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ARROW®

Pressure Injectable Peripherally Inserted Central Catheter (PICC) Product

Rx only.

Intended Purpose:

A peripherally inserted central catheter is intended to provide long-term (>30 days) venous access to the central circulation.

Indications for Use:

The Pressure Injectable PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the pressure injectable PICC may not exceed 300 psi (2068.4 kPa). The maximum pressure injection flow rate ranges from 4 mL/sec to 6 mL/sec. Refer to the product specific labeling for the maximum pressure injection flow rate for the specific lumen being used for pressure injection.

Contraindications:

The Pressure Injectable PICC is contraindicated wherever there is presence of device related infections or presence of thrombosis in the intended insertion vessel or catheter pathway. Clinical assessment of the patient must be completed to ensure no contraindications exist.

Clinical Benefits to be Expected:

The ability to gain access to the central circulation system through a single puncture site for applications that include fluid infusion, blood sampling, medication administration, central venous monitoring, and the ability to inject contrast media.

MRI Safety Information

The PICC is MR Safe

Contains Hazardous Substance:

Components manufactured using Stainless Steel can contain > 0.1% weight by weight of Cobalt (CAS # 7440-48-4) which is considered a category 1B CMR (Carcinogenic, mutagenic or toxic to reproduction) substance. The amount of Cobalt in the Stainless Steel components has been evaluated and considering the intended purpose and toxicological profile of the devices there is no biological safety risk to patients when using the devices as instructed within this IFU.

⚠ *General Warnings and Precautions*

Warnings:

1. **Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.**
2. **Read all package insert warnings, precautions and instructions prior to use. Failure to do so may result in severe patient injury or death.**
3. **Do not place/advance catheter into or allow it to remain in the right atrium or right ventricle. The catheter tip should be advanced into the lower 1/3 of the Superior Vena Cava. Catheter tip location should be confirmed according to institutional policy and procedure.**
4. **Clinicians must be aware of potential entrapment of the guidewire by any implanted device in circulatory system. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to reduce risk of guidewire entrapment.**
5. **Do not use excessive force when introducing guidewire, peel-away sheath over tissue dilator, or tissue dilator as this can lead to venospasm, vessel perforation, bleeding, or component damage.**
6. **Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block, and a perforation of vessel, atrial or ventricular wall.**
7. **Do not apply excessive force in placing or removing catheter or guidewire. Excessive force can cause component damage or breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained and further consultation requested.**
8. **Use only lumen(s) labeled "Pressure Injectable" for pressure injection to reduce risk of catheter failure and/or patient complications. Refer to the Arrow Pressure Injection Information label for pressure injection information.**
9. **Do not secure, staple and/or suture directly to outside diameter of catheter body or extension lines to reduce risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.**
10. **Air embolism can occur if air is allowed to enter a vascular access device or vein. Do not leave open needles, sheaths, or uncapped, unclamped catheters in central venous puncture site. Use only securely tightened Luer-Lock connections with any vascular access device to guard against inadvertent disconnection.**
11. **Clinicians should be aware that slide clamps may be inadvertently removed.**
12. **Clinicians must be aware of clinical conditions that may limit use of PICCs including, but not limited to:**
    - dermatitis
    - cellulitis, and burns at or about the insertion site
    - previous ipsilateral venous thrombosis
    - radiation therapy at or about insertion site
    - contractures
    - mastectomy
    - potential use for AV fistula
13. **Clinicians must be aware of complications/undesirable side-effects associated with PICCs including, but not limited to:**

- cardiac tamponade secondary to vessel, atrial, or ventricular perforation
- air embolism
- catheter embolism
- catheter occlusion
- bacteremia
- septicemia
- extravasation
- thrombosis
- inadvertent arterial puncture
- nerve injury/damage
- hematoma
- bleeding/hemorrhage
- fibrin sheath formation
- exit site infection
- vessel erosion
- catheter tip malposition
- dysrhythmias
- SVC syndrome
- phlebitis
- thrombophlebitis
- venous thromboembolism

Precautions:

1. **Do not alter the catheter except as instructed. Do not alter the guidewire or any other kit/set component during insertion, use or removal.**
2. **Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.**
3. **Use standard precautions and follow institutional policies for all procedures including safe disposal of devices.**
4. **If the package is damaged or unintentionally opened before use do not use the device. Dispose of the device.**
5. **Storage conditions for these devices require that they are kept dry and out of direct sunlight.**
6. **Some disinfectants used at catheter insertion site contain solvents which can weaken the catheter material. Alcohol, acetone, and polyethylene glycol can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.**
   - **Do not use acetone on catheter surface.**
   - **Do not use alcohol to soak catheter surface or allow alcohol to dwell in a catheter lumen to restore catheter patency or as an infection prevention measure.**
   - **Do not use polyethylene glycol containing ointments at insertion site.**
   - **Take care when infusing drugs with a high concentration of alcohol.**
   - **Allow insertion site to dry completely prior to skin puncture and before applying dressing.**
   - **Do not allow kit components to come into contact with alcohol.**
7. **Ensure catheter patency prior to use, including prior to pressure injection. Do not use syringes smaller than 10 mL to reduce risk of intraluminal leakage or catheter rupture. Power injector equipment may not prevent over pressurizing an occluded or partially occluded catheter.**
8. **Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.**

Kits/Sets may not contain all accessory components detailed in these instructions for use. Become familiar with instructions for individual component(s) before beginning the procedure.

A Suggested Procedure: Use sterile technique.

Prep Puncture Site:

1. Prepare clean skin with appropriate antiseptic agent and allow to dry.
2. Drape puncture site.
3. Apply sterile probe cover (where provided).
4. Administer local anesthetic per institutional policies and procedures.
5. Dispose of needle.

SharpsAway® II Locking Disposal Cup (where provided):

The SharpsAway II Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 1).

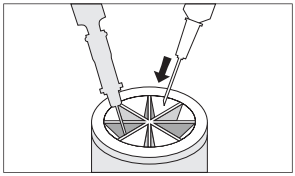

Figure 1

- Once placed into disposal cup, needles will be automatically secured in place so that they cannot be reused.

⚠ **Precaution: Do not attempt to remove needles that have been placed into SharpsAway II Locking Disposal Cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.**

- Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use.

⚠ **Precaution: Do not re-use needles after they have been placed into the foam SharpsAway system. Particulate matter may adhere to needle tip.**

Prepare Catheter:

Refer to Arrow® VPS® Instructions for use for additional instructions regarding preparation of VPS® Stylet (where provided). Refer to VPS Rhythm systems' (VPS Rhythm® Device or VPS Rhythm DLX™ Device) Operator's Manual for additional instructions regarding preparation of TipTracker™ or NaviCurve™ Stylet (where provided).

Trim Catheter if Required:

⚠ **Warning: Infusion of incompatible drugs through adjacent exit ports may cause precipitation and/or occlusion.**

6. Retract contamination guard (where provided).
7. Use centimeter marks on catheter body to trim catheter to desired length based on patient size and desired point of insertion.

Where Side-port connector and placement wire/stiffening stylet are provided follow steps 8 and 9.

8. Withdraw placement wire/stiffening stylet through septum to retract wire a minimum of 4 cm behind catheter cut location (refer to Figure 2).

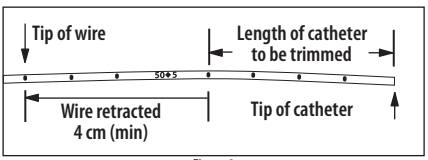

Figure 2

9. If provided with a braided placement wire that includes a handle, kink proximal end of placement wire at side-port connector to minimize risk of placement wire exiting distal tip of catheter during insertion (refer to Figure 3).

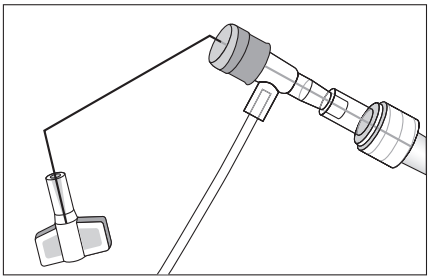

Figure 3

⚠ **Warning: Do not attempt to advance placement wire/stiffening stylet through septum.**

Catheter Trimmer (where provided):

- Insert catheter into hole on trimmer to desired cut location.
- Depress blade to cut catheter.

NOTE: Resistance when cutting catheter is likely caused by insufficiently retracted placement wire/stiffening stylet. Do not use catheter if placement wire/stiffening stylet has not been retracted.

