medCOMP®

Vascu-PICC® PERIPHERALLY INSERTED CENTRAL VEIN ACCESS CATHETER

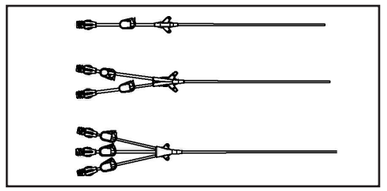
NURSING INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Vascu-PICC® Peripherally Inserted Central Vein Catheters are designed for Short or Long Term central venous catheterization (intravenous administration of fluids, medications, and/or when nutritional therapy is prescribed).
- This catheter may be inserted via the basilic, cephalic, or median cubital vein.

DESCRIPTION:

- This catheter is manufactured from soft radiopaque polyurethane material.



CONTRAINDICATIONS:

- This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.
- The presence of skin related problems around the insertion site (infection, phlebitis, scars, etc.)
- The presence of device related bacteremia or septicemia.
- History of mastectomy on insertion side.
- Previous history of venous/subclavian thrombosis or vascular surgical procedures at insertion site.
- Fever of unknown origin.

COMMON COMPLICATIONS:

- Aspectic Mechanical Phlebitis
- Catheter Occlusion
- Cellulitis
- Damge/Fracture of Catheter
- Drainage from Insertion Site
- Malposition/Migration
- Pinch-off Syndrome
- Sepsis
- Thrombosis

POTENTIAL COMPLICATIONS:

- Air Embolism
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Exit Site Infection
- Extravasation
- Hematoma
- Perforation of the Vessel
- Subcutaneous Hematoma
- Thromboembolism
- Vascular Thrombosis
- Before attempting the insertion, ensure that you are familiar with the common and potential complications and their emergency treatment should any of them occur.

WARNINGS:

- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter.
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- 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.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- This catheter is for Single Use Only.
- Do not resterilize the catheter or accessories by any method.
- Re-use may lead to infection or illness/ injury.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
  STERILIZED BY ETHYLENE OXIDE

STERILE	EO

- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any sign of product damage is visible.
- DO NOT use high-pressure injectors for contrast medium studies. Excessive pressures may damage catheter.

Note: Discard biohazard according to facility protocol.

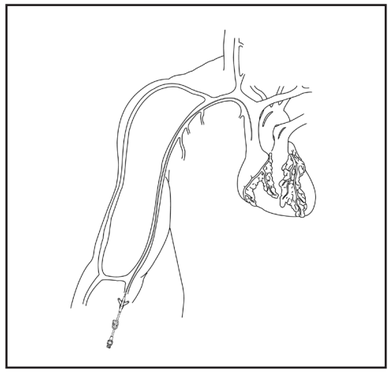
CATHETER PRECAUTIONS:

- Small syringes will generate excessive pressure and may damage the catheter. Ten (10)cc or larger syringes are recommended.
- Do not use sharp instruments near the extension lines or catheter lumen.
- Do not use scissors to remove dressing.
- Catheter will be damaged if clamps other than what is provided with this kit are used.
- Clamping of the tubing repeatedly in the same location will weaken tubing. Avoid clamping near the luer(s) and hub of the catheter.
- Examine catheter lumen and extension(s) before and after each infusion for damage.
- To prevent accidents, assure the security of all caps and connections prior to and between treatments.
- Use only Luer Lock (threaded) Connectors with this catheter.
- Repeated overtightening of luer lock connections, syringes, and caps will reduce connector life and could lead to potential connector failure.
- Confirm catheter tip position by x-ray prior to use. Monitor tip placement routinely per institution policy.
- The catheter allows for blood draws, intravenous therapy, and infusion of medications into the central venous system. Refer to standards of practice and institutional policies for compatible infusion agents for central venous access.
- Follow all contraindications, warnings, precautions, and instructions for all infusates as specified by their manufacture.

