

PRIMCROSS™ Guide Wire Instructions for Use

Product Structure and Composition

This product is composed of a radiopaque winding wire, a main core wire, a radiopaque protective layer and a surface coating. The material of the radiopaque winding wire is platinum-iridium alloy, the material of the main core wire is 304V stainless steel and the material of the radiopaque protective layer is tungsten-containing polyurethane. The proximal surface is coated with a PTFE coating, and the distal surface is coated with a PVP hydrophilic coating. The product is for single-use only, sterilized by ethylene oxide and has a shelf life of 3 years.

Scope of Application

This product is applicable for guiding diagnostic and therapeutic devices to enter the coronary arteries, peripheral blood vessels or neurovascular system during interventional procedures.

Contraindications

- (1) It is prohibited to use this product on patients who are medically diagnosed as being unfit for percutaneous transluminal intervention.
- (2) It is prohibited for use in neonates.

Warnings

- 1.It is only to be used by trained medical professionals under X-ray fluoroscopy.
- 2.This product must be used before the "expiry date" indicated on the packaging.
- 3.This product is provided sterile for single - use only. Do not reuse or resterilize. Do not use if the packaging is opened or damaged.
- 4.Do not modify this product for any purpose.
- 5.Do not soak the surface of this product in alcohol - based solutions, gluconic acid solutions, etc., or wipe the surface of this product with gauze or absorbent cotton soaked in such solutions. Also,

do not wipe with dry gauze or absorbent cotton. Otherwise, it may cause a significant reduction in surface lubricity due to damage to the hydrophilic coating or corrosion of the resin.

6.When resistance is felt when this product or its component system is in the blood vessel, do not forcibly push, drill, retract, or rotate the guide wire. It is necessary to confirm the cause of the resistance under X-ray fluoroscopy and take necessary measures.

7.This product must be used in a medical institution where emergency surgical procedures can be quickly performed.

8.After use, the product and its packaging should be disposed of in accordance with relevant laws and regulations.

Operating Methods or Instructions for Use

Preparation Before Use

- 1) Remove the guide wire together with the protective coil tube from the packaging bag.
- 2) Before removing the guide wire from the protective coil tube, inject heparin-containing physiological saline into the protective coil tube where the guide wire is placed to thoroughly moisten the entire length of the guide wire. Keep it moist until it is delivered to the interventional device during use to achieve a good hydrophilic effect.
- 3) When removing the guide wire from the protective coil tube, push the exposed part of the guide wire into the coil tube until the head end and the core part of the guide wire protrude from the protective coil tube. Then, gently hold the back part of the soft head of the guide wire and pull the guide wire completely out of the coil tube. Note that at this time, do not grasp the soft head part of the guide wire to avoid damaging the fragile head end of the guide wire.
- 4) Once the guide wire is removed, do not insert it back into the protective coil tube. Otherwise, it

may damage the hydrophilic coating. Therefore, it is necessary to fully inject heparin-added sterile physiological saline into the coil tube.

5) If necessary, carefully shape the front - end part of the guide wire, but do not use sharp-edged shaping devices. All models and specifications of products can be shaped at the head end, and the number of shaping times should not exceed 5 times.

6) Fill the inner lumen of the catheter used simultaneously with heparin-added sterile physiological saline in advance.

Operations During Use

For Monorail Systems

1) Carefully insert the guide wire through the guide wire lumen core of the interventional device.

2) Push the guide wire until its head end is close to the head end of the interventional device.

3) If a guiding catheter is used, pre-place the guiding catheter and insert the interventional device/guide wire combination through the hemostatic valve. Push the delivery system through the guiding catheter until it is close to the head end of the guiding catheter.

4) Tighten the hemostatic valve to seal around the interventional device to ensure that the guide wire can still move freely.

5) If necessary, connect a torque device to the guide wire to facilitate the operation of the guide wire.

6) Under fluoroscopy, push the guide wire out of the interventional device while ensuring that the interventional device does not move. Use the torque device to manipulate the guide wire to cross the lesion.

7) When advancing the interventional device along the guide wire to the lesion, ensure that the guide wire does not move.

8) If it is necessary to use a guide wire with a different head-end structure or a different type of guide wire, observe the movement of the guide wire under fluoroscopy and carefully remove the guide wire.

