English

InQwire® AMPLATZ

Guide Wires

INSTRUCTIONS FOR USE

DESCRIPTION:
Merit Medical Amplatz guide wires are fabricated from high quality stainless steel with PTFE coating. Amplatz wires have increased stiffness which provides added strength and stability. Guide wires are packaged in a plastic hoop fitted with a luer hub. This packaging facilitates compliance with the manufacturer recommended guidelines that the guide wire be flushed with saline or heparinized saline prior to use. Guide wires are supplied sterile and non-pyrogenic.

INDICATIONS FOR USE:
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.

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 use and when possible during the procedure, inspect the guidewire carefully for coil separation, bends or kinks which may have occurred. Do not use a wire which has a damaged tip.

PREPARATION FOR USE:
Caution: A guide wire is a delicate instrument. 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 adverse procedural complications and /or adverse patient outcomes. The physician should be familiar with the use of angiography products and the literature concerning the complications of angiography. Angiography should be undertaken only by an experienced angiographer.
Note: Distal tip of wire may be positioned inside the flush hoop to protect the fragile tip.

Note: Confirm guide wire and needle compatibility prior to use.

Caution: To avoid damaging the guide wire tip during removal from the flush hoop, slide proximal portion of guide wire body forward in the flush hoop loop allowing the distal wire tip to exit the flush hoop. Gently grasp guide wire tip and J straightener together as a unit and gently pull forward to withdraw the distal wire portion from the flush hoop.

1. Attach flush filled syringe to flush hoop luer.
2. Inspect and prepare the catheter or device to be used according to the manufacturer's instructions. This includes flushing the catheter to be used with saline solution.
3. Inject saline into hoop to completely fill loop until dripping out opposite end.

   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.
4. Detach syringe from flush hoop luer.
5. Dispense guide wire into the port of the catheter.

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

Caution: Advancement with excessive force may cause coil penetration and vessel damage.

INSTRUCTIONS 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. It is suggested that a catheter or PTFE vessel dilator replace the access needle as soon as the guide wire has reached the appropriate position.

1. Insert the guide wire J-straightener into the guide wire port of the intended catheter or device.
2. Carefully advance the distal guide wire tip through the J straightener and device lumen. Remove the J straightener by withdrawing it over the guidewire.

   Warning: Extreme care should be taken when manipulating a catheter and wire combination within the vessel 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 and catheter tip position under fluoroscopy. The guide wire and catheter should be removed as a unit when possible to prevent potential damage to the vessel wall.
3. Confirm guide wire tip placement under fluoroscopy to assure that the distal tip is intraluminal and in the intended vessel.
4. Hold the guide wire in position while manipulating the catheter over the guide wire to prevent unintended movement of the distal wire tip.

Warning: 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).
Warning: Always advance or withdraw a wire slowly. Free movement of the guidewire within a catheter provides valuable tactile information. 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. Test all systems for resistance prior to use.

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.

DISPOSAL: After use, dispose of product and packaging in accordance with hospital protocol.

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.

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: 088445048761E4

SYMBOL	DESIGNATION
	Single Use
	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

CE 2797

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