

Dear Chief Executives,

A Safety Alert (SA:002/08) on Peripherally Inserted Central Catheter (PICC) Line - Arrow 3 FG Brand (PC-01351-TW, All lot numbers) was sent out on 13 October 2008 advising AHSs to inform hospitals to suspend use of the device until further notice.

The Therapeutic Goods Administration (TGA) has undertaken an investigation with the manufacturer of this product and have advised there is no fault with the product, however it was identified that the product instructions needed to be improved.

The amended Product Instructions and "Tips for Practice" poster are attached. The product distributor has also mailed a copy of these documents directly to each hospital.

You are now advised that it is safe to use this product, provided the attached product instructions are followed.

Clinicians need to take particular note of the Catheter Trimming instructions outlined on the "Tips for Practice" poster.

Thank you

Kelvin Genn
Director, Quality and Safety Branch

Made Obsolete October 2021
Supersedes SA002/08 1st entry. TGA Recall completed.

First, Do No Harm

Tips for Practice:

Arrow® PICCs with Integral Placement Wire/Stylet

CAUTIONS:

- Trimming & shortening of catheters should be avoided whenever possible
- If trimming of the catheter is necessary, the catheters manufacturer's instructions should be carefully followed, taking precautions not to cut the wire.

1. PICCs with Integral Placement Wire / Stylet

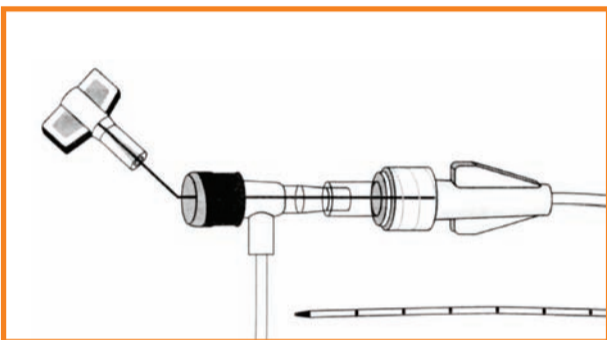


Fig.1

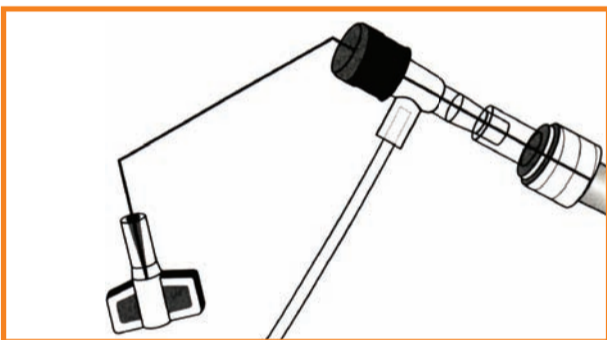


Fig.2

Catheter Trimming:

1. Retract Placement Wire a minimum of 4 cm behind where catheter is to be cut. Placement Wire should be withdrawn through septum.
2. Kink Proximal end of Placement Wire/ Stylet at connector with side-port. (Fig. 2)
3. Using trimming device, cut catheter straight across to maintain a blunt tip.

Warning: Do not cut placement wire when trimming catheter to minimise the risk of foreign embolism.

Caution: Check that there is no wire in cut catheter section, after trimming catheter. If there is evidence that placement wire / stylet has been cut or damaged, catheter should not be used.

Note: There should be very limited resistance when cutting catheter with supplied trimmer. Any greater resistance is likely to be caused by the placement wire – which has not been sufficiently retracted. If so, do not use catheter.

