

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

# ARROW®

## MAC™ Multi-Lumen Central Venous Access Product with ARROWgärd® Antimicrobial Surface and 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 access device 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.

MAC Multi-Lumen Access Catheters should be maintained in closely monitored environments (eg., critical care unit, operating room, recovery room), not on general nursing units.<sup>29</sup>

**Precaution: When using Central Venous Catheterization Product with Contamination Guard for use only with MAC™ Multi-Lumen Central Venous Access Device (MAC™ companion product), clinicians must be aware of the potential complication of Cardiac Tamponade (see complications warning included in all Arrow Central Venous Catheter Products) (refer to Fig. 1).**

The nominal amount of chlorhexidine, silver, and sulfadiazine applied to the external surface of the MAC™ Multi-Lumen Central Venous Access Device is 208 µg/cm, 31 µg/cm and 73 µg/cm, respectively.

To demonstrate effectiveness of the ARROWgärd® antimicrobial surface treatment, data were submitted to FDA on Arrow's 14 Fr. hemodialysis catheter, a device with identical external dimensions to the MAC™ Multi-Lumen Access Device. Sample results of chlorhexidine acetate, silver and sulfadiazine from a hemodialysis catheter containing identical external dimensions are 208 µg/cm, 40 µg/cm, and 85 µg/cm respectively. Antimicrobial activity associated with ARROWgärd Blue® on catheters and/or access devices has been demonstrated in the following ways:

### 14 Fr. Catheter *In Vitro* Results:

Antimicrobial activity associated with the ARROWgärd Blue® hemodialysis catheter has been demonstrated *in vitro* using a modified Kirby-Bauer technique utilizing the vertical catheter segment placement method, in the following ways:

- ARROWgärd Blue® hemodialysis catheters produced zones of inhibition greater than 9 mm in diameter after 24 hours against:<sup>30</sup>

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

- ARROWgärd Blue® hemodialysis catheters retained antimicrobial activity (zones of inhibition greater than 5 mm in diameter) after 7 days against:<sup>30</sup>

*Staphylococcus aureus (methicillin resistant)\**  
*Staphylococcus epidermidis*  
*Streptococcus pyogenes*  
*Klebsiella pneumoniae*  
*Xanthomonas maltophilia*  
*Escherichia coli (β-lactamase producer)*  
*Enterobacter faecalis*  
*Enterobacter cloacae*

\* **Note:** This is not the prevalent strain in catheter-related infections.

- Marked decreases in antimicrobial activity against all organisms are apparent at Day 7 of *in vitro* analysis.

### Clinical Efficacy:

Antimicrobial activity data associated with the ARROWgärd Blue® catheter have not been collected with the MAC™ Multi-Lumen Central Venous Access Device.

The following clinical study was conducted on the original formulation 7 Fr. and 12 Fr. ARROWgärd Blue® central venous catheters.

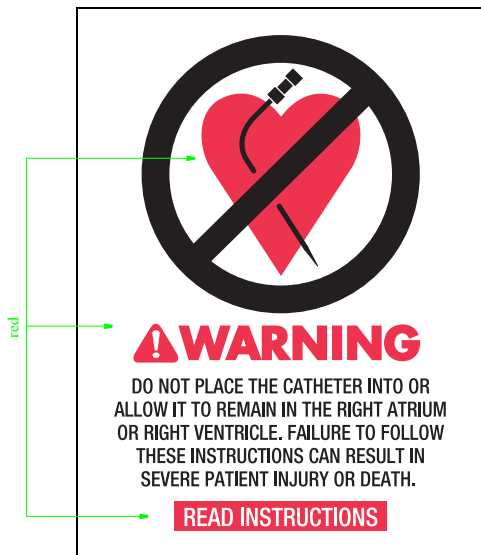


Fig. 1

**ARROWgärd® Antimicrobial Surface:** The Arrow® antimicrobial access device consists of our polyurethane access device, plus our ARROWgärd Blue® exterior antimicrobial surface treatment of chlorhexidine acetate and silver sulfadiazine.

