



Single-Lumen Central Venous Catheterization Product

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, spring-wire guide, or any other kit/set component during insertion, use, or removal.

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).

the tip of the indwelling catheter should be confirmed by visual imaging after insertion.^{2,3,6,14,16,19} Central venous catheters should be placed in the superior vena cava^{2,3,4,6,8,14,21} above its junction with the right atrium and parallel to the vessel wall^{10,21} and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.

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

Indications for Use:

The Arrow® Single-Lumen Catheter permits venous access to the central circulation.

Contraindications:

None known.

Warnings and Precautions:*

1. **Warning: Do not place catheter into or allow it to remain in right atrium or right ventricle.** Central vein catheters should be positioned so that distal tip of catheter is in superior vena cava (SVC) above the junction of SVC and right atrium and lies parallel to vessel wall. For femoral vein approach, catheter should be advanced into vessel so that the catheter tip lies parallel to vessel wall and does not enter right atrium.
2. **Warning: Practitioners must be aware of complications associated with central vein catheters including cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, catheter occlusion, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma, hemorrhage, and dysrhythmias.**
3. **Warning: Do not cut catheter to alter catheter length.**
4. **Warning: For high-pressure injection applications, only utilize catheters indicated for such applications. Catheters not indicated for high pressure applications can result in inter-lumen crossover or rupture with potential for injury.**
5. **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 disconnects. To lessen the risk of disconnects, only securely tightened Luer-Lock connections should be used with this device. Follow hospital protocol to guard against air embolism for all catheter maintenance.**
6. **Warning: Do not apply excessive force in removing spring-wire guide or catheter. If withdrawal cannot be easily accomplished, a visual image should be obtained and further consultation requested.**
7. **Warning: Practitioners must be aware of the potential for entrapment of spring-wire guide by any implanted**

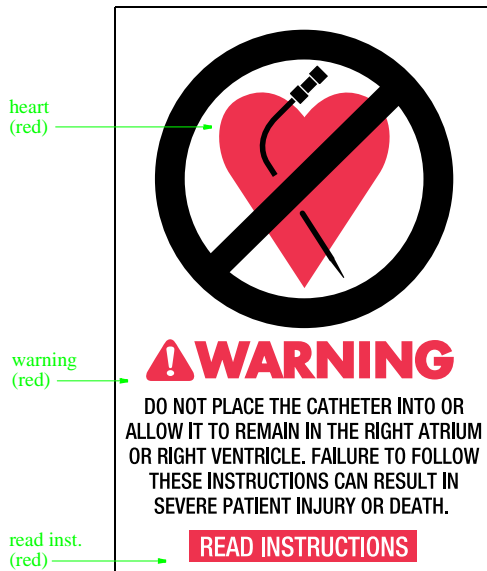


Fig. 1

Cardiac Tamponade: It has been documented by many authors that placement of indwelling catheters in the right atrium is a dangerous practice,^{2,3,4,6,8,14,16} that may lead to cardiac perforation and tamponade.^{2,3,4,6,8,14,16} Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it.¹⁸ Practitioners placing central venous catheters must be aware of this potentially fatal complication before advancing the catheter too far relative to patient size.

No particular route or catheter type is exempt from this potentially fatal complication.¹⁶ The actual position of

