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ARROW®

Single Lumen Infusion Catheter (SLIC®)

Rx only.

Indications for Use:

The SLIC® is a two-piece assembly consisting of an infusion catheter and an obturator. With SLIC obturator removed, the Arrow SLIC® permits access to the central venous circulation through an indwelling sheath/hemostasis valve. With the SLIC obturator in place, the SLIC occludes the hemostasis valve preventing air entry and blood loss through the valve.

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 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
11. **Hemostasis valve/side port assembly to SLIC connection and SLIC to obturator 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.**

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. If catheter is removed from sheath or catheter insertion is delayed, introduce the entire length of the SLIC assembly through the hemostasis valve/sheath assembly. Twist to lock (refer to Figure 1).

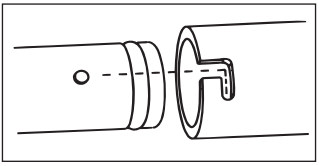

Figure 1

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

⚠ **Precaution: When SLIC assembly is inserted after catheter removal, use an appropriate antiseptic to prep the hemostasis valve housing prior to inserting the SLIC. Include the exposed portion of the valve on the top of the housing.**

The SLIC, with the obturator in place, occludes the hemostasis valve preventing air entry or blood loss through the valve.

⚠ **Warning: Connection between SLIC obturator and SLIC must be tightened securely and routinely examined to reduce the risk of disconnection and possible air embolism, hemorrhage or exsanguination.**

3. To use the SLIC for intravenous infusion, remove the blue-capped SLIC obturator by twisting counter clockwise. Hold the infusion port to maintain positive lock to hemostasis valve housing. Pull the SLIC obturator from the infusion catheter (refer to Figure 2). Immediately attach desired line to Luer-Lock hub.

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

Inspect the SLIC obturator to ensure the entire length has been withdrawn. Document the SLIC obturator withdrawal and start of infusion.

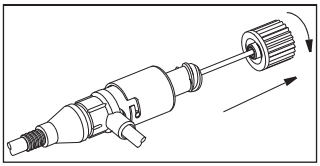

Figure 2

4. If the infusion through the SLIC is discontinued, the hub should be capped with a Luer-Lock injection cap and handled per hospital flushing protocol, or the SLIC should be withdrawn and replaced with a sterile Arrow obturator, sold separately, to ensure that leakage does not occur and inner seal is protected from contamination.

⚠ **Warning: Cover the lumen during any manipulation to reduce the risk of blood loss or the introduction of air into the sheath.**

5. Assess catheter tip placement in compliance with institutional policies and procedures.

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	Contains a medicinal substance	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								

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S-14701-134A (2021-03)

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