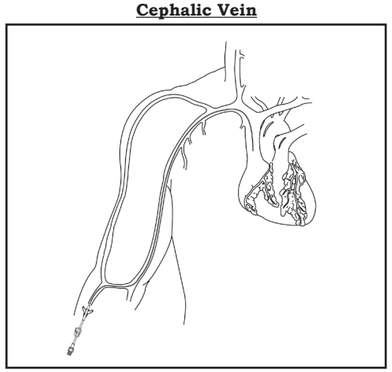
INSERTION SITES:

- The basilic, median cubital, or cephalic vein may be catheterized. The basilic vein is the preferred site.

Basilic Vein



Cephalic Vein



DIRECTIONS FOR INSERTION

- Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
- The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.
- Use standard hospital protocols when applicable.

PRIOR TO PLACEMENT:

Identify Insertion Site and Vein, taking into account the following variables:

- patient diagnosis
- age and size of patient
- unusual anatomical variables
- type and purpose of IV therapy
- anticipated dwell time of catheter

1. Apply tourniquet to arm above anticipated insertion site.
2. Select vein based on assessment.
3. Release tourniquet.

CATHETER MEASUREMENT:

4. Position the patient's arm at a 90° angle.

- SCV placement - Using measuring tape, measure from the anticipated insertion site over to the sternal notch, and then down to the third intercostal space.

Note: External measurement does not exactly duplicate the internal anatomy.

PREPARE CATHETER:

5. Preflush catheter.

Note: For insertion with a stiffening stylet, see Alternate Insertion Technique using Stiffening Stylet and Sideport Adaptor Section.

- Attach needleless access port(s) to female luer(s) of catheter.
- Attach a saline filled syringe to the needleless access port and completely flush catheter. For multi-lumen catheters, flush all lumens. Remove syringe(s) prior to clamping extension(s).

Caution: The needleless access port should not be used with needles, blunt cannula, or other non-luer connectors, or luer connectors with visible defects. If needle access is attempted, the needleless access port must be replaced immediately. Do not exceed 100 actuations.

6. The catheter may be trimmed to a shorter length, if necessary.
   - Using sterile scissors, cut the catheter squarely at a 90° angle at the desired length.

INSERTION:

- Strict aseptic technique and full barrier protection must be used during catheter insertion, maintenance, and removal procedures. Provide a sterile operative field. Use sterile drapes, instruments, and accessories. Wear gloves and mask.

7. Set up sterile field. Prep and drape insertion site following institution policy.
8. Apply tourniquet to arm above anticipated insertion site to distend the vein.

   Note: For insertion with OTN or safety introducer needle/catheter see Alternate Insertion Technique using OTN or Safety Introducer Needle/Catheter Section.

9. Insert the introducer needle with attached syringe into the target vein. Aspirate to ensure proper placement. Release tourniquet.
10. Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Draw the flexible end of marked .018" guidewire back into the advancer so that only the end of the guidewire is visible. Insert the advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.

    Caution: The length of the wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

11. Remove needle, leaving guidewire in the target vein. Thread sheath/dilator over the proximal end of the guidewire into target vein. Remove the guidewire leaving the sheath and dilator in the vein.

    Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/ dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/ dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted.

    Caution: Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.

12. Remove dilator from sheath.
13. Insert distal tip of catheter into and through the sheath until catheter tip is correctly positioned in the target vein.
14. Remove the tearaway sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

    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.

15. Make any adjustments to catheter under fluoroscopy. The distal tip should be positioned at the level of the caval atrial junction.

    Caution: Do not clamp the lumen portion of the catheter. Clamp only the extension(s). Do not use serrated forceps, use only the in-line clamp(s) provided.
16. 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.
17. Once adequate aspiration has been achieved, lumen(s) should be irrigated with saline filled syringe(s). Clamp(s) should be open for this procedure.

    Caution: Small syringes will generate excessive pressure and may damage the catheter. Ten (10)cc or larger syringes are recommended.

