

Large-Bore Multiple-Lumen Central Venous Catheterization Product with ARROW[†]g[†]ard[®] Antimicrobial Surface

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.

Central venous catheterization must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.

Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle (refer to Fig. 1).

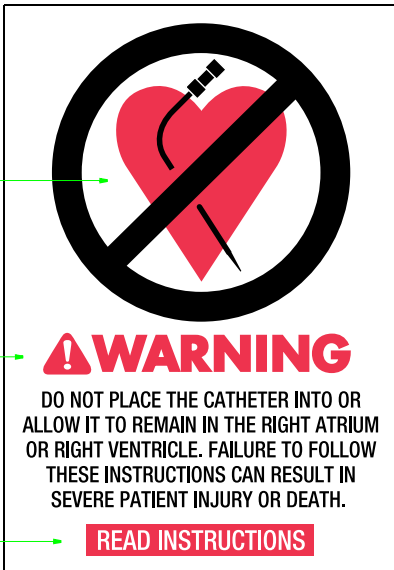


Fig. 1

Cardiac Tamponade: It has been documented by many authors that placement of indwelling catheters in the right atrium is a dangerous practice^{2,3,4,6,8,21,27} that may lead to cardiac perforation and tamponade.^{2,3,4,6,21,27} Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it.²⁹ 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.²⁷ The actual position of the tip of the indwelling catheter should be confirmed by x-ray after insertion.^{2,3,6,21,27,30} Central venous catheters should be placed in the superior vena cava^{2,3,4,6,8,21,33} above its junction with the right atrium and parallel to the vessel wall^{14,33} 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.

ARROW[†]g[†]ard[®] Antimicrobial Surface: The Arrow antimicrobial catheter consists of our standard polyurethane catheter with Blue FlexTip[®], plus an exterior antimicrobial surface treatment. Substantial antimicrobial activity associated with the 7 Fr. triple-lumen ARROW[†]g[†]ard[®] catheter has been demonstrated in the following ways:

- Significant antimicrobial activity associated with the Arrow catheter has been demonstrated using zone of inhibition bioassays against the following organisms:²²

Escherichia coli
Pseudomonas aeruginosa
Staphylococcus epidermidis
Staphylococcus aureus
Klebsiella pneumoniae
Candida albicans

- Contact inhibition of microbial growth on the surface of the Arrow catheter has been demonstrated against organisms commonly associated with nosocomial infections; e.g. *Staphylococcus epidermidis* and *Staphylococcus aureus*.²²
- Antimicrobial activity on the surface of the catheter during handling and placement has been demonstrated *in situ* in limited animal studies.
- The ARROW g⁺ard[®] catheter has demonstrated a significant decrease in the rate of bacterial colonization along the catheter in limited animal studies.
- A prospective randomized clinical trial of 403 catheter insertions in adult patients in a medical-surgical ICU showed that the antimicrobial catheters were 50% less likely to be colonized than control catheters (p=0.003) and 80% less likely to produce catheter related bacteremia (p=0.02).²⁰
- Arrow antimicrobial catheters retained antibacterial activity with zones of inhibition of 4 to 10 mm against *Staphylococcus aureus* and *Escherichia coli* after 10 days of implantation in rats.²²
- Complete data were obtained for 403 catheters (195 control catheters and 208 antimicrobial catheters) in 158 patients. Control catheters removed from patients who were receiving systemic antibiotic therapy occasionally showed low-level surface activity that was unrelated to the length of time the catheter had been in place (mean zone of inhibition \pm SD, 1.7 \pm 2.8 mm); in contrast, antimicrobial catheters uniformly showed residual surface activity (mean zone of inhibition, 5.4 \pm 2.2 mm; $P < 0.002$), which declined after prolonged periods *in situ*. Antimicrobial activity was seen with antimicrobial catheters that had been in place for as long as 15 days.²⁰
- Arrow antimicrobial catheters produced large zones of inhibition *in vitro* (range 10 to 18 mm) against the following microbes:

Methicillin-resistant *Staphylococcus aureus*
Gentamicin/methicillin-resistant *Staphylococcus aureus*
Staphylococcus aureus
Staphylococcus epidermidis
Escherichia coli
Pseudomonas aeruginosa
Klebsiella pneumoniae
Candida albicans

After 7 days of implantation the catheters retained 6-7 mm zones of inhibition against *Staphylococcus aureus*.¹²

- Antibacterial activity was retained against *Staphylococcus epidermidis* (10^6 bacterial concentration) from subcutaneous segments of ARROW g⁺ard[®] antimicrobial surface catheters for at least 120 hours and some up to 520 hours after insertion of the catheters into cardiac surgical patients (both double- and triple-lumen catheters). The zone of inhibition size varied in 7 Fr. triple-lumen catheters from 2.5 to 10 mm at 500 hours¹.

If the total amount of silver sulfadiazine and chlorhexidine contained in the antimicrobial surface was released from the catheter as a single dose, the blood levels of silver, sulfadiazine, and chlorhexidine that would be found would be less than the blood levels found after clinical usage of these compounds in established safe dosages as administered via mucous membranes and skin.

The potential exposure of patients to the two agents, silver sulfadiazine and chlorhexidine, on the antimicrobial surface is significantly less than that encountered when these compounds are used on burn wounds, on cutaneous wounds, or as mucosal irrigants.

No adverse effects of a toxicologic nature have been associated with the clinical use of this antimicrobial surface in spite of the fact that catheters have been placed in patients sensitive to sulfonamides but who were unaware of their sensitivity.¹⁰ However, hypersensitive reactions to chlorhexidine have been reported (May 1996) in Japanese patients (data on file, Arrow International, Inc.).

Indications for Use:

The large-bore multiple-lumen catheter permits venous access to the central circulation for rapid fluid administration. It may be inserted into the jugular, subclavian, or femoral veins.

The ARROWg^{ard}® antimicrobial surface catheter is intended to help provide protection against catheter-related infections. The catheter is not intended to be used as a treatment for existing infections, nor is it indicated for long-term use.

Contraindications:

The ARROWg^{ard}® antimicrobial surface catheter is contraindicated for patients with known hypersensitivity to chlorhexidine, silver sulfadiazine, and/or sulfa drugs. ARROWg^{ard}® antimicrobial surface has been reported to cause hypersensitive reactions in Japanese patients. The literature indicates that individuals of Japanese extraction are known to have had immediate hypersensitive reactions following topical chlorhexidine administration.^{11,13,18,19,24,25,31,34} If adverse reactions occur after catheter placement, remove catheter immediately.

Special Patient Populations:

Since controlled studies of the antimicrobial surface catheter in pregnant women²³ and patients with known sulfonamide hypersensitivity such as erythema multiforme and Stevens-Johnson syndrome¹⁰ have not been conducted, benefits of this catheter should be weighed against any possible risk.

Central Venous Catheterization

Warnings and Precautions:*

- Warning: Do not place the catheter into or allow it to remain in the right atrium or right ventricle. Central vein catheters should be positioned so that the distal tip of the catheter is in the superior vena cava (SVC) above the junction of the SVC and the right atrium and lies parallel to the vessel wall. For femoral vein approach, the catheter should be advanced into the vessel so that the catheter tip lies parallel to the vessel wall and does not enter the right atrium.**
- Warning: Practitioners must be aware of complications associated with central vein catheters including cardiac tamponade secondary to vessel wall, atrial or ventricular perforation, pleural and mediastinal injuries, air embolism, catheter embolism, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma formation, hemorrhage, and dysrhythmias.**
- Warning: Do not apply excessive force in removing guide wire or catheters. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.**
- Warning: The practitioner must be aware of potential air embolism/hemorrhage problems associated with large-bore catheters. Do not leave open needles or catheters in central venous puncture sites. To lessen the risk of disconnects, only securely tightened Luer-Lock connections should be used with this device. It is recommended that the extension lines be kept clamped at all times when not in use because of the catheter's large lumens. Follow hospital protocol to guard against air embolism/hemorrhage for all catheter maintenance.**
- Warning: Passage of the guide wire into the right heart can cause dysrhythmias, right bundle branch block,⁹ and vessel wall, atrial or ventricular perforation.**
- Warning: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients.**
- Precaution: Do not clamp the body of the large-bore catheter. Clamp only the extension lines and use only the clamps provided. Never use serrated forceps to clamp the extension lines.**
- Precaution: Indwelling catheters should be routinely inspected for desired flow rate, security of dressing, correct catheter position, and for secure Luer-Lock connection. Use centimeter markings to identify if the catheter position has changed.**
- Precaution: Only x-ray examination of the catheter placement can ensure that the catheter tip has not entered the heart or no longer lies parallel to the vessel wall. If catheter position has changed, immediately perform chest x-ray examination to confirm catheter tip position.**
- Precaution: For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.**

