ARROW

Peripherally Inserted Trimmable Central Catheter (PICC) Product – Seldinger Access

Safety and Efficacy Considerations:

The product is designed for single use only. Do not resterilize or reuse. Do not alter the catheter or any other kit/set component during insertion, use, or removal except as instructed.

Central venous catheterization must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.

Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Failure to follow these instructions can result in severe patient injury or death. Read instructions (refer to Fig. 1).

Fig. 1

Cardiac Tamponade: It has been documented by many authors that placement of indwelling catheters in the right atrium is a dangerous practice[1,2,4,5,7,15,16] that may lead to cardiac perforation and tamponade[1,2,4,5,15,16]. Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it[19]. Practitioners placing central venous catheters must be aware of this potentially fatal complication before advancing the catheter too far relative to patient size.

No particular route or catheter type is exempt from this potentially fatal complication[16]. The actual position of the tip of the indwelling catheter should be confirmed by x-ray after insertion[1,2,5,15,16,20]. Central venous catheters should be placed in the superior vena cava[1,2,4,5,7,15,21] above its junction with the right atrium and parallel to the vessel wall[11,21] and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.

Central venous catheters should not be placed in the right atrium unless specifically required for special relatively short term procedures, such as aspiration of air emboli during neurosurgery. Such procedures are nevertheless risk prone and should be closely monitored and controlled.

Indications for Use:

A peripherally inserted central venous catheter permits venous access to the central circulation through a peripheral vein. It offers an alternative method of intravenous therapy for select adult and pediatric patients.

Contraindications:

None known.

Central Venous Catheterization Warnings and Precautions:*

1. **Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Central vein catheters should be positioned so that the distal tip of the catheter is in the superior vena cava (SVC) above the junction of the SVC and the right atrium and lies parallel to the vessel wall.**
2. **Warning: Practitioners must be aware of complications associated with central vein catheters including cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma formation, hemorrhage, and dysrhythmias.**
3. **Warning: Do not apply excessive force in placing or removing catheter. If placement or withdrawal cannot be easily accomplished, an x-ray should be obtained and further consultation requested.**
4. **Warning: The practitioner must be aware of potential air embolism problems associated with leaving open needles or catheters in central venous puncture sites or as a consequence of inadvertent disconnects. To lessen the risk of air embolism, only securely tightened Luer-Lock connections should be used with this device. Follow hospital protocol to guard against air embolism for all catheter maintenance.**
5. **Warning: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients.**
6. **Warning: The practitioner must be aware of clinical conditions that may limit the use of PIC catheters such as: dermatitis, cellulitis and burns at or about the insertion site, previous ipsilateral venous thrombosis, radiation therapy, contractures, mastectomy, and potential use for AV fistula.**
7. **Precaution: Indwelling catheters should be routinely inspected for desired flow rate, security of dressing, correct catheter position and for secure Luer-Lock connection. Use centimeter markings to identify if the catheter position has changed.**
8. **Precaution: Only x-ray examination of the catheter placement can ensure that the catheter tip has not entered the heart or no longer lies parallel to the vessel wall. If catheter position has changed, immediately perform x-ray examination to confirm catheter tip position.**
9. **Precaution: For blood sampling from a two-lumen catheter, temporarily shut off remaining port through which solutions are being infused.**
10. **Precaution: Alcohol and acetone can weaken the structure of polyurethane material. Therefore, care should be taken when instilling drugs containing alcohol or when using high concentration of alcohol or acetone when performing routine catheter care and maintenance. Alcohol should not be utilized to declot polyurethane catheters. These agents may also weaken the adhesive bond between the StatLock® Anchoring Device and skin.**
11. **Precaution: The indications for use in children are the same as adults; however, insertion techniques are often modified according to the age and size of a child. If the practitioner is inexperienced in utilizing this product in a child, appropriate consultation should be sought.**

