

Inspected Dimensions: Folded Length: 7-1/2" (19 cm)
Folded Width: 5-1/2" (14 cm)

AGB⁺

ARROW[®]

ARROW⁺gard Blue PLUS[®] Antimicrobial Multiple-Lumen Central Venous Catheterization Product with Sharps Safety Features

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).

No particular route or catheter type is exempt from this potentially fatal complication.⁴³ The actual position of the tip of the indwelling catheter should be confirmed by x-ray after insertion.^{5,6,11,32,43,49} Central venous catheters should be placed in the superior vena cava^{5,6,7,11,14,32,52} above its junction with the right atrium and parallel to the vessel wall^{23,52} 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.

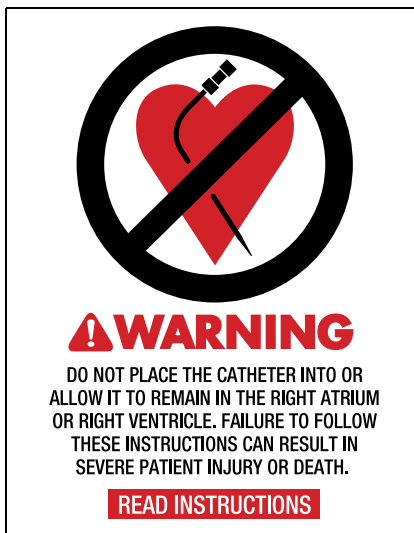


Fig. 1

Cardiac Tamponade: It has been documented by many authors that placement of indwelling catheters in the right atrium is a dangerous practice^{5,6,7,11,14,32,43} that may lead to cardiac perforation and tamponade.^{5,6,7,11,32,43} Although cardiac tamponade secondary to pericardial effusion is uncommon, there is a high mortality rate associated with it.⁴⁵ Practitioners placing central venous catheters must be aware of this potentially fatal complication before advancing the catheter too far relative to patient size.

Introduction:

Infection is the leading complication associated with intravascular devices. According to National Nosocomial Infection Surveillance System (NNIS) data, catheter-related bloodstream infections (CRBSIs) rank as the third most common nosocomial infection in intensive care units.³⁶ It has been estimated that over 200,000 of the nosocomial bloodstream infections that occur annually in the United States are associated with the use of intravascular devices, of which approximately 90% are central line related.³¹

Rationale for Antimicrobial Catheters:

Pathogenesis of Catheter-Related Bloodstream Infections:

Vascular catheter infections develop for many reasons, but they begin when a catheter becomes colonized by microorganisms entering through either one of two routes, or both: 1) colonization of the outside of the catheter, or 2) colonization of the inside of the catheter.⁴⁸ Colonization of the outside of the catheter can occur from skin microorganisms, contiguous infections, or hematogenous seeding of the catheter from a distant site.⁴⁸ Colonization of the inside of the catheter can happen through the introduction of microorganisms through the catheter hub or contamination of infusion fluid.⁴⁸ A prospective study by Mermel demonstrated that there was a 79% concordance between organisms on the infected catheters and the patient's skin.³³ Molecular subtyping of the skin organisms and catheter organisms substantiated the link between skin organisms colonizing the external surface of the catheter. It has also been documented that the source of colonization of catheters indwelling less than eight days comes predominantly from the skin (75-90%), followed by the hub, which is the primary source of infection for a catheter in place greater than eight days.⁴⁸

Technology has now been developed to protect the internal as well as the external surfaces of catheters against colonization. The binding of an antimicrobial to the entire indwelling external catheter surface proved to be effective for decreasing the risk of CRBSIs associated with external catheter colonization.^{3,9,13,31,58} As the pathogenesis of catheter-related bloodstream infections becomes more clearly understood, protection of the internal

surfaces is viewed as the next step in decreasing the risk of CRBSIs.

