ARROW®

Percutaneous Sheath Introducer Product

Safety and Efficacy Considerations:

Do not use if package has been previously opened or damaged. Warning: Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.

The product is designed for single use only. Do not resterilize or reuse. Do not alter the sheathor 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.

Indications for Use:

The Arrow Percutaneous Sheath Introducer 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 sheath introduction including vessel wall perforation,[16] pleural and mediastinal injuries,[1,12] air embolism,[5,8,11,13] sheath embolism, thoracic duct laceration,[2] bacteremia, septicemia, thrombosis,[3] inadvertent arterial puncture,[6] nerve damage, hematoma , hemorrhage,[4] and dysrhythmias.**

2. **Warning: Do not apply excessive force in removing guide wire, dilator or sheath. If withdrawal cannot be easily accomplished, a chest x-ray should be obtained and further consultation requested.**

3. **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 to guard against air embolism.**

4. **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/side port assembly and sheath. This will ensure that leakage does not occur and inner seal is protected from contamination.[13]**

5. **Warning: Care should be exercised in passing spring-wire guide. Use of excessive length of the guide wire into the right heart can cause dysrhythmias, right bundle branch block,[7] and vessel wall, atrial or ventricular perforation.**

6. **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.**

7. **Precaution: Do not suture directly to the outside diameter of the sheath to minimize the risk of cutting or damaging the sheath or impeding sheath flow.**

8. **Precaution: Indwelling sheaths should be routinely inspected for desired flow rate, security of dressing, correct position and for proper Luer-Lock connection.**

9. **Precaution: Maintain the insertion site with regular meticulous redressing using aseptic technique.**

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.**

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 using desired needle. In kits where provided, a SharpsAway® disposal cup is used for the disposal of needles. Push needles into foam after use. Discard entire cup at completion of procedure. **Precaution: Do not reuse needles after they have been placed into the disposal cup. Particulate matter may adhere to needle tip.**

5. Insert tip of desired catheter through rubber seal end of catheter contamination shield. Advance catheter through tubing and hub at other end (refer to Fig. 1).

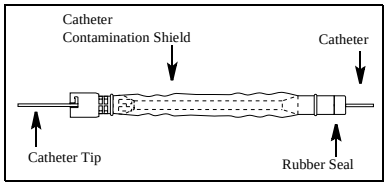

Fig. 1

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 sheath placement.

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

9. In kits where provided, use a 22 Ga. needle and syringe to locate central vein.

10. Insert introducer catheter/needle assembly with attached syringe into vein beside locater needle and aspirate. Remove locater needle. Withdraw needle and attached syringe from introducer catheter. 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.[9] Do not reinsert needle into introducer catheter.**

Alternate Technique:

Introducer needle may be used in the standard manner as alternative to catheter/needle assembly.

11. Because of the potential for inadvertent arterial placement, verify venous access via a wave form obtained by a calibrated pressure transducer (refer to Fig. 2).

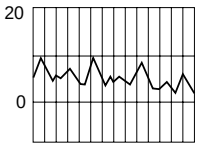

Fig. 2

If a pressure transducer is not available, check for pulsatile flow. Pulsatile flow is usually an indicator of inadvertent arterial puncture.

12. Use centimeter markings on spring-wire guide to adjust indwelling length according to desired depth of indwelling sheath placement. Centimeter marks are referenced from "J" end. One band indicates 10 cm, two bands 20 cm, and three bands 30 cm. Straighten spring-wire guide "J" by retracting into Arrow Advancer™ with thumb.

    Advance spring-wire guide through introducer needle into vein. 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.**

Alternate Technique:

If a simple straightening tube is preferred, the straightening tube portion of the Advancer™ can be disconnected from the unit and used separately. Separate the Advancer™ tip or straightening tube from the 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. Hold spring-wire guide in place and remove introducer needle or catheter. **Precaution: Maintain firm grip on spring-wire guide at all times.**

14. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the spring-wire guide. **Precaution: Do not cut guide wire.**

15. Thread tapered tip of dilator/sheath/valve 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 sheath through tortuous vessel. **Precaution: Do not withdraw dilator until the sheath is well within the vessel to minimize the risk of damage to sheath tip.**

16. Advance sheath/valve assembly off dilator into vessel, again grasping near skin and using slight twisting motion.

17. To check for proper sheath placement within the vessel, remove side port end cap and attach syringe for aspiration. Hold sheath/valve assembly in place and withdraw spring-wire guide and dilator sufficiently to allow venous blood flow to be aspirated into side port. **Precaution: Maintain firm grip on spring-wire guide at all times.**

18. Holding sheath/valve 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 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 side port to appropriate line as necessary.

19. Feed catheter through sheath/valve 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/side port assembly and sheath. This will ensure that leakage does not occur and inner seal is protected from contamination.[13]**
20. Hold catheter in place and reposition catheter contamination shield so that distal hub is approximately five inches (12.7 cm) from hemostasis valve/side port assembly (refer to Fig. 3).