11. **Precaution:** Alcohol and acetone can weaken the structure of polyurethane material. Therefore, care should be taken when instilling drugs containing alcohol or when using high concentration of alcohol or acetone when performing routine catheter care and maintenance. Alcohol should not be utilized to declog polyurethane catheters.

12. **Precaution:** Use of a syringe smaller than 10 ml to irrigate or declog an occluded catheter may cause intraluminal leakage or catheter rupture.⁷

Carefully read all warnings and precautions throughout procedure instructions.

Catheter Insertion 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 reuse needles after they have been placed into the disposal cup. Particulate matter may adhere to needle tip.**

4. Prepare the catheter for insertion by flushing each lumen and clamping or attaching the injection caps to the appropriate pigtails. Leave the distal pigtail uncapped for guide wire passage. **Warning: Do not cut the catheter to alter length.**

Arrow UserGard[®] Needle-Free Injection Hub (where provided)

Instructions for Use:

- Attach Luer end of UserGard[®] hub to syringe.
- Prepare injection site with alcohol or betadine per standard hospital protocol.
- Remove red dust cap.
- Press UserGard[®] hub onto injection site and twist to lock on pin (refer to Fig. 2).

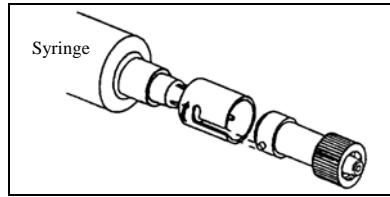


Fig. 2

- Inject or withdraw fluid as required.
 - Disengage UserGard[®] hub from injection site and discard. **Warning: To minimize the risk of possible air embolism, do not leave UserGard[®] hub connected to injection site.** Single use only.
5. 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.¹⁵ Do not reinsert needle into introducer catheter.**

6. 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 Raulerson Syringe. Observe for central venous placement via a wave form obtained by a calibrated pressure transducer. Remove transduction probe (refer to Fig. 3).

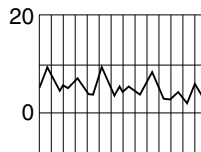


Fig. 3

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 syringe. Precaution: To minimize the risk of leakage of blood from syringe cap do not reinfuse blood with spring-wire guide in place.

Arrow Two-Piece Advancer™ Instructions:

- Using your thumb, straighten the “J” by retracting the spring-wire guide into the Advancer™ (refer to Figs. 4, 5).

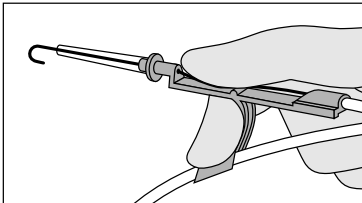


Fig. 4

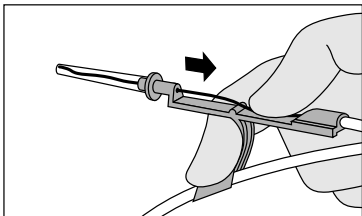


Fig. 5

When the tip is straightened, the spring-wire guide is ready for insertion. Centimeter marks on guide wire are referenced from “J” end. One band indicates 10 cm, two bands 20 cm, and three bands 30 cm.

