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ARROW®

Trauma Product

For short term use (<30 days)

Rx only.

Indications for Use:

The Arrow® Emergency Infusion Device (EID) permits placement of a sheath for rapid volume infusion.

Contraindications:

None known.

Clinical Benefits to be Expected:

The ability to access into the circulation and infuse large fluid volumes rapidly into a patient for treatment of shock or trauma.

⚠ *General Warnings and Precautions*

Warnings:

1. **Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.**
2. **Read all package insert warnings, precautions and instructions prior to use. Failure to do so may result in severe patient injury or death.**
3. **Do not apply excessive force in placing or removing sheath, dilator or guidewire. Excessive force can cause component damage or breakage. If damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained and further consultation requested.**
4. **Air embolism can occur if air is allowed to enter a vascular access device or vein. Do not leave open needles or uncapped, unclamped sheaths or catheters in venous puncture site. Use only securely tightened Luer-Lock connections with any vascular access device to guard against inadvertent disconnection.**
5. **Passage of guidewire into the right heart can cause dysrhythmias, right bundle branch block, and a perforation of vessel, atrial or ventricular wall.**
6. **Clinicians must be aware of complications/undesirable side-effects associated with percutaneous sheath introduction including, but not limited to:**

- vessel wall perforation
- pleural and mediastinal injuries
- air embolism
- sheath embolism
- thoracic duct laceration
- bacteremia
- septicemia
- thrombosis
- inadvertent arterial puncture
- nerve damage
- hematoma
- hemorrhage
- dysrhythmias

Precautions:

1. **Do not alter the sheath or any other kit/set component during insertion, use, or removal.**
2. **Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique and potential complications.**
3. **Use standard precautions and follow institutional policies for all procedures including safe disposal of devices.**
4. **Do not secure, staple and/or suture directly to outside diameter of sheath body to reduce risk of cutting or damaging the sheath or impeding sheath flow. Secure only at indicated stabilization locations.**
5. **Indwelling sheaths should be routinely inspected for desired flow rate, security of dressing, correct position and for proper Luer-Lock connection.**
6. **Maintain the insertion site with regular meticulous redressing using aseptic technique.**
7. **Some disinfectants used at device insertion site contain solvents which can weaken the device material. Alcohol, acetone, and polyethylene glycol can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between stabilization device and skin.**
   - **Do not use acetone on device surface.**
   - **Do not use alcohol to soak device surface or allow alcohol to dwell in a lumen to restore patency or as an infection prevention measure.**
   - **Do not use polyethylene glycol containing ointments at insertion site.**
   - **Take care when infusing drugs with a high concentration of alcohol.**
   - **Allow insertion site to dry completely prior to applying dressing.**

Kits/Sets may not contain all accessory components detailed in these instructions for use. Become familiar with instructions for individual component(s) before beginning the procedure.

A Suggested Procedure: Use sterile technique.

Prep Puncture Site:

1. Position patient as appropriate for insertion site.
   - Subclavian or Jugular approach: Place patient in slight Trendelenburg position as tolerated to reduce risk of air embolism and enhance venous filling.
   - Femoral approach: Place patient in supine position.
2. Prepare clean skin with an appropriate antiseptic agent.
3. Drape puncture site.
4. Administer local anesthetic per institutional policies and procedures.
5. Dispose of needle.

SharpsAway® II Locking Disposal Cup (where provided):

The SharpsAway II Locking Disposal Cup is used for disposal of needles (15 Ga. - 30 Ga.).

- Using one-handed technique, firmly push needles into disposal cup holes (refer to Figure 1).

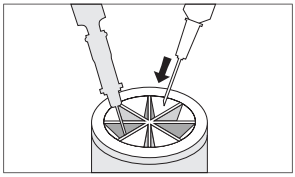

Figure 1

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

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

- Where provided, a foam SharpsAway system may be utilized by pushing needles into foam after use.

⚠ **Precaution: Do not re-use needles after they have been placed into the foam SharpsAway system. Particulate matter may adhere to needle tip.**

6. Insert introducer needle with attached Arrow Raulerson syringe into vein and aspirate.

⚠ **Precaution: Do not rely on blood aspirate color to indicate venous access.**

Verify Venous Access:

Utilize one of the following techniques to verify venous access because of the potential for inadvertent arterial placement:

- Central Venous Waveform:
  - Insert fluid primed blunt tip pressure transduction probe into rear of plunger and through valves of Arrow Raulerson Syringe and observe for central venous pressure waveform.
    - ◊ Remove transduction probe if using Arrow Raulerson Syringe.
- Pulsatile Flow (if hemodynamic monitoring equipment is not available):
  - Use transduction probe to open syringe valving system of Arrow Raulerson Syringe and observe for pulsatile flow.
  - Disconnect syringe from needle and observe for pulsatile flow.

