Peripheral Guide Wire

INSTRUCTIONS FOR USE

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Read these instructions before using the guide wire and observe the Indications for Use, Warnings, Precautions, Malfunction and Adverse effects and How to Use sections in the Instructions for Use. Failure to do so may result in complications, including serious injury to the patient or death.

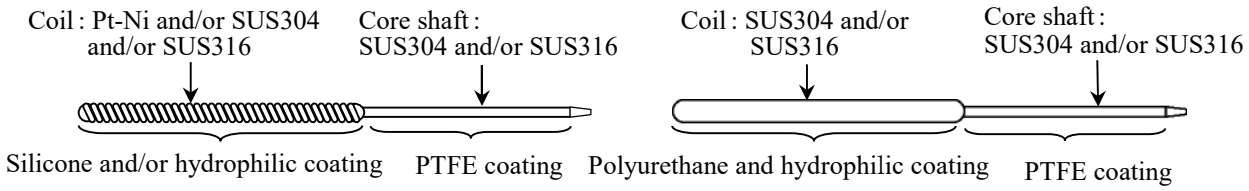
These Instructions for Use apply to the Peripheral Guide Wire. For details (length of the guide wire, length of radiopaque section,etc.), refer to the product label.

Description

This Peripheral guide wire has a coil-type distal end or a plastic covered-type distal end. The coil is partly or entirely radiopaque to facilitate selection of the blood vessel and confirmation of the position of the guide wire's distal end by fluoroscopy.

The core shaft surface is coated with Polytetrafluoroethylene (PTFE). About 2cm of the distal end can be shaped.

ASAHI INTECC detachable extension wire (hereafter "extension wire") is available to connect with the proximal end of this guide wire with a length of less than 300cm. The total length of the system after the connection will be 300cm to 400cm. Torque device may be included in the same package.



Indications for 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.

Warnings

- This guide wire is presterilized with ethylene oxide gas (EOG) and is intended for single use only. Do not reuse and/or resterilize. If reused or resterilized, the performance or quality of the guide wire may be compromised and there is a risk of complications, including infection.
- Do not use the guide wire after the expiration date indicated on the label. Discard any guide wire that exceeds the expiration date.
- This guide wire must be used only by a physician who is fully trained in PTA treatment.
- Do not use the guide wire in neurovascular.
- Never use this guide wire for pregnant or possibly pregnant patients. [X-ray may cause radioactive effects to the fetus.]
- Never use this guide wire to patients who are not eligible for surgical operation or who

have exhibited obvious and serious allergic reactions to contrast media or other types of drugs which are necessary for the procedure. [Life-threatening adverse events may result in the worst case.]

- The coil section is especially fragile, so do not bend or pull it more than necessary. [Otherwise, the guide wire may be damaged.]
- Do not use a damaged guide wire. Using a damaged guide wire may result in blood vessel damage and/or inaccurate torque response. Injury to the patient may result.
- Never use metallic cannula or metallic sheaths for insertion and withdrawal of the guide wire. [Otherwise, the surface of guide wire may be damaged significantly.]
- Do not use the guide wire in combination with catheters (atherectomy catheter, metallic dilator etc.) which metallic part may contact surface of this guide wire. [This guide wire may be damaged or separated.]
- Always advance and withdraw the guide wire slowly.
- Observe guide wire movement in the vessels. Before a guide wire is moved or torqued, the tip movement should be examined and monitored under fluoroscopy. Do not move or torque a guide wire without observing corresponding movement of the tip. [Otherwise, the guide wire may be damaged and/or trauma may occur.] In addition, ensure that the distal guide wire and its location in the vessel are visible during wire manipulations.
- Never push, auger, withdraw, or torque a guide wire that meets resistance. Torquing or pushing a guide wire against resistance may cause guide wire damage and/or guide wire tip separation or direct damage to a vessel. 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, do not allow the tip to remain in a prolapsed position.[Otherwise damage to the guide wire may occur.] Determine the cause of resistance under fluoroscopy and take any necessary remedial action.
- If any resistance is felt due to spasm or the guide wire being bent or trapped while operating the guide wire in the blood vessel or removing it, do not move or torque the guide wire. Stop the procedure. Determine the cause of resistance under fluoroscopy and take appropriate remedial action. If the guide wire is moved excessively, it may break or become damaged, which may cause blood vessel injury or result in fragments being left inside the vessel.
- This guide wire must be used in an institution where emergency surgical operation can be performed immediately. [If an emergency surgical operation is unavailable, in the worst case, life-threatening events may occur.]
- When torquing this guide wire inside the blood vessel, do not torque continuously in the same direction. This may cause the guide wire to become damaged or break apart, causing injury to the blood vessel or leaving fragments inside the vessel. When torquing the guide wire, rotate it clockwise and counterclockwise alternately. Do not exceed two rotations (720°) in the same direction.
- Do not push the guide wire more than necessary to advance the tip through the narrowed part of the vessel. (For example, do not push the guide wire when the distal tip of the guide wire is bent by the force of manipulation.) After crossing the targeted area, do not roughly twist, push or pull the guide wire. If the guide wire is moved excessively, it may be damaged or break apart, which may injure the blood vessel or leave fragments inside the vessel.

