Peripheral Guide Wire

INSTRUCTIONS FOR USE

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

Read these instructions carefully before using this guide wire and observe the Indications for Use, Contraindications, Warnings, Precautions, and How to Use sections in this 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.

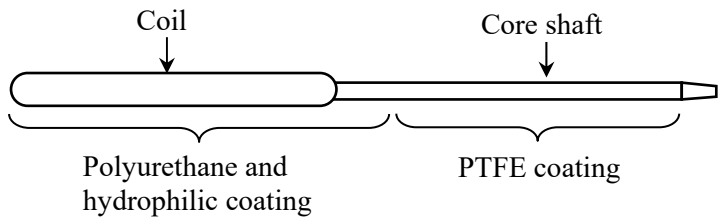
Descriptions

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

The guide wire surface is coated with polytetrafluoroethylene (PTFE) and/or hydrophilic polymer. The purpose of these surface coatings is to provide lubricity when the guide wire is passed through percutaneous catheters. About 2 cm of the distal end can be shaped. The product with a pre-shaped tip is also available as an option.

ASAHI INTECC detachable extension wire can be connected to the proximal end of this device. The total length after the connection will be 265 to 465 cm.

< Plastic covered-type >



Indications for Use

This product is designed to direct a catheter to the desired anatomical location in the peripheral vasculature (excluding coronary and cerebral vessels) during diagnostic or interventional procedures.

Contraindications

- Do not use the guide wire for pregnant patients or patients who may be pregnant (X-ray may affect the fetus).
- Do not use the guide wire for newborns or children.

- Do not use the guide wire for patients who cannot adapt to emergency surgery or patients who have experienced a serious allergic reaction to drugs required for the procedure such as a contrast medium.
- Patients who are contraindicated to anti-platelet and/or anticoagulant therapy.

Warnings

- This guide wire is presterilized with ethylene oxide gas (EOG) and is intended for single use only. Do not reuse or resterilize. If reused or resterilized, the performance or quality of this guide wire and package 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.
- This guide wire is not intended for use in carotid arteries.
- 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 needles or metallic sheaths for insertion and withdrawal of this guide wire. Otherwise, the surface of this guide wire may be damaged significantly.
- Do not use this guide wire in combination with catheters (atherectomy catheter, metallic dilator etc.) which metallic parts may contact surface of this guide wire. Otherwise, this guide wire may be damaged or break apart.
- Always advance and withdraw the guide wire slowly.
- Observe movement of this guide wire in the vessels. Before this guide wire is moved or torqued, the tip movement should be examined and monitored under fluoroscopy. Do not move or torque the 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 tip of this guide wire and its location in the vessel are visible during manipulations of the guide wire.
- Never push, auger, withdraw, or torque this guide wire that meets resistance. Torquing or pushing this guide wire against resistance may cause damage and/or tip separation of this guide wire or direct damage to a vessel. Resistance may be felt and/or observed under fluoroscopy by noting any buckling of the guide wire. If the prolapse of the guide wire tip 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 resistance is felt due to spasm, bending of the guide wire, or due to trap while operating this guide wire in the blood vessel or removing it, do not torque and/or pull the guide wire itself. 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.
- If resistance is felt between this guide wire and the other interventional devices while operating this guide wire in the blood vessel, avoid applying excessive force. When abnormal resistance is felt, remove the entire system from the patient's body and determine the cause. Otherwise, the guide wire may break or be damaged and may cause injury to the blood vessel or leave fragments 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 this guide wire from the interventional device or reinserting it. Otherwise, air embolism could occur.
- Flush the guide wire with heparinized and sterilized saline or other suitable solution while removing and reinserting it to prevent air from entering the interventional device. Perform exchange of this guide wire 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. Use the radiopaque marker of the interventional device to confirm the 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 perform stent placement using more than one guide wire or wire operation through stent strut. Otherwise, the stent may be damaged or the guide wire may break or break apart.
- Do not use in areas of vessel that are not or cannot be visualized.
- Do not connect this guide wire with detachable extension wires produced by the manufacturers excluding ASAHI INTECC. Otherwise, the guide wire may be damaged, or the detachable extension wire may be unintentionally detached. Please see the ASAHI® EXTENSION® instructions for use.
- Do not manipulate this guide wire while the detachable extension wire is connected. The detachable extension wire should be needed only for the sole purpose of insertion and/or removal of the interventional device used at the same time. Otherwise, the guide wire may be damaged, or the detachable extension wire may be unintentionally detached.
- When connecting/detaching the detachable 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 detachable 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 detachable extension wire may be unintentionally detached.
- If something abnormal is felt and/or detected on the connection while attaching/detaching the detachable extension wire to/from this guide wire, stop using this guide wire immediately. Otherwise, this guide wire may be damaged, or the detachable extension wire may be unintentionally

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.
- This device is coated with polytetrafluoroethylene (PTFE) and/or hydrophilic polymer. Lubricious coating is indicated on the label of the guide wire package. Please refer to "Special Instructions for hydrophilic coated guide wires:" in Section "How to Use" for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- During the procedure, use appropriate anticoagulation considering the condition of the patient.

