**SYNERGY™ CT PICC PERIPHERALLY INSERTED CENTRAL CATHETER INSTRUCTIONS FOR USE:**

**DESCRIPTION:**
- A family of peripherally inserted central catheters made from specially formulated biocompatible medical grade materials. Catheters are packaged in a tray with accessories necessary for a percutaneous microintroducer introduction (Modified Seldinger or Seldinger technique).

**INDICATIONS FOR USE:**
The SYNERGY™ CT PICC is indicated for short or long term (less than or greater than 30 days) peripheral access for the infusion of various systems for infusion, intravenous therapy, blood sampling and power injection of contrast media. All SYNERGY™ CT PICC products have a maximum recommended infusion rating of 5ml/uc.

**IMPORTANT INFORMATION PERTAINING TO POWER INJECTION:**
- Contrast media should be warmed to body temperature prior to power injection. Warning: Failure to warm contrast to body temperature prior to power injection may result in catheter failure.
- Vigorously flush the SYNERGY™ CT PICC catheter using a 30 cc or larger syringe and sterile normal saline prior to and immediately following the completion of power injection studies. This will ensure the patency of the catheter and prevent damage to the catheter. Resistance to flushing may require removal of the complete catheter occlusion. **Do not** proceed with power injection study until occlusion has been cleared. **Warning:** Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- **Do not** exceed the maximum flow rate printed on the catheter. **Warning:** Power injection and machine pressure limiting feature may not prevent overpressurization of an occluded catheter. Warning: Exceeding the maximum indicated flow rate may result in catheter failure and/or catheter tip displacement.
- **Warning:** The SYNERGY™ CT PICC catheter indication of power injection of contrast media implies the catheter’s ability to withstand the procedure, but does not imply the appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of the patient as it pertains to a power injection procedure.

**CONTRAINdications:**
- The presence of disease related infection, bacteremia, or septicaemia 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 prospective 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 proper device stabilization and/or access.

**POSSIBLE COMPLICATIONS:**
- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter Erosion through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Myncardial Erosion
- Perforation of Vessels or Viscus
- Phlebitis
- Spontaneous Catheter Tip Malposition or Retraction
- Thromboembolism
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery
- **Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment should they occur at any time.**

**WARNINGS:**
- In the 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 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 reuse. Reuse of catheter may result in cross-contamination, plastic degradation, catheter rupture, etc.
- **Do not re-thread the catheter or accessories by any method.**
- The manufacturer shall not be liable for any injury or damage by reuse or re-stereilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in unopened, undamaged package.

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**DIRECTIONS FOR MODIFIED Seldinger Technique:**
- 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 do 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:**
- Preflush catheter, sideport adapter, and needleless access port(s).
- Attach saline filled syringe to luer of sideport adapter and flush adapter and catheter. Clamp sideport extension and flush catheter lumen. Clamp needleless access port and completely flush catheter lumen. Remove syringe from needleless access port prior to clamping extension.

**INSERTION SITE:**
- The basics, medium antecubital, or cephalic vein may be punctured. The basilic vein above antecubital fossa is the preferred site.

**Warning:**
- The SYNERGY™ CT PICC features a lever-tapered catheter design. Placement of a larger catheter at or below the antecubital fossa may result in an increased incidence of phlebitis. Placement of the SYNERGY™ CT PICC catheter above the antecubital fossa is recommended.

**Basilic Vein:**
- 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.

**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 of the 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 lumen 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 uses.
- 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.
- The maximum pressure or pound per square inch [psi] of the power injector utilized should not exceed 300 psi.

**INSERTION:**
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- The SYNERGY™ CT PICC catheters feature a lever-tapered catheter design. Placement of a larger catheter at or below the antecubital fossa may result in an increased incidence of phlebitis. Placement of the SYNERGY™ CT PICC catheter above the antecubital fossa is recommended.

**Caution:**
- Never close clamp on catheter styel; styel and catheter damage may result.
- The needleless access port should not be used with needles, blunt cannulae, 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. Sterile 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.
- Apply tourniquet to arm above anticipated insertion site to distend the vein.
- 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 guidewire with forward motion into and past the needle hub into the target vein.
- 7. Open needle to introducer catheter and flush with sterile saline.
- Enter syringe from needleless access port prior to clamping extension.

**Caution:**
- Never attempt to cut or evacuate guidewire or catheter. The length of the wire inserted is determined by the size of catheter used. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a pulse oximeter 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.

**Note:** For alternate insertion method, see Directions for Seldinger Insertion Section.

**6.** Remove needle, leaving guidewire in the target vein. Thread sheath/dilator over the proximal end of the guidewire into and past the needle hub into the target 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. 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 3 cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrab the sheath/dilator a few centimeters (approximately 5 cm) 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 styel back beyond the point where the catheter is to be trimmed by at least 1 inch (3 cm). Cut catheter to length determined by marked guidewire.

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

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

**8.** Once proper catheter length and styel position has been achieved, tighten locking collar to keep styel 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 proximal vein.

**11.** Remove the tear-away sheath by slowly pulling it out of the vessel while simultaneously splitting it apart by grabbing 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. 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.

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) or larger syringes are recommended.

16. 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.

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 prior to use.

CATHETER SECUREMENT 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.

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

Caution: Do not attempt to reinset 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.

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