- A prospective, randomized, controlled clinical trial of 237 large-bore and central venous catheter insertions in 115 patients demonstrated that catheter-related bloodstream infections rates were 1.14/1000 catheter days for ARROWgärd Blue® catheters versus 3.95/1000 catheter days for nonimpregnated catheters (p=0.31).<sup>9</sup>

The following clinical study was conducted on the original formulation 7 Fr. triple-lumen ARROWgärd Blue® catheter.

- A prospective, randomized, controlled clinical trial of 403 central venous catheter insertions in 158 adult patients in a medical-surgical ICU showed that ARROWgärd 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).<sup>27</sup>
- 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.<sup>27</sup>
- Complete data were obtained for 403 central venous 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.<sup>27</sup>

The following clinical study was conducted on the original formulation 7 Fr. triple-lumen ARROWgärd Blue® catheter.

- The ARROWgärd Blue® catheter has demonstrated a significant decrease in the rate of bacterial colonization along the catheter in limited animal studies.<sup>15</sup>
- An independent review of 11 randomized clinical trials on the ARROWgärd 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.<sup>42</sup>

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.<sup>11</sup>

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.<sup>11</sup>

The reported incident rate as of June, 2001 for sulfa sensitivity reactions was 1 in over 7,000,000 ARROWgärd® devices used worldwide.

## Indications for Use:

The MAC™ Multi-Lumen Central Venous Access Device with ARROWgärd Blue® permits venous access and catheter introduction to the central circulation. It may be inserted into the jugular, subclavian, or femoral veins. The ARROWgärd® technology is intended to help provide protection against catheter-related infections. Clinical data have not been collected that demonstrate the use of the ARROWgärd® antimicrobial surface in decreasing catheter-related infections for this device. It is not intended to be used as a treatment for existing infections, nor is it indicated for long-term use.

## Contraindications:

The ARROWgärd Blue® antimicrobial catheter is contraindicated for patients with known hypersensitivity to chlorhexidine acetate, silver sulfadiazine, and/or sulfa drugs.

Hypersensitivity reactions are a concern with antimicrobial catheters, in that they can be very serious and even life-threatening. The ARROWgärd Blue® antimicrobial catheter was introduced worldwide in 1990, and six years elapsed before the first hypersensitivity reaction was reported in Japan in May 1996.<sup>11</sup>

To date (August 2003) the ARROWgärd Blue® reported incident rate has been extremely low, at 1 per 503,081 exposures, and the skin test confirmed rate is even lower, at 1 per 1,446,360 exposures. The vast majority of these episodes (17) 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.<sup>13,18,24,25,33,34,38,41</sup> Three (3) incidents have been reported in the UK, two (2) in the USA, and one (1) in New Zealand. **If adverse reactions occur after catheter placement, remove catheter immediately.**

## Special Patient Populations:

Controlled studies of the antimicrobial catheter have not been conducted in pregnant women,<sup>31</sup> pediatric or neonatal patients and patients with known sulfonamide hypersensitivity, erythema multiforme, Stevens-Johnson syndrome,<sup>12</sup> and glucose-6-phosphate dehydrogenase deficiency. The benefits of the use of this catheter should be weighed against any possible risk.

## 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.<sup>11</sup>**

Hypersensitivity reactions are a concern with antimicrobial catheters, in that they can be very serious and even life-threatening. The ARROWgärd Blue® antimicrobial catheter was introduced worldwide in 1990, and six years elapsed before the first hypersensitivity reaction was reported in Japan in May 1996.<sup>43</sup>

To date (August 2003) the ARROWgärd Blue® reported incident rate has been extremely low, at 1 per 503,081 exposures, and the skin test confirmed rate is even lower, at 1 per 1,446,360 exposures. The vast majority of these episodes (17) 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.<sup>13,18,24,25,33,34,38,41</sup>

Three (3) incidents have been reported in the UK, two (2) in the USA, and one (1) in New Zealand. If adverse reactions occur after catheter placement, remove catheter immediately.

