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 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 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.[19]

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).

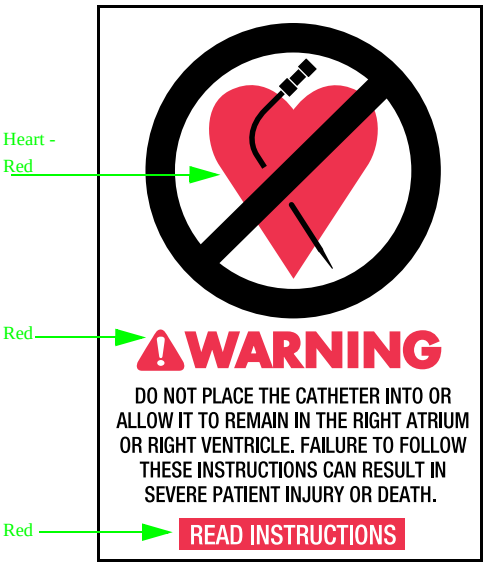

Fig. 1

Indications for Use:

The MAC™ Multi-Lumen Central Venous Access Product permits venous access and catheter introduction to the central circulation.

Contraindications:

None known.

Warnings and Precautions:*

1. **Warning: Practitioners must be aware of complications associated with percutaneous catheter introduction including vessel wall perforation,[22] pleural and mediastinal injuries,[2,17] air embolism,[7,12,16,18] sheath embolism, thoracic duct laceration,[4] bacteremia, septicemia, thrombosis,[5] inadvertent arterial puncture,[8] nerve damage, hematoma, hemorrhage,[6] dysrhythmias and occlusion.**
2. **Precaution: Promptly remove any intravascular catheter that is no longer essential.[11] 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) I.V. rate as per hospital protocol.**
3. **Warning: Do not apply excessive force in removing guide wire, dilator or catheter. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.**
4. **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.**
5. **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.[18]**
6. **Warning: Passage of the guide wire into the right heart can cause dysrhythmias, right bundle branch block,[9] 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. 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[3].

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: For blood sampling, temporarily shut off remaining port(s) through which solutions are being infused.**
11. **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.**
12. **Precaution: Indwelling catheters should be routinely inspected for desired flow rate, security of dressing, correct position and for proper Luer-Lock connection.**
13. **Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique.**
14. **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.
15. **Precaution: Some disinfectants used at the catheter insertion site contain solvents, which can attack the catheter material. Assure insertion site is dry before dressing.**
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). In kits where provided, the SharpsAway II™ 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).

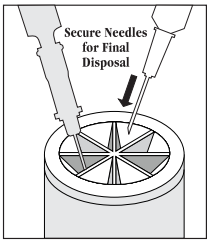

Fig. 2

   - Once placed into the disposal cup, needles will be automatically secure in place so that they cannot be reused.
   - Discard the entire cup, at completion of the procedure, into an approved sharps container

   Precaution: Do not attempt to remove needles that have been placed into cup. These needles are permanently secured in place. Damage may occur to the needle if it is forced out of the disposal cup.
4. 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**.
5. Ensure that double TwistLock™ of catheter contamination shield is fully opened (refer to Fig. 3).

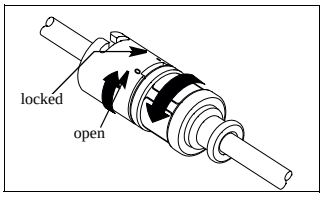

Fig. 3

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).

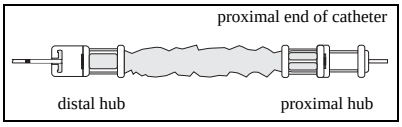

Fig. 4

6. Slide entire catheter contamination shield to proximal end of catheter.
7. 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.

8. Insert entire length of dilator through hemostasis valve into catheter pressing hub of dilator firmly into hub of hemostasis valve assembly. Place assembly on sterile field awaiting final placement.

9. 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.[13] Do not reinsert needle into introducer catheter.**

10. 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).

