MERIT H2O™ HYDROPHILIC GUIDE WIRE

INSTRUCTIONS FOR USE

Description:
Merit Medical hydrophilic guide wires are 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. Guide wires are supplied sterile, non-pyrogenic and are intended for single use only.

Indications for use:
Guide wires are used to facilitate the subsequent introduction(s) of intravascular devices during diagnostic and interventional Cardiology and Radiology angiographic procedures. Hydrophilic guide wires may also be utilized in other diagnostic and therapeutic Radiology procedures.

Warnings/Adverse Reactions:
Carefully read all instructions prior to use. Observe all warnings and cautions. Failure to do so may result in complications. Vessel trauma may result from the improper use of this device.

Care should be taken when manipulating a guide wire inside a vessel during device placement and removal. Guide wires should be manipulated only under fluoroscopy. If resistance occurs and the cause of resistance cannot be determined, remove the guide wire and device as a unit. Never advance the guide wire against resistance without first determining the reason for the resistance under fluoroscopy. Excessive force against resistance may result in damage to the wire and/or to the vessel.

Other potential adverse reactions which may result from the improper use of a guide wire include, but are not limited to:

Thrombus	Emboli
Arterial or venous vessel wall damage	Plaque dislodgment
Hematoma at the puncture site	Infection
Vessel perforation	Vessel spasm
Hemorrhage	Vascular thrombosis

The physician should be familiar with the literature concerning the complications of angiography.

Cautions:
AT LEAST 5 CM OF THE WIRE SHOULD PROTRUDE FROM THE DEVICE HUB AT ALL TIMES TO PREVENT THE WIRE FROM SLIDING ENTIRELY INTO THE DEVICE DUE TO THE LOW SLIDING FRICTION OF THIS WIRE.

AVOID MANIPULATING OR WITHDRAWING THE HYDROPHILIC GUIDE WIRE BACK THROUGH A METAL 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.

For single use only do not reuse, reprocess or resterilize. Inspect wire for damage prior to use, do not use any unit if package is opened or damaged. This device is sterilized by ethylene oxide gas. It is recommended that a plastic torque device be used to handle the hydrophilic guide wire. Use of a metal torque device may damage the guide wire surface coating. Federal law (USA) restricts this device to the sale and use only by or on the order of a physician.

Preparation for use:
1. Before attempting to remove the guide wire from its' dispenser, inject sterile heparinized saline solution into the 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 J-straightener device and pull from the dispenser. Once the straightener 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.

Instructions for use:
1. Fill intended device with heparinized saline solution before and during use to ensure smooth movement of the hydrophilic guide wire within the device.

2. Use of sterilized gauze moistened with heparinized saline solution and/or a torque device will facilitate handling of the wire.

3. 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.

4. Wipe the guide wire with 4x4 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.

5. Rehydrate the guide wire prior to re-insertion into any device or placement into a patient.

6. Use of alcohol, antiseptic solutions or other solvents must be avoided.

WARNING: THESE SOLUTIONS MAY ADVERSELY AFFECT THE SURFACE OF THE HYDROPHILIC GUIDE WIRE.

7. 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: Merit 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.

Troubleshooting:
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.

Package Contents:
Merit Medical Hydrophilic Guide Wire: Guide wire length, diameter, coating, tip, and core configurations are indicated on the product label. Merit Medical guide wires are packaged in a plastic hoop fitted with a luer hub. This packaging is provided to facilitate compliance with the manufacturer recommended guidelines that the wire must be flushed with saline or heparinized saline prior to use (See instructions for use).

Storage:
Guide wires should be stored in a cool, dry place.

MERIT MEDICAL®

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