INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION:
The Merit Prelude IDeal™ Hydrophilic Sheath Introducer consists of some or all of the following components. These components may be autoclaved or EtO sterilized.

• Wire Insertion Device

PRODUCT INFORMATION:

THE PRELIDE IDEAL HYDROPHILIC SHEATH INTRODUCER

1. Insert sheath appropriately.

WARNING: Failure to properly place the sheath may result in the sheath lying outside the vessel, which may cause injury to the patient. Follow manufacturer’s instructions for sheath introduction.

2. Insert appropriate access needle into vessel.

• Utilize appropriate anticoagulant therapy for patient during procedure.

3. Flush all components with heparinized saline or suitable isotonic solution. Be sure to wet the outer surface required.

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

• Appropriate flushing protocols should be utilized to prevent thrombus formation during procedural use.

5. Insert appropriate access needle into vessel.

• Do not use device with a power injector.

6. Hold guide wire in place while removing access needle. Apply manual pressure above puncture site during proceeding.

• Do not advance the introducer and/or guide wire if resistance is met.

7. Insert the introducer/dilator assembly over the guide wire into the vessel. Using a rotating motion, advance the assembly.

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

8. When fluid is obtained, remove the inner metal needle. While holding the plastic cannula portion of the access needle, carefully remove the dilator and guide wire together, leaving the sheath introducer in the vessel.

• This device is intended for single use only. Do not reuse or resterilize.

9. Remove the Prelude IDeal Hydrophilic Sheath components from package using proper aseptic technique.

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

10. Prior to beginning radial artery access, an assessment such as the Allen’s test should be performed to determine the presence/adequacy of dual arterial circulation to the hand.

• Prior to use, ensure that the sheath and dilator are the appropriate size for the access vessel and devices to be use.

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.

• Do not remove the Prelude IDeal Hydrophilic Sheath components from package prior to aspiration of blood from the needle hub. The sheath should not be used in a dry state.

12. Discard the sheath appropriately.

WARNING: Failure to discard the sheath appropriately may result in exposure to infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient.

Booth 1298 - TCT 2013

Press release

Merit Medical Systems Inc.

The Merit Prelude IDeal 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, femoral artery, and brachial artery. The Prelude IDeal Hydrophilic Sheath Introducer is designed to rapidly deliver diagnostic and therapeutic devices through the vascular system. The Prelude IDeal Hydrophilic Sheath Introducer is designed to provide rapid and efficient access through the vascular system.

PROOF OF USE:

The following information is provided to demonstrate that the device is being used properly. The device is designed to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries, including but not limited to the radial artery, femoral artery, and brachial artery. The Prelude IDeal 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, femoral artery, and brachial artery. The Prelude IDeal Hydrophilic Sheath Introducer is designed to rapidly deliver diagnostic and therapeutic devices through the vascular system. The Prelude IDeal Hydrophilic Sheath Introducer is designed to provide rapid and efficient access through the vascular system.

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