10. Cut catheter straight across (90° to catheter cross-section) using trimming device (where provided) to maintain a blunt tip.

⚠ **Warning: Do not cut placement wire/stiffening stylet when trimming catheter to reduce risk of damage to placement wire/stiffening stylet, wire fragment, or embolism.**

11. Inspect cut surface for clean cut and no loose material.

⚠ **Precaution: Check that there is no wire in cut catheter segment after trimming. If there is any evidence that placement wire/stiffening stylet has been cut or damaged, the catheter and placement wire/stiffening stylet should not be used.**

Flush Catheter:

12. Flush each lumen with sterile normal saline for injection to establish patency and prime lumen(s).
13. Clamp or attach Luer-Lock connector(s) to extension line(s) to contain saline within lumen(s).

⚠ **Warning: Do not clamp extension line when placement wire/stiffening stylet is in catheter to reduce risk of placement wire/stiffening stylet kinking.**

⚠ **Warning: Do not clamp extension line in close proximity of the extension line hub to reduce the risk of component damage.**

Gain Initial Venous Access:

14. Apply tourniquet and replace sterile gloves.

Echogenic Needle (where provided):

An echogenic needle is used to allow access to the vascular system for the introduction of a guidewire to facilitate catheter placement. The needle tip is enhanced for approximately 1 cm for clinician to identify exact needle tip location when puncturing the vessel under ultrasound.

Protected Needle/Safety Needle (where provided):

A protected needle/safety needle should be used in accordance with manufacturer's instructions for use.

15. Insert introducer needle or catheter/needle into vein.

⚠ **Precaution: Do not reinsert needle into introducer catheter (where provided) to reduce risk of catheter embolus.**

16. Check for non-pulsatile flow.

⚠ **Warning: Pulsatile flow is usually an indicator of inadvertent arterial puncture.**

⚠ **Precaution: Do not rely on blood aspirate color to indicate venous access.**

Insert 33 or 45 cm Guidewire (Access Wire):

Guidewire:

Kits/Sets are available with a variety of guidewires. Guidewires are provided in different diameters, lengths, and tip configurations for specific insertion techniques. Become familiar with the guidewire(s) to be used with the specific technique chosen before beginning the actual insertion procedure.

Arrow Advancer (where provided):

Arrow Advancer is used to introduce guidewire into a needle.

- Using thumb, retract guidewire tip. Place tip of Arrow Advancer – with guidewire retracted – into introducer needle (refer to Figure 4).

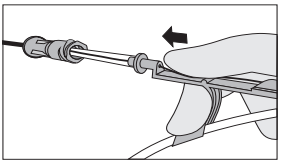

Figure 4

17. Advance guidewire into introducer needle.

⚠ **Warning: Do not insert stiff end of guidewire into vessel as this may result in vessel damage.**

18. Raise thumb and pull Arrow Advancer approximately 4 - 8 cm away from introducer needle. Lower thumb onto Arrow Advancer and while maintaining a firm grip on guidewire, push assembly into needle to further advance guidewire. Continue until guidewire reaches desired depth.

⚠ **Precaution: Maintain firm grip on guidewire at all times. Keep sufficient guidewire length exposed for handling purposes. A non-controlled guidewire can lead to wire embolus.**

⚠ **Warning: Do not withdraw guidewire against needle bevel to reduce risk of possible severing or damaging of guidewire.**

19. Remove introducer needle (or catheter) while holding guidewire in place.

Insert Catheter:

Refer to Arrow VPS Instructions for use for additional instructions regarding preparation of VPS Stylet (where provided). Refer to VPS Rhythm systems' (VPS Rhythm Device or VPS Rhythm DLX Device) Operator's Manual for additional instructions regarding preparation of TipTracker or NaviCurve Stylet (where provided).

Insertion using Peel-Away Sheath:

20. Ensure dilator is in position and locked to hub of sheath.
21. Thread peel-away sheath/dilator assembly over guidewire.
22. Grasping near skin, advance peel-away sheath/dilator assembly over guidewire with slight twisting motion to a depth sufficient to enter vessel.
23. If necessary, enlarge cutaneous puncture site with cutting edge of scalpel, positioned away from guidewire.

