GO2WIRE™

Steerable Guide Wire

INSTRUCTIONS FOR USE

DESCRIPTION:

The Merit GO2WIRE™ is a PTFE*coated steerable guide wire with a distal tip that is shapeable and radiopaque. The distal 100cm coil is precoated PTFE stainless steel coil wire. The remaining wire length is a stainless-steel guide wire coated with a white PTFE shrink tube. The proximal end of the extendable 145 cm and 175 cm wire configurations is a non-coated attachment section of 0.6 cm in length. * Polytetrafluoroethylene (PTFE), a synthetic polymer which has lubricious properties. Guide wires are supplied sterile and non-pyrogenic with a torque device. An optional guide wire extension device (not packaged with this device) is also available. The extension device facilitates catheter exchanges with the shorter length guide wires (145cm & 175cm) that are modified to accept the extension device. Refer to the GO2WIRE™ Extension Device instructions for use.

USER(S)

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

PATIENT POPULATION

The Merit GO2WIRE™ Guide Wires are 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 GO2WIRE™ Guide Wire is packaged in a plastic hoop, which is fitted with a flush port. This packaging is provided to facilitate compliance with the manufacturer recommended guidelines that the guide wire be flushed with saline or heparinized saline prior to use (See GUIDE WIRE PREPARATION – NOTE). Each carton contains three (3) guide wires, refer to catalog for ordering information.

INTENDED USE:

The Merit GO2WIRE™ Guide Wire is used to facilitate the placement and exchange of devices during diagnostic and interventional procedures in the peripheral circulatory system and the central circulatory system excluding the coronary arteries and the neurovasculature.

CLINICAL BENEFITS

The Merit GO2WIRE™ Guide Wire 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 GO2WIRE™ Guide Wire is designed with performance characteristics for use in a patient's vasculature system.

• Atraumatic distal flexible tip to facilitate introduction into the vasculature

• Surface coating to allow smooth passage of the guide wire 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.

POTENTIAL COMPLICATIONS:

Potential complications which may result from the use of the device include but are not limited to: Air Embolism/Thromboembolism, Allergic Reaction, Arteriovenous (AV) Fistula, Cardiac arrhythmia, Embolism, Hematoma, Hemorrhage, Infection or Sepsis/Infection, Myocardial Ischemia and/or Infarction, Pseudoaneurysm, Stroke (CVA)/Transient Ischemic Attacks (TIA), Thrombus, Vessel Occlusion, Vessel Perforation, Vessel Dissection, Vessel Trauma or Damage, Vessel Spasm, Wire Entrapment/Entanglement, Foreign body/ Wire Fracture. Some of the stated potential adverse events may require additional surgical intervention. Other potential access site complications leading to bleeding, dissection, or perforation that may require intervention.

INSPECTION PRIOR TO USE:

Product is sterile if package is unopened and undamaged. Prior to use, carefully examine all guide wires to verify that the sterile package or product has not been damaged in shipment. Prior to and during use, inspect the guidewire carefully for coil separation, bends or kinks which may have occurred. Do not use a damaged guide wire.

PRECAUTIONS:

PRIOR TO USE:

1. The physician should be trained with the use of angiography and angioplasty products and the potential procedural complications.

2. Confirm the compatibility of the guide wire with other interventional devices being used by testing the systems for any resistance prior to actual use. Free movement of the guide wire within the interventional device must be confirmed and maintained.

3. The guide wire should be completely hydrated with saline or heparinized saline prior to removal from the dispenser hoop.

4. To avoid guide wire tip damage during removal from the dispenser hoop, first remove the proximal guide wire body from the retention clip, then slide guide wire forward towards the flush hoop dispenser allowing the distal wire tip to exit.

NOTE: Distal tip of wire may be positioned inside the flush hoop to protect the fragile tip.

5. Gently grasp guide wire tip and J straightener together as a unit and gently pull forward to withdraw the fragile distal wire tip from the dispenser.

6. The tip of the guide wire may be shaped using standard tip shaping practices. Do not shape the wire surface against a sharp edge, this may result in damage to the wire surface.