⚠ **Warning: Pulsatile flow is usually an indicator of inadvertent arterial puncture.**

7. Using the two-piece Arrow Advancer, advance guidewire through syringe into vein.

⚠ **Warning: Aspiration with guidewire 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 guidewire in place.**

Arrow Advancer (where provided):

Arrow Advancer is used to straighten "J" Tip of guidewire for introduction of the guidewire into Arrow Raulerson Syringe or a needle.

- Using thumb, retract "J" (refer to Figure 2).

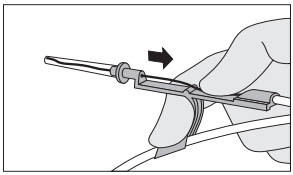

Figure 2

- Place tip of Arrow Advancer – with "J" retracted – into the hole in rear of Arrow Raulerson Syringe plunger or introducer needle.

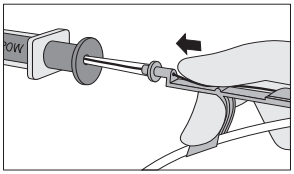

Figure 3

8. Advance guidewire into Arrow Raulerson Syringe approximately 10 cm until it passes through syringe valves or into introducer needle.
   - Advancement of guidewire through Arrow Raulerson Syringe may require a gentle twisting motion.
   - Raise thumb and pull Arrow Advancer approximately 4 - 8 cm away from Arrow Raulerson Syringe or introducer needle. Lower thumb onto Arrow Advancer and while maintaining a firm grip on guidewire, push assembly into syringe barrel to further advance guidewire (refer to Figure 3). Continue until guidewire reaches desired depth.

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 guidewire is used, prepare for insertion by sliding the plastic tube over the "J" to straighten. The guidewire should then be advanced in the routine fashion to the desired depth.

9. Advance the guidewire until triple band mark reaches rear of syringe plunger. Advancement of "J" tip may require a gentle rotating motion.

⚠ **Warning: Do not cut guidewire to alter length. Do not withdraw guidewire against needle bevel to minimize the risk of possible severing or damaging of guidewire.**

10. Hold guidewire in place and remove introducer needle and Raulerson syringe.

⚠ **Precaution: Maintain firm grip on guidewire at all times.**

Use centimeter markings on guidewire to adjust indwelling length according to desired depth of indwelling sheath placement.

11. Enlarge cutaneous puncture site with cutting edge of scalpel positioned away from the guidewire.

⚠ **Precaution: Do not cut guidewire.**

12. Thread tapered tip of dilator/sheath assembly over guidewire. 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.**

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

14. Holding sheath in place, remove guidewire 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 guidewire failure is extremely low, practitioner should be aware of the potential for breakage if undue force is applied to the wire.**

15. Use 30 mL syringe for initial blood sample, if desired.

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

17. 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.**

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

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

Sheath Removal Procedure:

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

1. Remove dressing.

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

2. If applicable, remove sutures from sheath.

⚠ **Precaution: Be careful not to cut sheath.**

⚠ **Warning: Exposure of the central vein to atmospheric pressure may result in entry of air into the central venous system.**

3. Remove sheath slowly, pulling it parallel to the skin. As sheath exits the site, apply pressure with a dressing impermeable to air. 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.
4. Upon removal of the sheath, inspect it to make sure that the entire length has been withdrawn.
5. Document removal procedure.

For reference literature concerning patient assessment, clinician education, insertion technique, and potential complications associated with this procedure, consult standard textbooks, medical literature, and Arrow International LLC website: www.teleflex.com

A pdf copy of this IFU is located at **www.teleflex.com/IFU**

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: **https://ec.europa.eu/growth/sectors/medical-devices/contacts_en**

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Symbol Glossary: Symbols are in compliance with ISO 15223-1.
Some symbols may not apply to this product. Refer to product labeling for symbols that apply specifically to this product.

								
Caution	Medical device	Consult instructions for use	Do not reuse	Do not resterilize	Sterilized by ethylene oxide	Single sterile barrier system with protective packaging inside		Single sterile barrier system
								
Keep away from sunlight	Keep dry	Do not use if package is damaged	Not made with natural rubber latex	Catalogue number	Lot number	Use by	Manufacturer	Date of manufacture
								
Importer								

EC REP

EU Authorized Representative and Importer:

CE 2797

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