9) Reshape the head end of the guide wire or prepare to use another guide wire.

10. Re-insert the guide wire according to steps 1) - 7).

For Rapid - Exchange Systems

1) Pre-place the guiding catheter, and then insert the guide wire introducer through the hemostatic valve connected to the guiding catheter.

2) Carefully insert the distal end of the guide wire into the guiding catheter through the introducer.

3) If a metal guide wire introducer is used, be sure to remove it before withdrawing or further manipulating the guide wire to avoid abrasion of the radiopaque protective layer and the hydrophilic coating.

4) Connect the torque device.

5) Under fluoroscopy, push the guide wire out of the guiding catheter to the selected blood vessel and use the torque device to manipulate the guide wire to cross the lesion.

6) If it is necessary to use a guide wire with a different head - end structure or a different type of guide wire, the guide wire can be removed according to the following steps.

a) Open the hemostatic valve and the coronary multi - way flushing switch, observe the movement of the guide wire under fluoroscopy, and slowly withdraw the guiding wire.

b) Close the hemostatic valve and the coronary multi-way flushing switch.

7) Reshape the head end of the guide wire or prepare to use another guide wire.

8) Re-insert the guide wire according to steps 2) to 5).

9) Remove the torque device and the guide wire introducer from the guide wire.

10) When advancing the interventional device along the guide wire to the lesion, ensure that the guide wire does not move.

Precautions

1.Before use please refer to the instructions for use of any interventional products used in conjunction with this product regarding the intended use, contraindications, and possible complications.

2.Before use please ensure that the model and specification of this product are suitable for the surgical operation requirements.

3.This product is precision-made and has a hydrophilic coating on the surface. Therefore, when removing the product from the coil tube or shaping the head end, it is necessary to operate with great care and caution.

4.To give full play to the lubricating performance of the surface of this product, before use, inject heparin-added sterile physiological saline into the coil tube and the inner lumen of the catheter used in conjunction. After confirming that all parts are moistened, the product can be taken out or inserted into the catheter used in conjunction. To prevent thrombus formation caused by the operation of the catheter and this product, the inner lumen of the catheter must be perfused with heparin-added sterile physiological saline, etc.

5.When passing this product through a stent indwelling in the body, operate with extreme care.

6.When rotating and manipulating this product in the blood vessel, do not perform more than 2 full turns (720 degrees) of torsion in the same continuous direction.

7.Do not use this product for stent placement using more than 2 guide wires or for guide wire operations that cross stent struts.

8.During the use of this product, if the product is

bent, broken, or otherwise deformed due to occasional loading, do not continue to operate in this state. Use must be discontinued.

9.Do not use this product simultaneously with sharp-edged instruments to avoid damage or breakage of this product.

10.This product must not come into contact with liquids other than angiographic contrast agents, water, and heparin - added sterile physiological saline.

11.All operations of this product must be carried out under sterile conditions, and it should be used immediately after opening.

12.If the coating is found to be peeling off before use or during soaking, do not use the product. Push the product carefully during use to avoid damaging the coating.

Storage and Transportation

<Storage Conditions>

Store at room temperature, in a dry and dark place. Do not bend or apply heavy pressure.

<Transportation Conditions>

During transportation, protect from heavy pressure, direct sunlight, and rain.

Production Date and Expiry Date

Production Date: See the product label for details.

Product Expiry Date: 3 years. It should be used within the validity period.

Statement

The single-use intravascular guide wire products produced by Hicicare Science Co., Ltd. are single-use sterile medical devices and must not be reused. The products are only for use by physicians who have received interventional system training and have certain interventional treatment experience. Please read the relevant warnings and precautions in the instructions carefully before use.

Production License and Medical Device

Registration Certificate

Medical Device Production License Number: Yue
Shi Yao Jian Xie Sheng Chan Xu 20224674

Medical Device Registration Certificate
Number/Product Technical Requirement Number:
Guo Xie Zhu Zhun 20233030140

Registrant/Manufacturer/After-sales Service Organization

Registrant/Manufacturer Name:

Guangdong Hicicare Science Co., Ltd.