⚠ **Warning: Do not cut guidewire to alter length.**

⚠ **Warning: Do not cut guidewire with scalpel.**

- **Position cutting edge of scalpel away from guidewire.**
- **Engage safety and/or locking feature of scalpel (where provided) when not in use to reduce the risk of sharps injury.**

⚠ **Precaution: Do not withdraw dilator until sheath is well within vessel to reduce risk of damage to sheath tip.**

⚠ **Precaution: Sufficient guidewire length must remain exposed at hub end of sheath to maintain a firm grip on guidewire.**

24. Check peel-away sheath placement by holding sheath in place, twisting dilator hub counterclockwise to release dilator hub from sheath hub, withdraw guidewire and dilator sufficiently to allow blood flow.
25. Holding sheath in place, remove guidewire and dilator as a unit (refer to Figure 5).

⚠ **Warning: Do not apply undue force on guidewire to reduce risk of possible breakage.**

⚠ **Warning: Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.**

26. Quickly occlude sheath end upon removal of dilator and guidewire to reduce risk of air entry.

⚠ **Warning: Do not leave open dilators or sheaths uncapped in venous puncture site. Air embolism can occur if air is allowed to enter a central venous access device or vein.**

27. Verify entire guidewire is intact upon removal.
28. Retract contamination guard (where provided).

Insertion using 80 or 130 cm Guidewire (where provided):

- Prepare guidewire for insertion by wetting guidewire with sterile normal saline for injection. Ensure that guidewire remains lubricious until it is inserted into patient/catheter.
- Insertion through the peel-away sheath:
  - If 80 cm guidewire is used, insert guidewire into distal lumen until soft tip of guidewire extends beyond catheter tip. Advance guidewire/catheter as a unit through peel-away sheath to final indwelling position, while maintaining control of distal end of guidewire.
  - If 130 cm guidewire is used, insert soft tip of the guidewire through peel-away sheath to desired depth. Thread catheter over guidewire and advance catheter over guidewire to final indwelling position using image guidance or fluoroscopy.
    - If resistance is met while advancing catheter, retract and/or gently flush while advancing catheter.

⚠ **Warning: Passage of guidewire into the right heart can cause dysrhythmias or perforation of vessel, atrial or ventricular wall.**

⚠ **Precaution: Maintain firm grip on guidewire at all times. Keep sufficient guidewire length exposed for handling purposes. A non-controlled guidewire can lead to guidewire embolus.**

Insertion using placement wire/stiffening stylet (where provided):

- Insert catheter through peel-away sheath to final indwelling position. Retract and/or gently flush while advancing catheter if resistance is met.

29. Withdraw peel-away sheath over catheter until sheath hub and connected portion of sheath is free from venipuncture site. Grasp tabs of peel-away sheath and pull away from the catheter (refer to Figure 6), while withdrawing from vessel until sheath splits down its entire length.

⚠ **Precaution: Avoid tearing sheath at insertion site which opens surrounding tissue creating a gap between catheter and dermis.**

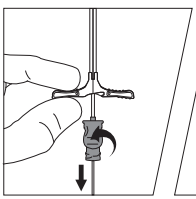

Figure 5

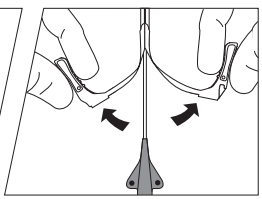

Figure 6

30. If catheter migrated during sheath removal, re-advance catheter to final indwelling position.
31. Remove placement wire/stiffening stylet or guidewire. Always verify guidewires are intact upon removal.

⚠ **Warning: Remove placement wire/stiffening stylet and side-port connector as a unit. Failure to do so may result in wire breakage.**

⚠ **Warning: Do not use short (33-45 cm) guidewire as a stiffening device.**

32. If there is any difficulty removing placement wire/stiffening stylet or guidewire, catheter and wire should be removed as a unit.

⚠ **Warning: Do not apply undue force on placement wire/stiffening stylet or guidewire to reduce the risk of possible breakage.**

Complete Catheter Insertion:

33. Check lumen patency by attaching a syringe to each extension line and aspirate until free flow of venous blood is observed.
34. Flush lumen(s) to completely clear blood from catheter.
35. Connect all extension line(s) to appropriate Luer-Lock connector(s) as required. Unused port(s) may be "locked" through Luer-Lock connector(s) using standard institutional policies and procedures.
    - Clamp(s) are provided on extension line(s) to occlude flow through each lumen during line and Luer-Lock connector changes.