12. **Precaution: This catheter should not be used as a midline catheter (i.e. distal end located in a vessel proximal to the SVC). Catheter tip must be placed in the central circulation.**
13. **Precaution: To prevent pressure induced damage to this catheter, do not expose it to pressures above 50 psi. Common sources of potentially high pressure include: syringes smaller than 10 cc used to irrigate or declot an occluded catheter (a fluid filled 1 cc syringe can exceed 300 psi[6]), certain radiographic procedures, and infusion pumps with occlusion pressure limits above 50 psi.**
14. **Precaution: The StatLock® Anchoring Device should be routinely inspected for adherence to the skin and connection to the catheter. At the same time, the catheter position should be checked using the centimeter marks on the catheter body.**

Carefully read all warnings and precautions throughout procedure instructions.

Catheter Insertion Procedure: Use sterile technique.

1. Explain procedure to patient. Have informed consent signed as required. Measure and record upper arm circumference.
2. Measure the patient to determine the length of catheter required to place the distal tip in the SVC.

   Adult: Extend arm approximately 45 to 90 degrees from the trunk. Measure the distance from the insertion site along the presumed anatomical course of the vessel to be catheterized. The catheter tip should lie in the distal one-third of the SVC above the right atrium and parallel to the SVC wall. If a StatLock® Anchoring Device will be used, add 1 to 1-1/2 inches (2.5 to 3.8 cm) to the catheter measurement.

   Pediatric: Measure the distance from the insertion site along the presumed anatomical course of the vessel to be catheterized. The catheter tip should lie in the distal one-third of the SVC above the right atrium and parallel to the SVC wall. When the insertion site is the saphenous vein, the catheter tip should lie in the distal one-third of the inferior vena cava (IVC) below the right atrium and parallel to the IVC wall. If a StatLock® Anchoring Device will be used, add 1 to 1-1/2 inches (2.5 to 3.8 cm) to the catheter measurement.
3. Position the patient for insertion.

   Adult: Position the patient as appropriate for the insertion site. Extend arm laterally 45 to 90 degrees from the trunk.

   Pediatric: Position the patient as appropriate for the insertion site.
4. Before beginning the procedure, perform a surgical scrub. Dress in protective clothing (mask, goggles, sterile gown, sterile gloves, and hair cover).
5. Prep and drape peripheral puncture site as required.
6. Perform skin wheal with a local anesthetic as needed. In kits where provided, a SharpsAway® disposal cup is used for the disposal of needles. Push needles into foam after use. Discard entire cup at completion of procedure. **Precaution: Do not reuse needles after they have been placed into the disposal cup. Particulate matter may adhere to needle tip.**
7. Prepare all equipment. To prepare for catheter trimming, retract the placement wire approximately 1 to 1-1/2 inches (2.5 to 3.8 cm) further than the point where the catheter is to be cut. **Warning: Do not cut the placement wire.** Kink the proximal end of the placement wire at the connector with side port to prevent the placement wire from extending beyond the distal tip of the catheter during insertion. Peel back the contamination guard exposing the catheter portion to be trimmed. Cut the catheter straight across (90 degrees to the catheter cross-section) to maintain a blunt tip.

8. Fill syringe with flush solution. For two-lumen catheter, flush proximal lumen with sterile saline solution. Clamp or attach injection cap to proximal lumen pigtail. Attach syringe to sidearm connected to proximal end of catheter. Flush the catheter. Do not remove syringe. For single lumen catheter attach syringe to sidearm and flush catheter. Do not remove syringe.

9. Locate vein using fluoroscopy, if available. Insert introducer needle into vein and aspirate. Disconnect the syringe and check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

10. Insert floppy tip of spring-wire guide through the introducer needle into vein. Advance the spring-wire guide in the routine fashion to the desired depth. **Warning: Do not cut spring-wire guide to alter length. Do not withdraw spring-wire guide against needle bevel to avoid possible severing or damaging of spring-wire guide.**

11. Hold spring-wire guide in place and remove introducer needle. **Precaution: Maintain firm grip on spring-wire guide at all times.**

12. Thread tapered tip of dilator/peel-away sheath assembly over spring-wire guide. Grasping near skin advance assembly with slight twisting motion to a depth sufficient to enter vessel. Dilator may be partially withdrawn to facilitate advancement of sheath through tortuous vessel. **Precaution: Do not withdraw dilator until the sheath is well within the vessel to prevent damage to sheath tip. Precaution: Sufficient guide wire length must remain exposed at hub end of sheath to maintain a firm grip on guide wire.**

13. Advance peel-away sheath over dilator into vessel, again grasping near skin and using slight twisting motion.

14. To check sheath placement, hold sheath in place and withdraw spring-wire guide and dilator sufficiently to allow venous blood flow.