18. Remove the syringe(s) and close extension clamp(s). Avoid air embolism by keeping catheter tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.
19. Confirm and document proper tip placement with fluoroscopy prior to use. The distal tip should be positioned at the level of the caval atrial junction.

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

    Note: If there is no blood return, verify catheter position before use.

CATHETER SECUREMENT AND DRESSING:

- The insertion site and external portion of the catheter should always be covered with a protective dressing.

20. Dress and secure the catheter following institutional policy. Provided in the tray for these purposes are the following: steri-strips, adhesive dressing, and a StatLock® Catheter Securement Device.

CATHETER MAINTENANCE

- **Dressing Changes** - A dressing should cover the insertion site at all times. The dressing should be changed per institutional policy or any time it becomes soiled, wet, or non-occlusive.

Note: During all dressing changes, the external length of the catheter should be assessed to determine if catheter migration has occurred. Periodically confirm catheter placement and tip location.

- **Flushing and Locking** - Flush and Lock- Follow institutional policy for flushing and locking catheter.
- The catheter should be flushed with normal saline prior to drug administration to remove locking solution.
- After drug administration, each lumen should be flushed again with normal saline and then locked to maintain patency.

Injection Caps - Injection cap(s) or needleless access port(s) should be changed per institutional policy. If using the supplied needleless access ports(s), do not exceed 100 actuations.

CATHETER PERFORMANCE

- Occluded/Partially Occluded Catheter - If resistance is encountered to aspirating or flushing, the lumen may be partially or completely occluded.

Warning: Do not flush against resistance.

- If the lumen will neither aspirate nor flush, and it has been determined that the catheter is occluded with blood, follow institutional declotting procedure.

CATHETER REMOVAL

1. Remove old dressing and inspect insertion site for redness, tenderness, and drainage.
2. Grasp catheter near insertion site and using a slow steady motion, remove catheter from vein.
3. If resistance is felt - STOP. Retape the catheter and apply a warm compress to the extremity for 20-30 minutes.
4. Resume removal procedure. If catheter remains “stuck”, notify the physician for further intervention.
5. Apply pressure, if necessary, until bleeding stops and dress site following institutional policy.

Note: Inspect catheter and measure length. It must be equal to baseline measurement taken when the catheter was inserted.

ALTERNATE INSERTION TECHNIQUE USING STIFFENING STYLET AND SIDEPORT ADAPTOR

PREPARE CATHETER:

1. Preflush catheter, sideport adaptor, and needleless access ports.

- Attach saline filled syringe to luer of sideport adaptor and flush adaptor and catheter. Clamp sideport extension and remove syringe. For multi-lumen catheters, attach needleless access port to remaining extension(s) and completely flush all lumens. Remove syringe from access port prior to clamping extension. Flush remaining needleless access port and set aside.

Caution: Never close clamp on catheter stylet; stylet and catheter damage may result.

Caution: The needleless access port should not be used with needles, blunt cannula, or other non-luer connectors, or luer connectors with visible defects. If needle access is attempted, the needleless access port must be replaced immediately. Do not exceed 100 actuations.

INSERTION:

2. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. Use sterile drapes, instruments, and accessories. Perform surgical scrub. Wear gown, cap, gloves, and mask.
3. Apply tourniquet to arm above anticipated insertion site to distend the vein.
4. Insert the introducer needle with attached syringe into the target vein. Aspirate to ensure proper placement. Release tourniquet.
5. Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Draw the flexible end of marked .018" guidewire back into advancer so that only the end of the guidewire is visible. Insert the advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.

   Caution: The length of the wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.
6. Remove needle, leaving guidewire in the target vein. Thread sheath/dilator over the proximal end of the guidewire into target vein. Remove the guidewire leaving the sheath and dilator in the vein.

   Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, re-grasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted.

   Caution: Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.
7. Loosen locking collar of sideport and withdraw stylet back beyond the point where the catheter is to be trimmed by at least ¼ inch (1cm). Cut catheter to length determined by marked guidewire.