2. **Warning:** Practitioners must be aware of complications associated with percutaneous access device introduction including vessel wall perforation,<sup>37</sup> pleural and mediastinal injuries,<sup>1,26</sup> air embolism,<sup>7,17,22,29</sup> sheath embolism, thoracic duct laceration,<sup>4</sup> bacteremia, septicemia, thrombosis,<sup>5</sup> inadvertent arterial puncture,<sup>8</sup> nerve damage, hematoma, hemorrhage,<sup>6</sup> dysrhythmias, and occlusion.
3. **Precaution:** Promptly remove any intravascular catheter that is no longer essential.<sup>16</sup> Evaluate the need for large-bore venous access against the patient's current therapy requirements. Should this device be used for continued venous access, maintain distal lumen sideport patency with KVO (Keep Vein Open) LV. rate as per hospital protocol.
4. **Warning:** Do not apply excessive force in removing guide wire, dilator or access device. 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, sheaths, or catheters in 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 for all sheath and side port maintenance.
6. **Warning:** Hemostasis valve must be occluded at all times to minimize the risk of air embolism or hemorrhage. If catheter introduction is delayed, or catheter is removed, temporarily cover valve opening with sterile-gloved finger until catheter or obturator is inserted. Use Arrow® obturator, either included with this product or sold separately, as dummy catheter with hemostasis valve assembly. This will ensure that leakage does not occur and inner seal is protected from contamination.<sup>26</sup>
7. **Warning:** Passage of the guide wire into the right heart can cause dysrhythmias, right bundle branch block,<sup>10</sup> and a perforation of the vessel wall, atrial or ventricular.
8. **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. 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.<sup>3</sup>
9. **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.
10. **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.

11. **Precaution:** For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.
12. **Precaution:** Do not suture directly to the outside diameter of access device to minimize the risk of cutting or damaging device or impeding device flow.
13. **Precaution:** Indwelling access devices should be routinely inspected for desired flow rate, security of dressing, correct position and for proper Luer-Lock connection.
14. **Precaution:** Maintain the insertion site with regular meticulous redressing using aseptic technique.
15. **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 access device 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 access device surface or to restore patency. Care should be taken when instilling drugs containing high concentration of alcohol. Always allow alcohol to dry completely prior to applying dressing.
16. **Precaution:** Some disinfectants used at the access device insertion site contain solvents, which can attack the catheter material. Assure insertion site is dry before dressing.
17. **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 area of anticipated venipuncture.
3. Drape puncture site as required.
4. Perform skin wheal with desired needle (25 Ga. or 22 Ga. needle). In kits where provided, the SharpsAway IIT™ Locking Disposal Cup is used for the disposal of needles. (15 Ga. - 30 Ga.)
  - Using one-handed technique, firmly push needles into disposal cup holes (refer to Fig. 2)

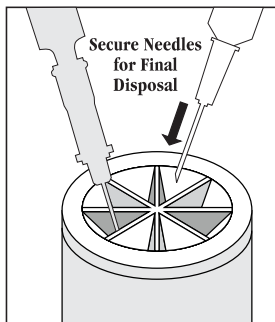


Fig. 2

- Once placed into disposal cup, needles will be automatically secured in place so that they cannot be reused.

- Discard entire cup, at completion of procedure, into an approved sharps container.

**Precaution: Do not attempt to remove needles that have been placed into cup. These needles are secured in place. Damage may occur to needles if they are forced out of disposal cup.**

5. Prepare flow-directed catheter according to manufacturer's instructions. Wet balloon with flush solution to facilitate passage through valve of catheter contamination shield. **Precaution: Do not inflate balloon prior to insertion through catheter contamination shield to minimize the risk of balloon damage.**
6. Ensure that double TwistLock™ of catheter contamination shield is fully opened (refer to Fig. 3).

