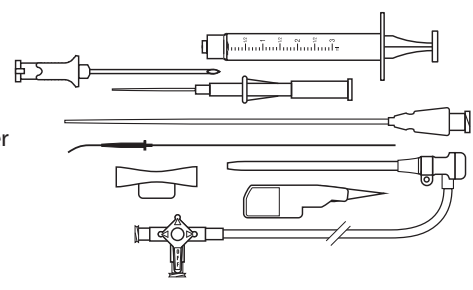
PreludeEASE™

Hydrophilic Sheath Introducer English

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION:
The Merit PreludeEASE™ Hydrophilic Sheath Introducer consists of some or all of the following components. These components may be packaged together or separately.



One (1) Sheath Introducer
One (1) Vessel Dilator
One (1) Mini Guide Wire
One (1) Access Needle
One (1) Syringe
One (1) Thumb Scalpel
One (1) BowTie™ Guide Wire Insertion Device

℞ Only Federal (USA) law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE:
The Merit PreludeEASE Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries, including but not limited to the radial artery, while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

The access needle with inner metal needle and outer plastic cannula is used to gain access to the vein or artery for placement of guide wires.

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

WARNINGS:
- 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 use the PreludeEASE hydrophilic sheath introducer in patients with an abnormal Allen's test or radial pulse, or insufficient dual arterial supply.
- Do not advance the introducer and/or guide wire if resistance is met.
- Do not reinsert the inner metal needle into the plastic cannula at any time.
- Do not use device with a power injector.
- Appropriate flushing protocols should be utilized to prevent thrombus formation during procedural use.

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.
- Utilize appropriate anticoagulant therapy for patient during procedure.
- Prior to use, ensure that the sheath and dilator are the appropriate size for the access vessel and devices to be 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.

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.

INSTRUCTIONS FOR USE:
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 judgment in treating any specific patient.

1. Identify the insertion site and prepare the site using proper aseptic technique and local anesthesia as required.
2. Remove the PreludeEASE Hydrophilic Sheath components from package using proper aseptic technique.
3. 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. The sheath should not be used in a dry state.

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

Warning: Do not wipe outer surface of the sheath introducer with dry gauze.

4. Insert vessel dilator into PreludeEASE Hydrophilic Sheath through hemostasis valve and snap into place.

Warning: Dilator must be securely snapped into place to avoid damage to the vessel.

5. Insert appropriate access needle into vessel.
   a. If a metal access needle is used, while holding the access needle, place the flexible end or J end of the guide wire through access needle into vessel.
   b. If an access needle with inner metal needle and outer plastic cannula is used, after appropriate access is obtained, remove the inner metal needle. While holding the plastic cannula portion of the access needle, place the flexible end or J end of the guide wire through the plastic cannula into the vessel.

Note – Refer to product labeling for appropriate guide wire compatibility with the system components.

Warning: Do not reinsert the inner metal needle into the plastic cannula at any time.

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

6. 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: 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.

7. 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 wet prior to insertion; the sheath should not be used in a dry state.

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

8. After introducer/dilator assembly has been placed into vessel, detach the dilator from the introducer by bending the dilator hub down slightly (this will unsnap 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.
9. 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.

10. Use caution when inserting and removing selected device(s) (wires, catheters, etc.) into PreludeEASE Hydrophilic Sheath.

Note: Hold the sheath in place when inserting, positioning, or removing the devices. Always exchange or remove devices slowly through the sheath.

11. REMOVAL: The sheath should be removed within 24 hours. Compression on the vessel, above the puncture site, should be started as the sheath is slowly removed. Non-occlusive compression 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.

12. Discard the sheath appropriately.

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