ASAHI

Neurovascular Guide Wire

AMK-DT244 Ver.1.00 / 11TS073

Legal manufacturer

Do not use if package is damaged

Do not reuse

Do not resterilize

Caution, consult accompanying documents

Use by

Keep dry

Keep away from sunlight

LOT number

Catalogue number

Sterilized using ethylene oxide

Unit

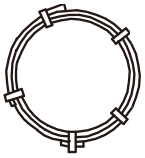
Consult instructions for use

RX ONLY

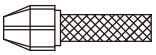
Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician

Only sterile and non pyrogenic in unopened packages

Contents



Guide Wire



Torque device

Inserter

Shaping device

EN

ASAHI Neurovascular 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 use and observe the Indications for Use, Warnings, Precautions, Malfunction and adverse events 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 Neurovascular Guide Wires. For details (length of the guide wire, length of radiopaque section, etc.), refer to the product label.

Descriptions

This Neurovascular 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 Polytetrafluoroethylene (PTFE) or hydrophilic coating.

Indications for Use

ASAHI Neurovascular Guide Wire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. **This guide wire is intended for use only in the neuro vasculature.**

Warnings

- This device is for single use only. Do not reuse or resterilize. If reused or resterilized, the performance or quality of this device may be compromised and there is a risk of complications, including infection.
- Do not use the device after the expiration date indicated on the label. Discard any device that exceeds the expiration date.
- This device must be used only by a physician who is fully trained in Interventional Radiology (IVR) treatment.
- This device 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 device regardless of the reason.
- The coil section is especially fragile, so do not bend or pull it more than necessary. Otherwise, the device may be damaged.
- Do not use a damaged device. Using a damaged device may result in blood vessel damage and/or inaccurate torque response. Injury to the patient may result.
- Always advance and withdraw the device slowly.
- Observe movement of this device in the vessels. Before this device is moved or torqued, the tip movement should be examined and monitored under fluoroscopy. Do not move or torque the device without observing corresponding movement of the tip. Otherwise, the device may be damaged and/or vessel trauma may occur. In addition, ensure that the distal tip of this device and its location in the vessel are visible during manipulations of the device.
- Never push, auger, withdraw, or press this device with enough force to feel resistance. Pressing or pushing this device against resistance may cause damage and/or tip separation of this device or direct damage to a vessel. Resistance may be felt and/or observed under fluoroscopy by noting any buckling of the tip of the device. If the prolapse of the device tip is observed, do not allow the tip to remain in a prolapsed position. Otherwise damage to the device 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 device being bent or trapped while operating the device in the blood vessel or removing it, do not move or torque the device. Stop the procedure. Determine the cause of resistance under fluoroscopy and take appropriate remedial action. If the device 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 device inside the blood vessel, do not torque continuously in the same direction. It

may be damaged or break apart, which may injure the blood vessel or leave fragments inside the vessel. When torquing the device, rotate it clockwise and counterclockwise alternately. Do not exceed two rotations (up to 720°) in the same direction. The tensile strength is 2.45 N (250 gf).

- Do not push the device more than necessary to advance the tip through the narrowed part of the vessel. (For example, do not push the device when the distal tip of the device is bent by the force of manipulation.) After crossing the targeted area, do not roughly twist, push or pull the device. If the device is moved excessively, it may be damaged or break apart, which may injure the blood vessel or leave fragments inside the vessel.
- When inserting or removing other devices over the guide wire, flush the concomitant device with heparinized saline or other suitable solution to prevent air from entering it. Perform exchange of this device carefully to prevent air entry and/or trauma. When reintroducing the device, confirm that the 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 device 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 device movement.
- Do not practice stent delivery when using this device for “Parallel Wire Technique”.
- Do not manipulate the device through strut of stent.
- Do not connect this device with detachable extension wires produced by the manufacturers excluding ASAHI INTECC. [Otherwise, the device may be damaged, or the detachable extension wire may be detached]
- Before use, inspect carefully and confirm all devices and packages are undamaged.
- Before use, confirm that the device is compatible with the interventional device to be used.
- Before use, confirm that the flexibility, shape, and size of the distal end of this device is compatible with the procedure.

