Hydrophilic Guidewire CE 0123

DESCRIPTION

The Hydrophilic Guidewire consist of guidewire, dispenser, channel clip, guidewire straightener, Luer lock connector. The guidewire are constructed from metallic core wire with a polymer coating. A hydrophilic coating is applied over the polymer jacket.

INTENDED USE

The Hydrophilic Guidewire is intended for percutaneous entry of peripheral vessels. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. The device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

CONTRAINDICATIONS

This guidewire is not intended for Percutaneous Transluminal Coronary Angioplasty use.

PRECAUTIONS AND WARNINGS

READ INSTRUCTIONS PRIOR TO USE.

DO NOT USE IF THE UNIT PACKAGING OR THE PRODUCT HAVE BEEN DAMAGED OR SOILED.

1. This device is presterilized with ethylene oxide gas and is intended for ONE TIME USE ONLY. DO NOT RESTERILIZE AND/OR REUSE. If resterilized or reused, the property or quality of the guidewire may be declined and there is a risk of complications, including infection.
2. Do not use the device after the expiration date indicated on the label. Discard any guidewire that exceeds the expiration date.
3. The device must be used only by a physician who is fully trained in PTA treatment.
4. Do not use the device in neurovascular.
5. Never use the device for pregnant or possibly pregnant patients. Because X-ray may incur radioactive effects to the fetus.
6. Never use the device to patients who are not eligible for surgical operation or who have exhibited obvious and serious allergic reactions to contrast media or other types of drugs which are necessary for the procedure. Because life-threatening adverse events may lead to the worst cases.
7. The coil section is especially fragile, so do not bend or pull it more than necessary. Otherwise, the device may be damaged.
8. Do not use a damaged guidewire. Using a damaged guidewire may result in blood vessel damage and/or inaccurate torque response that may injure the patient.
9. Do not reshape the guidewire by any means. Attempting to reshape the wire may cause damage to the guidewire.
10. Never use metallic cannula or metallic sheaths for insertion and withdrawal of the device. Otherwise, the surface of guidewire may be damaged significantly.
11. Do not use the device in combination with catheters (atherectomy catheter, metallic dilator etc.) which metallic part may contact surface of this guidewire.
12. Use proper technique to ensure and verify that no air enters the interventional device when pulling guidewire from the interventional device or reinserting it. Otherwise air thrombus could occur. Perform all guidewire exchanges slowly to prevent air entry and/or trauma.
13. Observe the guidewire movement in the vessels. Before a guidewire is moved or torqued, the tip movement should be examined under fluoroscopy and monitor guidewire movement in the vessels under fluoroscopy. Do not torque a guidewire without observing corresponding movement of the tip, or may result in the damage and trauma of vessel. In addition, make sure that the distal guidewire and its location in the vessel are visible

during wire manipulations. Do not use in areas of vessel that are not or cannot be visualized.

14. Torquing a guidewire against resistance may cause guidewire damage and/or guidewire tip separation and result in direct damage to vessels. Never push, auger, withdraw or torque a guidewire that meets resistance. Resistance may be felt and / or observed under fluoroscopy by nothing any buckling of the guidewire tip. If guidewire tip prolapsed is observed, do not allow the tip to remain in the prolapsed position. Otherwise, damage to the guidewire may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.If any resistance is felt due to spasm or the guidewire being bent or trapped while operating the guidewire in the blood vessel, do not move or torque the guidewire and stop the procedure. Determine the cause of resistance under fluoroscopy and take appropriate remedial action. If the guidewire is moved excessively, it may break or damage, which may cause blood vessel injury or lead to fragments being left inside the vessel.
15. Do not push the guidewire more than necessary to advance the tip through the narrowed part of the vessel. After crossing the targeted area, do not twist, push or pull the guidewire.
16. Free movement of the guidewire, the interventional device is an important feature of a steerable guidewire system because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable value if it is found to inhibit the guidewire movement.
17. The device must be used in an institution where emergency surgical operation can be performed immediately. If an emergency surgical operation is unavailable, in the worst case, life-threatening events may occur.
18. When torqueing this guidewire inside the blood vessel, do not torque continuously in the same direction, which may cause the guidewire to become damaged or break apart, causing injury to the blood vessel or leaving fragments inside the vessel. When torquing the guidewire, rotate it clockwise and counterclockwise alternately, do not exceed two rotations in the same direction.
19. Keep at least 5 cm of the guidewire protruding from the concurrent device's fitting at all times in case of the guidewire slide entirely into the concurrent device because of its low sliding friction.
20. Do not practice stent delivery when using this guidewire the "Parallel Wire Technique".
21. Do not manipulate the guidewire through stent struts.
22. Do not close the stopcock when the guidewire is inserting in the guide catheter. Otherwise, the guidewire may be damaged.
23. Movement of the guidewire within the catheter may be restricted when the catheter is positioned in tortuous vein sections. Slightly reposition the catheter to regain free movement of the guidewire. If the guidewire tip becomes entrapped within the vasculature, DO NOT TORQUE THE GUIDEWIRE.
24. When introducing the guidewire, confirm that the catheter tip is free within the vessel lumen and not pointed against the vessel wall. Failure to do so may result in vessel trauma upon guidewire exit of the catheter.
25. Use of alcohol, antiseptic solutions, or other solvents, which may adversely affect hydrophilic coating, must be avoided.
26. When using a drug or a device concurrently with the guidewire, the operator should have a full understanding of the properties/characteristics of the drug or device so as to avoid damage to the hydrophilic guidewire.