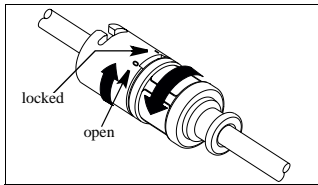


Fig. 3

Insert tip of desired catheter through proximal end of catheter contamination shield. Advance catheter through tubing and hub at other end (refer to Fig. 4).

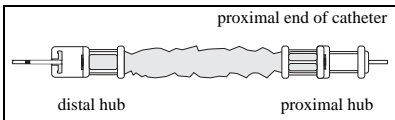


Fig. 4

7. Slide entire catheter contamination shield to proximal end of catheter.
8. If flow directed catheter is used, inflate and deflate balloon with syringe to ensure integrity. **Precaution: Do not exceed balloon catheter manufacturer's recommended volume.** Place catheter and catheter contamination shield on sterile field awaiting final placement.
9. Insert entire length of dilator through hemostasis valve into access device pressing hub of dilator firmly into hub of hemostasis valve assembly. Place assembly on sterile field awaiting final placement.
10. 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.<sup>20</sup> Do not reinsert needle into introducer catheter.**

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. 5).

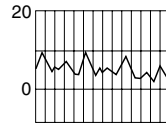


Fig. 5

#### 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. **Precaution: The color of the blood aspirated is not always a reliable indicator of venous access.<sup>20</sup>**

12. 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.**

#### Two-Piece Arrow Advancer™ Instructions:

- Using your thumb, straighten the “J” by retracting the spring-wire guide into the Arrow Advancer™ (refer to Figs. 6, 7).

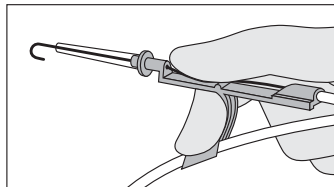


Fig. 6

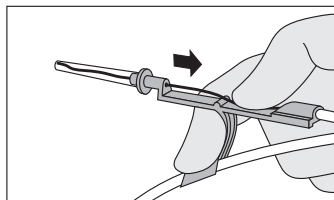


Fig. 7

When the tip is straightened, the spring-wire guide is ready for insertion. Centimeter marks 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 Arrow® Raulerson syringe plunger (refer to Fig. 8).

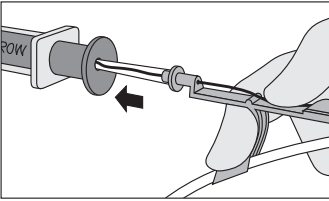


Fig. 8

- Advance spring-wire guide into the syringe approximately 10 cm until it passes through the syringe valves (refer to Fig. 9).

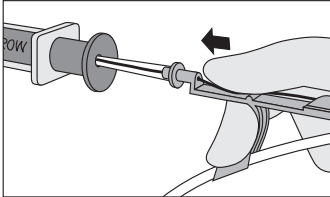


Fig. 9

- 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. 10).

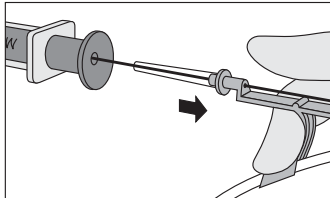


Fig. 10

#### 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.

13. Advance the 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.**
14. 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.** Use centimeter markings on spring-wire guide to adjust indwelling length according to desired depth of indwelling access device placement.

