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ARROW

Central Venous Catheter (CVC) Product

Rx only.

Indications for Use - CVC:

The Arrow catheter is indicated to permit short-term (< 30 day) central venous access for the treatment of diseases or conditions requiring central venous access, including, but not limited to the following:

- Lack of usable peripheral IV sites
- Central venous pressure monitoring
- Total parenteral nutrition (TPN)
- Infusions of fluids, medications, or chemotherapy
- Frequent blood sampling or receiving blood transfusions/blood products

Indications for Use - Pressure Injectable CVC:

In addition to the CVC indications for use, a Pressure Injectable CVC also includes:

- 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 the pressure injectable CVC may not exceed 400 psi.

Contraindications:

None known.

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.

⚠ *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.**

   For femoral vein approach, catheter should be advanced into vessel so catheter tip lies parallel to vessel wall and does not enter right atrium.

   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 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 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/undesirable side-effects 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
    - extravasation

Precautions:

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 institutional policies for all procedures including safe disposal of devices.**
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 stylet is removed from catheter prior to use.**
6. **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.**
7. **Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.**
8. **Confirm vein depth with ultrasound to ensure dilator length is appropriate for insertion.**

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. 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.

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).

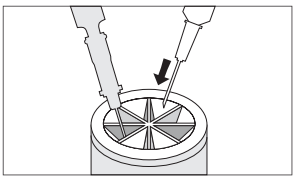

Figure 1

- 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:

6. Flush stylet (in distal lumen) with sterile normal saline for injection, do not clamp.
7. Retract the stylet 20-25 mm and replace to ensure free movement of the stylet within the catheter for insertion.
8. Flush additional lumens (if present) with sterile normal saline for injection to establish patency and prime lumen(s). Clamp or attach Luer-lock connector(s) to extension line(s) to contain saline within lumen(s).

⚠ **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.

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

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

Use of Y-hub :

9. Connect introducer needle to Y-hub with syringe, ensure they are secure **PRIOR TO USE.** Insert introducer needle into vein with Y-hub and syringe attached.

Alternatively, place Catheter-Over-The-Needle into vein, ensure blood return and thread catheter into vein, remove and discard needle. Attach Y-hub and syringe to introducer catheter and ensure they are secure PRIOR TO USE or proceed without use of Y-hub.

10. Aspirate to confirm flashback of blood.

⚠ **Precaution: Do not move introducer needle while holding securely at Y-hub or syringe (refer to Figure 2).**

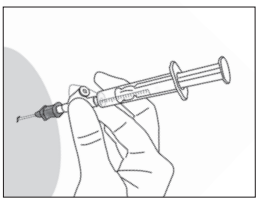

Figure 2

Verify Venous Access:

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

- Central venous pressure waveform.
- Pulsatile Flow (if hemodynamic monitoring equipment is not available).
  - Disconnect syringe from needle and observe for pulsatile flow.
- Use of ultrasound for venipuncture has been shown to increase successful insertion.

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

⚠ **Precaution: 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® GlideWheel™ Wire Advancer or Arrow Advancer (where provided):

Arrow Advancer is used to straighten J – tip or the angled tip of the guidewire for introduction of the guidewire into the Y-hub on the introducer needle.

- Using thumb, retract "J" (refer to Figure 3 GlideWheel or 3A Standard Advancer depending on which Arrow Advancer is provided).

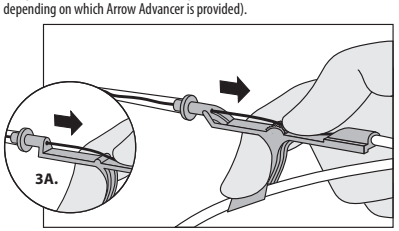

Figure 3

- Hold introducer needle or catheter with Y-hub in place securely. Place tip of Arrow Advancer – with J- tip or angled-tip retracted into the tip straightener into the Y-hub (refer to Figure 4).

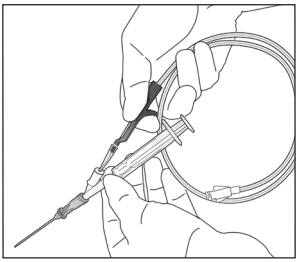

Figure 4

11. Lower thumb onto Arrow Advancer and while maintaining a firm grip on guidewire, push assembly into y-site and move thumb to further advance guidewire. Observe wire markings to ensure movement of guidewire until it reaches desired depth.
12. Use centimeter markings (where provided) on guidewire as a reference to assist in determining how much guidewire has been inserted.

NOTE: Centimeter markings are referenced from guidewire tip.

- ***Wide bands: each band denotes a 10 cm interval, with one band indicating 10 cm, two bands indicating 20 cm, etc.***
- ***Narrow bands: each band denotes 5 cm interval***

⚠ **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.**

⚠ **Precaution: Do not reinfuse blood to reduce risk of blood leakage from Y-hub side hole.**

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

13. Remove introducer needle, introducer needle with Y-hub assembly, introducer catheter, or introducer catheter with Y-hub assembly by retracting over-the-wire while holding guidewire in place.
14. Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling catheter placement.
15. 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.**

16. Use tissue dilator to enlarge tissue tract to the vein as required. Follow the angle of the guidewire slowly through the skin. Where guidewire introducer is attached to tip of dilator, insert proximal end of the guidewire along the groove of guidewire introducer into dilator. Confirm guidewire passes through dilator (refer to Figure 5). Remove the guidewire introducer similar as described for catheter on Figure 7.

