medCOMP®

1.9F & 2.6F PERIPHERALLY INSERTED CENTRAL VEIN ACCESS CATHETER

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The 1.9F and 2.6F Peripherally Inserted Central Vein Access Catheters are indicated for short or long term access to the central venous system via peripheral insertion in neonates, infants, and children. It may be used for administration of fluids, medication, and nutritional therapy.
- Recommended insertion sites are the median cubital vein of the elbow or the basilic vein.
- The long saphenous veins of the ankle may also be used.
- This catheter is not suitable for insertion through non-superficial veins.

DESCRIPTION:

- This catheter is manufactured from soft radiopaque polyurethane material that provides increased patient comfort and excellent biocompatibility.

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.
- 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:

- Aseptic Mechanical Phlebitis
- Catheter Occlusion
- Cellulitis
- Damage/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 above complications and their emergency treatment should any of them occur.

WARNINGS:

- Do not use infusion equipment which can exceed the working pressure of 1.0bar max/750mmHg (14.5 psi).
- Only use infusion equipment complying with standards, which do not exceed a shut-off pressure of 1.0bar.
- Bolus injections should be slow and must not exceed the maximum bolus pressure of 1.2bar/900mmHg (17.4 psi).
- 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 catheter if unusual resistance is encountered.
- 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 re-sterilize 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 reuse or re-sterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE

- 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.

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 over tightening 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.

INSERTION SITES:

- Recommended insertion sites are the median cubital vein at the elbow or the basilic vein.
- The long saphenous veins of the ankle may also be used.
- This catheter is not suitable for insertion through non-superficial veins.

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.

TECHNIQUE USING TWISTED WIRE STYLET AND SIDEPORT ADAPTER

PREPARE CATHETER

1. Preflush catheter, sideport adapter, and needleless access port, if included.

- Attach saline filled syringe to luer of sideport adapter and flush adapter and catheter. Assure the handle of the twisted wire stylet is firmly attached to the adapter.

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.

2. Determine the length of the catheter needed to reach the final position, using a measuring tape.

Note: Length of the catheter should be recorded prominently in the patient's chart.

3. Withdraw stylet back beyond the point where the catheter is to be trimmed by at least ¼ inch (1cm). Cut catheter.

Caution: Never attempt to cut stylet.

Caution: Always withdraw stylet back beyond catheter tip prior to insertion.

INSERTION

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

- Apply tourniquet to arm.
- 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. Dispose of any unshielded needles immediately.

2. Insert distal tip of the catheter into and through the introducer sheath until the catheter tip is correctly positioned.
3. Stabilize the catheter position by applying pressure to the vein proximal to the inserion site.
4. Remove the tear-away 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 few centimeters at a time.

5. 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.

6. 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 adapter and replace with needleless access port or injection cap. Attach saline filled syringe to catheter, aspirate lumen and then irrigate with saline. If using needleless access port, 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 adapter after insertion.

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

7. Confirm and document proper tip placement by x-ray before using the catheter.

CATHETER SECUREMENT AND WOUND DRESSING:

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

8. Cover the exit site with an occlusive dressing according to the facility policy.
9. 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** - Follow institutional policy for flushing and locking catheter.
- A running infusion should be maintained at all times to ensure patency. A lock may be substituted for an infusion. The extension tube must not be clamped and then released after locking. This can cause blood to be aspirated back into the catheter lumen and result in a blocked catheter.

Injection Caps - The injection cap or needleless access port should be changed per institutional policy. If using the supplied needleless access port, 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.

WARRANTY

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1.9F & 2.6F PICC's				
Catheter Size	**Gravity Flow**		**Full Length Priming Volume**	
1.9F X 20CM SINGLE LUMEN VASCU-PICC®	1.58 ml/min		0.17cc	
1.9F X 50CM SINGLE LUMEN VASCU-PICC®	0.73 ml/min		0.21cc	
	21Ga	23Ga	21Ga	23Ga
2.6F X 20CM DUAL LUMEN VASCU-PICC®	2.33 ml/min	0.90 ml/min	0.17cc	0.17cc
2.6F X 50CM DUAL LUMEN VASCU-PICC®	1.03 ml/min	0.40 ml/min	0.22cc	0.18cc

medCOMP®
1499 Delp Drive
Harleysville, PA 19438
Tel:215-256-4201
Fax:215-256-1787
www.medcompnet.com

CE 0434

EU REPRESENTATIVE
MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany

PN 40258 Rev. 10/15J