15. Holding sheath in place, remove guide wire and dilator as a unit. **Warning: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation. Warning: Although the incidence of spring-wire guide failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the wire.**

16. With sterile-gloved hands, using fluoroscopy if available, advance the PIC catheter through the peel-away sheath. If resistance is met while advancing the catheter, retract the catheter and/or gently flush the catheter while advancing.

17. Stop advancing the catheter 5 inches (13 cm) before reaching the indwelling tip position.

18. Withdraw the peel-away sheath until it is free from the venipuncture site.

19. Grasp the tabs of the peel-away sheath and pull the tabs apart, away from the PIC catheter, until the sheath splits down its entire length.

20. Advance the PIC catheter to its final indwelling position.

21. Check catheter placement by attaching a syringe to pigtail(s) and aspirating until venous blood is observed as permitted by the size of catheter lumen(s).

22. Flush lumen(s) with sufficient volume of flush solution to completely clear the aspirated blood from the lumen(s). **Warning: This product contains slide clamps which may be inadvertently removed and aspirated by children or confused adults. In such situations, practitioners should remove the clamps when not in use.** Slide clamps are provided on pigtails to occlude flow through each lumen during line and injection cap changes. **Precaution: To avoid damage to pigtail(s) from excessive pres-**

sures, each clamp must be opened prior to flushing through that lumen.

23. Remove placement wire.

24. Remove Luer-Lock sidearm assembly and connect pigtail(s) to appropriate Luer-Lock line(s) as required. Alternately, unused port(s) may be "locked" through injection cap(s) using standard hospital protocol.

25. Cleanse the insertion site per hospital protocol.

26. Secure the catheter. Use catheter clamp, fastener, and where provided, a StatLock® Anchoring Device and/or Steri-Strips®† as needed.

Catheter Clamp, Fastener and StatLock® Anchoring Device Instructions:

Initial Application:

- Cleanse and reprep the anticipated dressing site per agency protocol. Allow to dry thoroughly. The anchor pad will be placed so center of pad is within 1 to 1-1/2 inches (2.5 to 3.8 cm) of catheter insertion site.

- The catheter can be secured to the StatLock® by one of two methods depending on amount of catheter remaining outside of the body. **Precaution: Minimize catheter manipulation throughout this procedure to maintain proper catheter tip position.**

Primary Suture Hub Securement:

From earlier measurements, after the catheter is properly positioned the primary suture hub is within 1 to 1-1/2 inches (2.5 to 3.8 cm) from insertion site. Place suture hub wings over the StatLock® posts and press down (refer to Fig. 2). Snap the rigid suture hub fastener over the posts to secure the suture hub to the StatLock® (refer to Fig. 3).

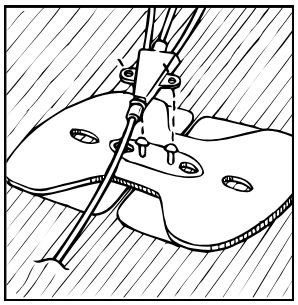

Fig. 2

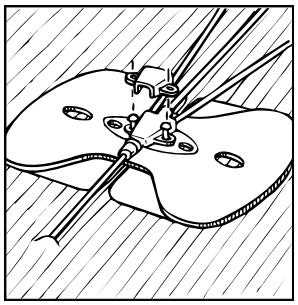

Fig. 3

Flexible Catheter Clamp and Rectangular, Rigid Fastener Securement:

If the primary suture hub cannot be used on the StatLock®, the catheter clamp and fastener (clamp assembly) should be used to secure the catheter. The clamp assembly should be applied to the area of the catheter that lies over the StatLock® posts.

