

Lunara[®] Neuro Guidewire

Instructions for Use

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Lunara[®] Neuro Guidewire

Instructions for Use

·RX-Only: Federal law (USA) restricts this product to sale by or on the order of a physician.

Warnings

- Carefully read all instructions thoroughly before use. Follow all warnings and precautions to avoid complications or adverse events. (All product and guidewire references in this instruction refer to the Lunara[®] Neuro Guidewire).
- This product is intended for use only in adults with relevant indications.
- The product is only to be used by physicians experienced or trained in vascular interventions.
- Contents supplied STERILE using an ethylene oxide(EO) process. Do not use if sterile barrier is damaged.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the guidewire and/or lead to guidewire failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the guidewire and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the guidewire may lead to injury, illness or death of the patient.
- To prevent damage to the surface coating of the guidewire, the guidewire surface must not come into contact with organic solvents such as alcohol or antibacterial agents.
- Always manipulate the guidewire slowly and gently. Never advance, withdraw, or torque if resistance is encountered; instead, identify the cause under fluoroscopy before taking corrective action. During manipulation with a torquer or rotating guidewire, continuously monitor the tip under fluoroscopy to prevent vascular perforation or guidewire damage.
- This product incorporates metallic materials. Do not use during MRI.
- Discard the device and packaging per institutional and local regulations. Handle all used materials as biohazardous waste.

Contraindications

- This product is not intended for use within the coronary vasculature.
- Contraindications for any combination guidewire that may apply.

Intended Use/Indications of Use

- This device is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

Clinical Benefit

- To facilitate access to neuro and peripheral vessels and improve the success rate of catheter placement.

Device Description

- The product consists of a guidewire (Fig. 1), a mandrel (Fig. 2) and a torque device (Fig. 3). The guidewire comprises core wire and coil, The core wire is made of nickel-titanium alloy and stainless steel, while the coil is made of platinum-nickel alloy and stainless steel. The distal surface of the guidewire is coated with a hydrophilic polyvinylpyrrolidone (PVP) coating, while the proximal surface is coated with a polytetrafluoroethylene (PTFE) coating. Schematic diagrams of the coiled tube (Fig. 4).

D1	0.012 in
D2	0.014 in
L1	400mm (Hydrophilic Coating)
L2	1530mm/2480mm(Hydrophobic coating)
L	2150mm/3100mm
S	Straight type
A	Angle type

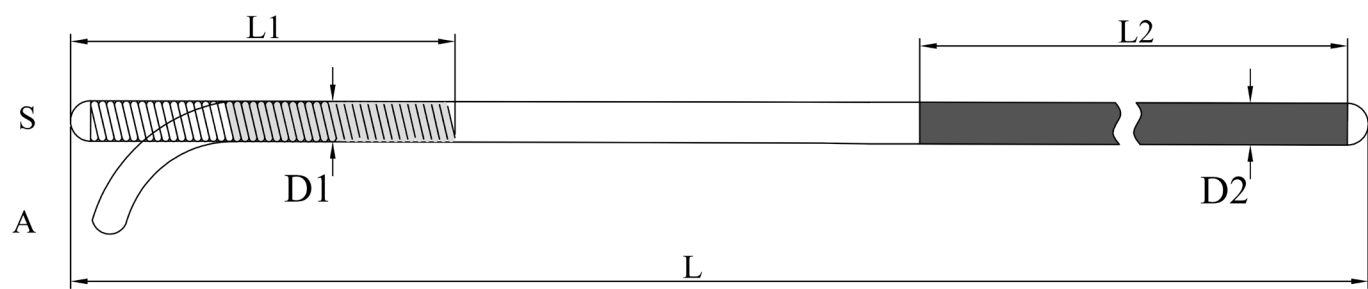


Fig. 1 Schematic diagram of guidewire structure

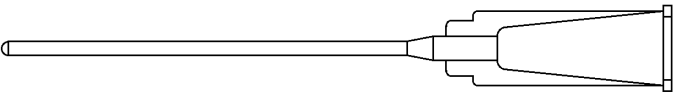


Fig. 2 Schematic diagram of mandrel

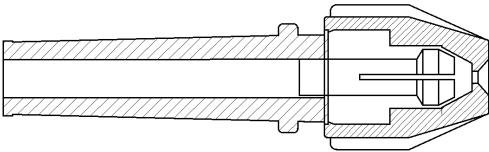


Fig. 3 Schematic diagram of torque device

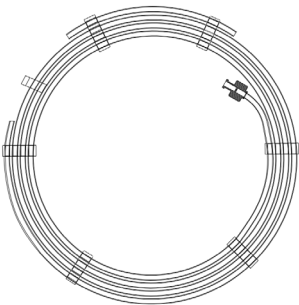


Fig. 4 Schematic diagram of protective packing

Performance Characteristics

·Contents are NON-PYROGENIC.