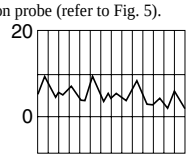

Fig. 5

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.[13]**

11. 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 for use:

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

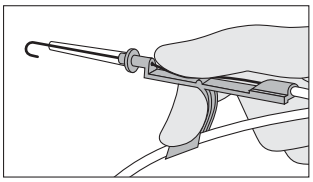

Fig. 6

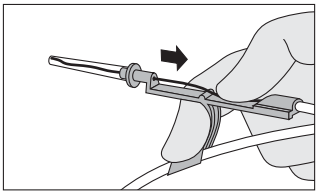

Fig. 7

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 Advancer™ – with "J" retracted – into the hole in the rear of the Arrow® Raulerson syringe plunger (refer to Fig. 8).

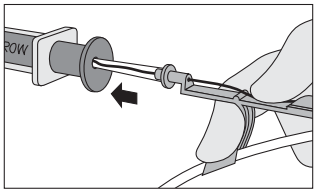

Fig. 8

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

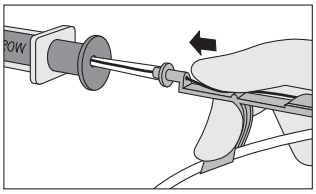

Fig. 9

- 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).

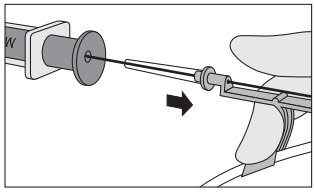

Fig. 10

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 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.

12. 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.**
13. 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 sheath placement.
14. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution: Do not cut guide wire.** In kits where provided, retract scalpel in the protected position. (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.**

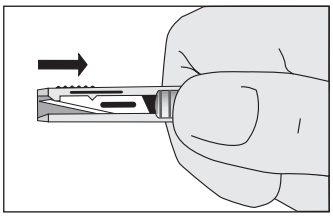

Fig. 11

15. 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 the catheter tip.**
16. Advance access device assembly off dilator into vessel, again grasping near skin and using slight twisting motion.
17. 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.**
18. 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: 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.** 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.**
19. 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.[18]**
20. 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).

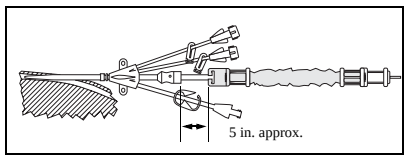

Fig. 12

21. 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).

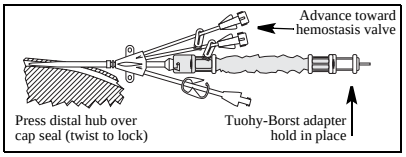

Fig. 13

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

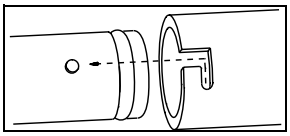

Fig. 14

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

23. 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.**

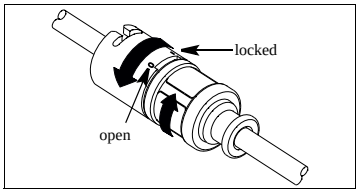

Fig. 15

24. Secure access device to patient using suture per hospital/agency protocol. **Precaution: Do not suture directly to the outside diameter of access device to minimize the risk of cutting or damaging access device or impeding flow.**
25. Dress puncture site per hospital protocol. **Precaution: Maintain the insertion site with regular, meticulous redressing using aseptic technique.**
26. 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 access device, do not use scissors to remove 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.[11] 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) I.V. 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 access device, do not use scissors to remove dressing.**
4. Using staple remover, remove staple(s), where applicable, or remove sutures from primary suture site. **Precaution: Be careful not to cut access device.**
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®† 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.[14,19,21,23]
7. Upon removal of the access device, inspect it to make sure that the entire length has been withdrawn.
8. 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.

†Vaseline is a registered trademark of Chesebrough-Pond's Inc.

STERILE EO

K-11142-104A (7/06)

ARROW INTERNATIONAL

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