ULTRASKIN™

CE 2797

LEPU MEDICAL

Hydrophilic Guide Wire

Instructions for Use

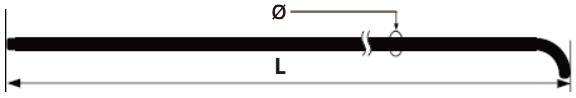
Read the following warnings, precautions and directions for use carefully before use.

1. Product Name

General name: Hydrophilic Guide Wire Trade: Ultraskin™

2. Device Description

The Ultraskin™ Hydrophilic Guide Wire consists of a nitinol core wire, a plastic jacket with hydrophilic coating. The wire distal curve comes in different shapes such as straight, J shaped and angled. The guide wire is radiopaque under fluoroscopy.



3. Performance Characteristics

- Coating: hydrophilic polymer coating further reduces friction to advance catheters more easily into peripheral vessel branches.
- Outer diameter: 0.018-0.038 inch (0.46-0.97mm).
- Length: the length is from 150 to 300 cm.
- Distal curve: straight, J angled and angled.
- Flexible length: 10 to 80mm.

4. Intended Purpose

The Ultraskin™ Hydrophilic Guide Wire is designed to direct a catheter to the desired coronary arteries during diagnostic or interventional procedure.

4.1. Medical Indications

The most frequent disease when should use Ultraskin™ Hydrophilic Guide Wire was further examination or interventional procedure of patients who were highly suspected of having coronary artery diseases including the following condition: angina, chest pain, arrhythmia, myocardial infarction, etc.

4.2. Contraindications

- Cerebrovascular.
- Have severe cardiopulmonary dysfunction and cannot tolerate surgery.
- Severe liver and kidney dysfunction.
- Hemorrhagic disease, such as bleeding and coagulation disorders.
- Physical condition of the patient cannot accept or tolerate interventional surgery.
- Patients with infection or other serious skin diseases at the site of Introducer.
- Fever and severe infectious diseases.

4.3. Intended Patient Populations

This device is suitable for any adult patients with the above disease or medical condition except for whom with contraindications. The safety and efficacy of Ultraskin™ Hydrophilic Guide Wire in pregnant women or men intending to father children and the immunocompromised patients have not been established.

4.4. Intended Users

The Ultraskin™ Hydrophilic Guide Wire should only be used by a physician, who has received the training on vascular interventional technique and been well trained in manipulation and observation of guide wires under fluoroscopy. Before use, the operator should have a full understanding of the using instruction, warnings and precautions.

5. Clinical Benefits to be Expected

High success rate of directing a catheter to the intended location.
Low rate of vessel damage.

6. Summary of Safety and Clinical Performance (SSCP)

The summary of safety and performance for the device is available on the website of Eudamed: https://ec.europa.eu/tools/eudamed

7. Device and Combination Using Products Selection

When used, has such as below devices to be used in combination with this product:

- Sheath;
- Angiographic catheter;
- Guiding catheter.

The sheath builds a channel between the skin and blood vessel. The guide wire enters the blood vessel from the sheath introducer and plays a directing role. The combination used catheters (angiographic catheter or guiding catheter) is delivered to the target location along the guide wire.
The combination used devices should be without sharp edges. The device cannot be used with a metal entry needle or a metal dilator.

The selection of guide wire should follow the method below:

Selection of guide wire diameter:

- The outer diameter of the guide wire should match the diameter of the lumen of the device to be introduced. Generally select the guide wire diameter recommended by the device to be introduced.

Selection of guide wire length:

- The selection of guide wire length depends on the length of the device to be introduced and the intended vascular in human body. Generally select the guidewire length recommended by the device to be introduced.

8. Residual Risks and Undesirable Side-effects

Residual risks and undesirable side-effects that may be related to the use of Hydrophilic Guide Wire can include but may not be limited to the following:

Puncture Related Residual Risks and Undesirable Side-effects:

- Access site complications
- Bleeding
- Hematoma
- Hemorrhage
- Tissue trauma

Coating Loss Related Residual Risks and Undesirable Side-effects:

- Additional surgical intervention
- Death
- Embolization
- Myocardial embolism

- Myocardial infarct or ischemia
- Pulmonary embolism
- Pulmonary infarct
- Sterile inflammation or granulomas at the access site
- Stroke/cerebral vascular accident (CVA)/transient ischemic attack (TIA)
- Thrombosis/Thrombus
- Tissue necrosis, transient or long-lasting
- Vascular occlusion,

