

15. Post-operative elevation of the patient's upper torso to 30° for a minimum of 12 hours is a helpful consideration.
16. Examine the device after it is removed from the patient to ensure no foreign material remains inside the patient.
17. If unable to tear sheath, stop the procedure.

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 AFFECT 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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## PEEL-CATH INTRODUCER SET

Peel-Cath Introducer Sets are intended for the placement of catheters or pacing leads into the central venous system via the subclavian vein.

### READ ALL WARNINGS, CAUTIONS AND INSTRUCTIONS PRIOR TO USE.

#### FOR SINGLE USE ONLY:

Destroy Introducer Set after use. Re-use may lead to infection or illness/injury.





#### STERILE AND NON-PYROGENIC:

Only if package is not damaged or open.

#### STORAGE AND USE INSTRUCTIONS:

Store product at normal room temperature. Use product on first in first out basis prior to expiration date on label. It is recommended that duplicates of each sterilized item be readily available when introducing a catheter or pacing lead. Thus, if aseptic technique is compromised, the procedure can continue.

#### WARNINGS:

- Recommended for venous use only.
- Never insert the stiff end of a guidewire.
- Never advance a guidewire if any resistance is met.
- Product is sterile in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE 
- Single use only. DO NOT RE-USE. Re-use may lead to infection or illness/injury. 
- Do not use if package is damaged. 
- Do not resterilize. 

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**DESCRIPTION:**

Peel-Cath Introducer Sets are designed to provide safe, simple and smooth introduction of catheters or pacing leads into the central venous system. Standard introducer sets contain an 18 gauge thin wall needle, 10cc syringe, guidewire, dilator and peel-cath sheath.

**INDICATIONS:**

Peel-Cath Introducer Sets are indicated for placement of catheters or pacing leads into the central venous system via the subclavian vein.

**CONTRAINDICATIONS:**

Although there are no absolute contraindications to vein puncture, special precautions should be exercised in patients with known bleeding disorders. Relative contraindications may include patients with prior irradiation of the subclavian vein, severe scoliosis, and chest trauma. Use of this introducer set may be contraindicated if there is a known or suspected vascular obstruction.

**POTENTIAL COMPLICATIONS:**

Possible complications include but are not limited to the following:

- Hematoma
- Thrombosis
- Sepsis
- Air Embolism
- Subclavian Artery Puncture
- Perforation/Trauma to Vessels
- Infection
- Thrombophlebitis
- Cellulitis
- Pneumothorax
- Bleeding

Training, experience and the awareness of possible complications prior to use are the best safeguards against these complications.

**PRECAUTIONS:**

- In the event of complications arising during the insertion of any introducer set devices and catheters used therewith, the following items should be readily available: antiarrhythmia drugs, defibrillator, and respiratory assist equipment.
- Verify correct catheter or lead position before removing sheath.
- Avoid puncture of the subclavian artery by keeping the puncture site away from the most lateral course of the vein and not angulating the needle too far posteriorly. If the artery is punctured, the needle should be removed and firm pressure applied over the puncture site for 10 minutes.
- The risk of pneumothorax can be reduced by avoiding too lateral or too deep a needle insertion. Generally, if three attempts at cannulation prove unsuccessful, another site should be chosen.
- Subclavian vein cannulation in patients with chronic obstructive pulmonary disease should be avoided. If cannulation is attempted but unsuccessful, a chest radiograph should be obtained to rule out pneumothorax before contralateral insertion is attempted.
- Aspiration of air into the venous system can be prevented by removing the syringe from the needle while the patient holds his or her breath or hums and immediately placing of the thumb or index finger over the hub of the needle. The guidewire, dilator and sheath should be inserted during withheld breath or expiration.

- 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 forcibly 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.

**INSTRUCTIONS FOR USE:**

(Read all Warnings and Precautions prior to use.)

The following instructions are provided as a general guide intended for informational purpose only; the physician should add to or alter procedural details with respect to their clinical experiences.

1. Distend the subclavian vein by raising the legs 45° or place patient in a 15° to 25° trendelenburg position. Locate the junction of the middle and medial thirds of the clavicle where the first rib proceeds beneath the clavicle. Needle insertion site should be approximately 1 to 2 cm lateral and inferior to this location.
2. Depress the area 1 to 2 cm beneath the junction of the distal and middle thirds of the clavicle with the thumb of the nondominant hand and place the index finger of the same hand approximately 2 cm above the sternal notch.
3. Administer a local anesthetic.
4. Attach the 18 gauge thin wall needle to the syringe. Insert needle under the clavicle at the point identified in step 1. Direct the needle toward the index finger above the sternal notch at a 20° to 30° angle with the thorax. Direct the bevel of the needle inferomedially to encourage guidewire passage into the innominate vein.
5. While maintaining gentle negative pressure within the syringe, advance the needle until it slips beneath the clavicle.
6. When the vein is entered, quickly remove the syringe from the 18 gauge thin wall needle and immediately cap the needle hub with your thumb or index finger.
7. Insert the flexible tip of the guidewire 10 to 15 cm through the needle. Verify correct position of guidewire by fluoroscopy.
8. While maintaining gentle pressure on the puncture site, remove the needle over the guidewire.
9. Make a small skin nick at the insertion site using a #11 blade scalpel with the guidewire exposed in the center. The incision should be parallel to the clavicle.
10. Advance the introducer set (dilator and sheath together) over the guidewire into the subclavian vein using a slight twisting motion. Leave approximately 8 cm exposed.
11. For models with locking dilator, rotate dilator 90° to disengage lock prior to removal.
12. Remove the guidewire and dilator together from the sheath.
13. Insert catheter or pacing lead of choice through sheath and into the subclavian vein.
14. When catheter or pacing lead is well advanced into the vein, remove the sheath by peeling it apart while withdrawing it from the insertion site.