



MERIT[®] LAUREATE[®]

HYDROPHILIC GUIDE WIRE

INSTRUCTIONS FOR USE

Carefully read all warnings, precautions and directions prior to use. Failure to do so may result in the improper use of this device which could cause the following complications:

- Shearing of the hydrophilic guide wire
- Release of plastic pieces or fragments from the hydrophilic guide wire which may need to be retrieved from the vasculature.
- Vessel trauma

Description:

Merit Medical hydrophilic guide wires are constructed from a high quality, steerable, metallic core wire with a polymer coating. A hydrophilic coating is applied over the radiopaque polymer jacket. Guide wires are supplied sterile and non-pyrogenic.

Indications for use:

The Merit Hydrophilic Guide Wire is intended to be used in the peripheral vascular system to facilitate the placement of devices during diagnostic and interventional procedures.

Contraindications:

These guide wires are not intended for Percutaneous Transluminal Coronary Angioplasty use.

Warnings/Adverse Reactions:

- Inspect wire for damage prior to use, do not use a wire that has been bent, kinked, or damaged. Use of a damaged wire may result in vessel damage or wire fragment release into the vessel.
- Do not reshape the hydrophilic wire by any means. Attempting to reshape the wire may cause damage to the wire.
- Do not manipulate or withdraw the wire through a metal entry needle or a metal dilator, or use this wire with devices which contain metal parts such as atherectomy catheters or laser catheters or metal torque devices. This may result in destruction and /or separation of the outer polyurethane coating requiring retrieval. A plastic entry needle is recommended when using this wire for initial placement, or a catheter, introducer sheath or vessel dilator should replace the needle as soon as the guide wire has been inserted into the vessel.
- Never advance the guide wire against resistance without first determining the reason for the resistance under fluoroscopy. If resistance occurs and the cause of resistance cannot be determined, remove the guide wire and device as a unit. Excessive force against resistance may result in damage to the wire and/or to the vessel.
- When manipulating, advancing, exchanging, or withdrawing a catheter over the wire, secure and maintain the guide wire in place under fluoroscopy to avoid unexpected guide wire advancement; otherwise damage to the vessel wall by the wire's tip may occur.
- The hydrophilic guide wire should be used only by a physician, who is well trained in manipulation and observation of guide wires under fluoroscopy.

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

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

Precautions:

- When using a drug or a device concurrently with the wire, the operator should have a full understanding of the properties/characteristics of the drug or device so as to avoid damage to the hydrophilic guide wire.
- Use care when manipulating this guide wire through a tightened Hemostasis valve.

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.
- Merit Medical hydrophilic 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).
- Contents of unopened, undamaged package are sterile and non-pyrogenic.

Preparation for use:

1. The surface of the hydrophilic guide wire is not lubricious unless it is wet. 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 make the guide wire very lubricious.

Warning: Failure to hydrate the 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 concurrent 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 non metal torque device will facilitate handling of the wire.
3. Insert the guide wire into the device and advance to the desired location.

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 a 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. Re-hydrate the guide wire prior to reinsertion into any device or placement into a patient. If additional resistance is felt after re-hydration, replace guide wire.

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.

Warning: Hydrophilic guide wires must be kept hydrated throughout the entire procedure. Re-hydrate as necessary when the surface starts to dry out.

R Only - Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

REUSE PRECAUTION STATEMENT

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 or resterilization may also create a risk of contamination of the device and/or cause patient infection or 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.



Do not withdraw through metal devices.

MERITMEDICA[®]



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