2. Removing Placement Wire / Stylet:

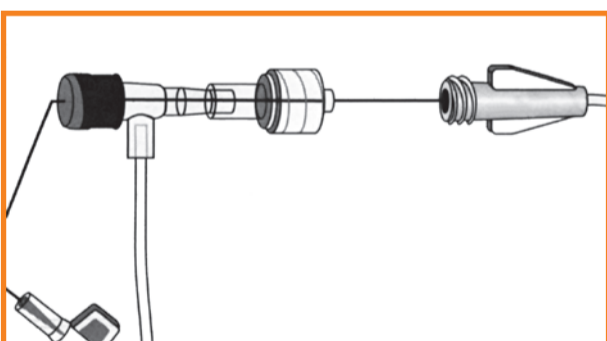


Fig.3

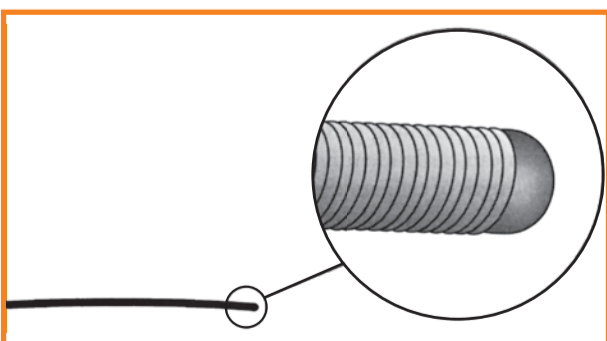


Fig.4

1. Remove placement wire and luer lock sidearm assembly as a unit. Failure to do so may result in wire breakage. (Fig. 3)
2. Examine tip of placement wire after removal to ensure wire has not been altered. (Fig. 4)
3. If there is any indication placement wire is damaged, catheter and placement wire should be removed together.

Caution: To minimise the risk of placement wire kinking, do not clamp extension line(s) when placement wire is in catheter.

Note: If placement wire remains in for X-Ray, instruct patient to keep arm at their side and not to bend or move arm. Moving and bending arm could potentially cause the wire to kink internally and make placement wire / stylet more difficult to remove.

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Peripherally Inserted Trimmable Central Venous Catheter Product with Placement Wire

Safety and Efficacy Considerations:

Do not use if package has been previously opened or damaged. **Warning: Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.**

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.

Procedure 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 (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^{1,2,4,5,7,17,18} that may lead to cardiac perforation and tamponade.^{1,2,4,5,17,18} Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it.²¹ 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 of catheter type is exempt from this potentially fatal complication.¹⁸ The actual position of the tip of the indwelling catheter should be confirmed by x-ray after insertion.^{1,2,5,17,18,22}

Central venous catheters should be placed in the superior vena cava^{1,2,4,5,7,17,23} above its junction with the right atrium and parallel to the vessel wall^{10,23} 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.

Warnings and Precautions:*

- 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.
- 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, hemorrhage and dysrhythmias.
- 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.
- Warning:** The practitioner must be aware of potential air embolism associated with leaving open needles or catheters in central venous puncture sites or as a consequence of inadvertent disconnections. To lessen the risk of air embolism, only securely tightened Luer-Lock connections should be used with this device. Follow hospital/agency protocol to guard against air embolism for all catheter maintenance.
- 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.
- Warning:** To minimize the risk of damage to the catheter if the placement wire is removed prior to catheter insertion, do not attempt to reinsert the placement wire.
- 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.
- 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.
- 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.
- Precaution:** Alcohol and acetone can weaken the structure of polyurethane materials. Check ingredients of prep sprays and swabs for acetone and alcohol content.
Acetone: Do not use acetone on catheter surface. Acetone may be applied to skin but must be allowed to dry completely prior to applying dressing.
Alcohol: Do not use alcohol to soak catheter surface or to restore catheter patency. Care should be taken when instilling drugs containing high concentration of alcohol. Always allow alcohol to dry completely prior to applying dressing.
These agents may also weaken the adhesive bond between the StatLock® Anchoring Device and skin.
- Precaution:** Some disinfectants used at the catheter insertion site contain solvents, which can attack the catheter material. Assure insertion site is dry before dressing.
- 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.

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13. **Precaution:** When catheter is placed with distal end located in a vessel proximal to the SVC (midclavicular or midline), practitioners must be aware of the risk of chemically induced thrombophlebitis.¹¹ When administering > 10% glucose solution/total parenteral nutrition, any medication with an osmolarity above 600 mOsm/liter, medications with an osmolarity between 400 and 600 mOsm/liter for more than 4 weeks, or any medication known to be irritating to vessels proximal to the vena cava, the catheter tip must be located in the central circulation.¹⁹

14. **Precaution:** To minimize the risk of pressure induced damage to catheter, do not expose to pressures above 50 psi. Common sources of potentially high pressure include: syringes smaller than 10 cc used to irrigate or de clot an occluded catheter (a fluid filled 1 cc syringe can exceed 300 psi⁶), certain radiographic procedures, and infusion pumps with occlusion pressure limits above 50 psi.

