
**INSTRUCTIONS FOR
USE**

EMBOSAFE™

ANGIODYNAMICS®
INCORPORATED

This product manufactured for:

ANGIODYNAMICS®
INCORPORATED

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EMBOSAFE™ is a trademark of AngioDynamics, Inc.

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Precautions

- **The EmboSafe™ 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 -12 mm Hg vacuum pressure the EmboSafe™ 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.
- For single use only. **DO NOT REUSE.**
- Federal (USA) law restricts this device to sale by or on the order of a physician.

Intended Use

The EmboSafe™ Valved Peelable Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Contraindications

The EmboSafe™ introducer is not designed for use in the arterial system or as a hemostatic device.

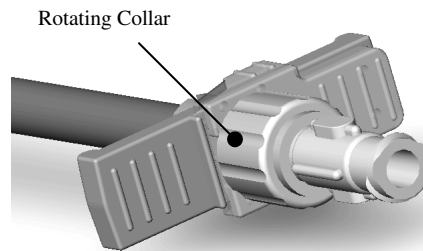
Potential Complications

- Subclavian artery puncture
- Pneumothorax
- Hemothorax
- Air embolism
- Hematoma formation
- Brachial plexus injury
- Subclavian vein thrombosis
- Wound infection
- Mediastinal widening

Instructions for Use

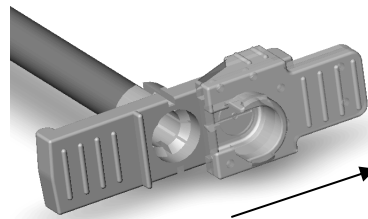
1. Remove the sheath/dilator assembly from the package, remove dilator from the sheath.

2. Slide the valve over the sheath opening, and insert the dilator through the valve and lock in place using the rotating collar.

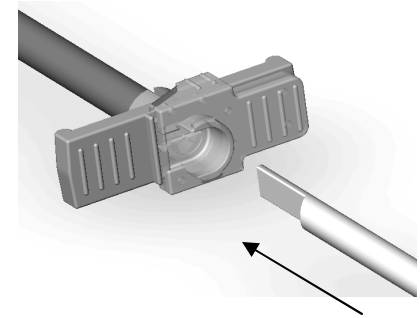


3. After percutaneous access has been achieved, and leaving the guidewire in place, advance the introducer/dilator assembly over the guidewire and into the vein.
4. Remove the dilator and guidewire from the introducer/dilator assembly by unlocking the rotating collar and gently withdrawing the dilator from the sheath.

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

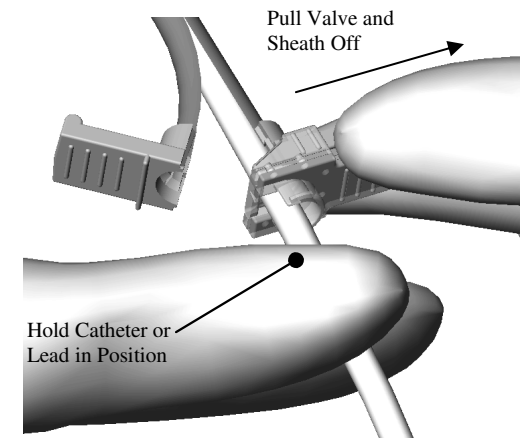


5. Advance a catheter or lead through the valve. To prevent kinking the catheter or lead, it may be necessary to advance in small steps by grasping the catheter or lead close to the sheath.



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

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



9. Remove the sheath from the patient.