15. 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, when applicable (refer to Fig. 11).** 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.**

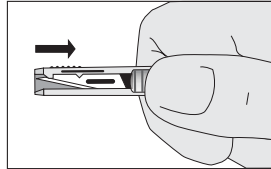


Fig. 11

16. Thread tapered tip of dilator/access device assembly over spring-wire guide. Grasping near skin, advance assembly with slight twisting motion to a depth sufficient to enter vessel. Dilator may be partially withdrawn to facilitate advancement of access device through tortuous vessel. **Precaution: Do not withdraw dilator until the access device is well within the vessel to minimize the risk of damaging tip.**
17. Advance access device assembly off dilator into vessel, again grasping near skin and using slight twisting motion.
18. To check for proper access device placement within the vessel, attach syringe to distal side port for aspiration. Hold access device assembly in place and withdraw spring-wire guide and dilator sufficiently to allow venous blood flow to be aspirated into distal side port. **Precaution: Maintain firm grip on spring-wire guide at all times.**
19. Holding access device assembly in place, remove guide wire and dilator as a unit. Place sterile-gloved finger over hemostasis valve. **Warning: To minimize the risk of possible vessel wall perforation do not leave tissue dilator in place as an indwelling catheter. Warning: 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. Flush and connect distal side port to appropriate line as necessary. Confirm and monitor proximal port by aspirating until free flow of venous blood is observed. Connect all extension lines 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 extension lines to occlude flow through each lumen during line and injection cap changes. **Precaution: To minimize the risk of damage to extension lines from excessive pressure, each clamp must be opened prior to infusing through that lumen.****
20. Feed catheter through access device assembly into vessel. Advance catheter to desired position. **Warning: Hemostasis valve must be occluded at all times to minimize the risk of air embolism or hemorrhage. If catheter introduction is delayed, temporarily cover valve opening with sterile-gloved finger until obturator is inserted. Use Arrow® obturator, either included with this product or sold separately, as dummy catheter with hemostasis valve assembly. This will ensure that leakage does not occur and inner seal is protected from contamination.<sup>29</sup>**

21. Hold access device in place and reposition catheter contamination shield so that distal hub is approximately five inches (12.7 cm) from hemostasis valve (refer to Fig. 12).

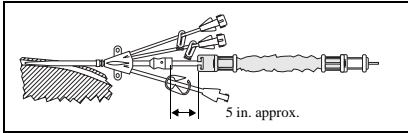


Fig. 12

22. Hold proximal hub of catheter contamination shield in place. Disengage distal hub from inner feed tube by pulling forward. Advance distal hub forward toward hemostasis valve/side port assembly. Hold assembly in place (refer to Fig. 13).

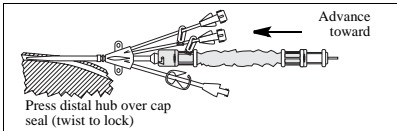


Fig. 13

23. Press distal hub of catheter contamination shield over assembly cap. Twist to lock (refer to Fig. 14).

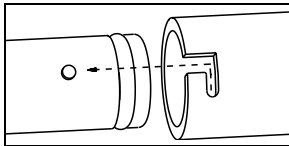


Fig. 14

- Orient slot in hub with locking pin on assembly cap.
- Slide hub forward over cap and twist.

24. While maintaining catheter position, twist the upper half of the distal hub in clockwise direction to lock catheter in place. Reposition proximal end of catheter shield as desired. Twist upper and lower halves in opposite directions to lock in place. Test the adapter by gently tugging on the catheter to ensure a secure grip on the catheter (refer to Fig. 15). **Precaution: Do not reposition proximal hub once locked in final position.**

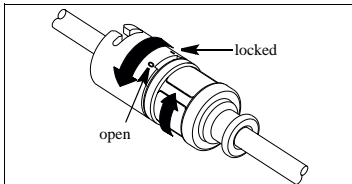


Fig. 15

25. In kits where provided, secure access device to patient using staple anchoring device or suture per hospital/agency protocol. Use triangular juncture hub with side wings as primary anchoring site. **Precaution: Do not staple or suture directly to the outside diameter of access device to minimize the risk of cutting or damaging access device or impeding flow.**

### Staple Anchoring Device Instructions:

- Position thumb and index finger of dominant hand on indented surface of staple anchoring device.
- Pass staple point through eye of access device suture hub (refer to Fig. 16).

