Pressure Injectable Multi-Lumen Central Venous Catheter (CVC) Catheterization Kit

Rx only.

Product Description:

The Arrow® Pressure Injectable CVC is a central venous catheter manufactured with medical grade, flexible polyurethane. A Pressure Injectable CVC may vary from two to four noncommunicating lumens. The catheter has a soft Blue FlexTip® that is more pliable than the catheter body. Lumens are connected to separate colorcoded extension lines which have hubs on the end that are standard Luer-Lock. Centimeter markings referenced from the tip are placed along length of indwelling catheter body to facilitate proper positioning. The kit components assist the clinician in maintaining maximal sterile barrier precautions (where provided).

Indications for Use:

The Arrow® CVC is indicated to provide short-term (< 30 days) central venous access for treatment of diseases or conditions requiring central venous access including, but not limited to:

- multiple infusions of fluids, medications, or chemotherapy
- infusion of fluids that are hypertonic, hyperosmolar, or have divergent pH values
- frequent blood sampling or blood/blood component infusions
- infusion of incompatible medications
- central venous pressure monitoring
- lack of usable peripheral IV sites
- replacement of multiple peripheral sites for IV access
- injection of contrast media
    - When used for pressure injection of contrast media, do not exceed the maximum indicated flow rate for each catheter lumen. The maximum pressure of power injector equipment used with pressure injectable CVC may not exceed 400 PSI.

Contraindications:

None known. See additional labeling for product specific contraindications.

⚠ *General Warnings and Cautions*

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.**
2. **Read all package insert warnings, cautions and instructions prior to use. Failure to do so may result in severe patient injury or death.**
3. **Do not place catheter into or allow it to remain in the right atrium or right ventricle. X-ray exam or other method in compliance with institutional policies and procedures must show catheter tip located in lower 1/3 of the Superior Vena Cava (SVC), in accordance with institutional guidelines.**
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 or tissue dilator as this can lead to 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. **Using catheters not indicated for high pressure injection for such applications can result in inter-lumen crossover or rupture with potential for injury.**
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 central venous access device or vein. Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Use only securely tightened Luer-Lock connections with any central venous 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 complications associated with central venous catheters including, but not limited to:**

- cardiac tamponade secondary to vessel, atrial, or ventricular perforation
- pleural (i.e., pneumothorax) and mediastinal injuries
- air embolism
- catheter embolism
- catheter occlusion
- thoracic duct laceration
- bacteremia
- septicemia
- thrombosis
- inadvertent arterial puncture
- nerve injury
- hematoma
- hemorrhage
- fibrin sheath formation
- exit site infection
- vessel erosion
- catheter tip malposition
- dysrhythmias

Cautions:

1. **Do not alter the catheter, 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 established institutional policies and procedures.**
4. **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 applying dressing.**
5. **Ensure catheter patency prior to use. Do not use syringes smaller than 10 mL (a fluid filled 1 mL syringe can exceed 300 psi) to reduce risk of intraluminal leakage or catheter rupture.**
6. **Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.**

⚠ *Warnings and Cautions related to Pressure Injection*

Warnings:

1. **Assess each patient for appropriateness of a pressure injection procedure. Pressure injection procedures must be performed by trained personnel well versed in safe technique and potential complications.**
2. **Obtain a visual image to confirm catheter tip position prior to each pressure injection.**
3. **Ensure patency of each lumen of catheter prior to pressure injection to minimize the risk of catheter failure and/or patient complications.**
4. **Discontinue pressure injections at first sign of extravasation or catheter deformation. Follow hospital protocol for appropriate medical intervention.**

Cautions:

1. **To minimize the risk of catheter failure and/or tip displacement, do not exceed ten (10) injections or catheter's maximum recommended flow rate located on product labeling and catheter luer hub.**
2. **Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.**
3. **Pressure limit settings on injector equipment may not prevent over pressurizing an occluded or partially occluded catheter.**
4. **Use appropriate administration set tubing between catheter and pressure injector equipment to minimize the risk of catheter failure.**
5. **Follow the contrast media manufacturer's specified instructions for use, contraindications, warnings, and precautions.**

A Suggested Procedure for Pressure Injection: Use sterile technique.

