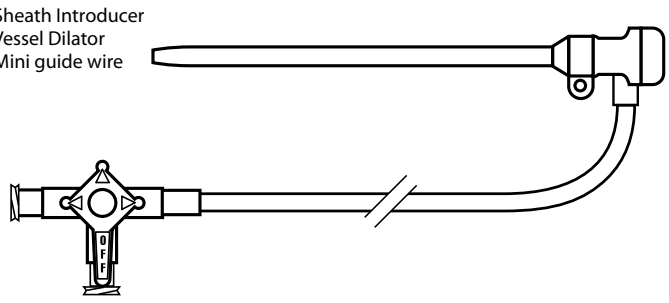
Prelude® Sheath Introducer

INSTRUCTIONS FOR USE

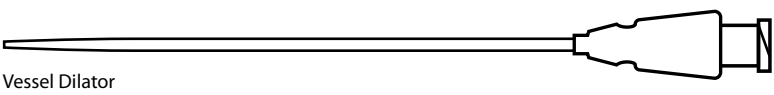
PRODUCT DESCRIPTION

The Prelude Sheath Introducer consists of the following components. These components may be packaged together or separately.

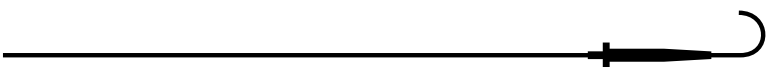
One (1) Sheath Introducer
One (1) Vessel Dilator
One (1) Mini guide wire



Sheath Introducer



Vessel Dilator



Mini Guide Wire

An obturator is also available as a separate component. The obturator supports the sheath introducer when it is left in place. An obturator that is one French size smaller or equal to the sheath French size should be used

INTENDED USE:
The Prelude Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

WARNINGS:
- Do not advance the introducer and/or guide wire if resistance is met.
- Do not leave the introducer in place for extended periods of time without a catheter or an obturator to support the cannula wall.
- Do not use device with a power injector.

CAUTIONS:
- Read instructions prior to use.
- **R_x Only - Caution**: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Store in a cool dry place.
- This device is intended for single use only. Do not reuse or resterilize .

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, risks normally associated with pecutaneous 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 Sheath Introducer components from package using proper aseptic technique.

3. Flush all components with saline or suitable isotonic solution. After flushing side port, turn stopcock to off position to maintain flush in side port and prevent bleed back upon insertion into the vessel.

4. Insert vessel dilator into Prelude Sheath Introducer through hemostasis valve and snap into place. Dilator must be securely snapped into place to avoid damage to the vessel.

5. 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.

6. 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.

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. Grasp the assembly close to the skin as it is being placed 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. After aspiration, flush the side port with a suitable solution. Stopcock should be turned off to maintain flush in side port.

10. Insert selected device(s) (wires, catheters, etc.) into Prelude Sheath Introducer.
    Note: Hold the sheath in place when inserting, positioning, or removing the devices. Always exchange or remove devices slowly through the sheath.

11. To temporarily suture the sheath in place, use the rotating suture ring.

12. REMOVAL :
- 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. **Note:** Collected fibrin at the tip of the sheath may be aspirated via the side arm tubing prior to removal of the sheath. Discard the sheath appropriately.
- If the sheath is to be left in place, an obturator of appropriate size should be place d into sheath. After the sheath is flushed, place the obturator through the sheath and snap into place. A suitable solution should be flushed through the side arm after obturator is placed. **Note**: An obturator that is one French size smaller than the sheath introducer should be used to allow flushing, infusion and pressure monitoring. When clinically indicated, the sheath and obturator may be removed (see above).

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