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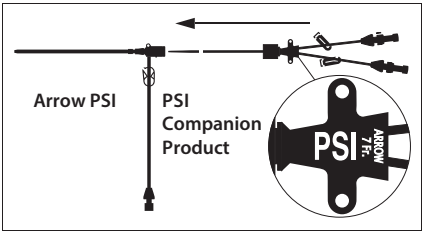
Central Venous Catheterization Product

for use only with Arrow® Percutaneous Sheath Introducer (8.5 Fr. and 9 Fr.)

Rx only.



Indications for Use:

The Central Venous Catheter permits venous access to the central venous circulation through a hemostasis valve on an indwelling percutaneous sheath introducer.

Contraindications:

None known.

Clinical Benefits to be Expected:

The ability to gain access to the central circulation system through a single puncture site for applications that include fluid infusion, blood sampling, medication administration, central venous monitoring, and the ability to inject contrast media.

⚠ *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 place/advance catheter into or allow it to remain in the right atrium or right ventricle. The catheter tip should be advanced into the lower 1/3 of the Superior Vena Cava.**

   For femoral vein approach, catheter should be advanced into vessel so catheter tip lies parallel to vessel wall and does not enter right atrium.

   Catheter tip location should be confirmed according to institutional policy and procedure.
4. **Clinicians must be aware of potential entrapment of the guidewire by any implanted device in circulatory system. It is recommended that if patient has a circulatory system implant, catheter procedure be done under direct visualization to reduce risk of guidewire entrapment.**
5. **Do not use excessive force when introducing guidewire or tissue dilator as this can lead to vessel perforation, bleeding, or component damage.**
6. **Do not apply excessive force in placing or removing catheter 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.**
7. **Using catheters not indicated for pressure injection for such applications can result in inter-lumen crossover or rupture with potential for injury.**
8. **Do not secure, staple and/or suture directly to outside diameter of catheter body or extension lines to reduce risk of cutting or damaging the catheter or impeding catheter flow. Secure only at indicated stabilization locations.**
9. **Air embolism can occur if air is allowed to enter a central venous access device or vein. Do not leave open needles or uncapped, unclamped catheters in central venous puncture site. Use only securely tightened Luer-Lock connections with any central venous access device to guard against inadvertent disconnection.**
10. **Clinicians should be aware that slide clamps may be inadvertently removed.**
11. **Clinicians must be aware of complications/undesirable side-effects associated with central venous catheters including, but not limited to:**
    - cardiac tamponade secondary to vessel, atrial, or ventricular perforation
    - pleural (i.e., pneumothorax) and mediastinal injuries
    - air embolism
    - catheter embolism
    - catheter occlusion
    - thoracic duct laceration
    - bacteremia
    - septicemia
    - thrombosis
    - inadvertent arterial puncture
    - nerve injury
    - hematoma
    - hemorrhage
    - fibrin sheath formation
    - exit site infection
    - vessel erosion
    - catheter tip malposition
    - dysrhythmias
    - extravasation
12. **Hemostasis valve to percutaneous sheath introducer connection must be secured and routinely examined to minimize the risk of disconnection and possible air embolism, hemorrhage, or exsanguination.**

Precautions:

1. **Do not alter the catheter, guidewire 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. **Some disinfectants used at catheter insertion site contain solvents which can weaken the catheter material. Alcohol, acetone, and polyethylene glycol can weaken the structure of polyurethane materials. These agents may also weaken the adhesive bond between catheter stabilization device and skin.**

- **Do not use acetone on catheter surface.**
- **Do not use alcohol to soak catheter surface or allow alcohol to dwell in a catheter lumen to restore catheter 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.**

5. **Ensure catheter patency prior to use. Do not use syringes smaller than 10 mL to reduce risk of intraluminal leakage or catheter rupture.**
6. **Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.**
7. **For blood sampling, temporarily shut off remaining port(s), if applicable, through which solutions are being infused.**

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.

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 the catheter for insertion by flushing each lumen and clamping or attaching injection caps to the appropriate extension lines, if applicable.

⚠ **Warning: Do not cut catheter to alter length.**

3. Prep hemostasis valve cap with appropriate antiseptic per hospital protocol. Include the exposed portion of the valve on the top of the cap. Occlude hemostasis valve with sterile-gloved finger.
   - With sterile-gloved fingers, peel back tail of peel-away catheter contamination guard to expose tip of catheter (Figure 1).

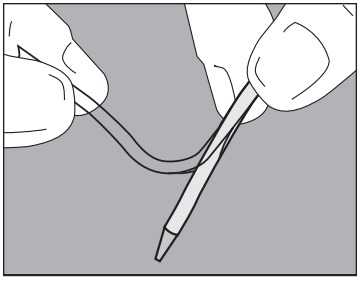


Figure 1

   - Grasping catheter body, still covered by the peel-away catheter contamination guard, advance catheter into hemostasis valve of percutaneous sheath introducer. Continue advancing catheter and peeling away the contamination guard until catheter hub locks on hemostasis valve (Figure 2).

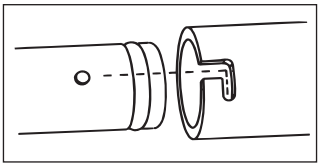


Figure 2

4. Assess catheter tip placement in compliance with institutional policies and procedures.
5. If catheter tip is malpositioned, assess and replace or reposition according to institutional policies and procedures.
6. Connect all extension lines to appropriate Luer-Lock line(s), if applicable. Unused ports may be "locked" through injection cap(s) using standard hospital protocol. Slide clamps are provided on extension line(s) to occlude flow through each lumen during line and injection cap changes.

⚠ **Precaution: To reduce the risk of damage to extension lines from excessive pressure, each clamp must be opened prior to infusing through that lumen.**

Catheter Patency:

Maintain catheter patency according to institutional policies, procedures and practice guidelines. All personnel who care for patients with central venous catheters must be knowledgeable about effective management to prolong catheter's dwell time and prevent injury.

Catheter Removal from Sheath Procedure:

1. Position patient as clinically indicated to reduce risk of potential air embolus.
2. Unlock catheter and withdraw catheter from sheath introducer. Temporarily cover valve opening with sterile-gloved finger until obturator is inserted. Apply obturator cap.

⚠ **Warning: Hemostasis valve must be occluded at all times to reduce the risk of air embolism or hemorrhage.**

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**

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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

Arrow International LLC
Subsidiary of Teleflex Incorporated
3015 Carrington Mill Blvd., Morrisville, NC 27560 USA
USA: 1 866 246 6990 | International: +1 919 544 8000

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