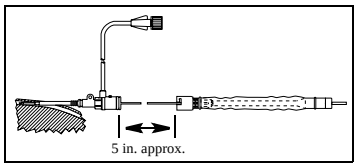

Fig. 3

21. Hold rear hub (seal end) 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. 4).

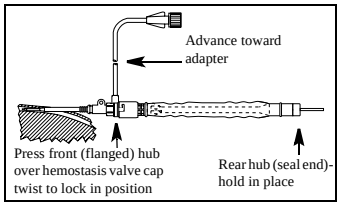

Fig. 4

22. Press distal hub of catheter contamination shield over assembly cap. Twist to lock (refer to Fig. 5).

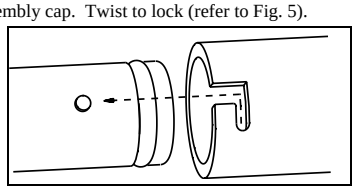

Fig. 5

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

23. Grasp catheter through front portion of catheter contamination shield and hold in place while repositioning rubber seal end as desired (refer to Fig. 6). **Precaution: Do not reposition rubber seal end on catheter once moved to this final position.**

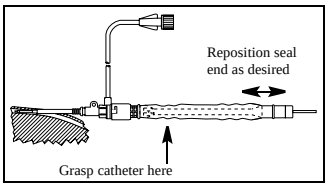

Fig. 6

24. Rubber seal end of catheter contamination shield should be secured with sterile tape to inhibit catheter movement (refer to Fig. 7). **Precaution: Do not apply tape to the transparent sheathing between the O-rings to minimize the risk of tearing material.**

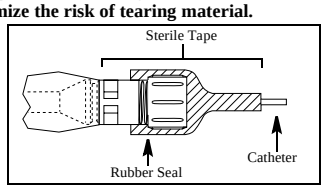

Fig. 7

25. Use suture tab to secure sheath and/or anchor with a purse string suture around the sheath suture ring. **Precaution: Do not suture directly to the outside diameter of the sheath to minimize the risk of cutting or damaging the sheath or impeding flow.**
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 sheath, do not use scissors to remove dressing.**
3. Withdraw catheter from sheath. **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.

Sheath Removal Procedure:

1. **Precaution: Place the patient in a supine position.**
2. Remove dressing, if applicable. **Precaution: To minimize the risk of cutting sheath, do not use scissors to remove dressing.**

3. If applicable, remove sutures from sheath. **Precaution: Be careful not to cut the sheath.**
4. Withdraw device from sheath. 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.**
5. **Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.** Remove sheath slowly, pulling it parallel to the skin. As sheath exits the site, apply pressure with a dressing impermeable to air, e.g. Vaseline® gauze. Because the residual sheath 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 sheath was indwelling.[10,14,15,17]
6. Upon removal of the sheath, inspect it to make sure that the entire length has been withdrawn.
7. 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. Arditis J, Giala M, Anagnostidou A. Accidental puncture of the right lymphatic duct during pulmonary artery catheterization. *Acta Anaesthesiol Scand.* 1988;32:67-68.
3. Benumof JL. Thrombosis after pulmonary-artery catheterization via the internal jugular vein. *NEJM.* 1982;306:1487. Letter.
4. 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.
5. Bristow A, Batjer H, Chow V, Rosenstein J. Air embolism via a pulmonary artery catheter introducer. *Anesthesiology.*1985;63:340-341. Letter.
6. Brzowski BK, Mills JL, Beckett WC. Iatrogenic subclavian artery pseudoaneurysms: case reports. *J Trauma.* 1990;30:616-618.
7. 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.
8. Hartung EJ, Ender J, Sgouropoulou S, Bierl R, Engelhardt W, Engemann R. Severe air embolism caused by a pulmonary artery introducer sheath. *Anesthesiology.* 1994;80:1402. Letter.
9. Jobes 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.
10. Kashuk JL, Penn I. Air embolism after central venous catheterization. *Surg Gynecol Obstet.* September 1984;159:249-252.
11. Kondo K, O'Reily LP, Chiota J. Air embolism associated with an introducer for pulmonary arterial catheters. *Anesth Analg.* 1984;63:871-872.
12. Macksood MJ, Setter M. Hydrothorax and hydromediastinum after use of an indwelling percutaneous catheter introducer. *Crit Care Med.* 1983;11:957-958.
13. Mihm FG, Rosenthal MH. Pulmonary artery catheterization. In: Benumof JL, ed. *Clinical Procedures in Anesthesia and Intensive Care.* Philadelphia, PA: JB Lippincott; 1992;419.
14. Paskin DL, Hoffman WS, Tuddenham WJ. A new complication of subclavian vein catheterization. *Ann Surg.* March 1974;179:266-268.
15. 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.
16. Roy RC. Possible hazards from catheter sheath introducers. *Crit Care Med.* 1984;12:616. Letter.
17. Thielen JB, Nyquist J. Subclavian catheter removal. *J Intravenous Nurs.* March/April 1991;14:114-118.

Arrow International, Inc. recommends that the user be acquainted with the reference literature.

*If you have any questions or would like additional reference information, please contact Arrow International, Inc.

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