POTENTIAL ADVERSE EVENTS

Potential adverse events that may occur during or after a procedure using guidewire.
Including but are not limited to:

1. The guidewires are not intended for use in the coronary or cerebral vasculature.
2. Trauma
3. Complications with hemorrhage
4. Complications with ischemia
5. Allergy
6. Embolism of distal vessels (Air, Organic, Thrombus)
7. Hypotension / Hypertension
8. Hemorrhage or infection of puncture sit
9. Vessel spasm / Convulsion
10. Fistula of artery or vein
11. Bradycardia /Palpitation
12. Femoral artery false aneurysm / Formation of false aneurysm
13. Arterial embolus / Thrombus / Blockage
14. Separation, buckling, bending or breakage of the guidewire and its withdrawal trouble
15. Damage to a vessel, including possible vessel perforation, vessel dissection and vessel rupture
16. Pulmonary thrombosis
17. Arterial mebolus/thrombus/occlusion
18. AV fistula
19. Peripheral vascular ischemia
20. Distal vascular embolism

INSTRUCTIONS FOR USE

PREPARATION

1. Be sure to flush the dispenser by injecting sterile heparinized saline solution into the luer lock connector to activate the hydrophilic coating before removing the guidewire from the dispenser.
2. Grasp the straightener and pull from the dispenser, once the straightener is separated from the dispenser, grasp the core of the guidewire to remove it totally from the dispenser. To avoid damaging the fragile guidewire tip, do not grasp the tip of the guidewire when removing it from the dispenser.
3. If the guidewire cannot easily be removed from its dispenser, inject more heparinized saline solution into the dispenser and then try again.

Device Placement

1. Fill catheter or the other concurrent device with heparinized saline solution before and during use to ensure smooth movement of the hydrophilic guidewire within the device.
2. Use of sterilized gauze moistened with heparinized saline solution and/or a non-metal torque device can facilitate handling of the guidewire.
3. Insert the guidewire into the device and advance to the desired location. Re-hydrate as necessary when the surface starts to dry out.

After Use

1. Remove excess blood from the guidewire surface by gauze moistened with heparinized saline solution. Do not use dry gauze as this may damage the guidewire surface resulting in increased resistance when the guidewire is reinserted into the device.

2. Replace it into its dispenser filled with heparinized saline solution by its proximal end. This guidewire can only be used during the same procedure on the same patient.
3. Re-hydrate the guidewire prior to reinserting into any device or placement into a patient. If fell any additional resistance after re-hydration, exchange it for another guidewire.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING


Keep dry


Do not use if package is damaged


Consult operating instructions


Keep away from sunlight


Date of Manufacture

Sterilized using ethylene oxide

Lot number


Do not reuse

Do not resterilize


Attention, see instructions for use

Catalog number


Use by

CE Mark

SCW Medicath Ltd.
NO.4 Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116 Guangdong, P.R.China
TEL: (86)755-89312160
FAX: (86)755-89312239

EC REP **Obelis s.a.**
Bd. Général Wahis 53, 1030 Brussels, Belgium