- Use proper technique to ensure and verify that no air enters the interventional device when pulling guide wire from the interventional device or reinserting it. [Otherwise air embolism could occur.]
- Flush the guide wire with heparinized saline or other suitable solution while removing and reinserting it to prevent air from entering the interventional device. Perform guide wire exchanges carefully 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 is not against the vessel wall. Failure to do so may result in trauma when the guide wire is removed. Use the radiopaque marker of the interventional device to confirm position.
- 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 the guide wire movement.
- Do not practice stent delivery when using this guide wire with the “Parallel Wire Technique”.
- Do not manipulate the guide wire through stent struts.
- Do not use in areas of vessel that are not or cannot be visualized.
- Do not connect this guide wire with extension wire produced by the manufacturers excluding ASAHI INTECC. [Otherwise, the guide wire may be damaged, or the extension wire may be detached.] Please see the EXTENSION® instructions for use.
- Do not manipulate this guide wire while the extension wire is connected. The extension wire should be need only for the sole purpose of insertion and/or removal of the intervention device used at the same time. [Otherwise, the guide wire may be damaged, or the extension wire may be detached.]
- When connecting/detaching the extension wire to/from this guide wire or inserting/removing combined interventional devices, the guide wire should be tightly secured and careful attention given to the motion of the tip of the guide wire under X-ray fluoroscopy. [Otherwise, the blood vessel may be damaged.]
- When connecting the extension wire with this guide wire, it should be securely inserted to the boundary line between non PTFE coating and PTFE coating at the proximal end of the guide wire. [Otherwise, the extension wire may be unintentionally detached.]
- If something abnormal is felt and/or detected on the connection while attaching/detaching the extension wire to/from to this guide wire, stop using the guide wire immediately. [Otherwise, the guide wire may be damaged, or the extension wire may be damaged/detached]
- Do not close the stopcock of the guiding catheter when the guide wire is inserted in the guiding catheter. [Otherwise, the guide wire may be damaged.]
- Use this guide wire carefully as the guide wire may penetrate the blood vessel. Otherwise, it may cause adverse events such as blood vessel perforation and coronary artery dissection. The higher torque performance, stiffer distal end, and/or higher advancement force may present a higher risk of perforation or injury than if using a more flexible guide wire. Therefore, use the most flexible guide wire that will treat the lesion (i.e., the guide wire with the smallest tip load that will treat the lesion), and

take due care to minimize the risk of perforation or other damage to blood vessels.

- Use the most suitable guide wire that will treat the lesion. There are patient risks when using any guide wire including those that may result from damage to, or breakage of, the guide wire. If guide wire damage or breakage occurs, it may cause damage to the vessel and injury to the patient, or death. Accordingly, care should be taken that all persons who operate the guide wire are properly trained in their use, that they observe proper technique, and that guide wires are used carefully in accordance with the Instructions for Use.

Precautions

- If the package is opened or damaged, do not use the guide wire. Do not open the package until just prior to use. Use sterile technique in handling and using the guide wire.
- Contraindications, warnings, precautions, and intended uses of interventional devices that are compatible with Peripheral Guide Wire are described in the Instructions for Use supplied with the respective interventional devices. Before using a Peripheral Guide Wire with other interventional devices(Sheath introducer, Shaping device, PCI/PTA guide wire, Guiding catheter, PCI/PTA dilatation catheter, Micro catheter, Support Catheter, Stent delivery system etc.), read the Instructions for Use of the other devices to ensure the other devices are compatible with the Peripheral Guide Wire. Ensure you choose the correct Peripheral Guide Wire and that its use is consistent with the contraindications, warnings, precautions, and Instructions for Use of both the other devices and Peripheral Guide Wire.
- Before use, make sure that tip flexibility, size and shape of this guide wire are suitable.
- Guide wires are delicate instruments and should be handled carefully. When taking the guide wire out of the holder tube, do not handle the guide wire roughly or pull it out abruptly.
- Inspect the guide wire carefully for bends, kinks, or other damage prior to use and whenever possible during the procedure.
- Never use metallic cannula or metallic sheaths for insertion and withdrawal of guide wire. [Otherwise, the surface of guide wire may be damaged significantly.]
- Take due care when using the guide wire to prevent bending or kinking, and stay within standard practice when using the guide wire.
- 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 fragile. 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.
- Verify which is the distal end before insertion and be sure to insert the flexible distal end (coiled end or plastic covered end).
- Do not wipe this guide wire using an organic solution such as alcohol.
- 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 modify this guide wire for any reason.
- For the holder with the distal end protection tube (Ref. How to Use, Figure 1), do not remove or insert the distal end protection tube while the guide wire is housed in the

holder.