15. **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.

A Suggested Procedure:

Use sterile technique.

1. Verify physician order. Physician order must include post-placement chest x-ray.
2. Explain procedure to patient. Have informed consent signed as required.
3. Measure and record upper arm circumference.
4. Utilizing tourniquet as necessary, identify appropriate vein for insertion.

Adult: PIC catheters are typically inserted into basilic, median cubital or cephalic veins (refer to Fig. 2).

Pediatric: PIC catheters are typically inserted into basilic, cephalic, scalp veins or saphenous veins.⁹ The most suitable vein depends on the size and maturity of child.

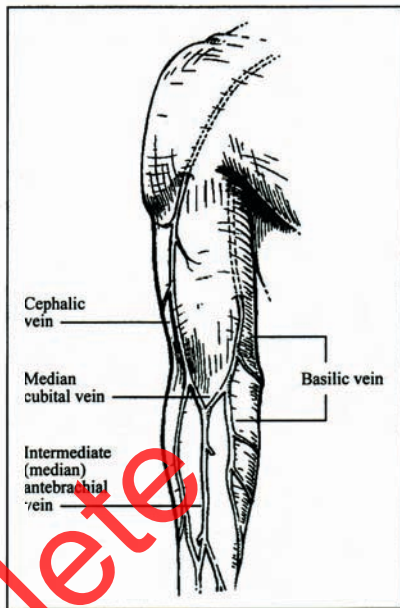


Fig. 2

5. Release tourniquet leaving in place beneath the arm.
6. Measure patient to determine length of catheter required to place the distal tip in SVC.

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

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

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7. Position patient for insertion.

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

Pediatric: Position patient as appropriate for insertion site.

8. Perform surgical scrub. Dress in protective clothing (mask, goggles, sterile gown, sterile gloves, hair cover).
9. Prepare venipuncture site utilizing appropriate antiseptics.
10. 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 re-use needles after they have been placed into disposal cup. Particulate matter may adhere to needle tip.**
11. Prepare all equipment (see Fig. 3).

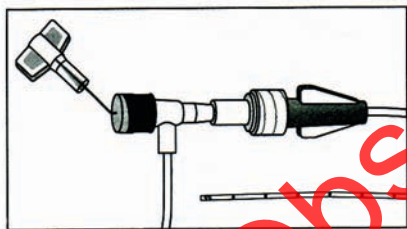


Fig. 3

12. Remove catheter tip protector. Retract placement wire 1-1/2 inches minimum (4 cm) behind where catheter is to be cut. The placement wire is to be withdrawn through septum (see Fig. 4). Kink proximal end of placement wire at connector with sideport (see Fig. 5). This minimizes the risk of placement wire extending beyond distal tip of catheter during insertion. (Do not attempt to advance placement wire through septum).

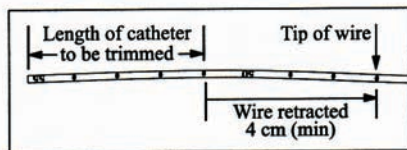


Fig. 4

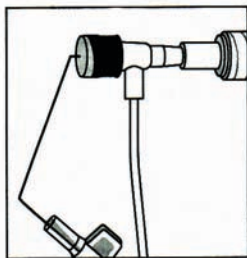


Fig. 5

13. Peel back contamination guard exposing catheter portion to be trimmed. Using the trimming device, cut catheter straight across (90° to catheter cross-section) to maintain a blunt tip. **Warning: Do not cut placement wire.**

Note: There should be very limited resistance when cutting catheter with supplied cutter. Any greater resistance is likely to be caused by placement wire – which has not been sufficiently retracted.

