



Valved Peelable Introducer Instructions for Use

Intended Use:

The Valved Peelable Introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system.

Precautions:

- The Valved Peelable Introducer is designed to reduce blood loss and the risk of air intake but it is not a hemostasis valve.
- It is not intended to create a complete two-way seal nor is it intended for arterial use.
- The valve will substantially reduce air intake. At -12mm Hg vacuum pressure the Valved Peelable Introducer may allow up to 4cc/sec of air to pass through the valve.
- Product is sterile in unopened, undamaged package.
- For single use only. **DO NOT REUSE.** Re-Use may lead to infection or illness/injury. ②
- Federal (USA) law restricts this device to sale by or on the order of a physician.

Contraindications:

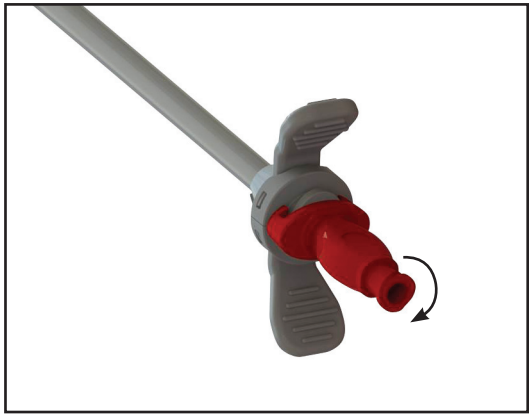
- The Valved Peelable Introducer is not designed for use in the arterial system or as a hemostatic device.

Potential Complications:

- Air Embolism
- Brachial Plexus Injury
- Hematoma Formation
- Hemothorax
- Mediastinal Widening
- Pneumothorax
- Subclavian Artery Puncture
- Subclavian Vein Thrombosis
- Wound Infection

Instructions for Use:

1. Remove the introducer assembly from the package, remove dilator from the sheath and reinsert it into the opposite end. Lock the dilator in place by rotating it ninety degrees clockwise.



2. After percutaneous access has been achieved, advance the introducer assembly over the guidewire and into the vein.

Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold the introducer close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the introducer towards the vein, regrasp the introducer a few centimeters above the original grasp location and push down on the introducer. Repeat procedure until introducer is inserted to appropriate depth based on patient anatomy and physician's discretion.

3. Remove the dilator and guidewire from the sheath by rotating the dilator ninety degrees counterclockwise to unlock the dilator from the sheath and gently withdraw the dilator and guidewire from the sheath.

Caution: Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.

4. Advance catheter through the valve. To prevent kinking the catheter, it may be necessary to advance in small steps by grasping the catheter close to the sheath.



5. After the catheter has been positioned, crack the sheath handle and valve in half.
6. Remove the sheath from the patient by slowly pulling out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS, PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY EFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

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