Prelude PRESTIGE™

Splittable Sheath Introducer

English

INSTRUCTIONS FOR USE

Read instructions prior to use.

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

For U.S.-California Only.

Proposition 65, a State of California voter initiative, requires the following notice:

WARNING

This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or birth defects or other reproductive harm.

INDICATIONS FOR USE

The introduction of various types of pacing/defibrillator leads and catheters into the venous vasculature.

WARNINGS

- This product is sensitive to light. Do not use if stored outside the protective outer carton.
- Store in a cool, dark, and dry place.

CAUTION

This device is intended for single patient use only. Read instructions prior to use. Read manufacturer's instructions for the use of catheters, guidewires and introducers.

PRECAUTIONS

- Do not alter this device in any way.
- 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.
- Never advance or withdraw the guide wire or sheath when resistance is met. Determine the cause by fluoroscopy and take remedial action.

ADVERSE EVENTS

Adverse events may include, but are not limited to the following:

- Blood loss/air embolism
- Vessel damage
- Infection
- Hemotoma formation
- Pneumothorax
- Hemothorax
- Catheter displacement

EQUIPMENT SUGGESTED *if not supplied*

- 18 g XTW introducer needle
- Luer slip syringe
- 0.038" (0.97 mm) diameter guidewire

USE STERILE TECHNIQUE *A suggested procedure*

1. Peel open package and place contents in sterile field.
2. Prep skin and drape in area of anticipated venipuncture.
3. Flush the needle, sheath, and dilator prior to use.
4. Insert the dilator into the sheath and attach dilator cap to sheath hub.
5. Insert the needle into vessel. Verify the needle position by observing venous blood return.
6. Aspirate the needle using the syringe.
7. Remove the syringe and insert soft tip of the guide wire through the needle into the vessel. Advance the guidewire to required depth. Leave an appropriate amount of the guidewire exposed. At no time should the guide wire be advanced or withdrawn when resistance is met. Determine the cause of resistance before proceeding.
8. Hold the guide wire in place and remove needle. Do not withdraw the guide wire back into the needle as this may result in separation of the guide wire.
9. Thread the dilator/sheath assembly over the guide wire.
10. Advance the dilator/sheath assembly with a twisting motion over the guide wire and into the vessel. Fluoroscopic observation may be advisable. Attaching a clamp or hemostat to the proximal end of the guide wire will prevent inadvertently advancing the guide wire entirely into the patient.
11. Once assembly is fully introduced into the venous system, remove the dilator cap from the sheath by unscrewing the dilator cap off the sheath hub.
12. Slowly retract the guide wire and dilator, leaving the sheath in position. Place thumb over the exposed orifice of the sheath to reduce air aspiration and/or blood loss.
13. Introduce the catheter through the sheath and advance it into position.
14. Split sheath by sharply snapping the sheath hub tabs and peeling sheath tube apart while withdrawing it from the vessel. Care must be exercised not to withdraw the catheter during this process.

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	Caution: Consult accompanying documents.
	Single use.
	Do not resterilize.
	Non-pyrogenic.
	Do not use if package is damaged.
STERILE EO	Sterilized using ethylene oxide.
	Keep away from sunlight/Keep Dry.
	Size
	Length

CE 0344

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