14. **Precaution: After trimming catheter, check that there is no wire in cut catheter segment. If there is any evidence that placement wire has been cut or damaged, catheter should not be used.**
15. Attach syringe to sidearm and flush distal lumen with sterile saline solution. Leave syringe in place. Place catheter on sterile field.
16. Reapply tourniquet and replace sterile gloves.
17. Drape site for maximal barrier protection.
18. Using peel-away sheath over needle, perform venipuncture. When flashback is established, advance needle and peel-away sheath as a unit until sheath is adequately within vessel.
19. Release tourniquet.

20. Hold sheath steady and remove needle.

Warning: To minimize the risk of possible sheath embolism, do not reinsert needle into sheath. Check for pulsatile flow as an indicator of inadvertent arterial puncture. Precaution: The color of blood is not always a reliable indicator of venous access.¹³

21. Grasp distal end of contamination guard, pull back to expose catheter tip, and advance catheter slowly through peel-away sheath. The

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contamination guard will peel off catheter as they are advanced simultaneously.

22. When catheter tip reaches the level of axillary line, position patient to decrease possibility of catheter tip malposition into internal jugular vein.

Adult: Ask patient to turn their head toward catheterized arm and drop their chin to shoulder.²⁰

Pediatric: Instruct patient as appropriate.

If resistance is met while advancing catheter, retract and/or gently flush while advancing.

23. Stop advancing catheter 2 inches (5 cm) before reaching pre-established insertion length.
24. Withdraw peel-away sheath until free from venipuncture site.
25. Grasp tabs of peel-away sheath and pull apart, away from catheter, until sheath splits down entire length.
26. Advance catheter to final indwelling position.
27. **Note:** If placement wire remains in for x-ray modification, instruct patient to keep arm at their side and not to move or bend arm. Moving and bending arm could potentially cause the wire to kink internally and make placement wire removal more difficult.
28. When catheter is in place, do not attempt to remove placement wire through septum of T-port assembly. Damage to wire may result. Remove Luer-Lock and arm assembly and placement wire as one unit (see Fig. 6). **Note:** Examine tip of placement wire after removal to assure that wire has not been altered (see Fig. 7). If there is any indication that placement wire is damaged, catheter and placement wire should be removed together.

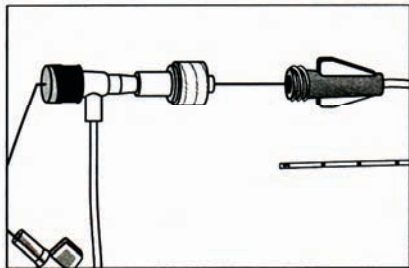


Fig. 6

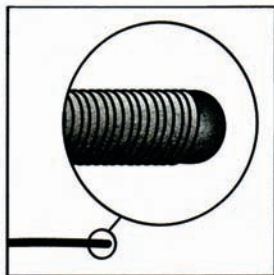


Fig. 7

29. Check catheter placement with syringe by aspirating through distal lumen until free flow of venous blood is observed. **Precaution: The color of blood is not always a reliable indicator of venous access.**¹³
30. Flush lumen with sufficient volume of solution to completely clear blood.
31. Connect pigtail to appropriate Luer-Lock line as required. Alternately, port may be "locked" through injection cap using standard hospital/agency protocol. **Warning: This product contains slide clamp which may be inadvertently removed and potentially aspirated, by children or confused adults. In such situations, practitioner should remove clamp when not in use. Slide clamp is provided on pigtail to occlude flow through lumen during line and injection cap changes. Precaution: To minimize the risk of damage to pigtail from excessive pressure, clamp must be opened prior to infusing through lumen.**

Arrow UserGard® Needle-Free Injection Hub (where provided) Instructions for Use:

- Attach Luer end of UserGard® hub to syringe.
- Prepare injection cap with alcohol or povidone iodine per standard hospital/agency protocol.
- Remove red dust cap from hub.

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- Press UserGard® hub onto injection cap and twist to lock on pin (refer to Fig. 8).

