CHIKAI Nexus 014

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, Contraindications, Warnings, Precautions, Malfunctions 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 CHIKAI Nexus 014 Neurovascular Guide Wires (hereafter called "the guide wire(s)"). For specifications of the respective product, refer to the product label.

Descriptions

This guide wire has a coil-type distal end. The coil is partly or wholly 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

This 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.**

Contraindications

None

Warnings

- 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.
- Do not use in areas of vessel that are not or cannot be visualized.
- Do not modify this guide wire regardless of the reason.
- Do not use a damaged device. Using a damaged device may result in blood vessel damage or inaccurate torque response. Injury to the patient may result.
- 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 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 press this guide wire with enough force to feel resistance. Pressing or pushing this guide wire against resistance may cause damage or tip separation of this guide wire or direct damage to a vessel. Resistance may be felt 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 be damaged including separation or the like, 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. It may be damaged including separation or the like, which may injure the blood vessel or leave fragments inside the vessel. When torquing the guide wire, rotate it clockwise and counterclockwise alternately. Do not exceed two rotations (up to 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 device is moved excessively, it may be damaged including separation or the like, 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 guide wire carefully to prevent air entry or trauma. When reintroducing the guide wire, 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 guide wire is removed. Use the radiopaque marker of the interventional device to confirm position.
- Do not connect the guide wire with detachable extension wires.
- 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 are compatible with the procedure.
- The distal end has vascular selectivity. However, if it is advanced into a thin peripheral area of the vessel, the penetrating force in the vessel becomes stronger, and there will be a higher risk of vessel damage such as vessel perforation. Therefore, when manipulating the guide wire or having a micro catheter or the like follow it, take extreme care. Do not perform catheter manipulation with the distal end of the guide wire being secured to the collateral since it will increase the risk of vessel perforation.
- Since the guide wire is provided with a hydrophilic coating at the distal end of the device in order to increase the lubricity, handle it with extreme care and appropriately 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.
- Never use metallic needles or metallic sheaths for insertion and withdrawal of this guide wire. Similarly, never use this guide wire with a metallic dilator, catheter, etc. whose metallic part

may come into direct contact with the surface of this guide wire. Otherwise, the surface of this guide wire may be damaged significantly.
- Do not manipulate the stopcock of the guiding catheter when the guide wire and/or other device is inserted in the guiding catheter fitted with a stopcock.
- Do not use solutions containing an organic solvent or an oil-based contrast medium, with this guide wire.
- Do not immerse the surface of the guide wire in alcohol or chlorhexidine gluconate solution or wipe it with gauze or absorbent cotton soaked with them. In addition, do not wipe the guide wire with dry gauze or absorbent cotton.
- Do not repeatedly bend and stretch the same position of the guide wire, or continuously turn it in a curved vessel for a long period of time.
- Do not let the guide wire come into contact with liquids other than an intravascular contrast medium or heparinized saline.
- If it is suspected that the guide wire manipulation cannot be continued, do not forcibly manipulate the guide wire, but pay a great deal of attention to any malfunction or adverse effects, and carefully remove the whole system. If it is judged that removal of the whole system may cause a malfunction or adverse effects, immediately abandon the neurointerventional procedure, and perform an emergency surgery procedure based on judgment of a physician.
- Appropriate anticoagulant therapy should be administered during surgery, taking into account the risk for hemorrhagic complications from anticoagulant therapy.
- 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 patients who cannot adapt to emergency surgery or patients who have experienced a serious allergic reaction to drugs required for the procedure such as contrast medium.
- Do not use the guide wire for patients for whom a physician judges it inappropriate to 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 aseptic technique in handling and using the guide wire.
- Contraindications, warnings, precautions, and intended uses of therapeutic devices that are compatible with the guide wire are described in the Instructions for Use supplied with the respective therapeutic devices. Before using the guide wire with other therapeutic devices, read the Instructions of those devices to ensure the other devices are compatible with the guide wire. Ensure you choose a guide wire suitable for the therapy and that its use is consistent with the contraindications, warnings, precautions, and Instructions for Use of both the other devices and the guide wire.
- This guide wire must be used only by a physician who is fully trained in neurointerventional 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.]
- Guide wires are delicate instruments and should be handled carefully. When taking the guide wire out of the holder tube, do not handle the device roughly or pull it out abruptly.
- The coil section is especially fragile, so do not bend or pull it more than necessary. Otherwise, the guide wire may be damaged.
- Inspect the guide wire carefully for bends, kinks, or other damage prior to use and whenever possible during the procedure.