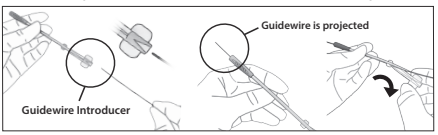

Figure 5

⚠ **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:

17. Thread tip of stylet over guidewire. Sufficient guidewire length must remain exposed at hub end of catheter to maintain a firm grip on guidewire. Use guidewire introducer similar as described for dilator on Figure 5.

    NOTE: Where guidewire Introducer is attached to tip of Catheter, push it by finger against catheter tip to assure its right position (refer to Figure 6). Insert proximal tip of the guidewire along the groove of guidewire introducer into catheter stylet. Confirm guidewire passes through Cathether. Remove the guidewire introducer.

⚠ **Warning: Do not reuse guidewire introducer.**

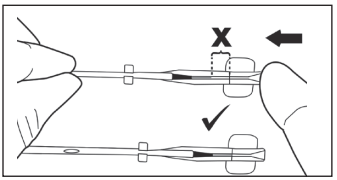

Figure 6

Guidewire Introducer removal **(refer to Figure 7)**:

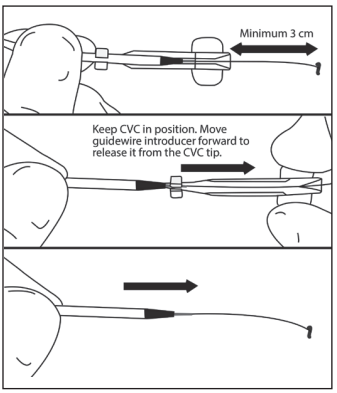

Figure 7

18. Grasping near skin, advance catheter and stylet into vein.

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

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.

⚠ **Precaution: 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 8).**

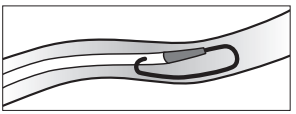

Figure 8

- 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 with stylet simultaneously.

20. Always verify entire guidewire is intact upon removal.
21. Retract the catheter stylet slowly from the catheter, immediately clamp the lumen to prevent air ingress.

⚠ **Precaution: If resistance is encountered when attempting to remove stylet after catheter placement pulling back on stylet may result in undue force being applied resulting in stylet breakage.**

- If resistance is encountered, withdraw catheter with stylet about 2-3 cm and attempt to remove stylet.

- If resistance is again encountered, remove catheter with stylet simultaneously.

⚠ **Warning: Do not apply undue force on guidewire or stylet to reduce risk of possible breakage. Always verify entire guidewire or stylet is intact upon removal.**

Complete Catheter Insertion:

22. Check lumen for patency by attaching a syringe to each extension line and aspirate until free flow of venous blood is observed.
23. Flush lumen(s) to completely clear blood from catheter.
24. 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:

25. Use a catheter stabilization device, catheter clamp and fastener, staples or sutures (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.

- After guidewire and stylet have 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, 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 9).

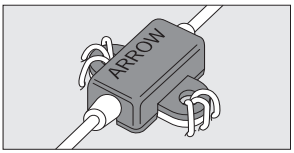

Figure 9

26. Ensure insertion site is dry before applying dressing per manufacturer's instructions.
27. Assess catheter tip placement in compliance with institutional policies and procedures.
28. If catheter tip is malpositioned, 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.

Pressure Injection Instructions - Use sterile technique.

⚠ **Warning: Do not use catheter for pressure injection unless "Pressure Injectable" is printed on the hub of the extension lines (refer to Figure 10).**

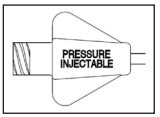

Figure 10

1. Obtain a visual image to confirm catheter tip position prior to each pressure injection.

⚠ **Precaution: Pressure injection procedures must be performed by trained personnel well versed in safe technique and potential complications.**

2. Identify lumen for pressure injection.
3. Check for catheter patency:
    - Attach 10 mL syringe filled with sterile normal saline.
    - Aspirate catheter for adequate blood return.
    - Vigorously flush catheter.

⚠ **Warning: Ensure patency of each lumen of catheter prior to pressure injection to minimize the risk of catheter failure and/or patient complications.**

4. Detach syringe and needleless connector (where applicable).
5. Attach pressure injection administration set tubing to appropriate extension line of catheter according to manufacturer's recommendations.

⚠ **Precaution: Do not exceed ten (10) injections or catheter's maximum recommended flow rate located on product labeling and catheter luer hub to minimize the risk of catheter failure and/or tip displacement.**

⚠ **Warning: Discontinue pressure injections at first sign of extravasation or catheter deformation. Follow institutional policies and procedures for appropriate medical intervention.**

⚠ **Precaution: Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.**

⚠ **Precaution: Pressure limit settings on injector equipment may not prevent over pressurizing an occluded or partially occluded catheter.**

⚠ **Precaution: Use appropriate administration set tubing between catheter and pressure injector equipment to minimize the risk of catheter failure.**

⚠ **Precaution: Follow the contrast media manufacturer's specified instructions for use, contraindications, warnings, and precautions.**

6. Inject contrast media in accordance with institutional policies and procedures.
7. Aseptically disconnect catheter lumen from pressure injector equipment.
8. Aspirate, then flush catheter lumen using 10 mL syringe or larger filled with sterile normal saline.
9. Disconnect syringe and replace with sterile needleless connector or injection cap on catheter extension line.

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. Ask patient to take a breath and hold it if removing internal jugular or subclavian catheter.
5. 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.**

6. 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.**

7. 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**

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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	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	Catalogue number	Lot number	Use by	Manufacturer
								
Date of manufacture								

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