Introducing the Spring-Wire Guide:

- Place the tip of the Advancer™ – with “J” retracted – into the hole in the rear of the Raulerson Syringe plunger (refer to Fig. 6).

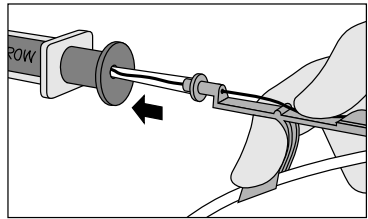


Fig. 6

- Advance spring-wire guide into the syringe approximately 10 cm until it passes through the syringe valves (refer to Fig. 7).

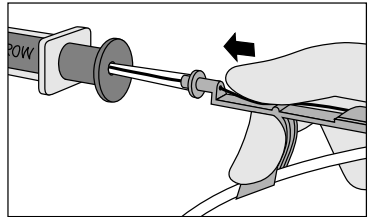


Fig. 7

- Lift your thumb and pull the Advancer™ approximately 4 cm to 8 cm away from the syringe. Lower thumb onto the 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. 8).

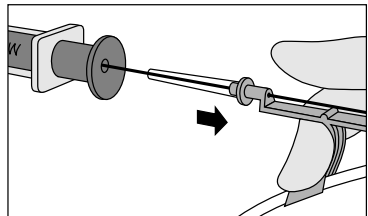


Fig. 8

Alternate Technique:

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

Separate the Advancer™ tip or straightening tube from the blue 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. Advance guide wire until triple band mark reaches rear of syringe plunger. 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 Raulerson syringe (or catheter). **Precaution: Maintain firm grip on spring-wire guide at all times.** Use centimeter markings on spring-wire guide to adjust indwelling length according to desired depth of indwelling catheter placement.
10. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution: Do not cut guide wire.** Use vessel dilator to enlarge site as required. **Warning: Do not leave vessel dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.**
11. Thread tip of multiple-lumen catheter over spring-wire guide. Sufficient guide wire length must remain exposed at hub end of catheter to maintain a firm grip on guide wire. Grasping near skin, advance catheter into vein with slight twisting motion.
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. 9).

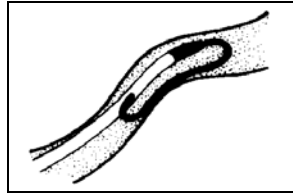


Fig. 9

- 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 wire.**
14. Verify that the entire spring-wire guide is intact upon removal.
 15. Check lumen placement by attaching a syringe to each pigtail and aspirate until free flow of venous blood is observed. Connect all pigtails to appropriate Luer-Lock line(s) as required. Unused port(s) may be “locked” through injection cap(s) using standard hospital protocol. Pinch/slide clamps are provided on pigtails to occlude flow through each lumen during line and injection cap changes. **Precaution: To minimize the risk of damage to pigtails from excessive pressure, each clamp must be opened prior to infusing through that lumen.**
 16. Secure and dress catheter temporarily.
 17. Verify catheter tip position by chest x-ray immediately after placement. **Precaution: X-ray 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 rotating suture wings as primary suture site. **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.**
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.
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Catheter Exchange Procedure:

1. Use sterile technique.
2. Proceed per hospital protocol. Cutting the catheter is not recommended due to the potential for catheter embolism.

Catheter Removal Procedure:

1. **Precaution: Place the patient in a supine position.**
2. Remove dressing. **Precaution: To minimize the risk of cutting the catheter do not use scissors to remove the dressing.**
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 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. Because the residual catheter track remains an air entry point until completely sealed, the occlusive dressing should remain in place for at least 24-72 hours dependent upon the amount of time the catheter was indwelling.^{16,26,28,32}
4. Upon removal of the catheter, inspect it to make sure that the entire length has been withdrawn.
5. Verify that the catheter was intact upon removal. 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.

Store product per conditions indicated on product label.

ARROW

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