ASAHI
PTCA Guide Wire

AMK-DT540 Ver.1.00 / 20TS002

SYMBOLS

Legal Manufacturer

Sterilized using ethylene oxide

Do not use if package is damaged

Consult instructions for use

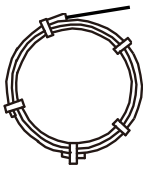
Do not reuse

Unit

Do not resterilize

Contents

Caution, consult accompanying documents

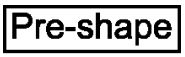


Guide Wire

Use by

Mini pre-shaped

Keep dry

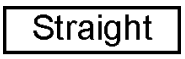


Pre-shaped

Keep away from sunlight

Straight

Lot number



Straight

Catalogue number

ASAHI PTCA Guide Wire
INSTRUCTIONS FOR USE

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 ASAHI PTCA Guide Wires. For details (length of the guide wire, length of radiopaque section, etc.), refer to the product label.

Descriptions

This PTCA 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 guide wire surface is coated with polytetrafluoroethylene (PTFE) and/or hydrophilic polymer and/or silicone. 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 is available to connect with the proximal end of this guide wire with a length of less than 300 cm. A total length after the connection will be 300 to 350 cm.

Indications for Use

ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA).
The ASAHI PTCA Guide Wires **are not intended for use in the neurovasculature.**

Contraindications

- This guide wire and package 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.
- 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.
- Do not use in areas of vessel that are not or cannot be visualized.
- Do not wipe this guide wire using an organic solution such as alcohol.
- 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.
- Do not modify this guide wire for any reason.

Warnings

- This guide wire must be used only by a physician who is fully trained in PTCA treatment.
- The coil section is especially fragile, so do not bend or pull it more than necessary. Otherwise, the guide wire may be damaged.
- Never use this guide wire for pregnant, possibly pregnant patients or infants. [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.]
- 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 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 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.
- Before use, make sure that tip flexibility, size and shape of this guide wire is suitable for the intended procedure.
- 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.
- Contraindications, warnings, precautions, and intended uses of interventional devices are described in the Instructions for Use supplied with the respective interventional devices. Before using an ASAHI PTCA Guide Wire with other interventional devices (Sheath introducer, Shaping device, PTCA guide wire, Extension wire, PTCA guiding catheter, PTCA dilatation catheter, Micro catheter and Stent), read the Instructions for Use of the other devices to ensure the other devices are compatible with the ASAHI PTCA Guide Wire. Ensure you choose the correct ASAHI PTCA Guide Wire and that its use is consistent with the contraindications, warnings, precautions, and Instructions for Use of both the other devices and ASAHI PTCA Guide Wire.

Precautions

- 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.
- 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.
- 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 guide wire with plastic covered-type distal end is very delicate against damage. Pay careful attention not to damage the plastic cover when shaping the tip. 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 (coiled end or plastic covered end).
- 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.
- 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.
- For the guide wire which proximal end is fixed between the holder clip and holder tube (A), the guide wire may be bent when removed without releasing the proximal end from the holder tube retaining it (A). Remove the holder tube from the holder clip before the guide wire is handled. (Ref. How to use, Figure 2)
- Take preventive measures against infection after use. Discard this guide wire and package as medical waste.

Malfunction and Adverse effects

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

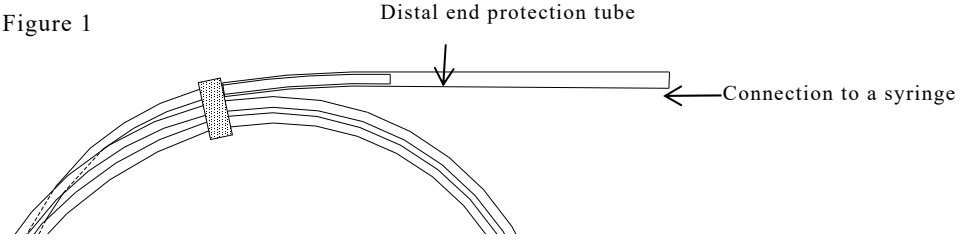
Kink of the guide wire
Abrasion of the guide wire coating
Insertion difficulty of guide wire
Removal difficulty of guide wire
Separation or breakage of the guide wire
Death
Infection
Dissection of blood vessels
Perforation of blood vessels
Bleeding complications
Embolism
Thrombus
Infarction
Ischemia
Arrhythmia
Spasm of blood vessels
Vascular occlusion
Blood pressure reduction
Allergic reaction