WARNING: The safety and effectiveness of the GO2WIRE™ Guide Wires has not been established in the coronary arteries or in the neurovasculature.

WARNING: Preclinical testing with this device showed 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.

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Competent Authority of the applicable Member State.

GUIDE WIRE PREPRATION:

1.Employ an aseptic technique during removal from the package and use.

2.Attach flush solution filled syringe to flush dispenser hoop.

3.Inject saline until dripping out opposite end to completely fill the dispenser hoop.

4.Detach syringe from flush dispenser hoop.

5.Inspect, prepare, and flush the associated device(s) to be used according to the manufacturer's instructions.

6.Dispense guide wire into the luer port of the catheter.

NOTE: To reduce the potential of clot formation, it is recommended that the guide wire be flushed with saline or heparinized saline prior to subsequent uses.

DIRECTIONS FOR USE:

WARNING:

Use extreme caution when withdrawing PTFE coated guide wires back through a metal needle, the sharp edge of the needle may scrape the coating.

1.Attach a compatible hemostasis valve to the catheter luer, if desired.

2.Insert the guide wire J-straightener into the hub luer of the intended catheter or device.

3.Carefully advance the distal guide wire tip through the J straightener and device lumen. Remove the J straightener by withdrawing it over the guidewire.

4.Attach a compatible torque device to the guide wire, if desired, to provide directional control of the guide wire tip.

a. Loosen the cap of the torque device
b. Insert the proximal end of the guide wire into the proximal end of torque device cap
c. Once torque device is located to the desired location on the wire, tighten the cap to secure the torque device onto the guide wire
d. Rotate the torque device to steer the guide wire to the desired location

5.Always advance and manipulate the guide wire under fluoroscopic guidance to:

a. Prevent potential damage to the vasculature
b. Confirm the guide wire placement and location
c. Assure the distal tip is intraluminal and in the intended vessel

6. Hold the guide wire in position while manipulating the catheter over the guide wire to prevent unintended movement of the distal wire tip.

WARNING RESISTANCE:

a. Wire advancement with excessive force may cause coil penetration and / or vessel damage. Never force a wire that meets resistance, immediately assess the tip under fluoroscopy to determine cause of resistance and/or the need for additional action to free the guide wire tip.

b. Manipulating a guide wire when resistance is felt may cause guide wire damage, tip separation, and / or vascular injury.

c. Extreme care should be taken when manipulating a catheter and wire combination to prevent possible intravascular tissue damage. If resistance is felt during advancement, manipulation, or removal, stop immediately and confirm wire position under fluoroscopy.

d. The guide wire and catheter should be moved and removed as a unit when possible.

e. When reintroducing a guide wire into a catheter or device within a vessel, confirm that the catheter tip is free within the lumen (i.e. not against the vessel wall).

f. Always advance or withdraw a wire slowly. Free movement of the guidewire within a vessel or catheter provides valuable tactile information.

g. Never push, twist, or withdraw a guidewire which meets resistance. Resistance may be felt tactilely or noted by tip buckling during fluoroscopy.

h. Test all systems for resistance prior to use.

EXTENSION DEVICE UTILIZATION:

Extending the length of the shorter wires (145 cm, 175cm) to facilitate catheter exchanges is achieved by attaching the distal end of the extension device to the proximal end of the guide wire tip sleeve. If extending the wire length is preferred, see manufacturers extension device instructions for use.

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

Rx ONLY: Caution - Federal Law (USA) 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.

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: 0884450BUDI318PR

SYMBOL	DESIGNATION
	Single Use
	Do Not Re-sterilize
	Caution
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use If Package is Damaged or Opened and Consult Instruction for Use
	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
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Non-Pyrogenic
MD	Medical Device
EC REP	Authorized Representative in European Community
	Manufacturer
REF	Catalog Number
	Date of Manufacture
LOT	Lot Number
	Single Sterile Barrier System
	Use-By Date
UDI	Unique Device Identifier

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CE 2797

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