Registrant/Manufacturer Address:

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Nansha District, Guangzhou, Guangdong, China

Production Address:

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Nansha District, Guangzhou, Guangdong, China

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Model Specifications

Model	Guide	Maximu	Protec	Head	Head End
Specification	Wire	m Outer	tive	End	Hardness
n	Lengt	Diameter	Layer	Shape	
	h/cm	/mm	Lengt		
	(Toler		h/cm		
	ance		(±1cm		
	+5%)		)		
GWP180-050S	180	≤0.36	28	Straight Head	Relatively Soft
GWP180-150S	180	≤0.36	28	Straight Head	Medium Hardness
GWP180-200S	180	≤0.36	28	Straight Head	Relatively Hard
GWP180-	180	≤0.36	28	J -	Relatively

050J				SHAPE D HEAD	Soft
GWP180-150J	180	≤0.36	28	J - SHAPE D HEAD	Medium Hardness
GWP180-200J	180	≤0.36	28	J - SHAPE D HEAD	Relatively Hard
GWP185-050S	185	≤0.36	28	Straight Head	Relatively Soft
GWP185-150S	185	≤0.36	28	Straight Head	Medium Hardness
GWP185-200S	185	≤0.36	28	Straight Head	Relatively Hard
GWP185-050J	185	≤0.36	28	J - SHAPE D HEAD	Relatively Soft
GWP185-150J	185	≤0.36	28	J - SHAPE D HEAD	Medium Hardness
GWP185-200J	185	≤0.36	28	J - SHAPE D HEAD	Relatively Hard
GWP300-050S	300	≤0.36	28	Straight Head	Relatively Soft
GWP300-150S	300	≤0.36	28	Straight Head	Medium Hardness
GWP300-200S	300	≤0.36	28	Straight Head	Relatively Hard
GWP300-050J	300	≤0.36	28	J - SHAPE D HEAD	Relatively Soft
GWP300-150J	300	≤0.36	28	J - SHAPE D HEAD	Medium Hardness
GWP300-200J	300	≤0.36	28	J - SHAPE D HEAD	Relatively Hard
GWS200-050S	200	≤0.36	35	Straight Head	Relatively Soft
GWS200-150S	200	≤0.36	35	Straight Head	Medium Hardness
GWS200-200S	200	≤0.36	35	Straight Head	Relatively Hard
GWS200-050J	200	≤0.36	35	J - SHAPE D HEAD	Relatively Soft
GWS200-150J	200	≤0.36	35	J - SHAPE D HEAD	Medium Hardness
GWS200-200J	200	≤0.36	35	J - SHAPE D HEAD	Relatively Hard
GWS300-050S	300	≤0.36	35	Straight Head	Relatively Soft
GWS300-150S	300	≤0.36	35	Straight Head	Medium Hardness
GWS300-200S	300	≤0.36	35	Straight Head	Relatively Hard
GWS300-050J	300	≤0.36	35	J - SHAPE D HEAD	Relatively Soft
GWS300-150J	300	≤0.36	35	J - SHAPE D HEAD	Medium Hardness

GWS300-200J	300	≤0.36	35	J - SHAPE D HEAD	Relatively Hard
GWT200-050S	200	≤0.36	38	Straight Head	Relatively Soft
GWT200-150S	200	≤0.36	38	Straight Head	Medium Hardness
GWT200-200S	200	≤0.36	38	Straight Head	Relatively Hard
GWT200-050J	200	≤0.36	38	J - SHAPE D HEAD	Relatively Soft
GWT200-150J	200	≤0.36	38	J - SHAPE D HEAD	Medium Hardness
GWT200-200J	200	≤0.36	38	J - SHAPE D HEAD	Relatively Hard
GWT300-050S	300	≤0.36	38	Straight Head	Relatively Soft
GWT300-150S	300	≤0.36	38	Straight Head	Medium Hardness
GWT300-200S	300	≤0.36	38	Straight Head	Relatively Hard
GWT300-050J	300	≤0.36	38	J - SHAPE D HEAD	Relatively Soft
GWT300-150J	300	≤0.36	38	J - SHAPE D HEAD	Medium Hardness
GWT300-200J	300	≤0.36	38	J - SHAPE D HEAD	Relatively Hard
GWL200-050S	200	≤0.36	45	Straight Head	Relatively Soft
GWL200-150S	200	≤0.36	45	Straight Head	Medium Hardness
GWL200-200S	200	≤0.36	45	Straight Head	Relatively Hard
GWL200-050J	200	≤0.36	45	J - SHAPE D HEAD	Relatively Soft
GWL200-150J	200	≤0.36	45	J - SHAPE D HEAD	Medium Hardness
GWL200-200J	200	≤0.36	45	J - SHAPE D HEAD	Relatively Hard
GWL300-050S	300	≤0.36	45	Straight Head	Relatively Soft
GWL300-150S	300	≤0.36	45	Straight Head	Medium Hardness
GWL300-200S	300	≤0.36	45	Straight Head	Relatively Hard
GWL300-050J	300	≤0.36	45	J - SHAPE D HEAD	Relatively Soft
GWL300-150J	300	≤0.36	45	J - SHAPE D HEAD	Medium Hardness
GWL300-200J	300	≤0.36	45	J - SHAPE D HEAD	Relatively Hard
GWF140-050S	140	≤0.41	25	Straight Head	Relatively Soft

