ASAHI Peripheral Vascular 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 device and observe the Indications for Use, Warnings, Precautions 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 ASAHI Peripheral Vascular Guide Wires. For details (length of the guide wire, length of radiopaque section, etc.), refer to the product label.

Descriptions

This peripheral vascular guide wire has a coil-type distal end. The coil is partly radiopaque to facilitate selection of the blood vessel and confirmation of the position of the guide wire's distal end by fluoroscopy. The distal end can be shaped.The core shaft surface is coated with hydrophilic polymer.

Indications for Use

ASAHI Peripheral Vascular Guide Wire is intended for use in the peripheral vasculature, to facilitate the exchange and placement of diagnostic and therapeutic devices such as vascular catheters during peripheral interventional procedures. **This guide wire is not intended for use in neuro- or coronary vasculature.**

Warnings

- Sterilized with ethylene oxide gas (EOG), this guide wire is for single use only. Do not reuse or resterilize. If reused or resterilized, the performance or quality of this 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 device that exceeds the expiration date.
- This guide wire must be used only by a physician who is fully trained in Interventional Radiology (IVR) treatment.
- 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.]
- Do not use in areas of vessel that are not or cannot be visualized.
- Do not modify this guide wire for any reason.
- 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.
- 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 vessel 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 tip 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 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.
- 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. The tensile strength is 2.45 N (250 gf).
- 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.
- 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 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 vessel 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 for “Parallel Wire Technique”.
- Do not manipulate the guide wire through strut of stent.
- Before use, inspect carefully and confirm all devices and packages are undamaged.
- Before use, confirm that the guide wire is compatible with the interventional device to be used.
- Before use, confirm that the flexibility, shape, and size of the distal end of this guide

wire is compatible with the procedure.

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.
- Contraindications, warnings, precautions, and intended uses of interventional devices that are compatible with ASAHI Peripheral Vascular Guide Wires are described in the Instructions for Use supplied with the respective interventional devices. Before using ASAHI Peripheral Vascular Guide Wire with other interventional devices (Sheath introducer, Shaping device, IVR guide wire, Guiding catheter, Micro catheter, Detachable coil, Dilatation catheter and Stent), read the Instructions of those devices to ensure the other devices are compatible with the ASAHI Peripheral Vascular Guide Wire. Ensure you choose the correct ASAHI Peripheral Vascular Guide Wire and that its use is consistent with the contraindications, warnings, precautions, and Instructions for Use of both the other devices and ASAHI Peripheral Vascular Guide Wire.
- 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 needles or metallic sheaths for insertion and withdrawal of this guide wire. Otherwise, the surface of guide wire may be damaged significantly.
- Never use catheters with a metallic part that may come into direct contact with the surface of this guide wire (atherectomy catheter, metallic dilator, etc.).(This guide wire may be damaged or severed.)
- When shaping the distal end, use the minimum force needed so that the coil is not damaged. Inspect the coil and guide wire for damage after shaping and before using.
- Take due care when shaping the tip of this guide wire. Be sure the guide wire is wet before shaping to avoid damaging the hydrophilic polymer coating.
- Verify which is the distal end before insertion and be sure to insert the flexible distal end (coiled end).
- Before withdrawing the guide wire,fill up the holder tube with heparinized saline for at least 30 seconds to moisten the whole guide wire.
- Do not wipe this guide wire using an organic solution such as alcohol.
- When fastening the torque device to the guide wire, be careful not to overfasten it. [When fixing the torque device to this guide wire, overfastening may damage it.]
- When changing the attachment position of the torque device on the guide wire, loosen the fastening of the torque device before moving it.
- Take preventive measures against infection after use. Discard this guide wire as medical waste.
- When withdrawing the guide wire from the holder tube, hold the guide wire proximal end part, slide the guide wire in the direction of Arrow (1) slowly, and withdraw the proximal end part of the guide wire from the protective tubing and tail clip (Figure 1). Then, confirm that the proximal end part of this guide wire is completely out of the tail clip. Moreover, hold this guide wire, pull it in the direction of Arrow (2), and withdraw it from the holder tube. (Figure 2)