- device in the circulatory system (ie. vena cava filters, stents). Review patient's history before catheterization procedure to assess for possible implants. Care should be taken regarding length of spring-wire guide inserted. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to minimize the risk of spring-wire guide entrapment.¹
8. **Warning:** Do not cut spring-wire guide to alter length. Do not withdraw spring-wire guide against needle bevel to minimize risk of possible severing or damaging of spring-wire guide.
 9. **Warning:** Do not use excessive force when introducing the spring-wire guide or tissue dilator as this can lead to vessel perforation and bleeding.
 10. **Warning:** Passage of spring-wire guide into the right heart can cause dysrhythmias, right bundle branch block,⁹ and a perforation of the vessel wall, atrial or ventricular.
 11. **Warning:** Aspiration with spring-wire guide in place will cause introduction of air into Arrow® Raulerson Syringe.
 12. **Warning:** Although the incidence of spring-wire guide failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the spring-wire guide.
 13. **Warning:** Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.
 14. **Warning:** Do not leave tissue dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.
 15. **Warning:** The occlusive dressing should remain in place for at least 24-72 hours dependent upon the amount of time the catheter was indwelling, since the residual catheter track remains an air entry point until completely sealed.^{12,15,17,20}
 16. **Warning:** Care must be taken to minimize the risk of sharps injury. Clinicians must adhere to US OSHA or other governmental standards for blood borne pathogens. 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.
 17. **Precaution:** To minimize the risk of catheter breakage, do not exert excessive force while removing the catheter.
 18. **Precaution:** Place patient in a supine position prior to catheter removal.
 19. **Precaution:** Do not use scissors to remove the dressing to minimize the risk of cutting the catheter.
 20. **Precaution:** Do not suture directly to the outside diameter of the catheter to minimize the risk of cutting or damaging the catheter or impeding catheter flow.
 21. **Precaution:** Use of a syringe smaller than 10 mL to irrigate or de clot an occluded catheter may cause intraluminal leakage or catheter rupture.
 22. **Precaution:** Do not cut spring-wire guide with scalpel when enlarging puncture site.
 23. **Precaution:** Maintain firm grip on spring-wire guide at all times.
 24. **Precaution:** Remove the catheter clamp and fastener prior to attempting a catheter exchange procedure.
 25. **Precaution:** Catheter clamp must be opened prior to infusing through catheter to minimize the risk of damage to the extension line from excessive pressure.
 26. **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 catheter position has changed.
 27. **Precaution:** Visual exam must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall and its distal tip positioned at a level above either the azygos vein or the carina of the trachea, whichever is better visualized.
 28. **Precaution:** Only visual imaging 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 obtain a visual image to confirm catheter tip position.
 29. **Precaution:** Do not reinfuse blood with spring-wire guide in place to minimize the risk of leakage of blood from Arrow® Raulerson Syringe cap.
 30. **Precaution:** Place patient in slight Trendelenburg position as tolerated to reduce the risk of air embolism. If femoral approach is used, place patient in supine position.
 31. **Precaution:** Maintain the insertion site with regular meticulous redressing using aseptic technique
 32. **Precaution:** Do not re-use needles after they have been placed into the foam SharpsAway® system. Particulate matter may adhere to needle tip.
 33. **Precaution:** The color of the blood aspirated into the Arrow® Raulerson Syringe is not always a reliable indicator of venous access.
 34. **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.
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.
 35. **Precaution:** Some disinfectants used at the catheter insertion site contain solvents, which can attack the catheter material. Assure insertion site is dry before dressing.
- A Suggested Procedure:
Use sterile technique.**
1. **Precaution:** Place patient in slight Trendelenburg position as tolerated to reduce the risk of air embolism. If femoral approach is used, place patient in supine position.
 2. Prep and drape puncture site as required.
 3. Perform skin wheal with desired needle (25 Ga. or 22 Ga. needle). 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 the foam SharpsAway® system. Particulate matter may adhere to needle tip.

- Prepare the catheter for insertion by flushing the lumen. Leave the catheter uncapped for guide wire passage.
Warning: Do not cut the catheter to alter length.
- Insert introducer needle with attached Arrow® Raulerson Syringe into vein and aspirate. (If larger introducer needle is used, vessel may be pre-located with 22 Ga. locator needle and syringe.) Remove locator needle.

Alternate Technique:

Catheter/needle may be used in the standard manner as alternative to introducer needle. If catheter/needle is used, Arrow® Raulerson Syringe will function as a standard syringe, but will not pass spring-wire guide. If no free flow of venous blood is observed after needle is removed, attach syringe to the catheter and aspirate until good venous blood flow is established. **Precaution: The color of the blood aspirated is not always a reliable indicator of venous access.¹¹**

- Because of the potential for inadvertent arterial placement, one of the following techniques should be utilized to verify venous access. Insert the fluid primed blunt tip transduction probe into the rear of the plunger and through the valves of the Arrow® Raulerson Syringe. Observe for central venous placement via a wave form obtained by a calibrated pressure transducer. Remove transduction probe (refer to Fig. 2).