GWF140-150S	140	≤0.41	25	Straight Head	Medium Hardness
GWF140-200S	140	≤0.41	25	Straight Head	Relatively Hard
GWF140-050J	140	≤0.41	25	J - SHAPE D HEAD	Relatively Soft
GWF140-150J	140	≤0.41	25	J - SHAPE D HEAD	Medium Hardness
GWF140-200J	140	≤0.41	25	J - SHAPE D HEAD	Relatively Hard
GWF180-050S	180	≤0.41	25	Straight Head	Relatively Soft
GWF180-150S	180	≤0.41	25	Straight Head	Medium Hardness
GWF180-200S	180	≤0.41	25	Straight Head	Relatively Hard
GWF180-050J	180	≤0.41	25	J - SHAPE D HEAD	Relatively Soft
GWF180-150J	180	≤0.41	25	J - SHAPE D HEAD	Medium Hardness
GWF180-200J	180	≤0.41	25	J - SHAPE D HEAD	Relatively Hard
GWM140-050S	140	≤0.41	35	Straight Head	Relatively Soft
GWM140-150S	140	≤0.41	35	Straight Head	Medium Hardness
GWM140-200S	140	≤0.41	35	Straight Head	Relatively Hard
GWM140-050J	140	≤0.41	35	J - SHAPE D HEAD	Relatively Soft
GWM140-150J	140	≤0.41	35	J - SHAPE D HEAD	Medium Hardness
GWM140-200J	140	≤0.41	35	J - SHAPE D HEAD	Relatively Hard
GWM180-050S	180	≤0.41	35	Straight Head	Relatively Soft
GWM180-150S	180	≤0.41	35	Straight Head	Medium Hardness
GWM180-200S	180	≤0.41	35	Straight Head	Relatively Hard
GWM180-050J	180	≤0.41	35	J - SHAPE D HEAD	Relatively Soft
GWM180-150J	180	≤0.41	35	J - SHAPE D HEAD	Medium Hardness
GWM180-200J	180	≤0.41	35	J - SHAPE D HEAD	Relatively Hard
GWE200-050S	200	≤0.41	38	Straight Head	Relatively Soft
GWE200-150S	200	≤0.41	38	Straight Head	Medium Hardness
GWE200-200S	200	≤0.41	38	Straight Head	Relatively Hard
GWE200-050J	200	≤0.41	38	J - SHAPE D HEAD	Relatively Soft

				HEAD	
GWE200-150J	200	≤0.41	38	J - SHAPE D HEAD	Medium Hardness
GWE200-200J	200	≤0.41	38	J - SHAPE D HEAD	Relatively Hard
GWE300-050S	300	≤0.41	38	Straight Head	Relatively Soft
GWE300-150S	300	≤0.41	38	Straight Head	Medium Hardness
GWE300-200S	300	≤0.41	38	Straight Head	Relatively Hard
GWE300-050J	300	≤0.41	38	J - SHAPE D HEAD	Relatively Soft
GWE300-150J	300	≤0.41	38	J - SHAPE D HEAD	Medium Hardness
GWE300-200J	300	≤0.41	38	J - SHAPE D HEAD	Relatively Hard

Instructions for Label Graphic Symbols

Icon	Explanation
	Do not reuse.
	Expiry date.
	Batch code.
	Refer to the instructions for use.
	Do not use if the packaging is damaged.
	Sterilized by ethylene oxide.
	Classification number.
	Production date.
	Warning.

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