Precautions

- If the package is opened or damaged, do not use the device. Do not open the package until just prior to use. Use aseptic technique in handling and using the device.
- Contraindications, warnings, precautions, and intended uses of interventional devices that are compatible with ASAHI Neurovascular Guide Wires are described in the Instructions for Use supplied with the respective interventional devices. Before using an Neurovascular Guide Wire with other interventional devices (Sheath introducer, Shaping device, IVR guide wire, IVR guiding catheter, Micro catheter, detachable coil, IVR dilatation catheter and Stent), read the Instructions of those devices to ensure the other devices are compatible with the ASAHI Neurovascular Guide Wire. Ensure you choose the correct ASAHI Neurovascular Guide Wire and that its use is consistent with the contraindications, warnings, precautions, and Instructions for Use of both the other devices and ASAHI Neurovascular Guide Wire.
- Guide wires are delicate instruments and should be handled carefully. When taking the device out of the holder tube, do not handle the device roughly or pull it out abruptly.
- Inspect the device 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 device. Otherwise, the surface of this device may be damaged significantly.
- Never use catheters with a metallic part that may come into direct contact with the surface of this device (atherectomy catheter, metallic dilator, etc.).
- 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.
- Use care when shaping the tip of this device. Be sure the device is wet before shaping to avoid damaging the surface coating.
- Verify which is the distal end before insertion and be sure to insert the flexible distal end (coiled end).
- Fill up the holder tube with heparinized saline for at least 30 seconds to moisten the whole guide wire.
- Do not wipe this device using an organic solution such as alcohol.
- Fasten the torque device to the guide wire firmly so that it may not loosen. Torque operation with a loose torque device may damage the coating.
- 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 device as medical waste.

Malfunction and adverse events

Use the most suitable guide wire that will treat the lesion. Care should be taken that all persons who operate the device are properly trained in their use, that they observe proper technique, and that devices are used carefully in accordance with the Instructions for Use. Possible malfunction and adverse

events of using this guide wire include, but are not limited to:

Failure to cross a lesion
Separation or breakage of the guide wire
Death
Infection
Vessel dissection
Damage to a vessel, including possible vessel perforation
Bleeding complications
Distal embolism
Thrombus
Infarction
Residue
Ischemia
Arrhythmia
Vasospasm
Vascular occlusion
Aneurysm rupture/perforation
Hemodynamic compromise
Aneurysm (false/dissecting)
Blood pressure reduction
Allergic reaction

How to Use

Preparations for use

a). Remove the holder tube containing the device from the sterile pack.
b). Before pulling the guide wire out of the holder tube, flush it with heparinized saline from the flush connector end into the holder tube to moisten the guide wire at least for 30 seconds. If it is difficult to pull the guide wire out of the holder tube, flush it again with heparinized saline.
c). Withdraw the guide wire from the holder tube.
d). After pulling the device out of the holder tube, inspect it to make sure that it is not damaged.
e). Shape the distal end of the guide wire into an intended shape as needed. Inspect the guide wire for damage before and after shaping the distal end.

How to Use

a). Before inserting the guide wire into an interventional device, wet it completely with heparinized saline.
b). Insert the guide wire into an interventional devices using the accompanying inserter.
c). Attach the accompanying torque device to the guide wire if necessary.
d). Select the target vessel by carefully advancing or rotating the guide wire by fluoroscopy.
e). After pulling the guide wire out of the body, remove blood and so on, and keep it wet.

Storage Condition

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

Contents

1 set per package

Disclaimer of Liability

By no means shall “ASAHI INTECC CO., LTD.” (hereinafter referred to as the “Company”) be liable for accidents, personal injuries, adverse effects due to any improper use of the product(s) or any other use inconsistent with these instructions. In no event shall the Company be liable for any damages either (i) arising out of storage of the product(s) after the shipment from the Company or (ii) due to selection of patients, surgery techniques, or any other medical activities by the medical institution that uses the product(s).

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Made in VIETNAM

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