

PRIMTHROUGH™ Guide Wire

Instructions for Use

1. Product Name

General name: Guide Wire

Trade: PRIMTHROUGH™

2. Device Description

PRIMTHROUGH™ guide wire is made of a Nitinol-304V core wire, a 304V coil and a PtNi coil with hydrophilic coating. The wire distal part can be shaped straight, angled or semicircled. The guide wire is visible under X-ray fluoroscopy imaging equipment.

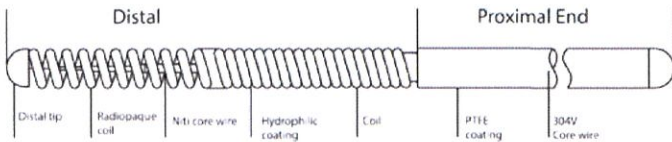


Figure 1 Schematic diagram of the PRIMTHROUGH™ PTCA Guide Wire

3. Intended Purpose

PRIMTHROUGH™ guide wire is used to diagnose during the angiography procedure, and guide catheters and other intervention devices to targeted positions during the vascular treatment procedure.

3.1 Medical indications

The PRIMTHROUGH™ Guide Wire is used for diseases that need minimally invasive surgery treatment (such as PTCA Guide Wire) and suggest the diagnostic or therapeutic device for target vessels treatment.

3.2 Contraindication

PRIMTHROUGH™ guide wire is **contraindicated** for the use in cerebrovascular system.

3.3 Intended Patient Populations

This device is suitable for any patients with the above disease or medical conditions except for the contraindicated ones.

3.4 Intended User

The PRIMTHROUGH™ Guide Wire should only be used by a physician who has been trained on angiography and percutaneous intervention. Before use, the operator must fully understand the using instruction, warnings and precautions.

3.5 The expected clinical benefits

- 1) Success of guiding a catheter to the desired anatomical location during diagnostic or interventional procedures.
- 2) Avoid the clinical adverse event.

4. Warning

Prior to the use of this product, please carefully examine the device to make sure its proper function and integrity. Failure to abide by the following warnings might result in to vessel

damage, abrasion of the hydrophilic coating, release of the polymeric fragments from the device and/or damage to or breakage/separation of the wire.

- Do not manipulate and/or withdraw the guide wire through a metal device, e.g. a metal entry needle, a metal guide wire introducer. Manipulation and/or withdrawal through a metal device may result in destruction and/or separation of the guide wire.

- Manipulate the guide wire slowly and carefully in the vessel while confirming the behavior and location of the wire tip under X-ray imaging.

- If feel any resistance or the tip behavior and/or location improper, stop manipulating the wire and double check the by X-ray imaging setup. Failure to exercise proper caution may result in bending, kinking and separation of the wire.

- If a retrieving device employed, e.g.a gripper, that must be after removing the wire out of the patient's vessel.

- Do not bend the guide wire repeatedly at the same point. It will result in deformation, breakage or separation of the wire.

The safety and effectiveness of the device has not been established or is unknown in vascular regions other than those specifically indicated.

5. Instruction for Use

Before use

- 1) Before taking out the guide wire from the wire dispenser, please inject normal saline with heparin into the hub end of the dispenser to immerse the entire guide wire. Please maintain its moisture for better hydrophilic effect during its usage with other interventional device.

- 2) Push the exposed sections of the guide wire into the dispenser until the tip and a portion of the core exit the end of the hoop. Then grasp the core of the wire to remove it totally from the dispenser. Avoid damaging the fragile guide wire tip. Do not grasp the tip of the wire while removing it from the dispenser.

- 3) Once the guide wire is out of the dispenser, please do not re-insert again.

- 4) The guide wire is fine device, so please operate with careful. Before its usage and during the operation, always examine for any bend, kink, or damage about the guide wire. If any is found, do not continue the operation with the defect.

- 5) Before the usage, make sure the diameter of the guide wire matches with the interventional device.

6) If indicated, the guide wire tip may be carefully shaped using standard tip-shaping practices as below. Carefully wrap the guide wire around the finger or mandrel. But do not use a shaping instrument with a sharp edge.



During operation

- Over the Wire System

- 1) Carefully insert the guide wire through the guide wire lumen hub of intervention device.
 - 2) Advance the guide wire until tip is just proximal to the interventional device tip.
 - 3) If using a guide catheter, engage the guiding catheter and insert the interventional device/guide wire assembly through the hemostatic valve. Advance the system through the guiding catheter until it is just proximal to the tip of the guiding catheter.
 - 4) Tighten the hemostatic valve to create a seal around the interventional device. Make sure the guide wire is free to move.
 - 5) If necessary, connect the guide wire to a torque device.
 - 6) Under X-ray, push the guide wire out of the interventional device, while ensuring that the interventional device is not dislocated.
- Use the torque device to control the guide wire across the lesion.
- 7) Also, make sure the guide wire is not dislocated along the path from its insertion into the interventional device to the lesion site.
 - 8) If it is necessary to use different head structure or different type guide wire, observe the movement of guide wire under x-ray vision and carefully remove it.
 - 9) Then, the guide wire can be re-shaped or another new guide wire is used.
 - 10) Re-insert the guide wire following step 1 to step 7.