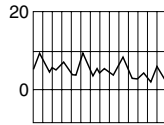


Fig. 2

Alternate Technique:

If hemodynamic monitoring equipment is not available to permit transducing a central venous wave form, check for pulsatile flow by either using the transduction probe to open the syringe valving system or by disconnecting the syringe from the needle. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

- Using the two-piece Arrow Advancer™ advance spring-wire guide through syringe into vein. **Warning: Aspiration with spring-wire guide in place will cause introduction of air into Arrow® Raulerson Syringe. Precaution: To minimize the risk of leakage of blood from Arrow® Raulerson Syringe cap do not reinsert blood with spring-wire guide in place.**

Arrow Two-Piece Advancer™

Instructions for Use:

- Using your thumb, straighten the “J” by retracting the spring-wire guide into the Arrow Advancer™ (refer to Figs. 3, 4).

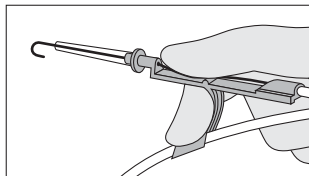


Fig. 3

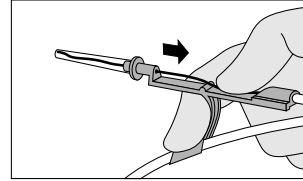


Fig. 4

When the tip is straightened, the spring-wire guide is ready for insertion.

Introducing the Spring-Wire Guide:

- Place the tip of the Arrow Advancer™ – with “J” retracted – into the hole in the rear of the Arrow® Raulerson Syringe plunger (refer to Fig. 5).

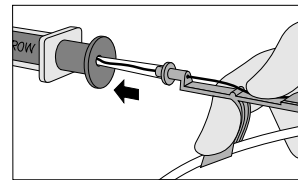


Fig. 5

- Advance spring-wire guide into the syringe approximately 10 cm until it passes through the syringe valves (refer to Fig. 6).

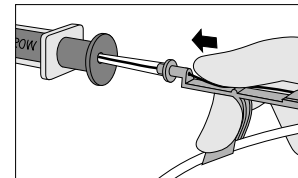


Fig. 6

- Raise your thumb and pull the Arrow Advancer™ approximately 4 - 8 cm away from the syringe. Lower thumb onto the Arrow Advancer™ and while maintaining a firm grip on the spring-wire guide, push the assembly into the syringe barrel to further advance the spring-wire guide. Continue until spring-wire guide reaches desired depth (refer to Fig. 7).

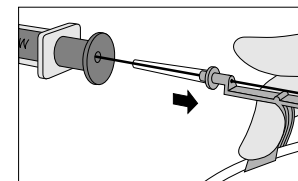


Fig. 7

Alternate Technique:

If a simple straightening tube is preferred, the straightening tube portion of the Arrow Advancer™ can be disconnected from the unit and used separately.

- Separate the Arrow Advancer™ tip or straightening tube from the blue Arrow Advancer™ unit. If the “J” tip portion of the spring-wire guide is used, prepare for insertion by sliding the plastic tube over the “J” to straighten. The spring-wire guide should then be advanced in the routine fashion to the desired depth.
8. Advancement of “J” tip may require a gentle rotating motion. **Warning: Do not cut spring-wire guide to alter length. Do not withdraw spring-wire guide against needle bevel to minimize the risk of possible severing or damaging of spring-wire guide.**
 9. Hold spring-wire guide in place and remove introducer needle and Arrow® Raulerson Syringe (or catheter). **Precaution: Maintain firm grip on spring-wire guide at all times.**
 10. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution: Do not cut spring-wire guide with scalpel when enlarging puncture site.** Use tissue dilator to enlarge puncture site as required. **Warning: Do not leave tissue dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.**
 11. Grasp distal end of contamination guard and pull back to expose catheter tip. Thread tip of single-lumen catheter over spring-wire guide. Sufficient spring-wire guide length must remain exposed at hub end of catheter to maintain a firm grip on spring-wire guide. Grasping near skin, advance catheter into vein with slight twisting motion. The contamination guard will peel off catheter as they are advanced simultaneously.
 12. Using centimeter marks on catheter as positioning reference points, advance catheter to final indwelling position. All centimeter marks are referenced from the catheter tip. Marking symbology is as follows: (1) numerical: 5, 15, 25, etc.; (2) bands: each band denotes 10 cm intervals, with one band indicating 10 cm, two bands indicating 20 cm, etc.; (3) each dot denotes a 1 cm interval.
 13. Hold catheter at desired depth and remove spring-wire guide. The Arrow® catheter included in this product has been designed to freely pass over the spring-wire guide. If resistance is encountered when attempting to remove the spring-wire guide after catheter placement, the spring-wire may be kinked about the tip of the catheter within the vessel (refer to Fig. 8).
 14. Verify that the entire spring-wire guide is intact upon removal.
 15. Check lumen placement by attaching a syringe to the catheter and aspirate until free flow of venous blood is observed. Connect appropriate Luer-Lock line as required, or “lock” through injection cap using standard hospital protocol. **Precaution: Catheter clamp must be opened prior to infusing through catheter to minimize the risk of damage to extension line from excessive pressure.**
 16. Secure and dress catheter temporarily.
 17. Verify catheter tip position by visual imaging immediately after placement. **Precaution: Visual exam must show the catheter located in the right side of the mediastinum in the SVC with the distal end of the catheter parallel to the vena cava wall 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.
 18. Secure catheter to patient. Use triangular juncture hub with integral suture ring and side wings as primary suture site. In kits where provided, the catheter clamp and fastener should be utilized as a secondary suture site as necessary. **Precaution: Do not suture directly to the outside diameter of the catheter to minimize the risk of cutting or damaging the catheter or impeding catheter flow.**