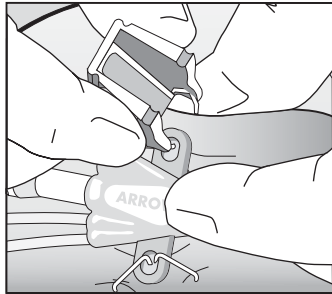


Fig. 16

- Tent skin and position with hub eye between staple opening. **Precaution: Do not place staple over access device body or extension lines except at indicated anchoring location to minimize the risk of damage to access device.**
- Firmly squeeze anchoring device together to close staple and secure access device to skin (refer to Fig. 17).

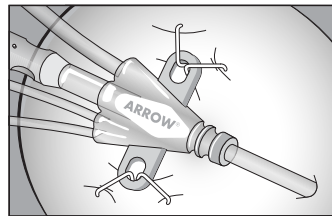


Fig. 17

- Repeat procedure through other suture eyes, if applicable. Discard anchoring device upon completion.
26. Dress puncture site per hospital protocol. **Precaution: Maintain the insertion site with regular, meticulous redressing using aseptic technique.**
  27. Record the insertion procedure on the patient's chart.

### Catheter Removal Procedure:

1. **Precaution: Place the patient in a supine position.**
2. Remove dressing, if applicable. **Precaution: To minimize the risk of cutting the access device, do not use scissors to remove the dressing.**
3. Twist distal hub of catheter contamination shield to allow removal from locking pin on hemostasis valve assembly. Withdraw catheter from valve. **Warning: Hemostasis valve must be occluded at all times to minimize the risk of air embolism or hemorrhage.** Temporarily cover valve opening with sterile-gloved finger until catheter or obturator is inserted.

## Access Device Removal Procedure:

1. **Precaution: Promptly remove any intravascular catheter that is no longer essential.<sup>16</sup> Evaluate the need for large-bore venous access against the patient's current therapy requirements. Should this device be used for continued venous access, maintain distal lumen sideport patency with KVO (Keep Vein Open) LV. rate as per hospital protocol.**
2. **Precaution: Place the patient in a supine position.**
3. Remove dressing, if applicable. **Precaution: To minimize the risk of cutting the access device, do not use scissors to remove the dressing.**
4. Using staple remover, remove staple(s), where applicable, or remove sutures from primary anchoring site.
5. Withdraw device from hemostasis valve. Cover hemostasis valve with sterile-gloved finger. **Warning: Hemostasis valve must be occluded at all times to minimize the risk of air embolism or hemorrhage.**
6. **Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.** Remove access device slowly, pulling it parallel to the skin. As access device exits the site, apply pressure with a dressing impermeable to air, e.g. Vaseline<sup>®</sup> gauze. Because the residual access device 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 access device was indwelling.<sup>22,34,36,39</sup>
7. Upon removal of the access device, inspect it to make sure that the entire length has been withdrawn.
8. Document removal procedure.

