Shunmei®

CE 2764

INSTRUCTION FOR USE

Hydrophilic Coated Guide Wire

CAUTION

Carefully read all instructions prior to use. **Observe all warnings and precautions noted throughout these instructions**. **Failure to do so may result in complications**.

DEVICE DESCRIPTION

The hydrophilic coated guide wire is supplied sterile, non-pyrogenic and is intended for single use. The device is constructed from a high quality, steerable, metallic core wire with a polymer coating utilizing a sophisticated construction process. A hydrophilic coating is applied over the radiopaque polymer jacket.

PACKAGE CONTENTS

1 – Hydrophilic coated guide wire

Note: Guide wire length, diameter, tip configurations are indicated on the product label.

INTENDED USE

Hydrophilic Coated Guidewire is intended to facilitate the placement of devices during diagnostic or interventional procedures.Hydrophilic coated guide wire is intended to be used in the coronary or peripheral vascular system.

CONTRAINDICATIONS

The relative contraindications as following:

- Uncontrolled severe ventricular arrhythmia;
- Uncontrolled hypertension;
- Uncontrolled cardiac dysfunction;
- Uncorrected hypokalemia, digitalis poisoning and electrolyte disorder;
- Febrile diseases;
- Hemorrhagic diseases;
- Allergy to contrast agents;
- Severe liver and kidney insufficiency;
- Serious lung diseases;
- Pregnancy;
- Psychological or physical diseases with poor prognosis;
- Contraindication of radial artery puncture: no radial pulse; Allen test was negative, indicating poor collateral circulation of the arcuate arch. Arteriovenous short circuit in renal dialysis.

WARNINGS

- The hydrophilic coated guide wire may slide entirely into the catheter, sheath introducer, vessel dilator or other device because of its low sliding friction. To prevent this, keep at least 5 cm of the wire protruding from the device fitting at all times.
- To prevent possible tissue damage, care should be taken when manipulating a device over a guide wire during the device's placement and withdrawal. If resistance is felt during device placement, discontinue the procedure and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, remove the guide wire and device as a unit to prevent possible damage and /or complications.
- When using a guide wire, potential exists for thrombus formation or emboli, arterial or venous wall damage and/or plaque dislodgment. The physician should be familiar with literature concerning the complications of angiography.
- The physician should evaluate their appropriateness according to individual patient condition and his or her medical training and experience.

PRECAUTIONS

- Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.
- Prior to use, inspect for damage. If damaged, do not use.
- Do not use this device if it is out of date.
- This device is sterilized by ethylene oxide gas and intended for single use only. Do not use if its packaging is opened or damaged. Do not resterilize and/or reuse.
- Avoid manipulating or withdrawing the hydrophilic coated guide wire back through a mental needle or cannula. A sharp edge may scrape the coating or shear the guide wire. A catheter, introducer sheath or vessel dilator should replace the needle as soon as the guide wire has been inserted into the vessel.
- It is recommended that a plastic torque device be used to handle the hydrophilic coated guide wire. Use of a metal torque device may damage the guide wire surface coating.
- The device is operated under sterile environment.
- After use, dispose the device according to hospital, administrative or government policies.

POTENTIAL COMPLICATIONS/ SIDE EFFECT

Potential adverse reactions or complications which may result from the improper use of the hydrophilic coated guide wire include, but are not limited to:

- Focal vasospasm
- Concertina effect
- Subintimal tracking and dissection
- Hematomas
- Thrombotic
- Coronary artery spasm
- Severe arrhythmia
- Hematoma at the puncture site
- Hematoma of forearm
- Radial spasm

HOW SUPPLIED

The hydrophilic coated guide wire is supplied sterile and non-pyrogenicfor single use only.

STORAGE

- Store the hydrophilic coated guide wire in a clean, cool, dry and dark place to avoid extended exposure to light and moisture.
- Storage environment should be rat-proofand moth-proofin order to keep the integrity of package.

- Keep it from contacting corrosion gas.
- Storage temperature: 0 θC to 40 θC
- Storage humidity: ≤80%

INSTRUCTIONS FOR USE

1. Before attempting to remove the guide wire from its' dispenser, inject sterile heparinized saline solution into the standard luer lock hub end of the dispenser to fill the dispenser coil. This will completely cover the guide wire surface, activate the hydrophilic coating, and will make the guide wire very lubricious.
   WARNING: Failure to hydrate dispenser hoop prior to guide wire removal may result in guide wire damage and or difficult removal from the dispenser.
2. After hydrating the guide wire, gently grasp the guide tube device and pull from the dispenser. Once the guide tube is separated from the dispenser, continue to remove the wire from the hoop.
3. If guide wire is not properly hydrated, it will be difficult to remove from the dispenser. Inject additional heparinized saline solution into dispenser and repeat step 2.
4. Fill intended device with heparinized saline solution before and during use to ensure smooth movement of the hydrophilic guide wire within the device.
5. Use of sterilized gauze moistened with heparinized saline solution and/or a torque device will facilitate handling of the wire.
6. Insert the guide wire into the device and advance to the desired position.
   WARNING: If movement of the wire within the device becomes diminished, remove guide wire and reactivate the hydrophilic coating by wetting its entire surface with a heparinized saline solution.
7. Wipe the guide wire with gauze moistened with heparinized saline solution to remove excess blood from the guide wire surface.
   WARNING: Do not use dry gauze as this may damage the guide wire surface resulting in increased resistance when the wire is reinserted into the device.
8. Rehydrate the guide wire prior to re-insertion into any device or placement into a patient.
9. Use of alcohol, antiseptic solutions or other solvents must be avoided.
   WARNING: These solutions may adversely affect the surface of the hydrophilic guide wire.
10. After cleaning the wire, place into the saline filled hoop, proximal end first. The wire may also be placed in a guide wire basin and completely covered with heparinized saline solution.

Note: Shunmei Medical does not recommend a particular technique for the use of this guide wire. The steps contained in the proceeding instructions are for informational purposes only. Each physician should evaluate their appropriateness according to individual patient condition and his or her medical training and experience.

TRUBLESHOOTING

If the guide wire does not move with ease upon re-insertion, withdraw and completely rehydrate the wire. If upon re-insertion, the wire does not move with ease, exchange for a new hydrophilic guide wire.

Product identification and Model

- Product identification: See lable information,include product name, pattern of guide wire tip shape.
- Model: HGWS, HGWA, HGWJ; Size：diameter：0.018in，0.025in，0.032in，0.035in，0.038in；length：45cm，150cm，180cm，260cm.

DIFINITIONS

	Caution		Keep dry
	Batch code		Non-pyrogenic
	Do not re-sterilize		Do not use if package is damaged.
	Use by date		Do not re-use
	Sterilized by ethylene oxide		Date of manufacture
	Catalogue number		Consult instructions for use
	Manufacturer		Keep away from sunlight
	Temperature limit		Authorized representative of European Community

SHUNMEI MEDICAL Co., Ltd.

Head Office: R401 of building B, No.8 of 1st Jinlong Road,Baolong Industrial Zone, LongGang District Shenzhen 518116, Guangdong ,China

Factory:

Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, HuiZhou, Guangdong, China

TEL:0086-0752-3306949

Email:nora@shunmed.com

Lotus NL B.V.

ADD: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

TEL: +31644168999

Email: peter@lotusnl.com

File No.:SM-IFU-HGW-001.A.7

Issue Date: 2021.05.10