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. For the holder with the distal end protection tube (Figure 1), a syringe can be connected to the distal end protection tube.
   c) Release the guide wire from the tail clip and slide the guide wire slowly, push distal end of the guide wire through the holder tube(B).(Figure 2) For the guide wire whose proximal end is fixed between the holder clip and holder tube (A), remove the holder tube from the holder clip and slide the guide wire slowly, push distal end of the guide wire through the holder tube(B). (Figure 3)

Figure 1



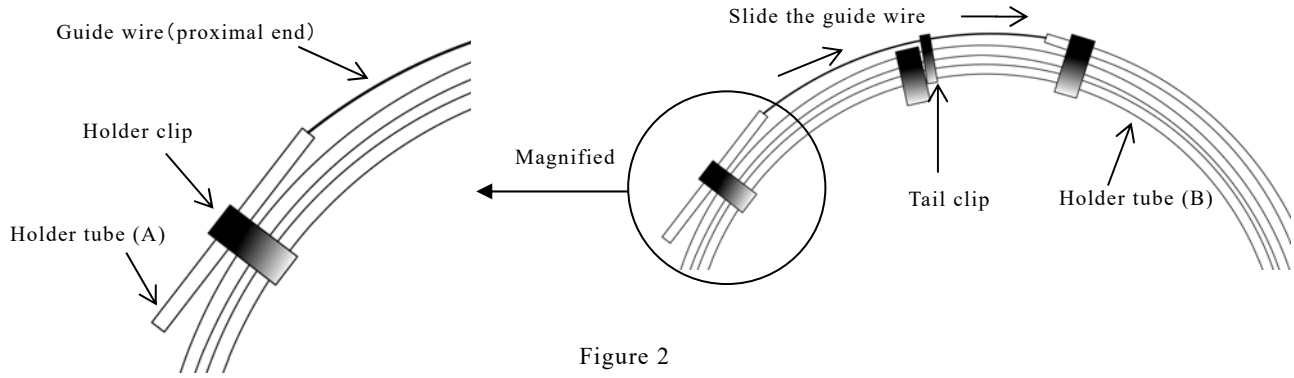


Figure 2

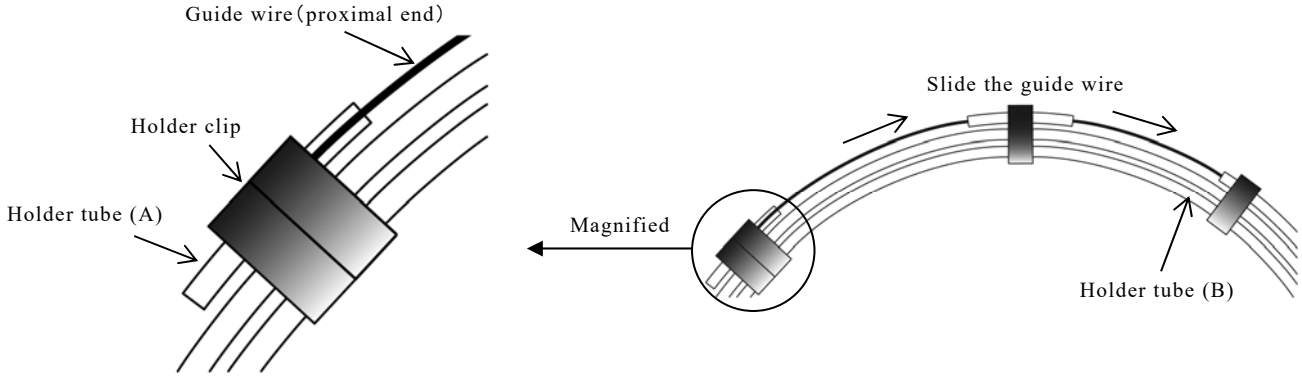


Figure 3

d) When the distal end of the guide wire is extended 5 to 6 cm beyond the other end of the holder tube (or the distal end protection 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 guide wire with plastic covered-type distal end is very delicate against damage. Pay careful attention not to damage the plastic cover when shaping the tip. 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 (or the distal end protection 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.
g) Fill the lumen of the interventional device with the heparinized and sterilized saline before inserting the guide wire.

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 this 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 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 Condition

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

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Country of origin for this product is indicated on the product label

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