

Jet Medical^{SA}

FLOWGUARD™ VALVED PEELABLE INTRODUCER

INSTRUCTIONS FOR USE

INTENDED USE:

The FlowGuard™ Valved Peelable Introducer is intended for use in the percutaneous insertion of catheters in the venous system.

PRECAUTIONS:

- The FlowGuard™ 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.
 - The valve will substantially reduce the rate of blood flow but some blood loss through the valve may occur.
- Product is sterile in unopened, undamaged package. STERILE EO
- For single use only. **DO NOT RE-USE.** Re-use may lead to infection or illness/injury. 2
- Do not use if package is damaged. 2
- Do not resterilize.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

Note: Discard biohazard according to facility protocol.

CONTRAINDICATIONS:

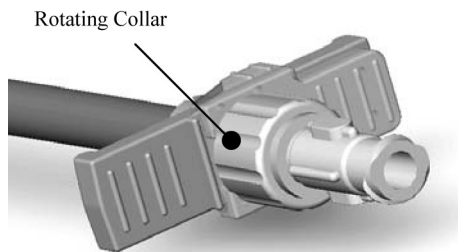
- The FlowGuard™ Valved Peelable Introducer is not designed for use in the arterial system or as a hemostatic device.

POTENTIAL COMPLICATIONS:

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

INSTRUCTIONS FOR USE:

- Remove the sheath/dilator assembly from the package, remove dilator from the sheath.
- Slide the valve over the sheath opening, and insert the dilator through the valve and lock in place using the rotating collar.



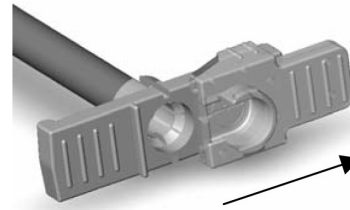
- After percutaneous access has been achieved, and leaving the guidewire in place, advance the introducer/dilator assembly over the guidewire and into the vein.

Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is inserted to appropriate depth based on patient anatomy and physician's discretion.

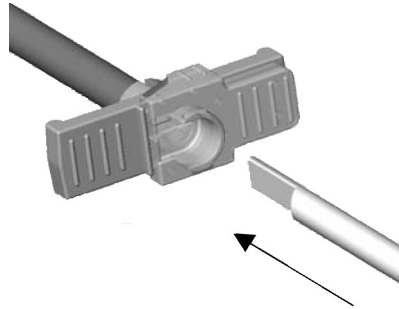
- Remove the dilator and guidewire from the introducer/dilator assembly by unlocking the rotating collar and gently withdrawing the dilator from the sheath.

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

Note: If the procedure does not allow the use of a valve, slide the valve away from the sheath opening.

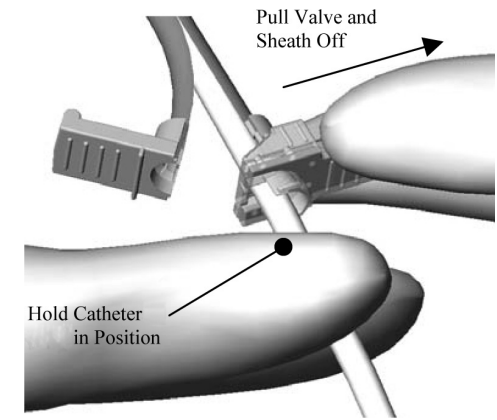


- Advance catheter through the valve. To prevent kinking the catheter, it may be necessary to advance in small steps by grasping the catheter close to the sheath.



- After the catheter has been positioned, crack the sheath handle in half.
- Peel the non-valved side of the handle partially away from the catheter.
- Near the valve, hold the catheter firmly in position and pull the valve off of the catheter.

Note: It is normal to experience some resistance while pulling the catheter through the slit on the valve.



- 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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