
PERCUTANEOUS CATHETER INTRODUCER with VALVED PEEL-AWAY SHEATH IFU's



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CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.

The FlowGuard™ Valved Peelable Introducer is intended for one time use only. Read instructions prior to use.

Indications

For use in the percutaneous insertion of leads or catheters into the venous system.

Contraindications

Not designed for use in the arterial system or as a hemostatic device.

Warnings

- Intended for **single patient use. DO NOT REUSE.**
- Norfolk Medical Products, Inc. products are single use devices and should never be reimplanted. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Precautions

- The FlowGuard™ Valved Introducer is designed to reduce blood loss and the risk of air intake but it is not a hemostatic valve.
 - It is not intended to create a complete two-way seal nor is it intended for arterial use.

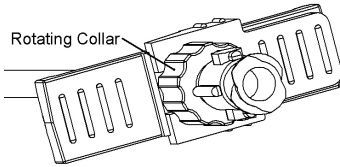
- The valve will substantially reduce air intake. At -12mm HG vacuum pressure the FlowGuard™ introducer may allow up to 4 cc/sec of air to pass through the valve.
- The valve will substantially reduce the rate of blood flow but some blood loss through the valve may occur.
- Inspect the container prior to opening. If the seal or package is damaged, contact Norfolk Medical Products, Inc.
- Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure.

Possible Complications

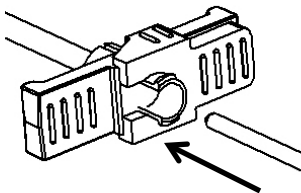
- Subclavian artery puncture
- Inadvertent vessel puncture
- Thrombosis
- Pneumothorax
- Hemothorax
- Air embolism
- Hematoma formation
- Brachial plexus injury
- Subclavian vein thrombosis
- Wound Infection
- Medlastinal widening

Continued on Reverse Side →

Instructions for Use

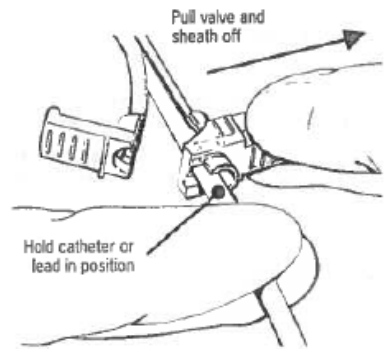


1. Remove components and insert the dilator through the valved sheath. Lock in place using the rotating collar.
2. Using aseptic technique, prepare the patient for access. Select the desired entry site.
3. Remove the needle protector.
4. Introduce the needle into the vein.
5. Insert guidewire into the proximal end of the needle and feed the guidewire through the needle. Advance a portion of the wire into the vein.
6. Leaving the guidewire in place, withdraw the needle from the vessel.
7. Advance the introducer over the guidewire and into the vein.
8. Remove the dilator and guidewire by unlocking the rotating collar and gently withdrawing the dilator from the sheath.
9. Advance a catheter or lead 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.



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

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



13. Remove the sheath from the patient.

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