Technology Development:

Antimicrobial central venous catheters (CVCs) were introduced by Arrow International in 1990 as the first product capable of significantly reducing the potential for catheter colonization and subsequent catheter-related bloodstream infections. The antimicrobial surface treatment, referred to as ARROWg^{ard}®, consists of two antimicrobial agents, chlorhexidine acetate and silver sulfadiazine, that are impregnated together into the indwelling external surface of the catheter. This combination has demonstrated broad spectrum *in vitro* efficacy when tested using the modified Kirby-Bauer technique.⁴ In addition, *in vivo* efficacy of the ARROWg^{ard} Blue® catheter has been demonstrated through several prospective clinical studies.^{3,9,12,31,58}

In spite of an improved understanding of risk factors and aseptic insertion techniques, catheter-related bloodstream infection remains a major concern. Cobb has suggested that central venous catheters should remain in place until there is a clinical indication for a change (i.e. fever without a known source or catheter malfunction), challenging the benefit of scheduled catheter replacements.¹⁰ This recommendation has led many institutions to routinely leave catheters in place longer than previously accepted catheter exchange protocols of 3 to 4 days. Subsequently, the need for an antimicrobial catheter to provide infection protection for a longer duration has emerged.

It has also been shown that a portion of CRBSIs are due to contamination of the catheter hub and intraluminal catheter colonization by organisms transmitted by the hands of unit personnel.^{30,47,38}

In light of these recent findings, two key areas of improvement to the **original** ARROWg^{ard} Blue® catheter technology were identified: 1) extend the effective duration of action of the external surface coating and 2) provide protection to the internal surfaces of the entire catheter (including extension lines and hubs).

Second generation antimicrobial catheters, known as ARROWg^{ard} Blue PLUS®, have been developed to address these needs. Compared to the **original** ARROWg^{ard} Blue®, ARROWg^{ard} Blue PLUS® catheters produce a longer duration of antimicrobial effect *in vitro* (modified Kirby-Bauer technique) against a broad range of clinically relevant microorganisms.¹⁵ In addition, comprehensive *in vitro* luminal adherence assay testing against the most common catheter-related infection-causing microorganisms have shown a significant reduction in intraluminal bacterial colonization when compared to untreated catheters.³⁴

Product Description:

The ARROWg^{ard} Blue PLUS® antimicrobial catheter consists of our standard polyurethane catheter with Blue FlexTip®, plus an external surface treatment of chlorhexidine acetate and silver sulfadiazine and an internal lumen impregnation of chlorhexidine and chlorhexidine acetate to the catheter body, extension lines, and extension line hubs. Compared to the **original** ARROWg^{ard} Blue® catheter, this new external surface treatment represents a three-fold increase in the amount of chlorhexidine acetate and an unchanged amount of silver sulfadiazine. The average amount of chlorhexidine, silver, and sulfadiazine applied to the external surface of the catheter is 425 µg/cm, 24 µg/cm, and 56 µg/cm, respectively. The average amount of chlorhexidine applied to the catheter body and extension line internal lumens is 22 µg/cm. For a 20 cm catheter,

the maximum total amount of chlorhexidine, silver, and sulfadiazine applied to the entire catheter is 12.9 mg, 0.56 mg, and 1.32 mg, respectively.

Intended Use:

The ARROWg^{ard} Blue PLUS® Multiple-Lumen Catheter permits venous access to the central circulation by way of the femoral, jugular, or subclavian veins.

The ARROWg^{ard}® technology is intended to provide protection against catheter-related bloodstream infections. It is not intended to be used as a treatment for existing infections nor is it indicated for long-term use (> 30 days). Superior clinical effectiveness and safety of the ARROWg^{ard} Blue PLUS® catheter in preventing CRBSI's compared to the **original** ARROWg^{ard} Blue® catheter has not been demonstrated.

See the Clinical Evaluations section for additional information.

Indications for Use:

The ARROWg^{ard} Blue PLUS® antimicrobial catheter is indicated to provide short-term (< 30 days) central venous access for the treatment of diseases or conditions requiring central venous access including, but not limited to:

1. multiple infusions of fluids, medications, or chemotherapy
2. infusion of fluids that are hypertonic, hyperosmolar, or have divergent pH values
3. total parenteral nutrition (TPN) therapy
4. frequent blood sampling or blood/blood component infusions
5. infusion of incompatible medications
6. central venous pressure monitoring
7. lack of usable peripheral IV sites
8. replacement of multiple peripheral sites for IV access

There are no specific guidelines for maximum indwelling times or catheter exchange.^{10,42} Catheters should remain indwelling or should be exchanged per hospital protocol.

