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ARROW®

Arterial Catheterization Product with Integral Needle Protection

For short term use (<30 days)

Rx only.

Integral needle protection is passive in design.

Indications for Use:

The Arrow® Arterial Catheterization Device permits access to the peripheral arterial circulation or other small vessels. The safety feature is intended to help minimize the risk of sharps injuries when using the device.

Contraindications:

None known.

Clinical Benefits to be Expected:

Permits access to the peripheral arterial circulation or to other small vessels. Facilitates continuous blood pressure measurement. Facilitates blood gas sampling and analyses.

⚠ *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. **To minimize the risk of air embolism and blood loss associated with disconnects use only securely tightened Luer Lock connections.**
4. **In brachial procedures, collateral flow cannot be guaranteed, and therefore intravascular clotting can result in tissue necrosis.**
5. **In radial artery procedures, practitioners must ascertain that definite evidence of collateral ulnar flow exists.**
6. **Accidental infusions of drugs or therapeutics or pressure injection into an arterial system may result in severe patient injury or death.**
7. **Do not attempt to override or defeat the locking needle protection mechanism.**
8. **This device is designed to reduce the risk of accidental needle sticks. However, care must still be taken to minimize the risk of sharps injury. Universal Precautions must be adhered to in accordance with CDC/OSHA standards for bloodborne pathogens, when starting or maintaining any IV catheter, to minimize the risk of exposure to contaminated blood. If catheter and needle are withdrawn together, the needle tip will not be protected.**
9. **Clinicians must be aware of complications/undesirable side-effects associated with arterial procedures including, but not limited to:**
   - **septicemia**
   - **vessel wall perforation**
   - **thrombosis**
   - **embolization**
   - **hematoma**
   - **arterial spasm**
   - **tissue necrosis**
   - **hemorrhage**
   - **peripheral ischemia and infarction**
   - **peripheral nerve injury**
   - **air embolism**
   - **site infection**
   - **cellulitis**
   - **catheter related blood stream infection (CRBSI)**

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 established institutional policies and procedures.**
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 or acetone-alcohol on or near the 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.**
   - **Allow insertion site to dry completely prior to applying dressing.**
5. **Indwelling catheter should be routinely inspected for desired patency, security of dressing, and possible migration.**

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.

Insertion Instructions

A Suggested Procedure: Use sterile technique.

Prepare for Insertion:

1. Assess for adequate Collateral Arterial Circulation.
   - Use of Ultrasound has been shown to increase success with catheter placement.
2. Prep and drape anticipated insertion site per institutional policies and procedures.

Where provided contoured outer trays may be used as an arm board.

3. Administer local anesthetic per institutional policies and procedures.

   - A Protected Needle/Safety Needle should be used in accordance with manufacturer's instructions for use.

4. Remove guard. Trial advance and retract guidewire through needle using guidewire handle to ensure proper function. When guidewire handle reaches the reference mark on guidewire tube, the tip of guidewire is positioned at needle tip.

⚠ **Precaution: Prior to insertion, ensure guidewire is returned to the original position before insertion or blood flashback may be inhibited.**

Insert Catheter:

5. Perform arterial puncture. Blood flashback in clear hub of introducer needle indicates successful entry into vessel (refer to Figure 1).

⚠ **Precaution: If both vessel walls are punctured, subsequent advancement of guidewire could result in inadvertent sub-arterial placement.**

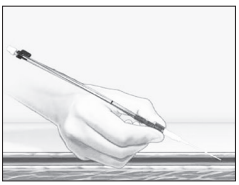

Figure 1

6. Once a blood flashback has been obtained, decrease the angle of the device to 10-20 degrees from the skin and advance entire placement device a maximum of 1 to 2 mm further into vessel to ensure that catheter is seated within the vessel (refer to Figure 2).

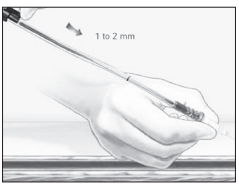

Figure 2

7. Stabilize position of introducer needle and carefully advance guidewire into vessel using guidewire handle (refer to Figure 3).