   Caution: Never attempt to cut stylet.

   Caution: Always withdraw stylet back beyond the tip of the catheter prior to insertion.
8. Once proper catheter length and stylet position has been achieved, tighten locking collar to keep stylet in place.
9. Remove dilator from sheath.
10. Insert distal tip of catheter into and through the sheath until catheter tip is correctly positioned in the target vein.
11. Remove the tearaway sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

    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.
12. Make any adjustments to catheter under fluoroscopy. The distal tip should be positioned at the level of the caval atrial junction.

    Caution: Do not clamp the lumen portion of the catheter. Clamp only the extension(s). Do not use the serrated forceps; use only the in-line clamp(s) provided.
13. Loosen locking collar of sideport. Remove the stylet by applying gentle pressure with one hand above the insertion site while grasping the stylet with the other hand and slowly pulling back with a constant motion. Remove sideport adaptor and replace with needleless access port. Attach saline filled syringe to needleless access port, aspirate lumen and then irrigate with saline. Remove syringe prior to clamping extension.

    Caution: If difficulty and/or bunching of the catheter lumen are experienced while removing the stylet, additional flushing of the catheter may be helpful. The catheter may need to be repositioned to allow for removal of the stylet.

    Caution: Do not attempt to reinsert stylet once it has been withdrawn.

    Caution: Never leave stylet in place after catheter insertion; injury may occur. Remove both stylet and sideport adaptor after insertion.
14. 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.
15. Once adequate aspiration has been achieved, lumen(s) should be irrigated with saline filled syringe(s). Clamp(s) should be open for this procedure.

    Caution: Small syringes will generate excessive pressure and may damage the catheter. Ten (10)cc or larger syringes are recommended.
16. Close the extension clamp(s), and remove the syringe(s). Avoid air embolism by keeping catheter tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.
17. Confirm and document proper tip placement with fluoroscopy prior to use. The distal tip should be positioned at the level of the caval atrial junction.

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

    Note: If there is no blood return, verify catheter position before use.
18. Continue following directions at "Catheter Securement and Dressing" Section.

ALTERNATE INSERTION TECHNIQUE USING OTN OR SAFETY INTRODUCER/CATHETER

1. Maintaining sterility, access target vein with introducer needle/catheter.

   - If using the safety introducer needle/catheter: Remove the protective cover in a straight outward motion.
   - Perform the venipuncture, and confirm entry into vein by observing for a flashback of blood.
   - Holding the needle stationary, advance the introducer sheath into the vein by pushing forward.

   Caution: Never reinsert the needle into the introducer as this could shear or sever the introducer.

   - Release the tourniquet. Support the introducer to avoid displacement. Apply digital pressure on the vessel, above the introducer tip, to minimize blood flow.
   - Withdraw the needle from the introducer sheath. Retract the needle by depressing the white button (if applicable). Dispose of any unshielded needles immediately.

   Caution: Do not withdraw needle from introducer without depressing the white button. (If needle retraction does not occur, depress the button again.)
2. Insert distal tip of the catheter into and through the introducer sheath until the catheter tip is correctly positioned according to the length determined by the measurement taken.
3. Stabilize the catheter position by applying pressure to the vein proximal to the insertion site.
4. Remove the tearaway sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).
5. Attach syringe(s) to extension(s) and open clamp(s). Blood should aspirate. If excessive resistance is experienced, the catheter may need to be repositioned.
6. Following aspiration, each lumen of the catheter should be filled with 10cc of normal saline to ensure patency.

   Caution: Small syringes will generate excessive pressure and may damage the catheter. Ten (10)cc or larger syringes are recommended.
7. Following normal saline flush, lock each catheter lumen as per institutional policy.
8. Confirm and document proper tip placement by x-ray before using the catheter.

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 without notice.

SYMBOL TABLE

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

*** This symbol is in accordance with ISO 15223**

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

Note: Temperature symbols : "This symbol only applies to kits with drugs".

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