Contraindications:

The ARROWg^{ard} Blue PLUS® antimicrobial catheter is contraindicated for patients with known hypersensitivity to chlorhexidine, silver sulfadiazine, and/or sulfa drugs.

Special Patient Populations:

Controlled studies of this product have not been conducted in pregnant women,³⁵ pediatric or neonatal patients, and patients with known sulfonamide hypersensitivity, erythema multiforme, Stevens-Johnson syndrome,¹⁷ and glucose-6-phosphate dehydrogenase deficiency. The benefits of the use of this catheter should be weighed against any possible risk.

Hypersensitivity Potential:

Although the amount of chlorhexidine acetate has been increased by approximately three-fold, the increase in chlorhexidine concentration is likely to cause only minimal change (whether increased or decreased) in the incidence of hypersensitivity, since the rate of change with dose is usually very slow.⁵⁶ In addition, the three-fold increase is a very small increment in allergy terms since a ten-fold increase is the standard when performing skin allergy tests.³⁷ Since there have been no confirmed, or even suspected, hypersensitivity reactions reported to the **original** ARROWg^{ard} Blue® catheter in the United States, the risk of hypersensitivity reactions due to the increased antimicrobial concentration of the ARROWg^{ard} Blue PLUS® antimicrobial catheter can not be quantified.

See the Warnings and Precautions section for additional information.

Pre-clinical Evaluations:

In vitro

Antimicrobial activity associated with the ARROWg^{ard} Blue PLUS[®] antimicrobial catheter has been demonstrated *in vitro* using the modified Kirby-Bauer technique utilizing the vertical catheter segment placement method, in the following ways:

- ARROWg^{ard} Blue PLUS[®] antimicrobial catheters produced zones of inhibition greater than 7 mm in diameter after 24 hours against¹⁵:

Candida albicans
Staphylococcus aureus
Staphylococcus aureus (methicillin resistant)
Staphylococcus epidermidis
Streptococcus pyogenes
Klebsiella pneumoniae
Xanthomonas maltophilia
Escherichia coli
Escherichia coli (β-lactamase producer)
Pseudomonas aeruginosa
Enterococcal faecalis
Enterobacter cloacae
Enterobacter aerogenes

- ARROWg^{ard} Blue PLUS[®] antimicrobial catheters retained antimicrobial activity (zones of inhibition greater than 5 mm in diameter) after 7 days against¹⁵:

Candida albicans
Staphylococcus epidermidis
Staphylococcus aureus
Staphylococcus aureus (methicillin resistant)
Streptococcus pyogenes
Klebsiella pneumoniae
Pseudomonas aeruginosa
Enterococcal faecalis
Enterobacter cloacae
Enterobacter aerogenes
Escherichia coli
Escherichia coli (β-lactamase producer)
Xanthomonas maltophilia

The ARROWg^{ard} Blue PLUS[®] antimicrobial catheter has demonstrated a significant decrease (a log₁₀ reduction between 2 and 5) in the amount of bacterial colonization to the catheter body and extension line internal lumens *in vitro* against³⁴:

Staphylococcus epidermidis
Staphylococcus aureus
Candida albicans
Enterobacter aerogenes

The ARROWg^{ard} Blue PLUS[®] antimicrobial catheter has demonstrated no loss on delivery or interaction of the internal lumen impregnation of chlorhexidine and chlorhexidine acetate when infused with 82 various parenteral drugs tested for compatibility.⁵⁴

In vivo

Antimicrobial activity associated with the ARROWg^{ard} Blue PLUS[®] antimicrobial catheter has been demonstrated *in vivo* in the following ways:

- After 7 days subcutaneous implantation in a rabbit animal model, residual antimicrobial activity (greater than 10 mm in diameter) was demonstrated against *Staphylococcus aureus* using the modified Kirby-Bauer technique.⁴⁶