## References:

1. Albertson TE, Fisher CJ, Vera Z. Accidental mediastinal entry via left internal jugular vein cannulation. *Intensive Care Med.* 1985;11:154-157.
2. Allgeyer DO, Herr GP, Szeftel A, Shapiro SM, et al. Evaluation of a Sharps Safety-Enhanced Device for Skin Fixation of Central Venous Catheters. *Anesthesiology.* 93(3A);2000:A-593.
3. Andrews RT, Bova DA, Venbrux AC. How much guidewire is too much? Direct measurement of the distance from subclavian and internal jugular vein access sites to the superior vena cava-atrial junction during central venous catheter placement. *Crit Care Med.* Jan. 2000;28:138-142.
4. Arditis J, Giala M, Anagnostidou A. Accidental puncture of the right lymphatic duct during pulmonary artery catheterization. *Acta Anaesthesiol Scand.* 1988;32:67-68.
5. Benumof JL. Thrombosis after pulmonary-artery catheterization via the internal jugular vein. *NEJM.* 1982;306:1487. Letter.
6. Benya RV. Fibrin sheath formation surrounding a pulmonary artery catheter sheath: eversion of the sleeve during catheter removal. *Crit Care Med.* 1990;18:345. Letter.
7. Bristow A, Batjer H, Chow V, Rosenstein J. Air embolism via a pulmonary artery catheter introducer. *Anesthesiology.* 1985;63:340-341. Letter.
8. Brzowski BK, Mills JL, Beckett WC. Iatrogenic subclavian artery pseudoaneurysms: case reports. *J Trauma.* 1990;30:616-618.
9. Collin GR. Decreasing Catheter Colonization Through the Use of an Antiseptic-Impregnated Catheter. *Chest* June 1999;115:1632-1640.

10. Eissa NT, Kvetan V. Guide wire as a cause of complete heart block in patients with preexisting left bundle branch block. *Anesthesiology.* 1990;73:772-774.
11. Farber T. ARROWg<sup>®</sup>ard™ antiseptic surface toxicology review. Monograph. Published by Arrow International, Inc. April, 1992.
12. FDA Public Health Notice. Potential hypersensitivity reactions to chlorhexidine-impregnated medical devices. Food and Drug Administration Web site. Available at: <http://www.fda.gov/cdrh/chlorhex.html>. Accessed October 26, 1999.
13. Fukui A, Ohsumi A, Takaori M. A case of anaphylactic shock induced by chlorhexidine gluconate. *J Japan Society Clin Anesthesia.* 1989;9:356-360.
14. Greene ES, Berry AJ, Jagger J, Hanley E, et al. Multicenter Study of Contaminated Percutaneous Injuries in Anesthesia Personnel. *Anesthesiology.* 1998;89:1362-72.
15. Greenfield JI, Sampath L, Popilskis SJ, et al. Decreased Bacterial Adherence and biofilm formation on chlorhexidine and silver sulfadiazine-impregnated central venous catheters implanted in swine. *Crit Care Med.* 1995;23:894-900.
16. Guidelines for the Prevention of Intravascular Catheter Related Infections. CDC. 2002;51(RR10;1-26).
17. Hartung EJ, Ender J, Sgouroupolou S, Bierl R, Engelhardt W, Engemann R. Severe air embolism caused by a pulmonary artery introducer sheath. *Anesthesiology.* 1994;80:1402. Letter.
18. Harukuni I, Ishizawa Y, Nishikawa T, Takeshima R, Dohi S, Naito H. Anaphylactic shock with ventricular fibrillation induced by chlorhexidine. *Japanese J Anesthesiology.* 1992;41:455-459.
19. Hightower D, March J, Ausband S, Lawrence BH. Comparison of Staples vs Suturing for Securing Central Venous Catheters. *Acad. Emerg. Med.* 1996;3:1103-1105.
20. Jobs DR, Schwartz AJ, Greenhow DE, Stephenson LW, Ellison N. Safer jugular vein cannulation: recognition of arterial punctures and preferential use of the external jugular route. *Anesthesiology.* 1983;59:353-355.
21. Kanegaye JT, Vance CW, Chan L, Schonfeld N. Comparison of skin stapling devices and standard sutures for pediatric scalp lacerations: A randomized study of cost and time benefits. *The Journal of Pediatrics.* 1996;130:808-13.
22. Kashuk JL, Penn I. Air embolism after central venous catheterization. *Surg Gynecol Obstet.* September 1984;159:249-252.
23. Kondo K, O'Reilly LP, Chiota J. Air embolism associated with an introducer for pulmonary arterial catheters. *Anesth Analg.* 1984;63:871-872.
24. Kubo H, Akiyama Y, Honda K, Nakajo N. Anaphylaxis following oral irrigation with chlorhexidine gluconate. *J Japanese Dental Society Anesthesiology.* 1985;13:659-663.
25. Layton GT, Stanworth DR, Amos HE. The incidence of IgE and IgG antibodies to chlorhexidine. *Clin Experimental Allergy.* 1989;19:307-314.
26. Macksood MJ, Setter M. Hydrothorax and hydromediastinum after use of an indwelling percutaneous catheter introducer. *Crit Care Med.* 1983;11:957-958.
27. Maki DG, Wheeler SJ, Stolz SM, Mermel LA. Clinical trial of a novel antiseptic-coated central venous catheter. Abstract of paper presented at 31st ICAAC Clinical Infections, Chicago, October 1, 1991.

