INDICATIONS FOR USE:
- Vascu-Line™ catheters are designed for long-term vascular access use in patients that lack adequate peripheral venous access. They are available in single and dual lumen catheters.
- Vascu-Line™ central venous catheters are designed for the administration of I.V. fluids, blood products, drugs, parenteral nutrition solutions, as well as blood withdrawal.

NOTES:
- While smaller lumen Vascu-Line™ catheters are used for infants weighing less than 10 kg, lumen sizes in catheters sized for children greater than 10 kg should be increased by 2 lumen sizes larger than comparable adult size catheters.

CONTRAINDICATIONS:
The device is contraindicated whenever:
- The patient is known or is suspected to be allergic to materials contained in the device.
- Severe chronic obstructive lung disease exists (proven percutaneous subclavian placement only).
- Past irradiation of prospective insertion site.
- Previous episodes of thoracentesis or other puncture surgical procedures at the prospective placement site.
- Local tissue factors will prevent proper device stabilization and/or access.

POSSIBLE COMPLICATIONS:
- Air Embolism
- Pneumothorax
- Broach Pleural Injury
- Cardiac Tamponade
- Catheter or Cuff Erosion through the Skin
- Catheter Embolism
- Catheter Occlusion, Damage or Blockage due to Compression between the Carotid and First Rib
- Catheter Related Septic Syndrome
- Exit Site Infection
- Defibrillation
- Extravasation
- Hemolysis
- Hypotension
- Hydrothorax
- Instrumentation to Implanted Device
- Laseration of the Veins or Vein Graft
- Perforation of Veins or Vein Graft
- Thrombus
- Pneumothorax
- Renting of the Chest Wall (Skin)
- Retained needle or stylet; stylet and catheter damage may result.
- Thrombus (venous or arterial)
- Ulceration
- Venous Thrombosis
- Vascular Injury
- Vessel can contribute to changes in the first rib and clavicle. Catheter can be inserted into the subclavian vein at the angle of the outer third of the clavicle lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein if it is possible to insert the wire more proximally (e.g. subclavian to internal jugular). If wire placement lead to compression of the catheter between the first rib and clavicle and can lead to severing or damaging of the catheter. A fluoroscopic or echocardiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle.

SAFETY INFORMATION:
- Do not attempt to advance the wire beyond the bevel of the needle while removing straightener from the needle hub to prevent guidewire damage or shearing.
- If the guidewire must be withdrawn while the guidewire is inserted into the catheter and guidewire as a unit to help prevent the needle from damaging or shearing the guidewire.

PREPARATION:
1. Preflush catheter, sidetport adapter, and catheter.
2. Attach saline filled syringe to luer to sidetport adapter and flush catheter. Clamp sidetport extension and remove syringe. If using double lumen catheter, attach needleless access port to remaining extant. Attach saline filled syringe to the needleless access port and completely fill the needleless lumen. Remove syringe from access port prior to clamping extension.

CAUTION:
- Never clamp catheter on the needleless access port.

The needleless access port should not be used with needles, blunt cannulas, or other non-luer connectors, or luer connectors with defects. If needleless access port is attempted, the needleless access port must be removed immediately. Do not exceed 100 overruns.

CAUTIONS:
- Patients requiring ventilator support are at increased risk of pneumothorax during subcutaneous catheter insertion, which may cause complications.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.

WARNINGs:
- Pretreatment of the patient’s skin, including the area of the proposed insertion site, is recommended. This can substantially decrease the risk of local complications.
- Local tissue factors will prevent proper device stabilization and/or access.

BE-USE may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages caused by reuse or removal (other than catheter or accessories).
- The catheter lumen is an open-ended design intended for use in the femoral or subclavian venous system.

There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows:

- Grade 1: Distortion present without tamponade
- Grade 2: Distortion present with tamponade
- Grade 3: Complete tamponade

RESISTANCE to infusion of fluids or blood.

When tunneling, the catheter must not be forced.

Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.

Do not insert guidewire beyond the bevel of the needle while preventing straightener from the needle hub to prevent guidewire damage or shearing.

If the guidewire must be withdrawn while the guidewire is inserted into the catheter and guidewire as a unit to help prevent the needle from damaging or shearing the guidewire.

Do not make a catheter with any instrument that might sever or damage the catheter.

Do not cut the catheter before removal from the patient.

Do not use scissors or any sharp-edged instruments as they could damage the catheter.

Hematoma
- Do not use sharp instruments near the insertion site.

Cardiac Arrhythmia
- Do not cut the catheter before removal from the patient.

Heparin
- Do not advance the guidewire or catheter forcibly from any component. The wire should be advanced slowly and if resistance is encountered. Stop advancing immediately.

Laceration of the Vessels or Viscus
- Do not use sharp instruments near the insertion site.