- After subcutaneous inoculation in a rabbit animal model, a significant decrease in the amount of bacterial colonization of *Staphylococcus aureus* to the external surface of the catheter has been demonstrated in limited animal studies.⁴⁶
- After removal of subcutaneously implanted catheter segments from a rabbit model, the *in vivo* half-life was found to persist beyond 7 days.⁴⁶

Clinical Evaluations:

Current Ongoing Clinical Investigation:

A multi-center, double-blind, randomized clinical study is being performed at nine hospitals across the United States. Patients are excluded from the study if they have a known hypersensitivity to chlorhexidine, silver sulfadiazine, and/or any other sulfa drugs. As of September 2000, there have been no reports of any unanticipated adverse device events, nor are there any reports of anaphylaxis/hypersensitivity to the ARROWg^{ard} Blue PLUS[®] antimicrobial catheters.

Prior Clinical Investigations:

Clinical study: The following clinical study was conducted on the **original** ARROWg^{ard} Blue[®] catheter at the University of Wisconsin³¹:

- A prospective, randomized, controlled clinical trial of 403 catheter insertions in 158 adult patients in a medical-surgical ICU showed that the **original** ARROWg^{ard} Blue[®] catheters were 50% less likely to be colonized at removal than the control catheters (13.5 compared to 24.1 colonized catheters per 100 catheters, p=0.005) and were 80% less likely to produce a bloodstream infection (1.0 compared to 4.7 infections per 100 catheters; 1.6 compared to 7.6 infections per 1000 catheter days, p=0.03).
- No adverse effects were seen from the antimicrobial catheter, and none of the isolates obtained from infected catheters in either group showed *in vitro* resistance to chlorhexidine or silver sulfadiazine.

Meta-analysis: The following meta-analysis was performed on the **original** ARROWg^{ard} Blue[®] catheter⁵⁸:

- An independent review of 11 randomized clinical trials on the **original** ARROWg^{ard} Blue[®] antimicrobial catheters (MEDLINE search from January 1966 to January 1998) concluded that central venous catheters impregnated with a combination of chlorhexidine acetate and silver sulfadiazine are effective in reducing the incidence of both catheter colonization and catheter-related bloodstream infections in patients at high risk for catheter-related infections.

Warnings and Precautions:

1. **Warning: Chlorhexidine-containing compounds have been used as topical disinfectants since the mid-1970's. An effective antimicrobial agent, chlorhexidine found use in many antiseptic skin creams, mouth rinses, and disinfectants used to prepare the skin for surgical procedures. In addition, chlorhexidine has been incorporated into cosmetic products where it reportedly functions as a cosmetic biocide. In the early 1990's, the FDA cleared three types of medical devices containing chlorhexidine: intravenous catheters, topical antimicrobial skin dressings, and an implanted surgical mesh.¹⁸**

Since its introduction in 1990, the **original** ARROWg^{ard} Blue[®] antimicrobial catheter has been reported to cause severe hypersensitivity reactions in a limited number of patients in Japan and the UK (first

case reported May 1996). There have been no reported incidents of hypersensitivity in the United States. The vast majority of these episodes have been endemic to individuals of Japanese extraction living in Japan. The literature indicates that individuals of Japanese extraction are known to have had similar hypersensitive reactions following topical chlorhexidine administration.^{19,21,28,29,39,40,50,55} If adverse reactions occur after catheter placement, remove catheter immediately.

Sensitivity reactions to the ARROWgard® products can be very serious and even life-threatening, but they are also very rare. Since the introduction of the original ARROWgard Blue® antimicrobial catheter in 1990, the worldwide reported incident rate due to hypersensitivity reactions is 0.0004% with a confirmed incident rate of 0.00015%.¹⁵

2. **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.
3. **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.
4. **Warning:** Do not apply excessive force in removing guide wire or catheter. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.
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:** Passage of the guide wire into the right heart can cause dysrhythmias, right bundle branch block,¹⁵ and a perforation of the vessel wall, atrial or ventricular.
7. **Warning:** Practitioners must be aware of the potential for entrapment of guide wire by any implanted 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 the length of spring-wire guide inserted.² It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to minimize the risk of guidewire entrapment.
8. **Warning:** This kit is designed to reduce the risk of accidental needle and sharps related sticks. Care must still be taken to minimize the risk of sharps injury. Clinicians must adhere to state/federal OSHA standards

for blood borne pathogens when starting, discontinuing, or maintaining a central venous catheter to minimize the risk of exposure.