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 aseptic technique in handling and using the guide wire and package.
- Contraindications, warnings, precautions, and intended uses of interventional devices used in the procedure are described in the Instructions for Use supplied with the respective interventional devices. Before using the guide wire with other interventional devices (Sheath introducer, Shaping device, Extension wire, Y connectors, Guiding catheter, PTA dilatation catheter, Micro catheter and Stent), read the Instructions for Use of the other devices to ensure the other devices are compatible with this guide wire. Ensure you choose a guide wire suitable for the therapy and that the other devices and the guide wire are used in a manner consistent with their contraindications, warnings, precautions, and Instructions for Use.
- Before use, make sure that tip flexibility, size and shape of this guide wire is suitable for the intended procedure.
- 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.
- 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 tip, 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. Check 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 (plastic covered end).
- Do not wipe this guide wire using an organic solution such as alcohol.
- Do not use this guide wire for the purposes other than described in the Indications for Use written in this document.
- Take due 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.
- Take preventive measures against infection after use. Discard this guide wire and package as medical waste.
- The guide wire has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of this guide wire in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Malfunctions and Adverse events

Possible malfunctions and adverse events through usage of this guide wire include, but are not limited to the following:

1. Malfunctions
   - Separation or breakage of the guide wire
   - Damage such as separation
   - Coming off of coating
2. Adverse events

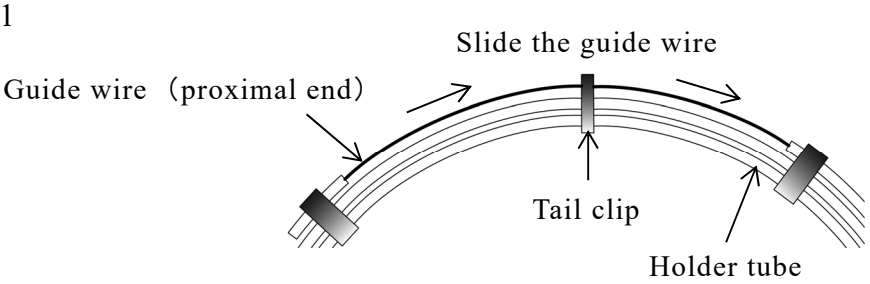
Death	Vascular occlusion	Dizziness
Infection	Thrombus	Headache
Hypotension	Ischemia	Vomiting
Bleeding complications	Arrhythmia	Vessel perforation
Embolism	Vessel dissection	Allergic reaction
Infarction	Vasospasm	

How to Use

1. Inspection prior to use
   a) Before use, inspect carefully and confirm the guide wire and package are undamaged.
   b) Before use, confirm that the guide wire is compatible with the interventional devices 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) Fill up the holder tube with heparinized and sterilized saline using a syringe to soak the entire device. Take note that heparinized and sterilized saline may spill out of the holder tube during at this time.

c) Release the guide wire from the tail clip and slide the guide wire slowly, and push distal end of the guide wire through the holder tube (Figure 1) .

Figure.1



d) When the distal end of the guide wire is extended 5 to 6 cm beyond the other end of the holder tube, if necessary, shape the tip in accordance with standard practice. When shaping the tip, 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. Check the coil and guide wire for damage after shaping and before using.
e) 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.
f) If resistance is felt when removing the guide wire from the holder tube, inject heparinized and sterilized saline into the holder tube again. Continue removing the guide wire after the resistance is not felt anymore. Be sure to inject enough heparinized and sterilized saline to the holder tube because hydrophilic coating may be damaged when removing the coated guide wire forcefully.

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 the guide wire) into the Y connector.
d) Advance the interventional device system through the guiding catheter until the tip of the guide wire 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 narrowed target lesion.
i) 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 the 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 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 narrowed target lesion.
g) Observe this 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 the 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 guide wire distal 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 this guide wire slowly while monitoring the movement of this 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 needle or metallic sheath 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 and sterilized 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 and sterilized 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 and sterilized saline.
4) Before inserting the guide wire into an interventional device, wet it completely with heparinized and sterilized saline.
5) Be sure to keep this guide wire soaked after it is pulled out of the patient's body.

Storage method

Do not keep the guide wire and package in a bent and/or heavily-loaded condition. This guide wire and

package must be kept out of water. Store in a cool, dark, and dry place.

Expiration date

The expiration date is indicated on the label of the guide wire package.

Contents

5 pieces / box

Symbols

	Pre-shaped		Straight

Liability Disclaimer

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