Shunmei®

CE 2764

INSTRUCTION FOR USE

Micro Guidewire

DEVICE DESCRIPTION

1. Micro Guidewire is a sterile, single-use, non-pyrogenic and disposable device. The device consists of Micro Guidewire, Insertion tool, Torquer and protective components containing Coil tube, Three toggle clips, Soft clip and Luer lock. According to different structures,the Micro Guidewire is divided into MGW ,MGWN, MGWNA,MGWNB,MGWNC, MGWND series.All of the series are optionally equipped with torquer and insertion tool.

For MGW series, the Guidewire is composed of core wire, coil wire, polymer jacket and hydrophilic coating. the whole guidewire is covered by polymer jacket with hydrophilic coating. The distal tip of Micro Guidewire is shapable and includes three kinds of tip shape: Straight tip, Angled 45° tip, Angled 60° tip. The length of Guidewire have 80cm, 135cm, 150cm, 165cm, 180cm, 185cm and the outer diameter have 0.014in(0.36mm), 0.018in(0.46mm) , it is mainly used for peripheral vasculature.

For MGWN series, the Guidewire is composed of Proximal core wire , distal core wire, proximal coil wire, distal coil wire. The coil wire coated with hydrophilic coating. MGWN115-14E is extension line. The distal tip of Micro Guidewire is straight tip .The length of Guidewire have 200cm ,300cm and the outer diameter have 0.014in(0.36mm). It is mainly used for neuro vasculature.

For MGWNA, MGWNB and MGWNC series: The product is composed of proximal core wire, distal core wire , coil wire， polymer jacket and hydrophilic coating. The distal tip is shapable and includes 2 kinds of tip shape :straight tip and pre-shaped tip. The length of Guidewire have 200cm, 300cm and the outer diameter is 0.014in(0.36mm) or proximal outer diameter :0.012in(0.30mm), distal outer diameter : 0.010in(0.25mm) 0.25mm (for NGWNC series),it is mainly used used for neuro vasculature.

For MGWND series: the Guidewire is composed of core wire, coil wire, polymer jacket and hydrophilic coating.The distal tip of Micro Guidewire is Straight tip. The length of Guidewire have 200cm and 300cm, the outer diameter is 0.014in(0.36mm) ,it is used for general vasculature, including neuro vasculature and peripheral vasculature.

PACKAGE CONTENTS

1 – Micro Guidewire

1- Torquer

1- Insertion tool

Note: Guidewire length, diameter, tip shape are indicated on the product label.

INTENDED USE

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

CONTRAINDICATIONS

Baseline platelet count < 50.000/μL,

Baseline blood glucose of < 50mg/dL or >400mg/dl,

Severe, sustained hypertension (SBP > 220 mm Hg or DBP > 110 mm Hg),

Cerebral vasculitis,

No indication of PCI,

Younger than 18 years old.

- Patients with severe diabetes
- Cancer
- Pregnancy Patients

WARNINGS

The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.

The Guidewire is provided sterile and non-pyrogenic unless the unit package is opened or damaged.

The Guidewire is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose in accordance with hospital and/or local government policy. Do not use if the packaging is breached or damaged.

Inspect the Guidewire prior to use for any irregularities or damage and discard if noted.

The Guidewire should be manipulated under fluoroscopic guidance. Do not advance or withdraw the Guidewire when excessive resistance is met until the cause of resistance is determined. Observe the tip response when turning the Guidewire and avoid turning in the same direction more than three times when the tip is stationary. Avoid kinking the tip of the Guidewire, as damage to the Guidewire might occur.

Precautions

Verify Guidewire compatibility when using other ancillary devices commonly used in

intravascular procedure. Physician must be familiar with percutaneous, intravascular technique and possible complications associated with the procedure.

The Guidewire has a lubricious surface and the distal platinum coil section should be hydrated prior to use.

Exercise care in handling the Guidewire to reduce the chance of accidental damage. Do not expose the Guidewire surface to organic solvents such as alcohol or medications, which might damage the Guidewire coatings and/or cause the Guidewire to loose lubricate.

Verify that the inner diameter of any diagnostic or therapeutic catheter to be used with the Guidewire is compatible with the outer diameter of the Guidewire prior to use.

Avoid repeated bending at the same point in order to avoid damage or separation of the Guidewire.

Take precaution when manipulating the Guidewire in tortuous vasculature to avoid damage to the Guidewire.

Precautions Required by the Manufacturer

SHUNMEI MEDICAL CO. LTD. precautions to be taken by:

The patient should be informed about the application risks before the application and the positive and negative effects should be explained.

The patient should be warned that the application device may have a certain life span that cannot replace the normal tooth, be damaged as a result of strenuous activity or trauma, and may be altered in the future.

Please read the product manual before use.

The product is single-used. Do not use again.

Check the expiration date of the product before use.

Use should be avoided in patient conditions described in contraindications.

Allergy and other reactions to the metal material should be considered, tested (if appropriate) before the operation, although they are not frequent.

Do not use the product in case of foreign matter or impurities in the package or on the product.

Do not use if the product is damaged.

Ensuring that the product fulfills the quality control competence.

Biocompatibility of the product has been demonstrated.