9. **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.
10. **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. Acetone may be applied to skin but must be allowed to dry completely prior to applying dressing.
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.
11. **Precaution:** Some disinfectants used at the catheter insertion site contain solvents, which can attack the catheter material. Assure insertion site is dry before dressing.
12. **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.
13. **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.
14. **Precaution:** For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.
15. **Precaution:** Use of a syringe smaller than 10 ml to irrigate or declot an occluded catheter may cause intraluminal leakage or catheter rupture.¹³
16. **Precaution:** Properly dispose of sharps in sharps container in accordance with state/federal OSHA standards for blood borne pathogens and/or institutional policy.

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). A SharpsAway II™ Locking Disposal Cup is used for the disposal of needles. Firmly push needles into disposal cup holes (refer to Fig. 2). Once placed into disposal cup, needles will be automatically secure in place so that they can not be reused. Discard entire cup at completion of procedure. **Precaution:** Do not attempt to remove needles that have been placed into cup. These needles are permanently secured in place. Damage may occur to needle if it is forced out of disposal cup.

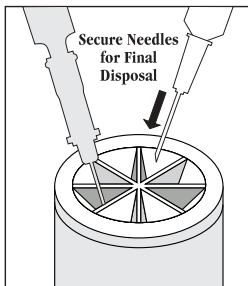


Fig. 2

Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use. **Precaution: The color of the blood aspirated is not always a reliable indicator of venous access.²⁴ Do not reinsert needle into introducer catheter.** 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 catheter to alter length.**

Arrow UserGard® Needle-Free Injection Hub Instructions for Use: (Where provided)

- 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. 3).

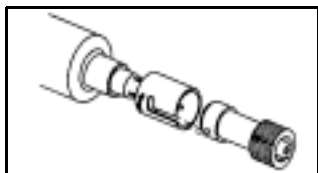


Fig. 3

- Inject or withdraw fluid as required.
 - Disengage UserGard® hub from injection site and discard. **Warning: To prevent 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. locater needle and syringe.) Remove locater 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.²⁴ 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. 4).

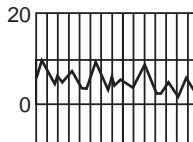


Fig. 4

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.

7. 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 Arrow Advancer™ (refer to Figs. 5, 6).

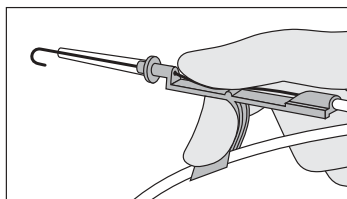


Fig. 5

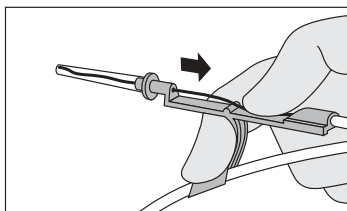


Fig. 6

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 Arrow Advancer™ – with “J” retracted – into the hole in the rear of the Raulerson Syringe plunger (refer to Fig. 7).

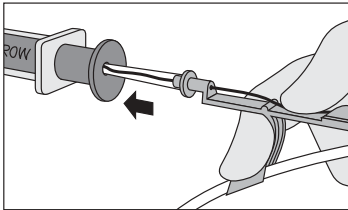


Fig. 7

- Advance spring-wire guide into the syringe approximately 10 cm until it passes through the syringe valves (refer to Fig. 8).

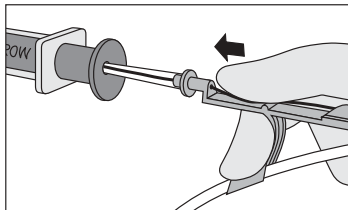


Fig. 8

- Raise your thumb and pull the Arrow Advancer™ approximately 4 cm to 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. 9).