- For the holder with the distal end protection tube (Ref. How to Use, Figure 1), remove the distal end protection tube before housing the guide wire in the holder again.
- Take preventive measures against infection after use. Discard this guide wire as medical waste.

Malfunction and Adverse effects

Possible complications and adverse events of guide wire use include, but are not limited to:

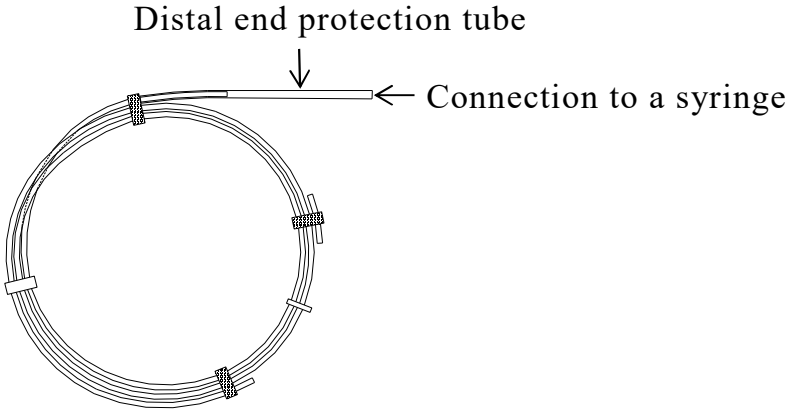
Trauma
Complications with hemorrhage
Complications with ischemia
Allergy
Embolism of distal vessels (Air, Organic, Thrombus)
Hypotension / Hypertension
Hemorrhage or infection of puncture sit
Vessel spasm / Convulsion
Fistula of artery or vein
Bradycardia / Palpitation
Femoral artery false aneurysm / Formation of false aneurysm
Arterial embolus / Thrombus / Blockage
Separation or breakage of the guide wire
Damage to a vessel, including possible vessel perforation
Vessel dissection
Death

How to Use

1. Inspection prior to use
   a) Before use, inspect carefully and confirm all devices and packages are undamaged.
   b) Before use, confirm that the guide wire is compatible with the interventional device to be used.
2. Preparation
   a) Select the most suitable guide wire for the affected area and remove the holder tube containing the guide wire from the sterile pack.
   b) Release the proximal end of the guide wire from the tail clip and slowly push it through the holder. For the holder with the distal end protection tube (Figure 1), a syringe can be connected to the distal end protection tube.
   c) 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 fragile. 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.
   d) 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.

Figure 1



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 interventional device tip.
c) Engage the guiding catheter and insert the interventional device system (with guide wire) into the Y connector.
d) 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.
e) Tighten the hemostatic valve of Y connector to create a seal around the interventional device. Ensure the guide wire movement is still permitted.
f) Check to make sure the guide wire moves smoothly.
g) Attach the torque device to the guide wire if necessary.
h) Advance this guide wire under fluoroscopy to pass through the lesion. Confirm by angiography that the guide wire has passed the target lesion.
i) Observe guide wire movement in the vessels. Before 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, trauma may occur.
j) Do not use in areas of vessel 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 guide wire distal tip and its location in the vessel are visible during interventional device manipulations.

■ Rapid exchange system

a) Engage the guiding catheter.
b) Insert the guide wire introducer into the Y connector of the guiding catheter.
c) Carefully insert the guide wire tip into the introducer.
d) 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.
e) Attach the torque device to the guide wire if necessary.
f) Advance the guide wire under fluoroscopy to pass through the lesion. Confirm by angiography that the guide wire has passed the target lesion.

g) 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, trauma may occur.
h) Do not use in areas of vessel that are not or cannot be visualized.
i) Remove the guide wire torque device and the guide wire introducer.
j) 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 exchange the guide wire

■ Over the wire system

a) Remove the guide wire slowly while monitoring the movement of the guide wire under fluoroscopy.
b) Insert the next guide wire in accordance with the directions in this "How to Use" section.

Special Instructions for hydrophilic coated guide wires:

■ **Precautions**

Avoid abrasion and peeling of the hydrophilic coating.
Do not withdraw or manipulate the guide wire in a metallic cannula or sharp-edged introducer device, as this may damage the hydrophilic coating.

■ **Preparations for use**

1)Before pulling the guide wire out of the holder tube, flush it with heparinized saline from the holder tube end. If it is difficult to pull the guide wire out of the holder tube, flush it again with heparinized saline.
2)After pulling the guide wire out of the holder tube, inspect it to make sure that it is not damaged.
3)If the surface of the guide wire becomes dry, the hydrophilic coating effect can be restored by wetting the surface with heparinized saline.
4)Before inserting the guide wire into an interventional device, wet it completely with heparinized saline.
5)After pulling the guide wire out of the body, and keep it wet.

Storage Condition

- Do not keep the guide wire in a bent and/or heavily-loaded condition.
- This guide wire must be kept out of water. Store in a cool, dark and dry place.

Expiry date

- Expiry date is printed on the package label.

Contents

- 5 pieces /box

Liability Disclaimer

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