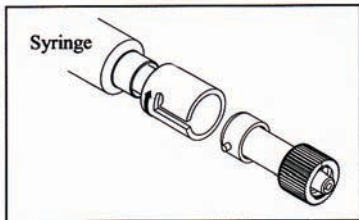


Fig. 8

- Inject or withdraw fluid as required.
- Disengage UserGard® hub from injection cap and discard. **Warning: To minimize the risk of possible air embolism, do not leave UserGard® hub connected to injection cap. Single use only.**

32. Cleanse insertion site per hospital/agency protocol.

33. Secure catheter. Where provided, a catheter clamp, fastener, StatLock® Anchoring Device or Steri-Strips®† may be used.

StatLock® Anchoring Device Instructions

Initial Application:

- Cleanse and prep anticipated dressing site per hospital/agency protocol. Skin prep should be applied to coat skin and maximize StatLock® adherence. 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 StatLock® by using the primary suture hub. **Precaution: Minimize catheter manipulation throughout this procedure to maintain proper catheter tip position. Provide strain relief placement of catheter under dressing.**

Primary Suture Hub Securement:

From earlier measurements, after catheter is properly positioned the primary suture hub is within 1 to 1-1/2 inches (2.5 to 3.8 cm) from the insertion site. Place suture hub wings over StatLock® posts and press down (refer to Fig. 9).

Snap StatLock® retainer wings to closed position to secure suture hub (refer to Fig. 10).

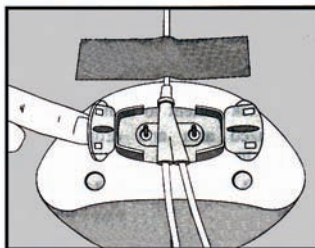


Fig. 9

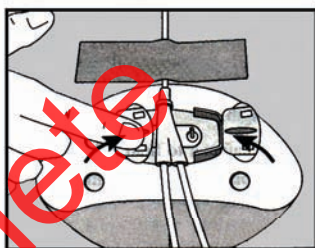


Fig. 10

- Remove paper backing from one half of StatLock® anchoring pad and press onto dry, prepared skin. Repeat process for other half of StatLock®.
- Complete sterile insertion site dressing according to established hospital/agency protocol.
- Document StatLock®/dressing application on patient's chart.
- Replace StatLock®/dressing per hospital/agency protocol. StatLock® anchoring device should be replaced at least every 7 days to ensure maximum adherence.

Alternate Technique:

- Apply Steri-Strips®† and sterile dressing or apply suture and sterile dressing according to hospital/agency protocol. **Precaution: Do not suture directly to outside diameter of catheter to minimize the risk of cutting or camaging the catheter or impeding catheter flow.**

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StatLock® Anchoring Device Removal :

- Remove dressing and sutures (if applicable).
 - Open StatLock® retainer wings and remove catheter from StatLock® posts.
 - Apply alcohol swab to StatLock® adhesive and gently lift pad off of skin.
 - Document StatLock® removal procedure on patient's chart.
34. Apply PICC label to dressing.
35. 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^{10,23} 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.¹⁴**
36. Complete the adhesive chart label and affix to patient chart. Document assessments and insertion procedure.
37. Check catheter tip position routinely using centimeter marks on catheter.

Heparinization:

1. A variety of "locking" solution concentrations may be utilized to maintain patency of catheter. The amount of heparin used, if any, and frequency of flushing depends on physician preference, hospital/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 priming volume is printed on product packaging.

Catheter Removal Procedure:

1. Remove dressing and sutures (if applicable). **Precaution: To minimize the risk of cutting catheter, do not use scissors to remove dressing.**
2. Open StatLock® retainer wings and remove catheter from StatLock® posts (if applicable).

3. Remove catheter by slowly pulling it parallel to skin. **Precaution: To minimize the risk of catheter breakage, do not exert excessive force if difficulty is encountered upon removal.** If resistance is met, apply heat for 20-30 minutes to area.^{16,25} Gently begin pulling catheter parallel to skin. If further difficulty is encountered, obtain an x-ray and consult physician.
4. Upon removal of catheter, measure and inspect to ensure that entire catheter length has been removed.
5. Apply alcohol swab to StatLock® adhesive and gently lift pad off of skin (if applicable).
6. Dress insertion site.
7. Document catheter removal and StatLock® removal (if applicable) procedure on patient's chart.

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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.

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