Improper Operation and Recognized Procedure Related Residual Risks and Undesirable Side-effects:

- Allergic reaction (to contrast, device or other)
- Aneurysm
- Angina or unstable angina
- Arrhythmia
- Additional surgical intervention
- Cardiac tamponade/pericardial effusion
- Delay the operation time/treatment
- Embolization (plaque, thrombus, device, tissue, or other)
- Exacerbation of Existing Condition
- Infection
- Stroke/cerebral vascular accident (CVA)/transient ischemic attack (TIA)
- Thrombosis/Thrombus
- Vascular occlusion
- Vasospasm
- Vessel trauma, perforation, dissection
- X-Ray radiation exposure complications (e.g. alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia)
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9. Facility Requirement

The procedure is typically conducted in a catheterization lab and the following equipments are recommended to be prepared to support the procedure or foreseeable emergencies:

- Gloves and gowns
- Special X-ray machine for cardiovascular system examination
- High-resolution see-through phosphor screen
- Blood pressure monitor system
- X-ray protective equipment
- Multi-channel physiological recorder
- Ambulance equipment

10. Instruction for Use

- Take out the Hydrophilic Guide Wire and the wire coil together from the package.
- Inject heparinized physiological saline solution into the wire coil through the coil hub by a syringe to ensure the Hydrophilic Guide Wire can slide smoothly within it.
- Take out the Hydrophilic Guide Wire from the wire coil and inspect the wire before use, to verify that it is lubricated. If the Hydrophilic Guide Wire cannot be easily taken out from the coil, inject more heparinized physiological saline solution into the coil and try again.
- The Hydrophilic Guide Wire may slide entirely into the catheter or slide out because of its low sliding friction.
- Keep at least 5cm of the wire extended length out of the hub of the catheter during introduction.

11. Precautions

Prior to use:

- Avoid exposure to water, direct sunlight, extreme temperatures and high humidity during storage. The product should be stored in a environment with a temperature limit of 0℃ to 40℃.
- The product should be used within the validity shelf life of two years.
- Do not use if the sterile packaging is damaged or unintentionally opened before use.
- The product has been sterilized by ethylene oxide gas. The device is intended for single use only. Do not reuse. Do not

resterilize.

- The device is intended for single-patient use and should not be reprocessed or used after reprocessing. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
- Do not attempt to use the Hydrophilic Guide Wire if it has been bent, kinked or damaged. Use of a damaged wire may result in damage to the vessel or the release of wire fragments into the vessel.
- Please carefully read the medical indications, contraindications, residual risks and undesirable side-effects of any interventional products used in combination with Hydrophilic Guide Wire.
- When using a device concurrently with the guide wire, the operator should have a full understanding of the properties / characteristics / of the device so as to avoid damage to the guide wire. For example when using the guide wire with any device that emits energy (laser, pressure, ultrasound, etc.) confirm that the guide wire is retracted into a position where it will not be impacted by the energy.
- The Hydrophilic Guide Wire contains a metallic core, do not use with any inappropriate equipment (e.g. MRI).
- Confirm the compatibility of the Hydrophilic Guide Wire diameter with the interventional device before actual use.
- For shapeable guide wire, if desired, gently shape the guide wire flexible tip using standard tip shaping practices. DO NOT use a shaping instrument with a sharp edge, otherwise the coating integrity may be damaged.
- For other guide wire, DO NOT reshape the guide wire by any means. Attempting to reshape the wire may cause damage, resulting in the release of wire fragments into the vessel.

Pre-conditioning:

- The surface of the Hydrophilic Guide Wire is not lubricous unless it is wet. Before taking it out of wire coil and inserting it through a catheter, fill the holder and the catheter with heparinized physiological saline solution.
- Use of alcohol, antiseptic solutions or other solvents must be avoided, because they may adversely affect the coating performance of the Hydrophilic Guide Wire.