Radiopaque for visualization during fluoroscopy.

Polyvinylpyrrolidone hydrophilic coating on the surface for reduced friction during use.

Operational Instruction

1. Confirm the dimensions of this product and its compatibility with the accompanying devices
2. Before use, please check the integrity of the pouch of the product, verify the information, and ensure that it remains within its expiry date.
3. Open the packaging and remove the coiled tube containing the product from the pouch.
4. Connect the flush connector at the end of the coiled tube to a syringe pre-filled with heparinized saline, and inject heparinized saline until saline overflow is observed at the inserter.
5. After allowing the guidewire to be fully moistened for 1 min, withdraw it from the coiled tube.

Warning Do not force out the guidewire if you encounter too much resistance when pulling it out, but re-inject heparinized saline and moisten it sufficiently before attempting to remove it.

6. If shaping of the guidewire tip is required, the mandrel included in this product may be used for the procedure. Appendix I provides the operational steps for guidewire shaping.

7. Select combination devices of appropriate specifications (e.g., introducer sheath, catheter) as necessary, and moisten their lumens with heparinized saline.

8. Put the torque device on the guidewire and position it as required. Tighten it by twisting the cap.

9. Carefully advance and rotate the wire under fluoroscopy to select the appropriate vessel. Carefully insert the guidewire tip into the catheter and advance the guidewire being careful not to damage the wire tip.

Precautions

·Inspect the guidewire for damage or imperfections (e.g., kinks, bends) before use. Do not use if damaged.

·Do not use if the distal end is bent or deformed. Do not insert the proximal end into the blood vessel.

·The hydrophilic coating of this product is polyvinylpyrrolidone (PVP). Upon activation, this coating may cause minor dimensional changes at the distal end due to swelling, yet this does not affect the product's compatibility with its combination devices.

·Confirm the compatibility of the guidewire with the catheter before use. The guidewire should move freely within the catheter.

·Do not soak the guidewire for longer than instructed or for extended periods when not in use, as this may impair coating performance.

Symbols

	Consult electronic instructions for use
	Do not use if package is damaged and consult instructions for use
	Quantity of contents
	Catalogue number
	Country of manufacturer and manufacturing date
	Use by date
	Lot number
	Manufacturer
	Do not re-use
	Do not re-sterilize
	Non-Pyrogenic
	Keep dry
	Caution
	Unique device identifier
	Keep away from sunlight
	This way up
	Fragile, handle with care
	Medical device
	EU Authorized Representative
	CE marking with notified body number
	Single sterile barrier system with protective packaging inside

- Exercise care when passing this product through tortuous or calcified vessels, needles, metal sheaths, stents, or other sharp-edged devices to prevent coating detachment or fragment retention in the vascular system.
- Avoid wiping the guidewire with gauze or excessively, as this may damage the coating.
- The safety and effectiveness of the product has not been established in the coronary vasculature.
- A Summary of the Safety and Clinical Performance (SSCP) for this guidewire is available at <https://ec.europa.eu/tools/eudamed>

Handling and Storage

Store at room temperature in a dry, well-ventilated environment.
Avoid excessive pressure, direct sunlight, rain and snow during transport.

Potential Adverse Events

Clinical complications or adverse events may result.

Follow instructions for use carefully.

Potential adverse events associated with guidewire use include, but are not limited to:

Material Loosening

Bends and Kinks

Breakage / Shredding / Separation

Difficult to removal or advancement

Coating Peeling, Bunching or Displacement

Contamination

Mangling / Fraying

Dissection

Embolism

Pseudoaneurysm

Vessel or aneurysm perforation

Vasospasm

Hematoma at the site of entry

Ischemia

Intracerebral/intracranial hemorrhage

Seizure

Stroke

Infection

Death

Adverse Events Reporting

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

Appendix I: Guidewire Tip Shaping Procedure

- 1.Hold the guidewire with one hand (at approximately 4-5 cm from the tip), and grasp the mandrel with the other hand.
- 2.Place the needle tip of the mandrel close to the guidewire tip (1-2 cm from the tip), positioning it at a 90° angle to the guidewire, as shown in Fig. 5.
- 3.Cautiously pull the mandrel toward the guidewire distal tip to implement shape, as shown in Fig. 6.

- 4.Repeat as needed to achieve desired shape (Taking the J-shaped configuration as an example, as shown in Fig. 7).
- 5.Inspect the shaped tip carefully for any damage.If damaged, do not use the guidewire.



Fig. 5



Fig. 6



Fig. 7

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