1. Remove injection cap from appropriate extension line of catheter.
2. Check for catheter patency:
   - Attach 10 mL syringe filled with sterile normal saline.
   - Aspirate catheter for adequate blood return.
   - Vigorously flush catheter.
3. Detach syringe.
4. Attach pressure injection administration set tubing to appropriate extension line of catheter according to manufacturer's recommendations.
5. Inject contrast media in accordance with hospital protocol.
6. Disconnect catheter from pressure injector equipment.
7. Flush catheter using 10 mL syringe (or larger) filled with sterile normal saline.
8. Disconnect syringe and replace with sterile injection cap on catheter extension line.

A Suggested Procedure: Use sterile technique.

Prep Puncture Site:

1. Position patient as appropriate for insertion site.
   - Subclavian or Jugular approach: Place patient in slight Trendelenburg position as tolerated to reduce risk of air embolism and enhance venous filling.
   - Femoral approach: Place patient in supine position.
2. Prepare clean skin with an appropriate antiseptic agent.
3. Drape puncture site.
4. Administer local anesthetic per institutional policies and procedures.
5. Dispose of needle.

Prepare Catheter:

6. Flush each lumen with sterile normal saline for injection to establish patency and prime lumen(s).
7. Clamp or attach Luer-Lock connector(s) to extension line(s) to contain saline within lumen(s).
8. Leave distal extension line uncapped for guidewire passage.

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

Gain Initial Venous Access:

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.

Arrow® Raulerson Syringe (where provided):

Arrow Raulerson Syringe is used in conjunction with Arrow Advancer for guidewire insertion.

9. Insert introducer needle or catheter/needle with attached syringe or Arrow Raulerson Syringe (where provided) into vein and aspirate.

⚠ **Warning: Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Air embolus can occur with these practices.**

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

Verify Venous Access:

Utilize one of the following techniques to verify venous access because of the potential for inadvertent arterial placement:

- Central Venous Waveform:
  - Insert fluid primed blunt tip pressure transduction probe into rear of plunger and through valves of Arrow Raulerson Syringe and observe for central venous pressure waveform.
    - ◊ Remove transduction probe if using Arrow Raulerson Syringe.
- Pulsatile Flow (if hemodynamic monitoring equipment is not available):
  - Use transduction probe to open syringe valving system of Arrow Raulerson Syringe and observe for pulsatile flow.
  - Disconnect syringe from needle and observe for pulsatile flow.

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

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

Insert Guidewire:

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 before beginning the actual insertion procedure.

Arrow Advancer (where provided):

Arrow Advancer is used to straighten "J" Tip of guidewire for introduction of the guidewire into Arrow Raulerson Syringe or a needle.

- Using thumb, retract "J" (refer to Figure 1).

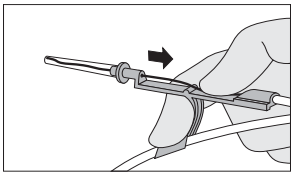

Figure 1

- Place tip of Arrow Advancer – with "J" retracted – into the hole in rear of Arrow Raulerson Syringe plunger or introducer needle (refer to Figure 2).

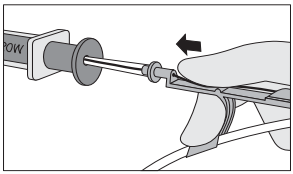

Figure 2

10. Advance guidewire into Arrow Raulerson Syringe approximately 10 cm until it passes through syringe valves or into introducer needle.
    - Advancement of guidewire through Arrow Raulerson Syringe may require a gentle rotating motion.
    - Raise thumb and pull Arrow Advancer approximately 4 - 8 cm away from Arrow Raulerson Syringe or introducer needle. Lower thumb onto Arrow Advancer and while maintaining a firm grip on guidewire, push assembly into syringe barrel to further advance guidewire. Continue until guidewire reaches desired depth.
11. Use centimeter markings (where provided) on guidewire as a reference to assist in determining how much guidewire has been inserted.

NOTE: When guidewire is used in conjunction with Arrow Raulerson Syringe (fully aspirated) and a 2-1/2" (6.35 cm) introducer needle, the following positioning references can be made:

- ***20 cm mark (two bands) entering back of plunger = guidewire tip at end of needle***
- ***32 cm mark (three bands) entering back of plunger = guidewire tip approximately 10 cm beyond end of needle***

⚠ **Caution: 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 aspirate Arrow Raulerson Syringe while guidewire is in place; air may enter syringe through rear valve.**

⚠ **Caution: Do not reinfuse blood to reduce risk of blood leakage from rear (cap) of syringe.**

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

12. Remove introducer needle and Arrow Raulerson Syringe (or catheter) while holding guidewire in place.
13. Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling catheter placement.
14. 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.**

15. Use tissue dilator to enlarge tissue tract to the vein as required. Follow the angle of the guidewire slowly through the skin.