Thrombus
- Do not insert guidewire beyond the bevel of the needle while preventing straightener from the needle hub to prevent guidewire damage or shearing.

Hematoma
- Do not cut the catheter before removal from the patient.

Cardiac Arrhythmia
- Do not use sharp instruments near the insertion site.
1. Palpate the catheter exit tunnel to locate the cuff. After reaching the insertion site, the lumen must be cut from the tunneler. Cut catheter squares (±0.5 mm) and pull the tab. Do not follow the initial insertion of this catheter to confirm proper placement prior to use.

2. Administer sufficient local anesthetic to the exit site and cuff location to completely anesthetize the area.

3. Make a 2 cm incision over the cuff, parallel to the catheter.

4. Dissect down to the cuff using blunt and sharp dissection as indicated.

5. When visible, grasp cuff with clamp.

6. Clamp catheter between the cuff and the skin. Before infusion begins all connections must be clamped immediately and replaced.

7. Make any adjustments to catheter underuscology. The distal tip should be positioned in the superior vena cava above the right atrium.

8. Do not clump the lumen portion of the catheter. Clamp only the extenison(s). Do not use the serrated forceps, use only in-line clamps provided.

9. Remove the wire from the catheter. Remove by applying gentle pressure with one hand above the insertion site while grasping the wire with the other hand and pulling slowly back with a constant force.

10. Follow Directions for Modified Seldinger Insertion, from step #21 on.

11. Insert the introducer needle with attached syringe into the target vein. Aspirate to assure proper placement.

12. Remove the syringe and place thumb over the needle hub to prevent damage to surrounding vessels. If there is no blood return, verify placement prior to use.

13. Remove needle, leaving guidewire in the target vein. Thread the sheath/dilator over the proximal end of the guidewire into the vein. Advance the guidewire until it reaches the caval atrial junction. Once the guidewire is in place, measure the depth of the guidewire by removing the markings on the wire. Remove the guidewire leaving the sheath and dilator in the vein.

14. Do not bend the sheath/dilator during insertion as bending will cause the sheath to tear. Never leave a sheath/dilator close to the tip (approximately 1 cm) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, rewrap the sheath/dilator (3 or 4 centimeters approximately 5 cm) above the original grasp location and push down firmly on the sheath/dilator. Repeat the procedure until sheath/dilator is fully inserted.

15. Never leave sheath in place as an indwelling catheter. Damage to the vein may occur.

16. Leave no sheath in place as an indwelling catheter. Damage to the vein may occur.

17. Attach syringe(s) to extension(s) and open clamp(s). Blood should aspirate easily. If excessive resistance to blood aspiration is experienced, the catheter may need to be repositioned to obtain adequate flow.

18. Once adequate aspiration has been achieved and the catheter tip is correctly positioned in the target vessel(s), the catheter should be flushed with saline filled syringes. Clamp(s) should be open for this procedure.

19. Remove the syringes and close extension clamps. Avoid air embolism by keeping catheter tubing in a horizontal plane at all times when not in use and by aspirating now and then irrigating the catheter with saline prior to each flush. While patient is in flexion, flush in tubings connections, purge air from the catheter and all connecting tubing and caps.

20. Confirm and document proper tip placement with fluoroscopy prior to use. The distal tip should be positioned in the superior vena cava above the right atrium.

21. Insert distal tip of catheter into and through the sheath until catheter tip is correctly positioned in the target vein.

22. Remove the tear-away sheath by slowly pulling the sheath out of the vein simultaneously widening the sheath by grasping the tabs and pulling them apart (apart approximately 5-15 cm). The sheath should be held securely during this procedure. Do not withdraw guidewire against needle as this may cause severing of guidewire.

23. Caution: Do not clamp the lumen portion of the catheter. Clamp only the extension(s). Do not use the serrated forceps, use only in-line clamps provided.

24. Insert catheter and extend to and position on patient’s chart.

25. Follow Directions for Modified Seldinger Insertion, from step #21 on.

26. Cover the insertion and exit site with occlusive dressings.

27. Suture the catheter to the skin and left in place. Suture the catheter in the target vein. Advance the guidewire until it reaches the caval atrial junction. Once the guidewire is in place, measure the depth of the guidewire by reading the markings on the wire. Remove the guidewire leaving the sheath and dilator in the vein.

28. Remove the catheter stylet and adapter sheath. First loosen the locking collar of the adapter sheath. Applying gentle pressure with the other hand, slowly withdraw the stylet with a constant motion. Clamp catheter extension and remove adapter sheath. Insert needleless accessors, advancing the catheter extension and attach saline filled syringes to reposition the catheter. Aspirate saline. Aspirate saline and then irrigate with saline. Remove syringe prior to clamping extension.