- Always advance and withdraw the guide wire slowly.
- 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.
- 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 guide wire. Be sure the guide wire is wet before shaping to avoid damaging the hydrophilic coating.
- Verify which is the distal end before insertion and be sure to insert the flexible distal end (coiled end).
- Fasten the torque device to the guide wire firmly so that it may not loosen. Torque operation with a loose torque device may cause the coating to come off.
- When changing the attachment position of the torque device on the guide wire, loosen the fastening of the torque device before moving it.
- If any resistance is felt during insertion into a catheter used with the guide wire, do not use it.
- Do not manipulate the guide wire with a torque device other than the supplied torque device. When attaching a torque device to the guide wire, or manipulating the guide wire using a torque device, carefully manipulate the guide wire so that the guide wire will not be damaged. Fasten the torque device with care not to excessively fasten it.
- To exert the lubricity of the guide wire's surface, inject heparinized saline into the guide wire holder tube and the lumen of the catheter to be used before using the guide wire. Confirm that the whole surface is wet, then take out the guide wire, and insert it into the catheter. To prevent eventual thrombus caused by the manipulation of the catheter and the guide wire, flush the catheter lumen with heparinized saline or other suitable solution.
- If bending is observed in the distal end of the guide wire during the procedure, do not manipulate the guide wire with the distal end being bent.
- Do not manipulate the guide wire while it is tightly secured with a Y-connector.
- If manipulation using two or more guide wires is performed, either guide wire may be tangled with the other guide wire or the other device inserted in the same catheter. Therefore, if it is necessary to perform manipulation using two or more guide wires, take extreme care.
- If the guide wire is bent or deformed due to an incidental load during use, stop using it.
- During the procedure, always check the distal end of the guide wire under fluoroscopy. In particular, in cases where the guide wire is not directly manipulated, such as moving the other devices used over the guide wire or performing kissing technique, always pay attention to the movement of the distal end of the guide wire so that the guide wire will not damage the vessel.
- If the guide wire meets resistance with the device used with the guide wire, do not apply an excessive force. If there is abnormal resistance, remove the whole system from the patient's body, and check the cause of the resistance.
- Remove blood or a contrast medium adhering to the surface of the guide wire using heparinized saline.
- Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors, when possible. The risk of X-ray radiation exposure complications may increase as procedure time and number of procedures increase.
- Take preventive measures against infection after use. Discard this guide wire as medical waste.

Malfunctions and Adverse effects

During use of this guide wire, the following malfunctions and adverse effects may occur. If the malfunctions and adverse effects are serious, it may induce death or serious complication(s). Note, however, that malfunctions and adverse effects are not limited to these.

1. Malfunctions
   Failure to cross a lesion
   Breakage or bending of the guide wire
   Damage such as separation
   Difficulty in removal
   Coating delamination
2. Adverse effects (in random order)
   Death
   Infection
   Vessel dissection or perforation
   Bleeding complications
   Distal embolism
   Thrombus
   Infarction
   Embolization or vascular damage caused by residue
   Ischemia
   Arrhythmia
   Vasospasm
   Vascular occlusion
   Aneurysm rupture/perforation
   Hemodynamic compromise
   Aneurysm (false/dissecting)
   Hypotension
   Tissue necrosis
   Sterile inflammation or granulomas at the access site
   Allergic reaction
   X-ray radiation exposure related adverse events (alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia)

How to Use

1. Inspection prior to use
   1-1. Inspect and confirm that the device and the package are undamaged.

2. Preparations for use
   2-1. Remove the holder tube containing the guide wire from the sterile pack.
   2-2-a. Connect a syringe to the yellow flush port attached to the holder tube.
   2-2-b. Connect a syringe to the flush port of the transparent cap attached to the holder tube.
   2-3. Inject at least 5mL of heparinized saline into the holder tube to soak the entire guide wire.
   2-4. After waiting for 30 seconds, release the proximal end of the guide wire from the tail clip, grasp the proximal end of the guide wire, and pull it out of the holder tube. If resistance is felt when pulling the guide wire out of the holder tube, inject heparinized saline again.
   2-5. Inspect the guide wire and confirm that it is not damaged.
   2-6. Shape the distal end of the guide wire into the intended shape using the accompanying shaping mandrel.

3. How to Use
   3-1. Before inserting the guide wire into a catheter, flush the catheter with heparinized saline.
   3-2. Insert the guide wire into the catheter using the accompanying introducer.
   3-3. Attach the accompanying torque device to the guide wire if necessary.
   3-4. Select the target vessel by carefully advancing or rotating the guide wire under fluoroscopy.
   3-5. When removing the guide wire from the body, wipe off blood. And keep wet to maintain activation of the hydrophilic coating.

Storage method

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.

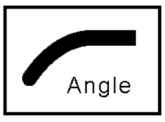
Expiration date

The expiration date is indicated on the label of the device package.

Contents

1 set per package

Symbols

	Straight		1mm Pre-shape
	Angle		

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ASAHI INTECC CO.,LTD.
3-100 Akatsuki-cho, Seto, Aichi 489-0071 JAPAN

Distributor:
ASAHI INTECC USA, INC.
Tel : 855-286-9473 (Customer Support)
E-Mail : customersupport@asahi-intecc.com

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