English

Diagnostic Guide Wires

INSTRUCTIONS FOR USE

DESCRIPTION
Merit Medical guide wires are fabricated from high quality stainless steel utilizing a sophisticated construction process and are available with or without a PTFE coating. Guide wires are supplied sterile, non-pyrogenic, and are intended for single use only.

Merit Medical guide wires are packaged in a plastic hoop, which is fitted with a luer hub. This packaging is provided to facilitate compliance with the manufacturer recommended guidelines that the wire be flushed with saline or heparinized saline prior to use (See directions for use - Note).

INDICATIONS
Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.

CONTRAINDICATIONS
InQwire diagnostic guide wires, are contraindicated for use in the coronary and cerebral vasculature.

POTENTIAL COMPLICATIONS
Potential complications which may result from the use of the device include but are not limited to: Air Embolism/Thromboembolism, Allergic Reaction, Cardiac Arrhythmia, Amputation, Arteriovenous (AV) Fistula, Breathing Difficulty, Death, Embolism, Hematoma, Hemorrhage, Hemoglobinuria, 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.

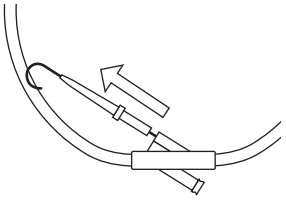
PRECAUTIONS
Angiography should be undertaken only by an experienced angiographer.

FOR ONE TIME USE ONLY
Guide wires will collect blood and other foreign material in their lumens; neither autoclaving nor ultrasonic cleaning will completely remove foreign material, therefore guide wires are recommended for one-time use.

Inspect all guide wires prior to use. Do not use any unit if the package is open or damaged.

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

All guide wires are secured in the hoop dispenser by the locking J-tip straightener. To avoid damaging the guide wire during removal from the flush hoop, grasp the J-tip straightener near the base and slide it forward approximately 5mm or until the J-tip straightener is no longer attached to the flush hoop adaptor. Holding both the guide wire and J-tip straightener, continue to dispense guide wire from the hoop.



Do not use excessive force to advance the moveable core while the guide wire is in a vessel. Advancement with excessive force may cause coil penetration and vessel damage. Never push, auger, or withdraw a guidewire which meets resistance as the could potentially affect other indwelling devices.

Avoid withdrawing PTFE coated guide wires back through a metal needle. The sharp edge of the needle may scrape the coating. It is suggested that a catheter or PTFE vessel dilator replace the needle as soon as the guide wire has reached the appropriate position.

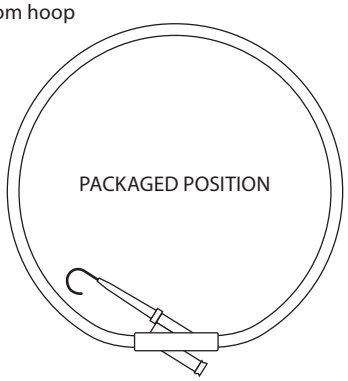
During advancement of the catheter and guide wire within the aorta, it is recommended that the guide wire be removed at the appropriate level of the aorta.

Care should be taken when manipulating a catheter during placement and withdrawal to prevent possible intravascular tissue damage. If resistance is felt during advancement, manipulation or removal from the catheter, stop immediately and confirm the guide wire tip position under fluoroscopy. Note proximity of other potential indwelling devices within the patient's anatomy. Never push, auger, or withdraw a guidewire which meets resistance as this could potentially affect other indwelling devices. Resistance may be felt tactilely or noted by tip buckling during fluoroscopy.

A guide wire is a delicate instrument and remains the most fallible instrument used in a percutaneous procedure. Any time that a guide wire is used there is a possibility of thrombus formation/emboli, vessel wall damage, and plaque dislodgement, which could result in myocardial infarction, cardiac arrhythmia, stroke or death. The physician should be familiar with the use of angiography products and the literature concerning the complications of angiography.

