STERILE EO

INSTRUCTIONS FOR USE

COMMON COMPLICATIONS:
- Aseptic Mechanical Phlebitis
- Catheter Occlusion
- Cellulitis
- Damage/Fracture of Catheter
- Drainage from Insertion Site
- Malposition/Migration
- Pinch-Off Syndrome
- Thrombosis

POTENTIAL COMPLICATIONS:
- Air Embolism
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Exit Site Infection
- Extravasation
- Hematoma
- Perforation of the Vessel
- Subcutaneous Hematoma
- Thromboembolism
- Venous Thrombosis

Prior to attempting the insertion, ensure that you are familiar with the potential complications and their emergency treatment should any of them occur.

WARNINGS:
- Do not use infusion equipment which cannot exceed the working pressure of 1.0 max/570mmHg (14.5 psi).
- Only use infusion equipment with standards, which do not exceed a shut-off pressure of 1.0bar.
- Bolus injections should be slow and must be administered in the direction of a physician.
- Attach saline filled syringe to luer lock stylet prior to insertion.
- Do not use sharp instruments near the extension lines or catheter.
- Do not wash or clean the inner surface of catheter.

Caution:
- Do not attempt to reinsert stylet once it has been withdrawn.
- Do not clamp the lumen portion of the catheter.
- Only clamp catheter with in-line clamp(s) and catheter lumen are experienced while removing the stylet, additional flushing of the catheter lumen is recommended.

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.
- Do not re-sterilize the catheter or accessories if any signs of product damage are visible.
- Do not use high-pressure injectors for contrast medium studies. Excessive pressure may damage the patient.
- This is not a right atrium catheter. Atrial 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.

Potential Precautions:

1. Insert distal tip of the catheter into and through the introducer sheath until the catheter tip is correctly positioned.
2. Stabilize the catheter port by applying pressure to the vein proximal to the insertion site.
3. Remove the tear-away sheath by slowly pulling it out of the vessel while simultaneously applying the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

In conclusion, 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 Serious and Wound Dressing

- Gluten/Casein
- Non-sterile
- Anoxic

- CATHETER MAINTENANCE

- The catheter should be readjusted and repositioned at least once a day.

- Holding the needle stationary, advance the introducer sheath into the vein by pushing forward.

- The skin is not perforated by the needle, but rather the needle is inserted into the skin and then released after locking. This can cause the needle to be aspirated back into the catheter lumen and result in a blocked catheter.

Catheter Care and Accessory Insertion

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

- The use of 10cc or larger syringes are recommended.

- The presence of skin issues, such as wound, ulcers, etc., may also be used.

- Refer to the institution’s catheter access policy or any time the dressing becomes soiled, wet, or non-occlusive.

- The injection cap or syringe adapter must not be clamped immediately and then released after locking. This can cause the needle to be aspirated back into the catheter lumen and result in a blocked catheter.
WARRANTY

Medcomp® warrants that this product was manufactured according to applicable standards and specifications. Patient condition, clinical treatment, and product maintenance may effect 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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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.

1.9F & 2.6F PICC's

<table>
<thead>
<tr>
<th>Catheter Size</th>
<th>Gravity Flow 1.9F X 20CM SINGLE LUMEN VASCU-PICC®</th>
<th>Full Length Priming Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.9F X 20CM SINGLE LUMEN VASCU-PICC®</td>
<td>1.58 ml/min</td>
<td>0.15cc</td>
</tr>
<tr>
<td>1.9F X 50CM SINGLE LUMEN VASCU-PICC®</td>
<td>0.73 ml/min</td>
<td>0.21cc</td>
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<tr>
<td>2.6F X 20CM DUAL LUMEN VASCU-PICC®</td>
<td>2.33 ml/min</td>
<td>0.17cc</td>
</tr>
<tr>
<td>2.6F X 50CM DUAL LUMEN VASCU-PICC®</td>
<td>1.03 ml/min</td>
<td>0.17cc</td>
</tr>
</tbody>
</table>

EU REPRESENTATIVE

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