⚠ **Precaution: Do not advance guidewire unless there is free blood flashback in needle hub.**

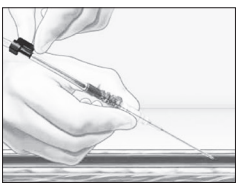

Figure 3

When the reference mark on the clear feed tube coincides with the edge of the internal cylinder of the guidewire handle the tip of the guidewire is located at the needle tip.

⚠ **Warning: To reduce the risk of guidewire damage, do not retract guidewire against edge of needle while in vessel.**

⚠ **Precaution: If resistance is encountered during guidewire advancement do not force feed, withdraw entire unit and attempt new puncture.**

8. Firmly hold introducer needle hub in position and advance catheter/needle protection assembly, over guidewire into vessel (refer to Figure 4).

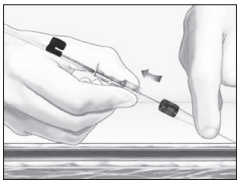

Figure 4

Complete Insertion:

9. Grasp catheter hub in one hand and needle hub in the other hand (refer to Figure 5).

⚠ **Precaution: Do not grasp or contact needle protection assembly.**

Remove guidewire assembly by withdrawing needle hub longitudinally to vessel. The needle protection assembly will remain attached to proximal end of catheter hub until needlepoint passes through assembly and activates during withdrawal.

⚠ **Precaution: Listen for audible click to confirm that needle protection assembly has been activated.**

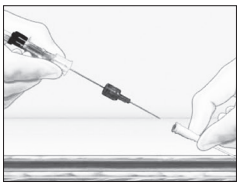

Figure 5

Visual inspection can also confirm that needle tip is enclosed in needle protection assembly (refer to Figure 6).

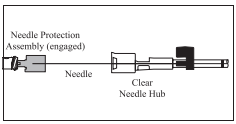

Figure 6

⚠ **Precaution: Once the catheter is partially threaded off the needle, do not attempt to advance needle into catheter again – this may cause catheter damage. Do not attempt to remove needle protection assembly from needle.**

Secure Catheter:

10. Attach stopcock, injection cap or connecting tubing to catheter hub. Secure catheter to patient in preferred manner using suture wings, suture groove or wing clip, where provided.

⚠ **Warning: Care should be exercised that the catheter is not inadvertently kinked at the hub area when securing catheter to the patient as this may result in catheter damage, breakage and loss of arterial monitoring capabilities.**

⚠ **Warning: Do not apply tape, staples, or sutures directly to the catheter body to reduce risk of damaging catheter, impeding catheter flow, or adversely affecting monitoring capabilities. Secure only at indicated stabilization locations.**

⚠ **Precaution: Avoid placement or securement in an area of flexion.**

Catheter Stabilization Device (where provided):

A catheter stabilization device should be used in accordance with manufacturer's instructions for use.

11. Document insertion procedure.

Care and Maintenance:

Dressing:

Dress according to institutional policies, procedures, and practice guidelines. Change immediately if the integrity becomes compromised (e.g. dressing becomes damp, soiled, loosened or no longer occlusive).

⚠ **Precaution: Minimize catheter manipulation throughout procedure to maintain proper catheter tip position.**

Catheter Patency:

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

Catheter Removal Instructions:

Use aseptic technique per institutional policies and procedures.

1. Remove dressing.

⚠ **Warning: Do not use scissors to remove dressing to reduce the risk of cutting the catheter.**

2. Remove catheter securement device or sutures being careful not to cut catheter.
3. Remove Catheter slowly.

⚠ **Warning: Do not use excessive force in removing catheter. If resistance is met on removal, stop and follow institutional policies and procedures for difficult to remove catheters.**

⚠ **Warning: Exposure of arterial circulation to atmospheric pressure may result in entry of air into circulation.**

4. Apply pressure at site after catheter is removed per institutional policies and procedures.
5. Cover site with a sterile occlusive dressing.
6. Document catheter removal procedure including confirmation that entire catheter length has been removed per institutional policies and procedures.

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	Temperature Limitation	Catalogue number	Lot number	Use by
								
Manufacturer	Date of manufacture							

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