Prelude ROADSTER™
Guide Sheath

English

INSTRUCTIONS FOR USE

DESCRIPTION

The Prelude Roadster™ Guide Sheath Introducer is designed to perform as a guiding sheath and/or standard sheath introducer. The sheath utilizes a flat coiled wire to provide kink resistance as well as flexibility. The sheath comes in 4-8 Fr and in lengths of 45, 65 and 90 cm. The sheath will be offered in multiple shapes: straight, multipurpose, hockey stick and renal. The distal 35cm of the sheath is hydrophilic coated. The sheath is radiopaque and has a marker band located approximately 5mm from the distal tip of the sheath. NOTE: The tip of the sheath is also radiopaque so position of the marker band to the tip can be visually verified under fluoroscopy imaging.

The product consists of the following components:

One (1) Sheath Introducer
One (1) Vessel Dilator
One (1) Hemostasis Valve Adapter (HVA)

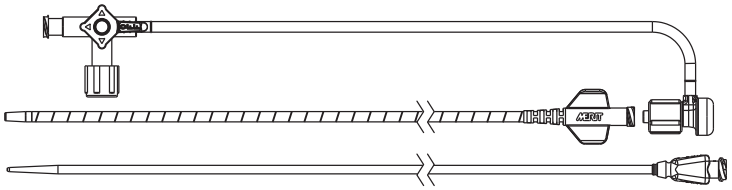
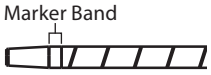


*Image above shows the Prelude Roadster Guide Sheath Straight

The Prelude Roadster Guide Sheath has a marker band located approximately 5mm from the distal tip.



INDICATIONS FOR USE

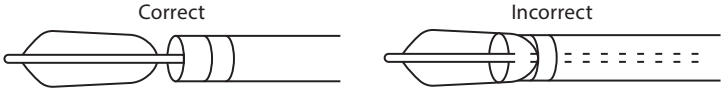
The Prelude Roadster Guide Sheath Introducer is indicated to be used for the introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature.

CONTRAINDICATIONS

Radial access is contraindicated if there is an abnormal Allen's Test, radial pulse, or insufficient dual arterial supply.

WARNINGS

- Extreme care should be taken when manipulating a sheath 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.
- Do not use device with a power injector.
- Prior to beginning radial artery access, an assessment such as the Allen's test should be performed to assess the presence/adequacy of dual arterial circulation to the hand.
- Do not leave the introducer in place for extended periods of time without a catheter or obturator to support the cannula wall.
- Appropriate flushing protocols should be utilized to prevent thrombus formation during procedural use.
- The sheath is radiopaque and has a marker band located approximately 5mm from the distal tip of the sheath. When inflating a balloon at, or close to the sheath tip, do not inflate it inside the distal end of the sheath



CAUTIONS

- Read instructions prior to use.
- Store in a cool, dry place.
- This device is intended for single use only. Do not reuse or resterilize.
- This device is sterile if package is unopened or undamaged.
- This device is non-pyrogenic.
- This device should be used by clinicians with adequate training in the use of the device.
- Follow appropriate anticoagulant protocols if required during the procedure.
- Prior to use, ensure the sheath and dilator are sized appropriately for the vessel and devices being used

CLINICAL BENEFIT STATEMENT

The Prelude Roadster Guide Sheath provides access to the patient's vessel during diagnostic or interventional procedures. The clinician can introduce a variety of diagnostic and therapeutic devices through the sheath, minimizing trauma to the vessel and surrounding tissue. In addition, the device has a hemostasis valve, minimizing the potential of patient blood loss.

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to: air embolism, infection, hematoma, bleeding, perforation or laceration of the vessel wall, thrombus formation, pseudo aneurysm formation, guide wire embolization, vessel spasm, and risks normally associated with percutaneous diagnostic and/or interventional procedures.

INSPECTION PRIOR TO USE

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

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.

INSTRUCTIONS FOR USE

The following instructions provide technical direction but do not replace 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 judgment in treating any specific patient.

1. Identify and prepare the insertion site using proper aseptic technique and local anesthesia as required.
2. Remove the Prelude Roadster Guide Sheath components from package using proper aseptic technique.
3. Ensure the valve and the sheath are tightly connected before use.
4. Flush all components with heparinized saline or suitable isotonic solution. Be sure to wet the outer surface of the sheath introducer to activate the hydrophilic coating with wet gauze or place in saline basin prior to use. The sheath should not be used in a dry state.

   NOTE: Be sure to use in a hydrated state prior to use.

   WARNING: After flushing side port, turn stopcock to off position to maintain flush in the side port and prevent bleed back upon insertion into the vessel.

   WARNING: Do not wipe outer surface of the sheath introducer with dry gauze.
5. Dilator must be securely snapped into place to avoid damage to the vessel.

   WARNING: Dilator must be securely snapped into place to avoid damage to the vessel.
6. Insert appropriate access needle into vessel. While holding the access needle, place the flexible end or J end of the guide wire through access needle into vessel.

   NOTE: Refer to product labeling for appropriate guide wire compatibility with the system components.

   WARNING: Do not advance the guide wire if resistance is met. Determine the cause of resistance before proceeding.
7. Hold guide wire in place while removing access needle. Apply manual pressure above puncture site during needle removal and until the introducer/ dilator assembly is placed.

   WARNING: Do not withdraw the guide wire through the needle because it may damage the guide wire.
8. Insert the introducer/dilator assembly over the guide wire into the vessel using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel.

   WARNING: Ensure that the surface of the sheath is hydrated prior to insertion; the sheath should not be used in a dry state.

   NOTE: Placing sheath in saline basin prior to use will ensure adequate hydration before placing into the vessel.

WARNING: During insertion, hold assembly near distal tip while passing over the guide wire and into the vessel to avoid buckling.

9. After introducer/dilator assembly has been placed into vessel and target destination has been reached, detach the dilator from the HVA by bending the dilator hub down slightly (this will unsnap the dilator hub from the introducer HVA cap). While holding the sheath, carefully remove the dilator leaving the sheath introducer in the vessel.
10. Aspirate from the side port extension to remove any potential air or debris. After aspiration, flush the side port with a suitable solution.

    WARNING: Stopcock handle must be turned to the off position (toward the sheath hub) to prevent inadvertent blood loss.
11. Use caution when inserting and removing selected device(s) (wires, catheters, etc.) into Prelude Roadster Guide Sheath.

    NOTE: Hold the sheath in place when inserting, positioning, or removing the devices to prevent un-intentional sheath movement. Always exchange or remove devices slowly through the sheath.
12. REMOVAL: The sheath should be removed at the end of the procedure or when clinically indicated. **Prior to removal of the sheath, reinsert the dilator and secure dilator to the sheath. Remove the sheath/dilator as a whole unit.** Compression on the vessel, above the puncture site, should be started as the sheath is slowly removed. Non-occlusive compression or closure device should be used to achieve hemostasis once the sheath is removed.

    NOTE: Collected fibrin at the tip of the sheath may be aspirated via the side arm tubing prior to removal of the sheath.
13. DISPOSAL: After use, dispose of product and packaging in accordance with hospital protocol.

SYMBOL	DESIGNATION
	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.
	Max Guide Wire
	Single Sterile Barrier System
	Use by date: YYYY-MM-DD
	Date of Manufacture: YYYY-MM-DD
	Manufacturer
	2D barcode

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