Prelude®

Large O.D. Introducer Guide Wire

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION:
The Prelude® Large O.D. Introducer Guide Wire is composed of a stainless-steel core wire inside a stainless-steel coil. The guide wire is welded at the distal and proximal ends and has a polished weld finish. The stainless steel construction provides radiopacity. Specifications includes:

- Outer diameter range: 0.035"& 0.038"
- Length range: 50 - 80 cm
- Tip shape – straight and double ended J3mm / straight
- Wire stiffness profiles: Standard and Firm body shaft with a flexible atraumatic tip

HOW SUPPLIED:
The Prelude Large O.D. Introducer Guide Wire is supplied sterile, non-pyrogenic, and is intended for single patient use only. The wire is packaged in a plastic dispenser hoop with a J-straightener that facilitates advancement into the associated device. Units are packaged individually in a sterile barrier with 10 units per carton. Refer to catalog for ordering information.

SPECIAL STORAGE AND/OR HANDLING:
The Prelude Large O.D. Introducer Guide Wires should be kept dry.

INTENDED USE:
The Prelude Large O.D. Introducer Guide Wire is intended to facilitate the placement of introducer sheaths during diagnostic and interventional procedures.

INDICATIONS FOR USE:
The Prelude Large O.D. Introducer Guide Wire is indicated for use in patients with disease and/or lesions of the peripheral vasculature only.

CONTRAINDICATIONS:
There are no known contraindications.

PATIENT POPULATION:
The Prelude Large O.D. Introducer Guide Wire is designed for use during diagnostic and interventional procedures on adult patients by trained physicians. Using their education and experience, the physician determines based on the individual patient, the appropriate guide wire and access kit to obtain and support introduction into the vasculature.

USER(S):
For use by physicians trained in vascular access for diagnostic and interventional radiology, cardiology, nephrology, and vascular surgery procedures.

CLINICAL BENEFITS:
The Prelude Large O.D. Introducer Guide Wire has indirect clinical benefits for the patient since it facilitates percutaneous sheath placement and access for other endovascular medical devices in achieving their intended purpose, without having a direct therapeutic or diagnostic function itself. It is used to gain vascular access.

PERFORMANCE CHARACTERISTICS:
The Prelude Large O.D. Introducer Guide Wire is designed with performance characteristics for use in a patient's vasculature system.

- Atraumatic distal flexible tips to facilitate introduction into the vasculature.
- Guide wire body stiffness that supports successful delivery of introducer sheaths.

These performance characteristics aid in a safe and effective completion of the procedure.

POTENTIAL COMPLICATIONS:
Potential complications include, but are not limited to: infection, hematoma, bleeding, laceration of the vessel wall, thrombus formation, pseudo aneurysm formation, guide wire embolization, vessel spasm, inflammation, and risks normally associated with percutaneous diagnostic and/or interventional procedures.
Other potential access site complications leading to bleeding, or dissection that may require intervention. Some of the stated potential complications may require additional surgical intervention.

WARNINGS:

- 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 use if package is damaged or opened.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- If a metal needle is used, do not withdraw the guide wire through the needle after it has been inserted because a sharp edge may damage the guide wire.
- If resistance is met during introduction, avoid manipulating a metal needle over the guide wire, this could result in shearing of the guide wire possibly leading to damage of the blood vessel, as well as potential release of wire fragments into the vasculature. Remove both the wire and needle as a unit and apply pressure above the insertion site to confirm hemostasis prior to regaining access.
- Guide wires should be used under fluoroscopic guidance.
- Do not advance the guide wire if resistance is felt. If resistance is met, monitor tip position and movement under fluoroscopic guidance prior to advancing the wire. Manipulate the guide wire slowly and carefully to avoid damage to the vessel wall. In the event of a malfunction of the device and/or changes in the performance of the device, exercise caution as this may indicate a change that may affect the safety of the device.
- After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
- This device contains stainless-steel alloy components that contain Cobalt (EC No.: 231-158-0; CAS No.: 7440-48-4) defined as CMR 1B in a concentration above 0.1% weight by weight. Please consider the risk and impact of using this device, especially in children, pregnant or breastfeeding women, or other vulnerable patient groups.
- 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.

INSTRUCTIONS FOR USE:
Prior to use, carefully read all warnings noted in these instructions. Failure to do so may result in complications. Product is sterile if package is not opened or damaged.

Carefully examine all guide wires to verify that the product has not been damaged in shipment.

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the device. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the clinician's experience and judgement in treating any specific patient.

1. Remove guide wire from packaging using aseptic technique.
2. Remove the J-straightener and guide wire together as a unit from the dispenser hoop.
3. Prepare guide wire per hospital protocol.
4. After appropriate access is gained, while holding the access needle, place the flexible end of the guide wire through the needle into the vessel. A J-straightener may be used to aid insertion into the access needle.
   WARNING: Do not advance the guide wire if resistance is met. Determine the cause of resistance before proceeding.
   WARNING: Do not withdraw guide wire through access needle.
5. Apply manual pressure above puncture site to minimize blood loss until the appropriate introducer sheath/dilator assembly is placed.
6. Hold the guide wire in place while removing access needle and insert appropriate introducer sheath/dilator assembly over the guide wire into the vessel.
7. After the introducer sheath/dilator assembly has been placed into vessel, detach the dilator from the introducer sheath. While holding the introducer sheath, carefully remove the dilator and guide wire together as a unit, leaving the introducer sheath in the vessel.
8. Continue to follow introducer sheath instructions for use for appropriate care management during procedural use.

SYMBOL	DESIGNATION
REF	Catalog Number
LOT	Lot Number
	Caution
	Consult Instructions for Use. For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within seven days, call U.S.A or E.U. Customer Service
STERILE EO	Sterilized using Ethylene Oxide
	Do not use if package is damaged and Consult instructions For Use
	Single Use
	Use By
	Do Not Resterilze
	Non-pyrogenic
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single Sterile Barrier System
	Keep dry
	Manufacturer
EC REP	Authorized Representative in European Community
MD	Medical Device
	Date of Manufacture
UDI	Unique Device Identifier
	2D Barcode
	Contains Cobalt

MERIT MEDICAL®

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
EC Customer Service +31 43 3588222

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