ADVERSE EVENTS

Potential complications include, but are not limited to:

- Vasospasm,
- Vascular injury,
- Vessel oraneurysm pertoralion,
- Hematoma at the site of entry,
- Embolism,
- Ischemia,
- Intracerebral/intracranial
- Hemorrhage,
- Pseudoaneurysm,
- Seizure,
- Stroke,
- Infection,
- Death,
- Thrombus formation

HOW SUPPLIED

The Micro Guidewire is supplied sterile and non-pyrogenic for single use only. Do not use if the package is opened and /or damaged.Use the device prior to the "Use By" date noted on the product label .Do not use if labeling is incomplete or illegible.

STORAGE

• Store the product at room temperature and in a clean, dry and dark place to avoid extended exposure to light and moisture.

• Storage environment should be rat-proof and moth-proof in order to keep the integrity of package.

• Keep it from contacting corrosion gas.

- Storage temperature: 0℃ to 40℃
- Storage humidity: ≤ 80%

INSTRUCTIONS FOR USE

PREPARATION FOR USE

Before removing the guidewire, hydrate the hydrophilic segment by flushing heparinized saline through the coil tube using a syringe attached to the Luer lock (see Figure 1).

To prevent damage to the guidewire, gently remove the soft clip that holds the wire in place in the protective race track. Gently remove the guidewire by pulling it from the coil tube. If resistance is met, repeat the flushing procedure until the guidewire can be easily removed from the coil tube. Inspect the guidewire thoroughly to insure it is not damaged.

If tip shaping is desired, gently bend the distal tip using fingers or by winding the tip round the Insertion tool as shown (Figure 2) until the desired shape is achieved.

Figure 1

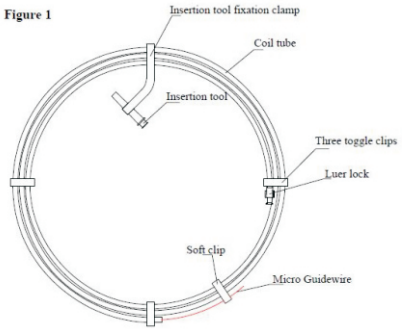
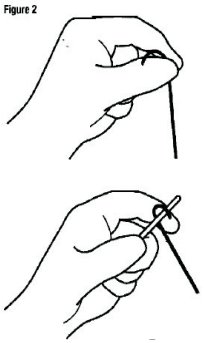


Figure 2



DIRECTIONS FOR USE

Prior to inserting the guidewire into the catheter, flush the catheter lumen with heparinized saline to prime the catheter and provide smooth movement of the guidewire within the catheter. A hemostatic Y-connector may be attached to catheter hub and used to facilitate the flushing process.

Carefully insert the distal section of the guidewire into the catheter and advance. A guidewire Insertion Tool may be used to facilitate insertion of the guidewire distal tip through a Y-adapter and into the catheter hub. Advance the Hydrophilic Guidewire until the distal lip is near the distal end of the catheter. Gently tighten the hemostatic Y-connector to maintain position.

Slip the torque device over the proximal end of the guidewire to the desired location. Secure the torque device in place by tightening the rotating knob. The torque device may be repositioned by loosening and retightening the rotating knob.

During navigation in the vasculature, loosen the hemostatic Y-connector, and advance and rotate the guidewire by rotating the torque device in either direction to facilitate vessel selection. To aid in catheter navigation, gently rotate the guidewire as it is advanced.

Between uses, rinse the guidewire in a basin of heparinized saline and wipe it gently with sterile, wet gauze and place in a basin of heparinized saline or a flushed coil tube to keep the hydrophilic surface

wet until use.

Take preventive measures against infection after use. Discard this product as medical waste.

Product identification and Model

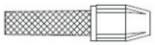
- Product identification: See label information,include product name, pattern of guide wire tip shape.

- Specification information:

Micro Guidewire	Product Series Name	Tip shape
Shun SV	Micro Guidewire - MGW Series	Straight Tip
		45° Angle Tip
		60° Angle Tip
Shun Traverse	Micro Guidewire - MGWN Series	Straight - Soft Tip
		Straight-Support Tip
		Note:There is not tip shape for MGW115-14E of model
Shun Syncess	Micro Guidewire - MGWNA Series	Straight - Soft Tip
		Pre-shaped - Soft Tip
		Straight -Standard Tip
		Pre-shaped-Standard Tip
Shun Syncess 14	Micro Guidewire - MGWNB Series	Straight-Distal Segment 35cm Tip
		Straight-Distal Segment 45cm Tip
		Straight-Support-Distal Segment 35cm Tip
Shun Syncess 10	Micro Guidewire - MGWNC Series	Straight Tip
Shun Tranpass	Micro Guidewire - MGWND Series	Straight Tip
		Straight-Standard Tip
		Straight-Soft Tip
		Straight -Floppy Tip

DIFINITIONS

	Caution		Keep dry
LOT	Batch code		Non-pyrogenic
	Do not re-sterilize		Do not use if package is damaged.
	Use by date		Do not re-use

STERILE EO	Sterilized by ethylene oxide		Date of manufacture
REF	Catalogue number		Consult instructions for use
	Manufacturer		Keep away from sunlight
STRAIGHT	Guidewire tip shape: Straight	EC REP	Authorized representative of European Community
ANGLED 60°	Guidewire tip shape: Angled 60°	ANGLED 45°	Guidewire tip shape: Angled 45°
	Insertion tool		Torquer
CE 2764	CE mark and NB ID Number		

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**

Web: **www.shunmed.com**

EC REP **Lotus NL B.V.**

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

Tel: **+31644168999**

Email: **peter@lotusnl.com**

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