ARROW®

Trauma 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 sheath or any other kit/set component during insertion, use, or removal.

Trauma product use must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.

Indications for Use:

The Arrow Trauma Product permits venous access 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, pleural and mediastinal injuries, air embolism, sheath embolism, thoracic duct laceration, bacteremia, septicemia, thrombosis, inadvertent arterial puncture, nerve damage, hematoma, hemorrhage 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 maintenance to guard against air embolism.**

4. **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,[3] and vessel wall, atrial or ventricular perforation.**

5. **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.**

6. **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.**

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

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

9. **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.

10. **Precaution: Some disinfectants used at the catheter insertion site contain solvents, which can attack the catheter material. Assure insertion site is dry before dressing.**

11. **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). A SharpsAwayII™ Locking Disposal Cup is used for the disposal of needles. Firmly push needles into disposal cup holes (refer to Fig. 1). Once placed into disposal cup, needles will be automatically locked 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 locked in place. Damage may occur to needle if it is forced out of disposal cup.**

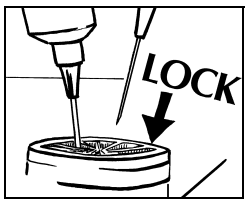

Fig. 1

Where provided, a foam SharpsAway® system may be utilized by pushing needles into foam after use. **Precaution: Do not reuse needles after they have been placed into the foam cup. Particulate matter may adhere to needle tip.**

5. Insert introducer needle with attached Arrow Raulerson syringe into vein and aspirate. **Precaution: The color of blood aspirated is not always a reliable indicator of venous access.[4]**

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 waveform obtained by a calibrated pressure transducer. Remove transduction probe (refer to Fig. 2).

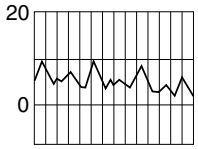

Fig. 2

Alternate Technique:

If hemodynamic monitoring equipment is not available to permit transducing a central venous waveform, 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 Advancer™ (refer to Figs. 3, 4).

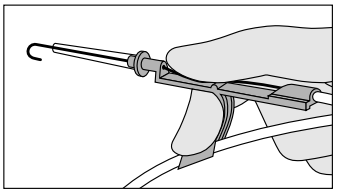

Fig. 3

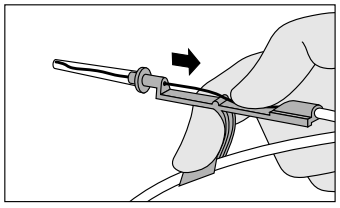

Fig. 4

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

Introducing the Spring-Wire Guide:

- Place the tip of the Advancer™ – with "J" retracted – into the hole in the rear of the Raulerson Syringe plunger (refer to Fig. 5).

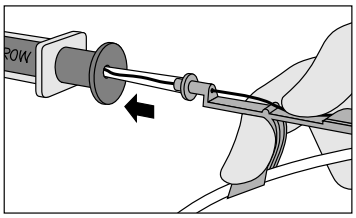

Fig. 5

- Advance spring-wire guide into the syringe approximately 10 cm until it passes through the syringe valves (refer to Fig. 6).

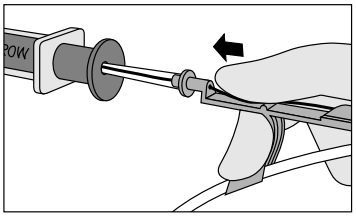

Fig. 6

- Raise your thumb and pull the Advancer™ approximately 4 cm to 8 cm away from the syringe. Lower thumb onto the Advancer™ and while maintaining a firm grip on the spring-wire guide, push the assembly into the syringe barrel to further advance the spring-wire guide. Continue until spring-wire guide reaches desired depth (refer to Fig. 7).

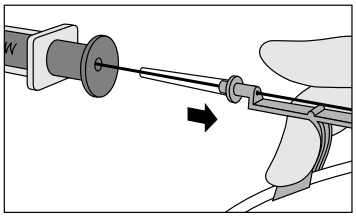

Fig. 7

Alternate Technique:

If a simple straightening tube is preferred, the straightening tube portion of the Advancer™ can be disconnected from the unit and used separately.
Separate the Advancer™ tip or straightening tube from the blue Advancer™ unit. If the "J" tip portion of the spring-wire guide is used, prepare for insertion by sliding the plastic tube over the "J" to straighten. The spring-wire guide should then be advanced in the routine fashion to the desired depth.

8. Advance 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.**

9. Hold spring-wire guide in place and remove introducer needle and Raulerson syringe. **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.

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

11. Thread tapered tip of dilator/sheath 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.**

12. Advance sheath off dilator into vessel, again grasping near skin and using slight twisting motion.

13. Holding sheath in place, remove spring-wire guide and dilator. Cover sheath hub connection with sterile-gloved finger to minimize the risk of air embolism. **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**.

14. Use 30 cc syringe for initial blood sample, if desired.

15. Flush infusion tubing and securely attach to sheath hub.

16. Use suture 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.**

17. Cover puncture site with sterile dressing and affix caution label contained in kit.

18. Record insertion procedure on the patient's chart.

Sheath Removal Procedure:

1. **Precaution: Place the patient in a supine position.**

2. Remove dressing. **Precaution: To minimize the risk of cutting the sheath, do not use scissors to remove the dressing.**

3. If applicable, remove sutures from sheath. **Precaution: Be careful not to cut sheath.**

4. **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 a least 24-72 hours dependent upon the amount of time the sheath was indwelling.[5,8,10]

5. Upon removal of the sheath, inspect it to make sure that the entire length has been withdrawn.

6. Document removal procedure.

References:

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3. 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.

4. 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.

5. Kashuk JL, Penn I. Air embolism after central venous catheterization. *Surg Gynecol Obstet.* September 1984;159:249-252.

6. Macksood MJ, Setter M. Hydrothorax and hydromediastinum after use of an indwelling percutaneous catheter introducer. *Crit Care Med.* 1983;11:957-958.

7. Paskin DL, Hoffman WS, Tuddenham WJ. A new complication of subclavian vein catheterization. *Ann Surg.* March 1974;179:266-268.

8. 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.

9. Roy RC. Possible hazards from catheter sheath introducers. *Crit Care Med.* 1984;12:616. Letter.

10. Thielen JB, Nyquist J. Subclavian catheter removal. *JIN.* 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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