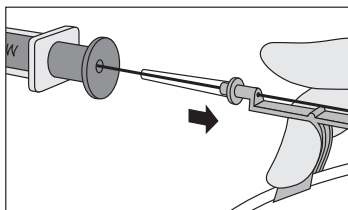


Fig. 9

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.

- 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.**
- 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.
- Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution: Do not cut guide wire. Retract scalpel in the protected position (refer to Fig. 10).** Use tissue dilator to enlarge site as required. **Warning: Do not leave tissue dilator in place as an indwelling catheter to minimize the risk of possible vessel wall perforation.**

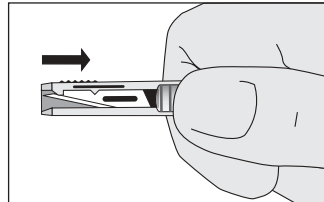


Fig. 10

- 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. **Precaution: Catheter clamp and fastener must not be attached to catheter until spring-wire guide is removed.**
- 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.
- 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. 11).



Fig. 11

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. 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 using staple anchoring device, sutures, or StatLock® anchoring device (where provided). Use triangular juncture hub with 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 staple directly to the outside diameter of the catheter to minimize the risk of cutting or damaging the catheter or impeding catheter flow.** Dress insertion site according to hospital protocol.

Staple Anchoring Device Instructions (where provided):

- Position thumb and index finger of dominant hand on indented surface of staple anchoring device.
- Pass staple point through eye of catheter suture hub (refer to Fig. 12).

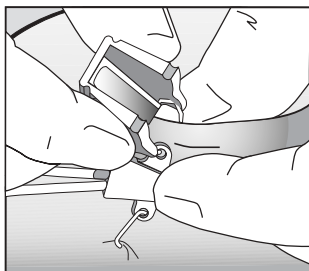


Fig. 12

- Tent skin and position with hub eye between staple opening. **Precaution: Do not place staple over catheter body or extension lines except at indicated anchoring location to minimize the risk of damage to catheter.**
- Firmly squeeze anchoring device together to close staple and secure catheter to skin (refer to Fig. 13).

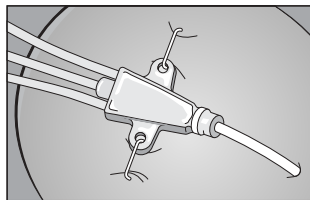


Fig. 13

- Repeat procedure through other suture eyes, if applicable. Discard anchoring device upon completion.

**Catheter Clamp and Fastener (where provided)
Instructions for Use:**

- After spring-wire guide has been removed and the necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter, as required, to ensure proper tip location (refer to Fig. 14).

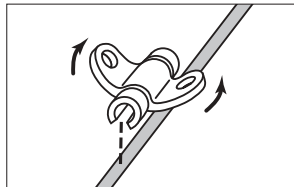


Fig. 14

- Snap rigid fastener onto catheter clamp (refer to Fig. 15).

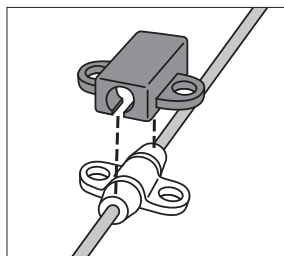


Fig. 15

- Secure catheter to patient by stapling or suturing the catheter clamp and fastener to the skin, using side wings to minimize the risk of catheter migration (refer to Fig. 16).

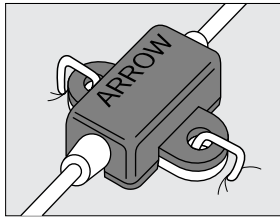


Fig. 16

19. 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, resecure, and re-verify.
20. Dress puncture site per hospital protocol. **Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique.**
21. 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: Prior to attempting a catheter exchange procedure, remove catheter clamp and fastener (where provided).**
3. 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 catheter, do not use scissors to remove dressing.**
3. **Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.** Using staple remover, remove staple(s) from catheter clamp, where applicable, and primary suture site. 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.^{26,41,44,51}
4. Upon removal of the catheter, inspect it to make sure that the entire length has been withdrawn.
5. Document removal procedure.

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