To apply the flexible catheter clamp, spread wings of clamp and position on catheter as required to ensure proper placement over the StatLock® posts (refer to Fig. 4).

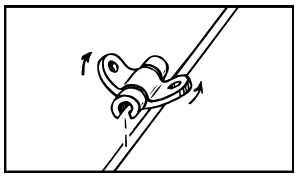

Fig. 4

Snap rectangular, rigid fastener onto flexible catheter clamp (refer to Fig. 5).

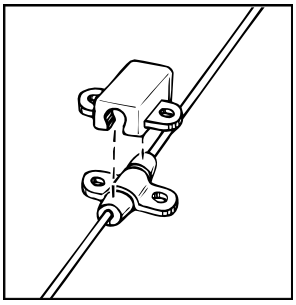

Fig. 5

As a unit, snap catheter clamp assembly onto the StatLock® posts (refer to Fig. 6).

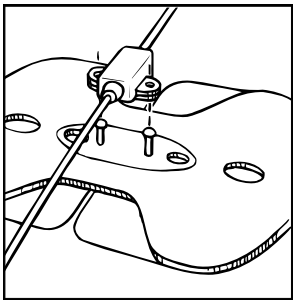

Fig. 6

- Remove paper backing from one half of the StatLock® anchoring pad and press onto dry, prepared skin. Repeat process for other half of StatLock®.
- Complete sterile insertion site dressing according to established agency protocol.
- Document StatLock®/dressing application on the patient's chart.
- Replace the CVC/PICC StatLock®/dressing per agency protocol‡.

Alternate Technique

- Apply Steri-Strips® and sterile dressing, if provided, according to agency protocol.

StatLock® Anchoring Device Removal and Replacement:

- Follow instructions provided with the StatLock® product.

27. Apply PICC label to dressing.
28. Obtain chest x-ray immediately to verify tip placement. **Precaution: X-ray exam must show the catheter located in the right side of the mediastinum in the SVC above its junction with the right atrium and parallel to the vessel wall[11,21] and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.** If catheter tip is malpositioned, reposition and re-verify. **Precaution: If difficulty is encountered in visualizing the catheter tip with x-ray, a small amount of radiopaque dye may be injected to assist in locating the tip[13].**
29. Complete the adhesive chart label and affix to patient chart. Document assessments and insertion procedure.
30. Check catheter tip position routinely.

Heparinization:

1. A variety of "locking" solution concentrations may be utilized to maintain patency of the catheter. The amount of heparin used, if any, and the frequency of flushing depends on physician preference, agency protocol, and patient condition[3,8].
2. The volume of heparin solution should be equal to, or slightly more than, the volume of the lumen that is being locked.

Catheter Removal Procedure:

1. Remove dressing. **Precaution: To avoid cutting the catheter, do not use scissors to remove the dressing.**
2. To remove the catheter from the anchoring device, using a hemostat, twist off the tip of the StatLock® posts. Lift the catheter from anchoring device.
3. Remove the catheter by slowly pulling it parallel to the skin. **Precaution: To prevent**

catheter breakage, do not exert excessive force if difficulty is encountered upon removal. If resistance is met, apply heat for 20-30 minutes to the area[14,23]. Gently begin pulling the catheter parallel to the skin. If further difficulty is encountered, obtain an x-ray and consult physician.

4. Upon removal of the catheter, measure and inspect to ensure that the entire catheter length has been removed.
5. Dress the insertion site.
6. Document catheter removal procedure on patient's chart.

References:

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Arrow International, Inc. recommends that the user be acquainted with the reference literature.

*If you have any questions or would like additional reference information, please contact Arrow International, Inc.

† Steri-Strip® is a registered trademark of 3M Health Care.

‡ StatLock® Anchoring Device should be replaced at least every 7 days to ensure maximum adherence.

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