INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

The Merit PreludeEASE Hydrophilic Sheath Introducer is intended to facilitate access and provide a sheath for placement of various guide wires during percutaneous procedures.

INDICATIONS FOR USE:

The Merit PreludeEASE Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various guide wires. These procedures are typically performed by a physician or qualified healthcare provider using proper aseptic technique and local anesthesia as required.

POTENTIAL COMPLICATIONS:

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 procedures. The techniques and procedures described do not represent all medically acceptable procedures. 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 procedures. The techniques and procedures described do not represent all medically acceptable procedures.

INSTRUCTIONS FOR USE:

1. Identify the sheath and introducer size using a map appropriate to the vessel size. The appropriate sheath and introducer size should be used.

2. 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.

3. Insert vessel dilator into PreludeEASE Hydrophilic Sheath through the introducer. 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.

4. Insert vessel dilator into PreludeEASE Hydrophilic Sheath through the introducer. 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.

5. Insert the metal access needle into the vessel. The access needle with inner metal needle and outer plastic cannula is intended to provide access and facilitate the percutaneous introduction of various guide wires. These procedures are typically performed by a physician or qualified healthcare provider using proper aseptic technique and local anesthesia as required.

6. If a metal access needle 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. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel.

7. If an access needle with a metal cannula is used, after appropriate access is obtained, remove the metal cannula. While holding the cannula portion of the access needle, place the flexible end or J end of the guide wire through the metal cannula into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel. Using a rotating motion, advance the introducer/dilator assembly through the tissue into the vessel.

8. After introducer/dilator assembly has been placed into vessel, insert the metal access needle and guide wire together, leaving the sheath introducer in the vessel. Hold the guide wire in place while removing access needle. Apply manual compression on the vessel, above the puncture site, should be started immediately.

9. 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. Remove the inner metal needle using a stylet. 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.

10. Ensure that the dilator handle is turned to the off position. Stopcock handle must be turned to the off position (toward the axis of the sheath) while removing access needle. Do not remove access needle while holding the sheath introducer in the vessel.

11. REMOVAL: The sheath should be removed within 24 hours. Compress debris. After aspiration, flush the side port with a suitable solution.

12. Discard the sheath appropriately.