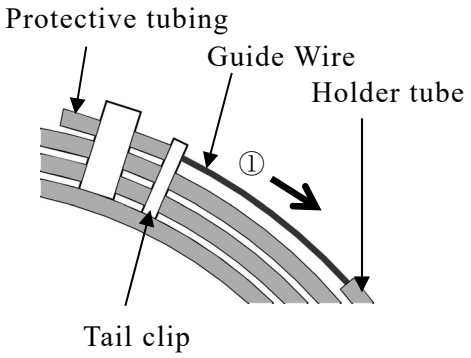


Figure 1

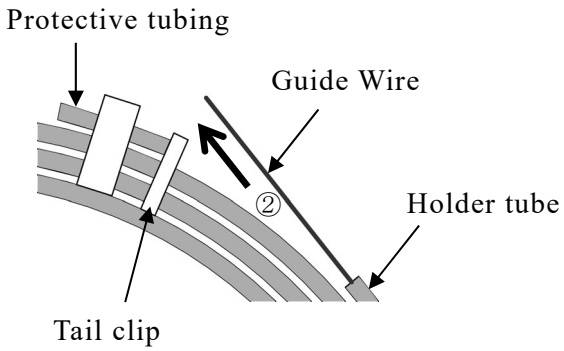


Figure 2

Adverse Reactions/Events

Use the most suitable guide wire that will treat the lesion. 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 wire are used carefully in accordance with the Instructions for Use. Possible complications and adverse events of using this guide wire include, but are not limited to:

- Buckling, bending, separation or breakage of this guide wire and its withdrawal trouble
- Death
- Vessel damage, such as dissection, perforation, rupture
- Cerebral infarction
- Cerebral thrombosis
- Other cerebral strokes
- Subarachnoid bleeding
- Bleeding complications
- Ischemic complications
- Cerebral ischemia
- Peripheral vascular ischemia
- Allergy
- Distal vascular embolism (air, tissue, thrombotic)
- Hypotension/Hypertension
- Infection or complications at the puncture site
- Angiospasm/Vasospasm
- AV fistula
- Bradycardia/palpitation
- Femoral false aneurysm/false aneurysm formation
- Arterial embolus/thrombus/occlusion
- Cerebral apoplexy/cerebral vascular accident
- Pulmonary thrombosis

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(s) to be used.

2. Preparation

a) Remove the holder tube containing the guide wire from the package. In addition, remove the small bag containing the inserter, torque device, and shaping device, if required.

b) Fill up the holder tube with heparinized saline using a syringe to moisten the whole of this guide wire at least for 30 seconds. If it is difficult to remove this guide wire, flush the holder tube again with heparinized saline. However, keep in mind that heparinized saline may blow out from the holder tube tip.

c) Grasp the guide wire proximal end part, slide the guide wire in the direction of Arrow (1) slowly, and withdraw the proximal end part of the guide wire from the protective tubing and tail clip (Fig. 1 of Precautions) Then, confirm that the proximal end part of this guide wire is completely out of the tail clip. Grasp this guide wire, pull it in the direction of Arrow (2), and withdraw it from the holder tube. (Fig. 2 of Precautions) (Withdraw this guide wire from the other side than the flush connector.) Then, if resistance is felt, fill up the holder tube again with heparinized saline. Still, if resistance is felt, replace this guide wire with a new one. [Forced withdrawal may damage or rupture this guide wire.] After pulling the guide wire out of the holder tube, inspect it to make sure that it is not damaged.

3. How to use

a) When shaping the tip of this guide wire, be sure that the guide wire is wet and bend it little by little using the accompanying shaping device. When shaping, do not bend acutely or repeatedly the same location. [Core wire inside coil may break causing damage and rupture of this guide wire.] Before and after forming the tip, check this guide wire for any damage.

b) Before inserting this guide wire, fill up the catheter to be used with heparinized saline.

c) A catheter injected with contrast medium or embolization material should be filled up with heparinized saline before inserting this guide wire.

d) Insert the tip of this guide wire into the inserter carefully.

e) Using the inserter, insert this guide wire into the catheter to be used.

f) Use of the accompanying torque device will improve usability.Be careful not to overfasten the torque device. [When fixing the torque device to this guide wire, overfastening may damage it.]

g) Advance the guide wire to the target vessel by carefully manipulating and/or rotating under fluoroscopy.

h) After pulling the guide wire out of the body, wipe it off with gauze soaked in heparinized saline, 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.

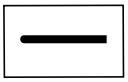
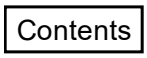
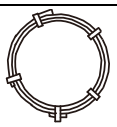
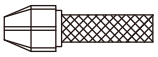
Expiration date

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

Contents

1 set per package

Symbols

	Straight		Angle
	Contents		Guide Wire
	Torque device		
		Inserter	
		Shaping device	

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