28. Maki DG, Wheeler SJ, Stolz SM, Mermel LA. Prevention of central venous catheter-related bloodstream infection by use of an antiseptic-impregnated catheter. *Ann Int Med.* August 15, 1997;127:257-266.
  29. Mihm FG, Rosenthal MH. Pulmonary artery catheterization. In: Benumof JL, ed. *Clinical Procedures in Anesthesia and Intensive Care.* Philadelphia, PA: JB Lippincott; 1992:419.
  30. Modak SM, Sampath L. Development and evaluation of a new polyurethane central venous antiseptic catheter: reducing central venous catheter infections. *Infections in Medicine.* June 1992;23-29.
  31. Modak SM. (Written communication, June 1991).
  32. Occupational Exposure to Bloodborne Pathogens; Needlestick and Other Sharps Injuries. 66 Federal Register 5317 (2001)(Codified at 29 CFR-1910.1030).
  33. Okano M, Nomura, Hata S, et al. Anaphylactic symptoms due to chlorhexidine gluconate. *Arch Dermatol.* 1989;125:50-52.
  34. Okano M, Nomura M, Okada N, Sato K, Tashiro M. Four cases presenting anaphylactic reactions due to topical application of Hibitane®. *Skin Research.* 1983;25:587-592.
  35. Paskin DL, Hoffman WS, Tuddenham WJ. A new complication of subclavian vein catheterization. *Ann Surg.* March 1974;179:266-268.
  36. Phifer TJ, Bridges M, Conrad SA. The residual central venous catheter track – an occult source of lethal air embolism: case report. *J Trauma.* 1991;31:1558-1560.
  37. Roy RC. Possible hazards from catheter sheath introducers. *Crit Care Med.* 1984;12:616. Letter.
  38. Takeda K, Inoue K, Matsuya T, et al. An allergic shock possibly induced by the chlorhexidine; report of a case. *J Osaka Univ Dent Soc.* 1985;30:221-225.
  39. Thielen JB, Nyquist J. Subclavian catheter removal. *J Intravenous Nurs.* March/April 1991;14:114-118.
  40. Tomkins DP, Van Der Walt JH. Needleless and Sharp-Free Anaesthesia. *Anaesthesia and Intensive Care.* 1996;24:164-7.
  41. Tsuneto S, Watanabe S, Koyama K, Nakayama K, Saito H, Saito K. Anaphylactic shock induced by chlorhexidine mixed in the vial of lidocaine. *J Japan Society Clin Anesthesia.* 1987;7:272-277.
  42. Veenstra DL, Saint S, Saha S, et al. Efficacy of Antiseptic – impregnated central venous catheters in preventing catheter-related bloodstream infection, A meta – analysis. *JAMA.* 1999;281:261-267.
  43. Data on file, Arrow International, Inc.
- 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.
- †Vaseline is a registered trademark of Chesebrough-Ponds Inc.

**ARROW**<sup>®</sup>  
INTERNATIONAL

2400 Bernville Road  
Reading, PA 19605 USA  
1-800-523-8446  
1-610-378-0131  
8 a.m. - 8 p.m. EST