⚠ **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.**

Advance Catheter:

16. Thread tip of catheter over guidewire. Sufficient guidewire length must remain exposed at hub end of catheter to maintain a firm grip on guidewire.
17. Grasping near skin, advance catheter into vein with slight twisting motion.

⚠ **Warning: Do not attach catheter clamp and fastener (where provided) until guidewire is removed.**

18. Using centimeter marks on catheter as positioning reference points, advance catheter to final indwelling position.

NOTE: Centimeter marking symbology is referenced from catheter tip.

- ***numerical: 5, 15, 25, etc.***
- ***bands: each band denotes a 10 cm interval, with one band indicating 10 cm, two bands indicating 20 cm, etc.***
- ***dots: each dot denotes a 1 cm interval***

19. Hold catheter at desired depth and remove guidewire.

⚠ **Caution: If resistance is encountered when attempting to remove guidewire after catheter placement, guidewire may be kinked around tip of catheter within vessel (refer to Figure 3).**

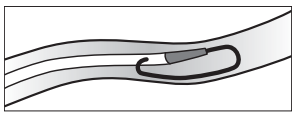

Figure 3

- In this circumstance, pulling back on guidewire may result in undue force being applied resulting in guidewire breakage.
- If resistance is encountered, withdraw catheter relative to guidewire about 2-3 cm and attempt to remove guidewire.
- If resistance is again encountered, remove guidewire and catheter simultaneously.

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

20. Always verify entire guidewire is intact upon removal.

Complete Catheter Insertion:

21. Check lumen patency by attaching a syringe to each extension line and aspirate until free flow of venous blood is observed.
22. Flush lumen(s) to completely clear blood from catheter.
23. 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.
    - Slide clamp(s) are provided on extension lines to occlude flow through each lumen during line and Luer-Lock connector changes.

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

Secure Catheter:

24. Use a catheter stabilization device, catheter clamp and fastener, staples or sutures (where provided).
    - Use triangular juncture hub with side wings as primary suture site.
    - Use catheter clamp and fastener as a secondary suture site as necessary.

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

Grip-Lok Catheter Stabilization Device (where provided):

The GRIP-Lok should be used in accordance with the manufacturer's instructions for use provided.

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.

- After guidewire has been removed and necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter making sure catheter is not moist, as required, to maintain proper tip location.
- 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 4).

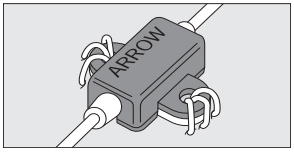

Figure 4

25. Ensure insertion site is dry before applying dressing per manufacturer's instructions.
26. Assess catheter tip placement in compliance with institutional policies and procedures.
27. If catheter tip is malposition, assess and replace 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 central venous catheters must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury.

Catheter Removal Instructions:

28. Position patient as clinically indicated to reduce risk of potential air embolus.
29. Remove dressing.
30. Release catheter and remove from catheter securement device(s).
31. Ask patient to take a breath and hold it if removing internal jugular or subclavian catheter.
32. Remove catheter by slowly pulling it parallel to skin. If resistance is met while removing catheter STOP

⚠ **Caution: 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.**

33. 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.**

34. 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, Inc. website: www.teleflex.com

en

Symbol Glossary: Symbols are in compliance with ISO 15223-1

				STERILE EO				LATEX
Caution	Consult instructions for use	Do not reuse	Do not resterilize	Sterilized by ethylene oxide	Keep away from sunlight	Keep dry	Do not use if package is damaged	Not made with natural rubber latex

			
Catalogue number	Lot number	Use by	Manufacturer

0086

EC REP Teleflex Medical
IDA Business and Technology Park
Dublin Road, Athlone, Co. Westmeath, Ireland

Arrow International, Inc.
Subsidiary of Teleflex Incorporated
2400 Bernville Road | Reading, PA 19605 USA
1-800-523-8446 | 1-610-378-0131

S-15703-120A (6/18)

Teleflex®