medCOMP®

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.

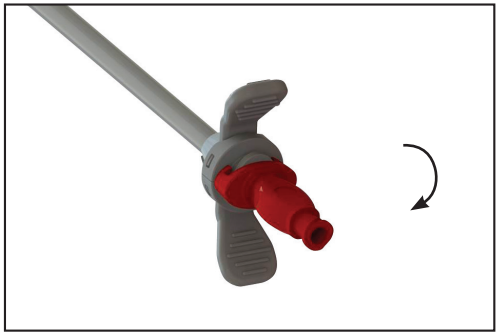
PRECAUTIONS:
- The Valved Peelable Introducer is designed to reduce blood loss and the risk of air intake but it is not a hemostasis valve.
- It is not intended to create a complete two-way seal nor is it intended for arterial use.
- The valve will substantially reduce air intake. At -12mm Hg vacuum pressure the Valved Peelable Introducer may allow up to 4cc/sec of air to pass through the valve.
- For single use only. **DO NOT RE-USE.** Re-use may lead to infection or illness/injury.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Product is sterile in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE STERILE EO
- Do not use if package is damaged.
- Do not resterilize.
- Discard biohazard according to facility protocol.
- Caution when using this device. Be aware of sharps.
- Do not use if components are damaged, deformed or missing.
- Do not proceed if resistance is felt or interaction between components is failing.
- Do not insert or withdraw the guidewire forcibily from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or sheath/dilator and guidewire must be removed together.

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

POTENTIAL COMPLICATIONS:
- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Hematoma Formation
- Hemothorax
- Mediastinal Widening
- Perforation/Trauma to Vessel
- 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.



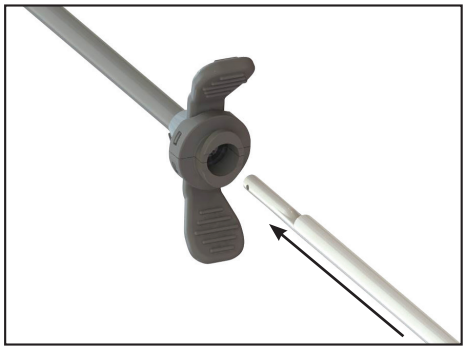
2. After percutaneous access has been achieved, advance the introducer assembly over the guidewire and into the vein.

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).

7. Examine the device after it is removed from the patient to ensure no foreign material remains inside the patient.

8. If unable to tear sheath, stop the procedure.

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.

SYMBOL TABLE

5.1.1	Manufacturer *	5.6.3	Non-pyrogenic *
5.1.4	Use-by Date *	5.3.2	Keep Away from Sunlight *
5.4.2	Do Not Re-use *	5.2.6	Do Not Resterilize *
5.3.4	Keep Dry *	Rx Only	Prescription Use Only ***
5.1.5 LOT	Batch/Lot Number *	5.1.6 REF	Catalogue Number *
5.2.8	Do Not Use if Package is Damaged *		
5.1.2 EC REP	Authorized Representative in the European Community *		
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide *		
5.4.4	Caution, consult Accompanying Documents *		

*** This symbol is in accordance with ISO 15223-1.**

***** FDA guidance Use of Symbols in Labeling.**

Medcomp® does not recommend a particular technique for the use of this device. The physician should evaluate the appropriateness of the device according to individual patient conditions and his or her medical training and experience.

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.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents without notice.

Medical Components, Inc.
1499 Delp Drive
Harleysville, PA 19438 U.S.A.
Tel:215-256-4201
Fax:215-256-1787
www.medcompnet.com

CE 2797

EC REP
MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany

PN 40397BSI **Rev. 3/19 B**