29. Do not attempt to reinset stylet once it has been withdrawn.

30. Never leave stylet in place after catheter insertion; injury may occur. Remove both catheter stylet and adapter sheath after insertion.

31. Attach syringe(s) to extension(s) and open clamp(s). Blood should aspirate easily. If excessive resistance to blood aspiration is experienced, the catheter may need to be repositioned to obtain adequate flow.

32. Once adequate aspiration has been achieved and the catheter tip is correctly positioned in the target vessel(s), the catheter should be flushed with saline filled syringes. Clamp(s) should be open for this procedure.

33. Remove the syringes and close extension clamps. Avoid air embolism by keeping catheter tubing in a horizontal plane at all times when not in use and by aspirating now and then irrigating the catheter with saline prior to each flush. While patient is in flexion, flush in tubings connections, purge air from the catheter and all connecting tubing and caps.

34. Confirm and document proper tip placement with fluoroscopy prior to use. The distal tip should be positioned in the superior vena cava above the right atrium.

35. Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.

36. Note: If there is no blood return, verify catheter position prior to use.

37. Cause: fluid may be in the patient for arrhythmia throughout this period.

38. Caution: Due to risk of exposure to HIV or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

39. Sterile technique should always be strictly adhered to.

40. Clinically recognized infection should be treated promptly per institutional policy.

41. Do not clump the lumen portion of the catheter. Clamp only the extension(s). Do not use the serrated forceps, use only in-line clamps provided.

42. Do not remove the syringe and place thumb over the needle hub to prevent damage to surrounding vessels. If there is no blood return, verify placement prior to use.
9. Apply pressure to proximal tunnel approximately 10-15 minutes or until bleeding stops.
10. Suture incision and apply dressing in a manner to promote optimal healing.
11. Check catheter for integrity and measure catheter when removed. It must be equal to the length of catheter when it was inserted.

### 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.

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 in accordance with all relevant regulatory requirements.

Medcomp® is a registered trademark of Medical Components, Inc.

### Symbol Table

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>*</td>
<td>Keep Dry</td>
</tr>
<tr>
<td>*</td>
<td>Do Not Re-use</td>
</tr>
<tr>
<td>*</td>
<td>Non-pyrogenic</td>
</tr>
<tr>
<td>*</td>
<td>Keep Away from Sunlight</td>
</tr>
<tr>
<td>*</td>
<td>Sterilized Using Ethylene Oxide</td>
</tr>
<tr>
<td>*</td>
<td>Do Not Use if Package is Damaged</td>
</tr>
<tr>
<td>*</td>
<td>Use By Date</td>
</tr>
<tr>
<td>*</td>
<td>Do Not Resterilize</td>
</tr>
<tr>
<td>*</td>
<td>Batch/Lot Number</td>
</tr>
<tr>
<td>*</td>
<td>Catalogue Number</td>
</tr>
<tr>
<td>*</td>
<td>Caution, consult Accompanying Documents</td>
</tr>
<tr>
<td>*</td>
<td>Prescription Use Only</td>
</tr>
</tbody>
</table>

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

*** FDA guidance Use of Symbols in Labeling.

### Catalogue

<table>
<thead>
<tr>
<th>Catheter Size</th>
<th>Gravity Flow</th>
<th>Full Length Priming Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>4F X 60CM SINGLE LUMEN (Cuff @2cm, Cuff @5cm)</td>
<td>11.80 ml/min</td>
<td>0.90cc</td>
</tr>
<tr>
<td>4F X 60CM DUAL LUMEN (Cuff @2cm, Cuff @5cm)</td>
<td>1.40 ml/min</td>
<td>1.44cc</td>
</tr>
<tr>
<td>5F X 60CM DUAL LUMEN (Cuff @2cm, Cuff @5cm)</td>
<td>8.11 ml/min</td>
<td>0.63cc</td>
</tr>
</tbody>
</table>

### Vascular Line

- **Catheter Size**: 4F X 60CM SINGLE LUMEN (Cuff @2cm, Cuff @5cm)
- **Gravity Flow**: 11.80 ml/min
- **Full Length Priming Volume**: 0.90cc

- **Catheter Size**: 4F X 60CM DUAL LUMEN (Cuff @2cm, Cuff @5cm)
- **Gravity Flow**: 1.40 ml/min
- **Full Length Priming Volume**: 1.44cc

- **Catheter Size**: 5F X 60CM DUAL LUMEN (Cuff @2cm, Cuff @5cm)
- **Gravity Flow**: 8.11 ml/min
- **Full Length Priming Volume**: 0.63cc

**Medical Components, Inc.**
2409 Delp Drive
Harleysville, PA 19438 U.S.A.
Tel:215 256-4201
Fax:215 256-1787
www.medcompset.com