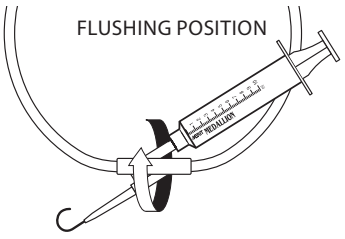
In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

FLUSH HOOP INSTRUCTION GUIDE
1. Attach flush filled syringe to flush port luer
2. Rotate syringe clockwise (as pictured)
3. Inject saline into hoop
4. Detach syringe from hoop



5. Dispense guide wire

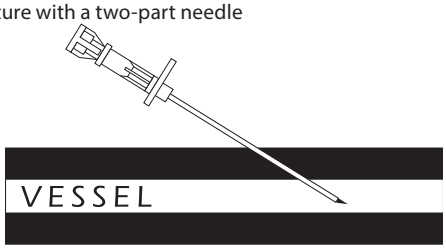
Note: In order to reduce the potential of clot formation, it is recommended that the guide wire be flushed with saline or heparinized saline prior to use. Attach a filled syringe to the luer hub located at the end of the plastic hoop, flush several times. After flushing, remove guide wire from hoop and use as described above.



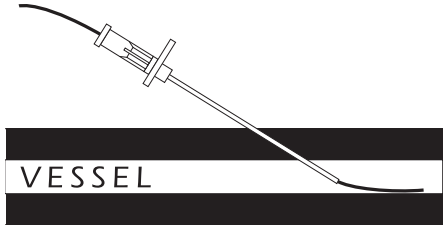
DIRECTIONS FOR USE
NOTE: Confirm guide wire and needle compatibility prior to use.

The following schematic shows a typical procedure for percutaneous entry utilizing the Seldinger technique. Variations in individual patient anatomy may preclude the utilization of this technique.

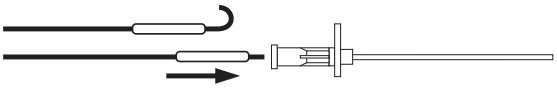
1. Vessel puncture with a two-part needle



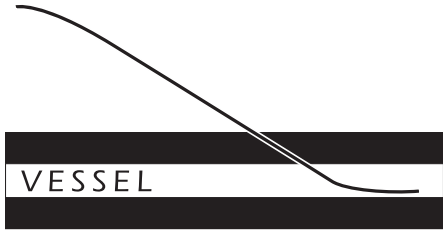
2. When using a two-part needle remove stylet leaving cannula in place, insert flexible (distal) end of guide wire through cannula and into vessel



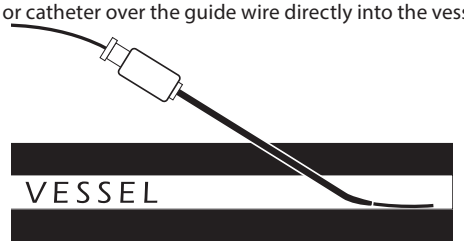
3. "J" guide wires are shipped with "J" straightener to aid in the insertion of the wire into the puncture needle. Advance the straightener until 2-3 mm of the tip extends from the tip. Insert wire into hub and through needle. Remove "J" straightener proximally and discard.



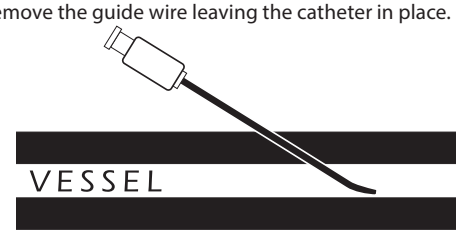
4. Remove needle cannula leaving the guide wire within the lumen of the vessel.



5. Pass dilator or catheter over the guide wire directly into the vessel.



6. Carefully remove the guide wire leaving the catheter in place.



NOTE: Device is sterilized as stated on the package label.

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.

NOTE: Sterile if package is unopened and undamaged.

NOTE: Device is non-pyrogenic.

HOW SUPPLIED: Individually packaged 5-10 per box, refer to catalog for ordering information.

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.

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
Rx 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

MERITMEDICAL®

CE 2797

www.merit.com

Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748

EC REP **Authorized Representative:**
Merit Medical Ireland Ltd,
Parkmore Business Park West,
Galway, Ireland
EU Customer Service +31 43 358 82 22

Basic UDI-DI: 088445048407DF

400635007_003 ID 2020-06-02