Prelude®

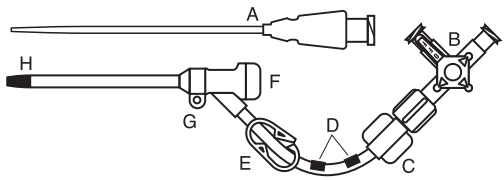
Short Sheath Introducer

INSTRUCTIONS FOR USE

The Merit Prelude® Short Sheath Introducer consists of the following components. These components may be packaged in a single pouch.

One (1) Sheath introducer with marker tip and detachable stopcock
One (1) Vessel dilator

A. Dilator
B. Detachable stopcock
C. Side port extension
D. Removable arterial/ venous (red/blue) indicators
E. Snap clamp
F. Sheath introducer hub with hemostasis valve
G. Rotating suture ring
H. Radiopague marker tip



INTENDED USE STATEMENT
The Merit Prelude Short Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries, including a native arteriovenous fistula or an arteriovenous graft, while maintaining hemostasis for a variety of diagnostic and therapuetic procedures.

INDICATIONS FOR USE STATEMENT
The Merit Prelude Short Sheath Introducer is indicated for use in patients that require percutaneous access for interventional therapies and diagnostic procedures per physician assessment.

PATIENT POPULATION STATEMENT
The Merit Prelude Short Sheath Introducer is intended for patients that require percutaneous access for interventional therapies and diagnostic procedures per physician assessment.

INTENDED USER STATEMENT
The Merit Prelude Short Sheath Introducer is intended for use by physicians with training in percutaneous endovascular procedures.

CLINICAL BENEFITS
The Prelude product line devices provide access and allow percutaneous introduction of various devices into a patient's vasculature, while maintaining hemostasis for a variety of diagnostic and interventional procedures.

WARNINGS
- Do not advance the introducer and/or guide wire if resistance is met.
- Do not use a power injector to inject through the side port of the sheath introducer.
- Remove any potential air and/or debris from the device utilizing standard flush protocol prior to attempting infusion through side port of sheath introducer.
- Inspect device prior to use.
- Utilize caution when attempting a second needle/sheath access after the first introducer sheath has been placed to prevent accidental perforation of the first introducer sheath.
- Always flush device appropriately according to hospital protocol to prevent potential clot formation and/or debris accumulation in the fluid path.
- Do not leave the introducer in place for extended periods of time without a catheter or an obturator to support the cannula wall.

CAUTIONS
- Read instructions prior to use
- RX Only
- Store in a cool dry place
- 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.

POTENTIAL COMPLICATIONS AND RESIDUAL RISKS
Potential complications include, but are not limited to:
- Air embolism
- Bleeding
- Infection
- Hematoma
- Perforation or laceration of the vessel wall
- Pseudo aneurysm formation
- Guide wire embolization
- Vessel spasm
- Risks normally associated with percutaneous diagnostic and/or interventional procedures.

INSTRUCTIONS FOR USE
1. Identify the insertion site and prepare the site using proper aseptic technique and local anesthesia as required.

2. Remove the Prelude Short Sheath Introducer components from package using proper aseptic technique.
3. Flush all components with saline or suitable isotonic solution. The side port of the device has a snap clamp; ensure that clamp is open during flushing.
4. After flushing side port, turn stopcock to off position to maintain flush in side port and prevent bleed back upon insertion into the vessel. Close snap clamp on side port extension.
5. The side port of the device includes two removable indicators – red indicates arterial and blue indicates venous use. Select the appropriate color and leave in place on the side port tubing; remove and discard the other. If indicators are not necessary, remove and discard both.
6. Insert dilator into Prelude Short Sheath Introducer through hemostasis valve and snap into place. Dilator must be securely snapped into place to avoid damage to the vessel.
7. 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 the guide wire size that is compatible with the system components.

   WARNING: Do not advance the guide wire if resistance is met. Determine the cause of resistance before proceeding.

   NOTE: If a crossed catheter technique is utilized, the punctures should be greater than 11cm apart. This distance ensures that during hemodialysis the Prelude Short Sheaths are sufficiently separated for use as arterial and venous conduits.
8. Hold guide wire in place and remove access needle. Hold pressure at the site until the introducer/dilator assembly is placed.

   WARNING: If a needle with a metal cannula is used, do not withdraw the guide wire after it has been inserted because it may damage the guide wire.
9. 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. Grasp the assembly close to the skin as it is being placed into the vessel to avoid buckling.
10. After introducer/dilator assembly has been placed into vessel, detach the dilator from the introducer by bending the dilator hub down slightly (this will un-snap the dilator hub from the introducer cap). While holding the sheath, carefully remove the dilator and guide wire together, leaving the sheath introducer in the vessel.
11. Aspirate from the side port extension to remove any potential air. After aspiration, flush the side port with a suitable solution. Stopcock should be turned off to maintain flush in side port. In addition, ensure that clamp is closed to also maintain flush in side port.
12. Insert selected device(s) (wires, catheters, etc.) into Prelude Short Sheath Introducer.

    NOTE: Hold the sheath in place when inserting, positioning, or removing the devices. Always exchange or remove devices slowly through the sheath.
13. To temporarily suture the sheath in place, use the rotating suture ring.
14. REMOVAL
    a. The sheath may be removed when clinically indicated. Compression on the vessel, above the puncture site, should be started as the sheath is slowly removed. Discard the sheath appropriately.

       NOTE: Collected fibrin at the tip of the sheath may be aspirated via the side port tubing prior to removal of the sheath.

    b. Follow standard protocol for achieving hemostasis at the insertion site.
15. HEMODIALYSIS
    a. If the sheath is to be used for temporary access for hemodialysis, aspirate from the side port extension to remove any potential air. After aspiration, flush the side port with a suitable solution. Stopcock should be turned off to maintain flush in side port. In addition, ensure that clamp is closed to also maintain flush in side port.
    b. Patient should be accompanied to dialysis center by appropriate personnel.
    c. Following standard protocol, side port of sheath introducer can be connected to hemodialysis circuit.
    d. At conclusion of dialysis, refer to step 14 for sheath removal.

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

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.

	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 Number. For printed copy available within seven calendar days, 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.
	Single sterile barrier system
	Use by date: YYYY-MM-DD
	Date of manufacture: YYYY-MM-DD
	Manufacturer
EC REP	Authorized Representative in European Community
	Keep Dry
	Keep away from sunlight

CE 2797

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EC REP

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