⚠ **Warning: Open clamp prior to infusion through lumen to reduce risk of damage to extension line from excessive pressure.**

Secure Catheter:

36. Use catheter stabilization device and/or catheter clamp and fastener to secure catheter (where provided).
    - Use catheter hub as primary securement site.
    - Use catheter clamp and fastener as a secondary securement site as necessary.

⚠ **Precaution: Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.**

Catheter Stabilization Device (where provided):

A catheter stabilization device should be used in accordance with manufacturer's instructions for use.

Catheter Clamp and Fastener (where provided):

A catheter clamp and fastener are used to secure catheter when an additional securement site other than the catheter hub is required for catheter stabilization.

⚠ **Warning: Do not attach catheter clamp and fastener until either guidewire or placement wire/stiffening stylet is removed.**

- After guidewire has been removed and necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter body making sure catheter surface is not moist to maintain proper securement.
- Snap rigid fastener onto catheter clamp.
- Secure catheter clamp and fastener as a unit to patient by using either catheter stabilization device, stapling or suturing. Both catheter clamp and fastener need to be secured to reduce risk of catheter migration (refer to Figure 7).

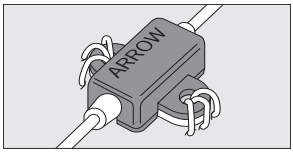

Figure 7

37. Ensure insertion site is dry before applying dressing per manufacturer's instructions.
38. Assess catheter tip placement in compliance with institutional policies and procedures.
39. If catheter tip is malpositioned, assess the situation and replace the catheter or reposition according to institutional policies and procedures.

Care and Maintenance:

Dressing:

Dress according to institutional policies, procedures and practice guidelines. Change immediately if the integrity becomes compromised (e.g. dressing becomes damp, soiled, loosened or no longer occlusive).

Catheter Patency:

Maintain catheter patency according to institutional policies, procedures and practice guidelines. All personnel who care for patients with PICCs must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury.

Catheter Removal Instructions:

1. Position patient as clinically indicated to reduce risk of potential air embolus.
2. Remove dressing.
3. Release catheter and remove from catheter securement device(s).
4. Remove catheter by slowly pulling it parallel to skin. If resistance is met while removing catheter **STOP**

⚠ **Precaution: Catheter should not be forcibly removed, doing so may result in catheter breakage and embolization. Follow institutional policies and procedures for difficult to remove catheter.**

5. Apply direct pressure to site until hemostasis is achieved followed by an ointment-based occlusive dressing.

⚠ **Warning: Residual catheter track remains an air entry point until site is epithelialized. Occlusive dressing should remain in place for at least 24 hours or until site appears epithelialized.**

6. Document catheter removal procedure including confirmation that entire catheter length and tip has been removed per institutional policies and procedures.

For reference literature concerning patient assessment, clinician education, insertion technique, and potential complications associated with this procedure, consult standard textbooks, medical literature, and Arrow International LLC website: www.teleflex.com

A pdf copy of this IFU is located at **www.teleflex.com/IFU**

Patient Information Provided

Complete *International Implant Card* with appropriate information. Present the completed card to the patient along with the *Patient Information Booklet*. If the Patient Information Booklet has been discarded a translated copy can be found at **www.teleflex.com/IFU**

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Symbol Glossary: Symbols are in compliance with ISO 15223-1.
Some symbols may not apply to this product. Refer to product labeling for symbols that apply specifically to this product.

								
Caution	Medical device	Consult instructions for use	Contains a medicinal substance	Contains hazardous substances	Do not reuse	Do not resterilize	Sterilized by ethylene oxide	
								
Single sterile barrier system with protective packaging inside		Single sterile barrier system	Keep away from sunlight	Keep dry	Do not use if package is damaged	Not made with natural rubber latex	MR safe	Catalogue number
								
Lot number	Use by	Manufacturer	Date of manufacture					

"Rx only" is used within this labeling to communicate the following statement as presented in the FDA CFR : Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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