Fig. 8

In this circumstance, pulling back on the spring-wire guide may result in undue force being applied resulting in spring-wire guide breakage. If resistance is encountered, withdraw the catheter relative to the spring-wire guide about 2-3 cm and attempt to remove the spring-wire guide. If resistance is again encountered remove the spring-wire guide and catheter simultaneously. **Warning: Although the incidence of spring-wire guide failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the spring-wire guide.**

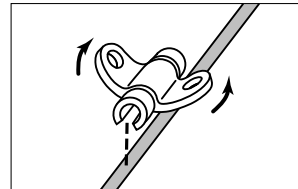


Fig. 9

- Snap rigid fastener onto catheter clamp (refer to Fig. 10).

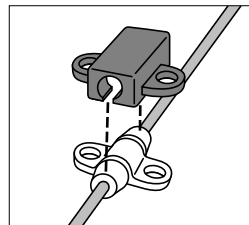


Fig. 10

Catheter Clamp and Fastener

Instructions for Use:

- After spring-wire guide has been removed and line has been connected or locked, spread wings of rubber clamp and position on catheter as required to ensure proper tip location (refer to Fig. 10). **Precaution: Catheter clamp and fastener must not be attached to catheter until spring-wire guide is removed.**

- Secure catheter to patient by suturing catheter clamp and fastener to skin, using side wings to minimize the risk of catheter migration (refer to Fig. 11).

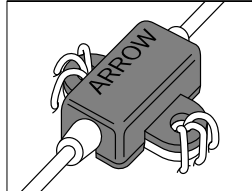


Fig. 11

19. Dress puncture site per hospital protocol. **Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique.**
20. Record on the patient's chart the indwelling catheter length as to centimeter markings on catheter where it enters the skin. Frequent visual reassessment should be made to ensure that the catheter has not moved.

Catheter Exchange Procedure:

1. Use sterile technique.
2. **Precaution: Remove the catheter clamp and fastener prior to attempting a catheter exchange procedure.**
3. Proceed per hospital protocol. Cutting the catheter is not recommended due to the potential for catheter embolism.

Catheter Removal Procedure:

1. Place the patient in a supine position.
2. Remove dressing. **Precaution: Do not use scissors to remove the dressing to minimize the risk of cutting the catheter**
3. **Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.** Remove suture(s) from catheter clamp and primary suture site. Be careful not to cut the catheter. Remove catheter slowly, pulling it parallel to the skin. As catheter exits the site, apply pressure with a dressing impermeable to air, e.g. Vaseline[®] gauze. **Warning: The occlusive dressing should remain in place for at least 24-72 hours dependent upon the amount of time the catheter was indwelling, since the residual catheter track remains an air entry point until completely sealed.**^{12,15,17,20}
4. Upon removal of catheter, inspect it to make sure that entire length has been withdrawn.
5. Document removal procedure.

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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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