English

SPLASHWire®
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. The metallic core wire is utilized throughout the entire length of the wire body. The polymer coating (jacket) extends across the entire length of the guide wire surface. A hydrophilic coating is applied over the radiopaque polymer jacket. The hydrophilic coating extends across the entire length of the guide wire surface. The hydrophilic coating, when activated, provides lubricity across the entire polymer surface allowing the guide wire to navigate through the vasculature. Guide wires are supplied sterile and non-pyrogenic.

USER(S)

For use by physicians trained in diagnostic and interventional radiology, cardiology, nephrology, and vascular surgery procedures.

PATIENT POPULATION

The Merit Hydrophilic Guide Wire is designed for use during diagnostic and interventional procedures by trained physicians. Using their education and experience, the physician determines based on the individual patient, the appropriate guide wire to support the associated device(s) to be used during the procedure. The guide wire navigates the anatomy and facilitates placement of the associated device(s).

HOW SUPPLIED

The Merit Hydrophilic Guidewire is packaged in a plastic hoop fitted with a flush port. 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). Each carton contains five (5) guidewires, refer to the catalog for ordering information.

INTENDED USE/INDICATIONS FOR USE

The Merit Hydrophilic Guide Wire is used to facilitate the placement of devices during diagnostic and interventional procedures. The Merit Hydrophilic Guidewire is indicated for use in patients with disease and/or lesions of the peripheral vasculature or central circulatory system, excluding coronary arteries and cerebral vasculature.

CONTRAINDICATIONS

The Merit Hydrophilic Guidewire should not be used in the coronary arteries or cerebral vasculature.

CLINICAL BENEFITS

The Splashwire Hydrophilic Guidewire has indirect clinical benefits for the patient since it assists other medical devices in achieving their intended purpose, without having a direct therapeutic or diagnostic function itself. It is used to gain vascular access and placement of compatible diagnostic or therapeutic medical devices that have a direct therapeutic or diagnostic function.

PERFORMANCE CHARACTERISTICS

The Merit Hydrophilic Guide Wire is designed with performance characteristics for use in patient's vasculature system.

- Atraumatic distal flexible tip to facilitate introduction into the vasculature
- Hydrophilic coating that when activated provides lubricity across the entire polymer surface, allowing the guidewire to navigate through the vasculature.
- Guide wire body stiffness that supports successful delivery of associated devices
- These performance characteristics aid in the safe and effective completion of the procedure.

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.

WARNINGS

- 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.
- In the EU any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the applicable member states.

POTENTIAL COMPLICATIONS

- Thrombus
- Emboli
- Arterial or venous vessel wall damage
- Plaque dislodgment
- Hematoma at the puncture site
- Infection
- Vessel perforation
- Vessel spasm
- Hemorrhage
- Vascular thrombosis
- Other potential access site complications leading to bleeding, dissection, or perforation that may require intervention.

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.
- Contents of unopened, undamaged package are sterile and non-pyrogenic.

PREPARATION FOR USE

1. Employ an aseptic technique during removal from the package and during use
2. 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 flush port 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 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.
3. 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.
4. 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.

PRIOR TO USE

CAUTION: The safety and effectiveness of the Merit Hydrophilic Guide Wire has not been established in the Coronary or Neuro vasculature.

WARNING: Preclinical testing with this device shows the potential for clot formation in the absence of anticoagulation. Appropriate anticoagulation therapy should be considered to reduce the potential for thrombus formation on the device.

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 through out the entire procedure. Re-hydrate as necessary when the surface starts to dry out.

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

WARNING: After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.

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.

For a copy of this device's current European Summary of Safety and Clinical Performance (SSCP), please go to the European database on medical devices (Eudamed), where it is linked to the basic UDI-DI. https://ec.europa.eu/tools/eudamed

Basic UDI -DI: 0884450BUDI336PT

Do not withdraw through metal devices.

	Caution
	Do not use if package is damaged and consult instruction for use
REF	Catalog number
LOT	Batch code
MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
STERILE EO	Sterilized using ethylene oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single sterile barrier system
	Use by date: YYYY-MM-DD
	Date of manufacture: YYYY-MM-DD
	Manufacturer
EC REP	Authorized Representative in European Community
	Keep away from sunlight
	Keep dry
	Non-pyrogenic

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CE 2797

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