**INSTRUCTIONS FOR USE**

**DESCRIPTION:** A family of peripherally inserted central catheters made from specially formulated medical grade material.

**INDICATIONS FOR USE:**
- The Pro-PICC® CT catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media, and for temporary placement of the central venous pressure monitor. For blood sampling, infusion, or therapies, use a 4F or larger catheter. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

**IMPORTANT INFORMATION PERTAINING TO POWER INJECTION:**
- Contrast media should be warmed to temperature prior to power injection. **Warning:** Failure to warm contrast to body temperature prior to power injection may result in catheter failure.
- Do not exceed the maximum flow rate print on the catheter. **Warning:** Exceeding the maximum indicated flow rate may result in catheter failure and/or catheter tip displacement.
- Do not advance the guidewire or catheter if unusual resistance is encountered. **Warning:** 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 replaced together.
- Federal Law (USA) restricts this device to sale by or on the order of a physician. **Warning:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

**CONTRAINDICATIONS:**
- The presence of device related infection, bacteremia, or sepsis is known or suspected.
- 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.
- There has been past irradiation of the respective insertion site.
- There have been previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- There are local tissue factors that may prevent device placement and/or access.

**POSSIBLE COMPLICATIONS:**
- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmias
- Cardiac Tamponade
- Dilation erosion through the skin
- Catheter embolism
- Catheter occlusion
- Catheter related sepsis
- Encephalitis
- Hypotension
- Intracranial hemorrhage
- Pulmonary embolus
- Fibron Sheath formation
- Hemotoma
- Intolerance reaction to implanted device
- Laceration of the vessels or veins to the heart or great vessels
- Perforation of vessels or veins
- Tachyarrhythmia
- Phlebitis
- Spontaneous catheter tip malposition or retraction
- Venous thrombosis
- Venous thrombosis in a compartmentalized venous system
- Vessel erosion
- Risks normally associated with local and general anesthesia, surgery, and post-operative recovery.

**WARNING:** Before the attempt, ensure that you are familiar with all possible complications and their emergency treatment should any of them occur.

**WARNING:** The basic, moistened, cuffed, or cephalic vein catheter. The basic vein above antecubital fossa is the preferred site.

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

**Caution:** The needless access port should not be used with needles, blunt cannulas, or other non-sterile connectors. Do not use connectors with visible defects. If needle access is attempted, the needless access port may be placed immediately. Do not exceed 100 actuations.

**INSERTION**

1. Strict aseptic technique must be used during insertion, maintenance, and catheter removal. **Warning:** A sterile operative field. Use sterile drapes, instruments, and accessories. Perform sterile operative field. Use sterile drapes, instruments, and accessories. Perform

**INSERTION SITES:**
- The basic, moistened, cuffed, cephalic vein catheter.

**DIRECTIONS FOR MODIFIED 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.

**STERILE EO**
- Sterilized by ethylene oxide

**Caution:** Never attempt to cut stylet.

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

**Caution:** Once proper catheter length and position has been achieved, tighten locking collar to keep stylet in place.

**Caution:** Never dilute from shunt.

**Caution:** Insert distal tip of catheter into and through the shunt until catheter tip is correctly positioned in the target vein.

**Caution:** Do not pull apart the portion of the shunt that remains in the vessel. To avoid vessel damage, pull back the shaft as far as possible and tear the shunt only few centimeters at a time.

**Caution:** Do not make any adjustments to catheter under fluoroscopy. The distal tip should be positioned at the level of the carotid artery.

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

**Caution:** Do not clamp the lumen of the catheter. Clamping the catheter with any object may cause vessel damage, pull back the catheter over the other hand and slowly pulling back with a constant motion. Remove sideport adapter and replace with needless access port. Attach saline filled syringe to needless 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 styel, additional flushing of the catheter may be helpful. The catheter may need to be repositioned to allow for removal of the styel.

**Caution:** Do not attempt to reintroduce styel into the lumen of the catheter.

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

**Caution:** Loosen locking collar of sideport and withdraw stylet to the point where the catheter is to be trimmed by at least 1/2 inch (1cm). Cut catheter to length as placed immediately. Do not exceed 100 actuations.

