procedure should be carried out aseptically.

- If the package is opened or damaged, do not use the product. Do not open the package until just prior to use. Use aseptic technique in handling and using the guide wire.
- Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged guide wires. Using a damaged guide wire may result in vessel damage and / or inaccurate torque response.
- Confirm the compatibility of the guide wire diameter with the interventional device before actual use.
- Free movement of the guide wire within the interventional device is an important feature of a steerable guide wire system because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.
- Never attach the torque device to the modified portion of the proximal end of the extendable guide wire; otherwise, guide wire damage may occur.
- Never use metallic needles or metallic sheaths for insertion and withdrawal of guide wire. Otherwise, the surface of guide wire may be damaged significantly.
- Use care when shaping the tip of this guide wire. Be sure the guide wire is wet before shaping to avoid damaging the surface coating.
- Do not wipe this guide wire using an organic solution such as alcohol.
- The device is operated under sterile environment.
- Take preventive measures against infection after use. Discard this product as medical waste.

SIDE EFFECTS

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

- Acute myocardial infarction,
- Hypotension,
- Coronary artery dissection, Arterial perforation, Arterial rupture, Coronary artery injury,
- Myocardium ischemia,
- Coronary artery spasm,
- Bradycardia, Palpitation,
- Arteriovenous fistula,
- Unstable angina pectoris,

- Arrhythmia including the ventricular fibrillation,
- Formation of femoral false aneurysm, false aneurysm,
- Allergy for medicines,
- Total occlusion of coronary artery,
- Distal embolization,
- Vessel perforation
- Intimal tear,
- Vessel damage,
- Vessel Spasm,
- Haemotoma at the puncture site,
- Infections,
- Pain,
- Acute shunt closure,
- Temporary modification of blood flow

POTENTIAL COMPLICATONS

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

- Infectious disease and puncture site complication
- A hemorrhagic complication
- Kidney perforation,
- Cardiac perforation
- Cerebral infarction,

HOW SUPPLIED

The PTCA Guide Wire is supplied sterile and non-pyrogenic for single use only. Do not use if the package is open or damaged.

STORAGE

- Store the product 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. Inspection prior to use

1) Before use, inspect carefully and confirm all devices and packages are undamaged.

2) Before use, confirm that the guide wire is compatible with the interventional device to be used.

2. Preparation

1) Select the most suitable guide wire for the affected area and remove the holder tube containing the guide wire from the sterile pack.

2) Release the proximal end of the guide wire from the tail soft clip and slowly push it through the holder.

3) When the distal end of the guide wire is extended 5 to 6 cm beyond the holder, if necessary, shape the tip in accordance with standard practice. When shaping the distal end, use the minimum force needed so that the coil is not damaged. 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 end. Inspect the coil and guide wire for damage after shaping and before using.

4) Gently grasp the guide wire which came out from the distal end of the holder tube at the point as close to the holder tube as possible and pull the guide wire out slowly and carefully.

3. Procedures for insertion

Over-the-wire system

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

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

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

4) Advance the interventional device system through the guiding catheter until the tip of the device system is just proximal to the tip of the guiding catheter.

5) Tighten the hemostatic valve of Y connector to create a seal around the interventional device. Ensure the device movement is still permitted.

6) Check to make sure the guide wire moves smoothly.

7) Attach the torque device to the guide wire if necessary.

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

9) Observe 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.

10) Do not use in areas of vessel that are not or cannot be visualized.

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

Rapid exchange system

1) Engage the guiding catheter.

2) Insert the guide wire introducer into the Y connector of the guiding catheter.

3) Carefully insert the guide wire tip into the introducer.

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

5) Attach the torque device to the guide wire if necessary.

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

7) Observe guide wire movement in the vessels. Before a 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.

8) Do not use in areas of vessel that are not or cannot be visualized.

9) Remove the guide wire torque device and the guide wire introducer.

10) Track the interventional device over the guide wire while preventing the guide wire from moving, and

advance until the lesion is reached. Ensure that the distal guide wire tip and its location in the vessel are visible during interventional device manipulations.

4. Procedures to change the guide wire Over-the-wire system

1) Remove the guide wire slowly while monitoring the movement of the guide wire under fluoroscopy.

2) Insert the next guide wire in accordance with the directions in this “How to Use” section.

Product identification and Model

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

Tip shape：Straight/shapable tip, Angled tip,1mm Pre-shape tip.

Tip stiffness: 0.3g, 0.6g, 0.7g, 0.8g, 0.9g, 1.0g, 1.5g, 1.7g, 2.0g, 2.7g, 2.9g, 3.0g, 3.5g, 4.0g, 4.1g, 4.5g, 6.0g, 9.0g, 12g, 20g.

Tip coating material: Hydrophilic coating, Polymer jacket & hydrophilic, Hydrophilic with uncoating , without coating.

Core wire: Single, Composite

Outer diameter:0.010in(0.26mm), 0.014in(0.36mm), 0.018in(0.46mm)

Length:150cm ,165cm ,190cm, 300cm,330cm

DIFINITIONS

	**Caution**		**Keep dry**
	**Batch code**		**Non-pyrogenic**
	**Do not re-sterilize**		**Do not use if package is damaged.**
	**Use by date**		**Do not re-use**
	**Sterilized by ethylene oxide**		**Date of manufacture**
	**Catalogue number**		**Consult instructions for use**
	**Manufacturer**		**Keep away from sunlight**
	**Temperature limit**		**Authorized representative of European Community**

Shunmei®

CE	CE Marking	2764	Notified Body ID number

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