- Rail Type Systems(Bare Wire Technique)

- 1) Pre-set the guide wire catheter and insert the guide wire introducer via the attached hemostatic valve.
- 2) Via the guide wire introducer, the distal tip of guide wire can be inserted into the catheter.
- 3) If a metal guide wire introducer is used, be sure to remove it before withdrawing or further manipulating the wire to avoid damage to the hydrophilic coating.
- 4) Connect the torque device.
- 5) Under x-ray, advance the guide wire out of the guiding catheter to the designated blood vessel. Use the torque device to control guide wire across the lesion site.
- 6) If a different tip configuration or guide wire is indicated, the guide wire may be removed as follows:

- a) Open the hemostatic valve and flush line on the coronary manifold. Slowly withdraw the guide wire while observing guide wire movement under x-ray.
- b) Close the hemostatic valve and coronary manifold flush line.
- 7) Reshape the guide wire tip according to standard practice or prepare the next guide wire.
- 8) Re-insert the guide wire following step 2 to step 5.
- 9) Remove the torque device and the wire guider from the wire.
- 10) Make sure the guide wire is not dislocated along the path from its insertion into the interventional device to the lesion site.

6. Precautions

- 1) The device is sterilized with ethylene oxide. Do not use it if the package is open or damaged.
- 2) The device should be used within the period of validity.
- 3) This device should be used only by physicians trained in angiography and percutaneous Coronary intervention(PCI).
- 4) Carefully read all instructions before use. Check all warnings and precautions noted throughout these instructions.
- 5) Refer to the instructions supplied with any interventional devices to be used in conjunction with Balancium"guide wire for their intended uses, contraindications, and potential complications.
- 6) Examine the tip movement under X-ray before manipulating, moving or torqueing the guide wire. Then observe the guide wire under X-ray for tip bucking, which is a sign of resistance.
- 7) Do not push, auger, withdraw or torque any guide wire that meets resistance.
- 8) Do not allow the guide wire tip to remain in a prolapsed condition.
- 9) Do not torque a guide wire if the tip becomes entrapped within the vasculature.
- 10) Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system.
- 11) Consider that if a secondary wire is placed in bifurcation branch, this wire may need to be retracted prior to stent deployment because there is additional risk that the secondary wire may become entrapped between the vessel wall and the stent.
- 12) Do not expose the guide wire to any substance which reacts with coating, such as water, alcohol.
- 13) Contents supplied STERILE using Ethylene Oxide sterilization process. Do not use if sterile barrier is damaged. If it was already damaged before use, please call your company representative. The device is designed and intended for SINGLE USE ONLY. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

Reuse, reprocessing of re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

7. Residual Risks and Undesirable Side-effects

Potential residual risks and undesirable side-effects associated with use of this device include, but not limited to, the following:

- Death
- Myocardial infarction/myocardial embolism
- Hemorrhage or hematoma
- Vessel trauma, perforation and dissection
- Arrhythmia
- Angina/unstable angina
- Thrombosis/Thrombus
- Allergic reaction and infection
- Aneurysm/false aneurysm
- Tissue necrosis
- Stroke including transient ischemic attack, cerebral infarct

and embolic stroke

- Acute re-occlusion
- Additional surgical intervention
- Pulmonary embolism/pulmonary infarct
- Guide wire fracture, kinking
- Coating shedding
- Cardiac tamponade/Pericardial effusion

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 patient is established.

8. Storage and Expiry Date

- 1) During transportation process, the product must be kept away from damp, sunshine, rain, high temperature, stress and impact.
- 2) It must be stored in shady, dry, well-ventilated clean room with room temperature and relative humidity less than 80%, but without corrosive gas.
- 3) The period of validity is three years if this product is stored under the specified conditions.

9. Explanation of Symbols

SYMBOL	DESCRIPTION
	CATALOGUE NUMBER
	BATCH CODE
	USE BY
	DO NOT REUSE
	DO NOT USE IF PACKAGE IS DAMAGED
	TEMPERATURE LIMIT
	CAUTION
	CONSULT INSTRUCTIONS FOR USE
	MANUFACTURER
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	MEDICAL DEVICE
	UNIQUE DEVICE IDENTIFIER
	SINGLE STERILE BARRIER SYSTEM AND STERILIZED USING ETHYLENE OXIDE
	SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE AND STERILIZED USING ETHYLENE OXIDE
	COBALT(CAS NO. 7440-48-4) MAY BE PRESENT IN THE DEVICE



GUANGDONG HICICARE SCIENCE CO., LTD

Address: 6th Floor, Building 5, NO.6 Nan Jiang 2nd Road, Nansha

District, Guangzhou, Guangdong, 511462, P.R. China

Tel: +86-20-84969556

Fax: +86-20-84969556