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

**Caution:** Once proper catheter length and position has been achieved, tighten locking collar to keep stylet in place.

**Caution:** Never dilute from shunt.

**Caution:** Insert distal tip of catheter into and through the shunt until catheter tip is correctly positioned in the target vein.

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**Caution:** Do not attempt to reintroduce styel into the lumen of the catheter.

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

**Caution:** Loosen locking collar of sideport and withdraw stylet to the point where the catheter is to be trimmed by at least 1/2 inch (1cm). Cut catheter to length as placed immediately. Do not exceed 100 actuations.
Gravity Flow
Full Length Priming Volume
19 Ga
Purple Luer
0.57cc
28.40 ml/min
15.43 ml/min

Caution:
- Ensure adequate suction has been achieved, lumen(s) should be irrigated with saline filled syringe(s). Clamp(s) should be open for this procedure.
- Small syringes will generate excessive pressure and may damage the catheter. Ten [10] or larger syringes are recommended.

16. Remove the syringe(s) and close extension clamps. 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.

18. Cover the exit site with an occlusive dressing.

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

CATHETER REMOVAL AND WOUND DRESSING:
- The insertion site and external portion of the catheter should always be covered with a protective dressing.

18. Cover the exit site with an occlusive dressing according to the facility policy.

19. Record catheter length, catheter lot number, and tip position on patient’s chart.

DIRECTIONS FOR SEDLINGER INSERTION

1. Follow directions for Modified Seldinger Insertion, up to step #5.

2. Remove needle, leaving guidewire in the targeted 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.

3. Cut catheter to length determined by marked guidewire.

4. Insert proximal end of wire into distal tip of catheter lumen. Feed catheter lumen into the vessel following the guidewire. Advance catheter lumen along the guidewire until the distal tip is correctly positioned in the target vein. The distal tip should be positioned at the level of the caval atrial junction.

Caution: A skin knick may be required to feed the catheter smoothly into the vessel.

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

6. Remove the wire from the catheter. Remove by applying gentle pressure with one hand above the insertion site while grasping the 130cm wire with the other hand and pulling slowly back with a constant motion.

7. Follow Directions for Modified Seldinger Insertion, from step #14 on.

POWER INJECTION PROCEDURE

1. Remove the injection/needleless cap from the Pro-PICC® CT catheter.

2. Using a 10cc or larger syringe(s), aspirate catheter lumen(s) to assure patency and remove locking solution. Discard syringe(s).

3. Attach a 10cc or larger syringe filled with sterile normal saline and vigorously flush the catheter with the full 10cc of sterile normal saline. Warning: Failure to verify catheter patency prior to power injection studies may result in catheter failure.

4. Detach syringe.

5. Attach the power injection device to the Pro-PICC® CT catheter per manufacturer’s recommendations.

Warning: Always use connector tubing between power injector syringe and catheter. Do not attempt to connect power injector syringe directly to the catheter. Damage may result.

6. Complete power injection study taking care not to exceed the flow rate limits.

Warning: Exceeding the maximum indicated flow rate may result in catheter failure and/or catheter tip displacement.

7. Disconnect the power injection device.

8. Flush the Pro-PICC® CT catheter with 10cc of sterile normal saline, using a 10cc or larger syringe. For multi-lumen catheters, flush all lumens after power injection.

9. Replace the injection/needleless cap on the Pro-PICC® CT catheter.

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 measured to determine if catheter migration has occurred. Periodically confirm catheter placement and tip location by imaging method.

- 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, 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 follow procedure.

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/securement device 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. Caution: Do not apply direct pressure to the insertion site or along the course of the vein.

Warning: Forceful removal can result in vein or catheter rupture.

4. Apply pressure on site a few minutes to promote hemostasis as needed. Apply a sterile occlusive dressing per institutional policy.

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

Trouble shooting:
- Resistance is felt during removal – STOP!!! NEVER pull against resistance
  a. Release any pressure along catheter path
  b. Venous spasm may cause resistance, waiting a few minutes may allow the patient and the vein to relax
  c. Warm packs placed proximal to the insertion site may help relax the vein walls and resolve the venous spasm
  d. Reposition the limb and try again after 20 minutes

Continued resistance: STOP, clean, secure the catheter, re-dress, and notify the physician.

PN 40271
Rev. 10/15K

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.

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