Manipulation:

- The entire operation should be carried out aseptically.
- Do not manipulate or withdraw the Hydrophilic Guide Wire through a metal entry needle or a metal dilator. Manipulation and/or withdrawal through a metal dilator may result in destruction and/or separation of the outer polyurethane coating requiring retrieval. A plastic entry needle is recommended when using this wire for initial placement.
- Do not use the Hydrophilic Guide Wire with devices which contain metal parts such as atherectomy catheters, laser catheter, or metal introduction / torque devices as they may cause the Hydrophilic Guide Wire plastic coating to shear and/or sever the wire.
- Do not slip a tightened up torque to device or Y-connector over the wire, as this may result in damage to the wire.
- Due to the slippery nature of the hydrophilic coating on the Hydrophilic Guide Wire, the operator may encounter some difficulties in handling the wire.
- Before move a guide wire, the tip movement should be examined under fluoroscopy. Do not torque a guide wire without observing corresponding movement of the tip, otherwise, vessel trauma may occur.
- If any resistance is felt or if the tip's behavior and/or location seem improper, stop manipulating the Hydrophilic Guide Wire and/or the catheter and determine the cause by fluoroscopy. Continuing to manipulate or rotate the Hydrophilic Guide Wire or failure to exercise proper caution may result in bending, kinking, and separation of the guide wire's tip, damage to the catheter, or damage to the vessel.
- In the event that the device should not move freely, it may be appropriate to recommend that the user determine the source of resistance, exercise caution when removing the device, and exchange the device for a new one to complete the procedure.
- When manipulating the device through stents or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage. This may result in adverse events requiring additional intervention.
- After removal from the patient's vessel, and prior to reinserting it into the same patient during the same catheterization, the Hydrophilic Guide Wire should be rinsed in a bowl full of heparinized physiological saline solution. Any blood residues still adhering to the wire can be removed by wiping once with a gauze moistened with heparinized physiological saline solution.
- Avoid wiping the device with dry gauze as this may damage the device coating. Avoid excessive wiping of the coated device.
- When reinserting the Hydrophilic Guide Wire back into the holder, take care not to damage the wire's hydrophilic polymer coating with the edge of the holder.

12. Warnings

- 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.
- A tight fit between the subject device and ancillary devices may exacerbate frictional forces during use which could contribute to unanticipated coating loss such as peeling, flaking shedding, delamination, or sloughing off might result in damage to the vessel, shearing of the Hydrophilic Guide Wire, and release of plastic fragments from the Hydrophilic Guide Wire. Such pieces or fragments from the wire may have to be removed from the vessel.

- The safety and effectiveness of the coated device has not been established or is unknown in vascular regions other than those specifically indicated. DO NOT use the device in vascular regions other than those specifically indicated.
- The Hydrophilic Guide Wire should be used immediately after opening the package and be disposed safely and properly after use, following local regulations for medical waste management. The disposal of the guide wire should mind the infection or microbial hazards.
- Guidewires should be used under fluoroscopic guidance. The physician should follow the fluoroscopy precautions and/or warnings to ensure the safety of the device use associated with fluoroscopy for both patients and clinical operators.
- Manipulate the Hydrophilic Guide Wire slowly and carefully in the vessel while confirming the behavior and location of the wire's tip under fluoroscopy. Improper manipulation of the Hydrophilic Guide Wire without fluoroscopic confirmation may result in vessel perforation.
- When exchanging or withdrawing a catheter over the Hydrophilic Guide Wire, secure and maintain the guide wire in place under fluoroscopy to avoid unexpected guide wire advancement; otherwise damage to the vessel wall by the wire's tip may occur.
- A retrieving device, such as a gripper or basket forceps can only be used after the Hydrophilic Guide Wire has been removed from the patient's vessel. Using a retrieving device while the Hydrophilic Guide Wire is in the vessel may cause the Hydrophilic Guide Wire to break.
- Do not apply repetitive bending force to one specific point of the device as this may cause damage to the Hydrophilic Guide Wire.
- Consider the use of systemic heparinization to prevent or reduce the possibility of thrombus formation on the surface of the Hydrophilic Guide Wire.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patients is established.

13. Explanation of Symbols

Symbol	Explanation of Symbol	
REF	Catalogue number	
LOT	Batch code	
	Date of manufacture	
	Use-by date	
	Caution	
	Consult instructions for use or consult electronic instructions for use	
40°C 0°C	Temperature limit	
MD	Medical Device	
	Do not re-use	
	Do not use if package is damaged and consult instructions for use	
STERILE EO		Single sterile barrier system
	STERILE EO	Sterilized using ethylene oxide
STERILE EO		Single sterile barrier system with protective packaging outside
	STERILE EO	Sterilized using ethylene oxide

Symbol	Explanation of Symbol
	Do not resterilize
	MR unsafe
UDI	Unique Device Identifier
	Manufacturer
EC REP	Authorized representative in the European Community/ European Union
CE 2797	CE Mark And Identification Number Of Notified Body

Do not use with metal entry needle.

eIFU Indicator The exact same pdf version e-IFU can also be found on the website of Lepu Medical: https://en.lepumedical.com/e-ifu/

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