medCOMP®

PERIPHERALLY INSERTED CENTRAL VEIN ACCESS CATHETER

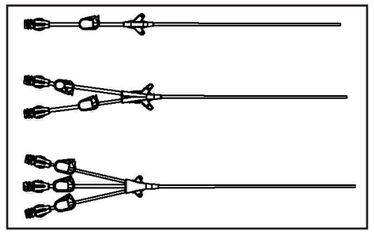
INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Peripherally Inserted Central Vein Access Catheters are designed for Long- or Short-Term peripheral access to the central venous system for intravenous therapy and blood sampling, and allows for central venous pressure monitoring.
- 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.
- The patient's body size is insufficient to accommodate the size of the implanted device.
- The patient is known or is suspected to be allergic to materials contained in the device.
- Past irradiation of prospective insertion site.
- Local tissue factors will prevent proper device stabilization and/or access.

COMMON COMPLICATIONS:

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

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.
- This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion, or cardiac tamponade.

Note: Discard biohazard according to facility protocol.

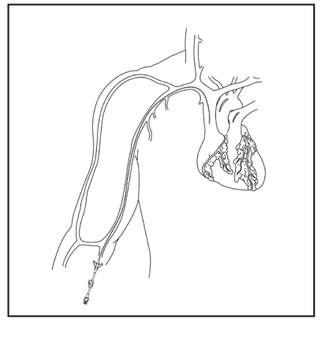
CATHETER PRECAUTIONS:

- Small syringes will generate excessive pressure and may damage the catheter. The use of 10cc 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.

PICC / Basilic Vein Insertion



DIRECTIONS FOR SELDINGER 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.

PREPARE CATHETER:

4. 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.

INSERTION:

5. 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.
6. Apply tourniquet to arm above anticipated insertion site to distend the vein.
7. Insert the introducer needle with attached syringe into the target vein. Aspirate to insure proper placement. Release tourniquet.
8. 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.

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

9a. For PICC catheter insertion, 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.

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.

10. For PICC catheter insertion, measure and cut catheter to length determined by marked guidewire.
11. Remove dilator from sheath.
12. Insert distal tip of catheter into and through the sheath until catheter tip is correctly positioned in the target vein.
13. 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.

14. Make any adjustments to catheter under fluoroscopy.

14a. For PICC catheter insertion, 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.

15. 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.
16. 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. The use of 10cc or larger syringes are recommended.

17. 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.
18. Confirm and document proper tip placement with fluoroscopy prior to use.

18a. For PICC catheter insertion, 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 WOUND DRESSING:

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

19. Cover the exit site with an occlusive dressing according to the facility policy.
20. Record catheter length, catheter lot number, and tip position on patient's chart.

INFUSION

- Before infusion begins, all connections should be examined carefully.
- Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.
- If a leak is found, the catheter should be clamped immediately and replaced.

Caution: Only clamp catheter with in-line clamps provided.

- Necessary remedial action must be taken prior to the continuation of the treatment.

Note: Excessive blood loss may lead to patient shock.

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 the dressing 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 catheter according to your institutional policy.
- 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 port(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.

Infection:

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.

- Sterile technique should always be strictly adhered to.
- Clinically recognized infection should be treated promptly per institutional policy.

CATHETER REMOVAL

Warning: Only a clinician familiar with the appropriate techniques should attempt the following procedures.

Caution: Always review facility protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

1. Wash hands, gather equipment.
2. Remove old dressing and inspect insertion site for redness, tenderness, and drainage.
3. Grasp catheter near insertion site and using a slow steady motion, remove catheter from vein.
4. If resistance is felt - STOP. Retape the catheter and apply a warm compress to the extremity for 20-30 minutes.
5. Resume removal procedure. If catheter remains “stuck” follow institutional policy for further intervention.
6. 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. If using multi-lumen catheter, attach needleless access port to remaining extension. Attach saline filled syringe to the needleless access port and completely flush catheter lumen. Remove syringe from needleless 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 insure 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.

6a. For PICC catheter insertion, 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.

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.

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.

12a. For PICC catheter insertion, 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. Continue following directions at step #14 of "Insertion" Section.

VASCU PICC				
Catheter Size	**Gravity Flow**		**Full Length Priming Volume**	
3F X 60CM SINGLE LUMEN VASCU PICC	3.25 ml/min		0.42cc	
4F X 60CM SINGLE LUMEN VASCU PICC	11.80 ml/min		0.60cc	
4F X 60CM DUAL LUMEN VASCU PICC	3.0 ml/min		1.44cc	
5F X 60CM SINGLE LUMEN VASCU PICC	38.30 ml/min		0.92cc	
5F X 60CM DUAL LUMEN VASCU PICC	8.81 ml/min		0.63cc	
6F X 60CM DUAL LUMEN VASCU PICC	18.52 ml/min		0.74cc	
	18Ga	19Ga	18Ga	19GA
5F X 60CM TRIPLE LUMEN VASCU PICC	13.73 ml/min	3.33 ml/min	0.64cc	0.33cc
Taperless				
Catheter Size	**Gravity Flow**		**Full Length Priming Volume**	
3F X 60CM SINGLE LUMEN TAPERLESS	2.4 cc/min		0.42cc	
4F X 60CM SINGLE LUMEN TAPERLESS	11.7 cc/min		0.61cc	
5F X 60CM SINGLE LUMEN TAPERLESS	44 cc/min		0.92cc	
4F X 60CM DUAL LUMEN TAPERLESS	2.75 cc/min		0.43cc	
5F X 60CM DUAL LUMEN TAPERLESS	7.5 cc/min		0.57cc	
	19Ga	18Ga	19Ga	18Ga
5F X 60CM TRIPLE LUMEN TAPERLESS	3 cc/min	12 cc/min	0.33cc	0.60cc

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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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 NON 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 15223-1.**

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

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

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