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Arrow™ Endurance™ Extended Dwell Peripheral Catheter System

Rx only

Product Description:

The Arrow™ Endurance™ Extended Dwell Peripheral Catheter System is a sterile, single use peripheral intravascular device designed to permit access to the peripheral vascular system. The insertion device consists of an ergonomically designed handle with an integral echogenic needle that contains a passively-activated needle protection mechanism, guidewire with slider advancer and single-lumen catheter (refer to Figure 1). The insertion device is designed to allow the user to intuitively advance the guidewire and release the catheter with minimal insertion steps. The catheter is advanced over the needle and threaded over a guidewire into a peripheral vessel.

Throughout catheter insertion, blood is contained within the device to aid in prevention of blood exposure. The catheter system consists of a translucent, radiopaque, silicone coated, polyurethane catheter, a needle with openings to enhance flashback visibility, a seal in the catheter hub designed to reduce blood exposure, a stabilization platform with a strain relief nose designed to reduce kinking at the hub of the catheter, extension tubing with Luer hub, a vent plug, and a clamp.

Arrow Endurance Extended Dwell Peripheral Catheter System can be placed in the peripheral venous circulation as an extended dwell peripheral IV (less than 30 days).

Arrow Endurance Extended Dwell Peripheral Catheter System can be placed in the peripheral arterial circulation as an arterial catheter (less than 30 days).

The catheter's exterior surface contains a hydrophobic silicone coating to ease insertion of the catheter. The coating extends from catheter's distal tip to approximately 0.5 cm - 1 cm from the juncture hub nose.

Indications for Use:

The Arrow Endurance Extended Dwell Peripheral Catheter System permits access to the patient's peripheral vascular system for short-term venous use (less than 30 days) to sample blood, administer fluids, and perform high pressure contrast injections at a maximum of 325 psi.

The Arrow Endurance Extended Dwell Peripheral Catheter System permits access to the patient's peripheral vascular system for short-term use (less than 30 days) to facilitate arterial blood pressure measurement and blood sampling.

The safety feature is intended to minimize the risk of sharps injuries.

The Arrow Endurance Extended Dwell Peripheral Catheter may be used for any patient population with consideration given to adequacy of anatomy and appropriateness of the procedure.

The Arrow Endurance Extended Dwell Peripheral Catheter may be used in hospitals, clinics, and other advanced clinical facilities.

Contraindications:

None known.

MRI Safety Information:

The catheter is MR Safe.

Contains Hazardous Substance:

Components manufactured using Stainless Steel can contain > 0.1% weight by weight of Cobalt (CAS # 7440-48-4) which is considered a category 1B CMR (Carcinogenic, mutagenic

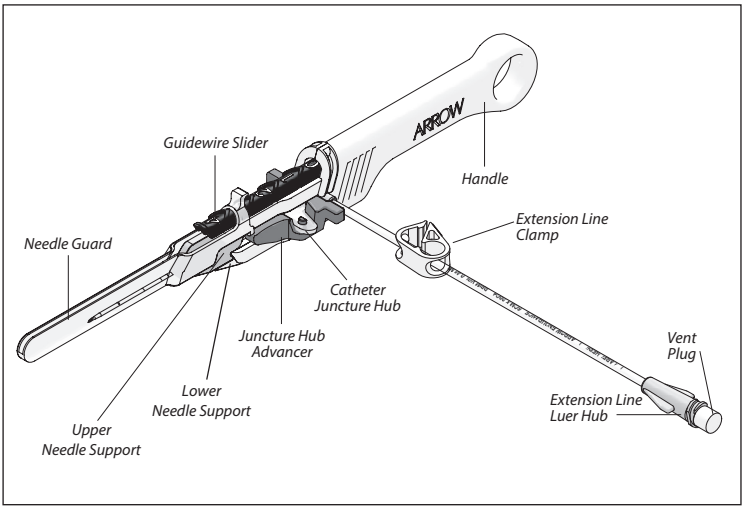

Figure 1

or toxic to reproduction) substance. The amount of Cobalt in the Stainless Steel components has been evaluated and considering the intended purpose and toxicological profile of the devices there is no biological safety risk to patients when using the devices as instructed within this IFU.

⚠ *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. **Safety of the Endurance Extended Dwell Catheter System has not been established for use in neonates and infants with a body weight of ≤ 10 kg.**

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. **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 skin puncture and prior to applying dressing.**
   - **Do not allow kit components to come into contact with alcohol.**
4. **Indwelling catheter should be routinely inspected for desired patency, security of dressing, and possible migration.**
5. **Do not use syringes smaller than 3 mL to flush or infuse to reduce risk of catheter damage.**
6. **Continuous vesicant therapies, Parenteral Nutrition or infusates with an extreme pH or osmolarity are inappropriate for delivery through a peripheral vein.**
7. **The safety and effectiveness of the device has not been established, or is unknown, in vascular regions other than those specifically indicated.**

⚠ *Venous Use Warnings*

Warnings:

1. **Practitioners must be aware of complications associated with peripheral venous catheterization including but not limited to: phlebitis, thrombophlebitis, venous thrombosis, occlusion, infiltration, catheter embolus, septicemia, inadvertent arterial puncture, nerve injury, hematoma, air embolism, site infection, and cellulitis.**
2. **Therapies not appropriate for administration via a peripheral vein include vesicants, known irritants, parenteral nutrition solutions, drug/solutions with pH <5 and >9 or osmolarity >600 mOsm/L.**
3. **This device was not evaluated for delivery of blood and blood products and may cause an increased risk of hemolysis.**

⚠ *Pressure Injection Warnings and Precautions*

Warnings:

1. **Assess each patient for appropriateness of a pressure injection procedure.**
2. **Pressure injection procedures must be performed by trained personnel well versed in safe technique and potential complications.**
3. **Do not pressure inject if catheter is placed into an artery. Pressure injection into an artery may result in severe patient injury or death.**
4. **Ensure catheter patency prior to pressure injection to reduce risk of catheter failure and/or patient complications. Inability to obtain brisk blood return or to flush easily indicates a possible problem with the catheter and catheter should not be used.**
5. **Avoid kinking or obstructing the catheter system during pressure injection to reduce risk of catheter failure.**
6. **Discontinue pressure injection at first sign of infiltration/ extravasation.**

Precautions:

1. **Do not exceed maximum pressure limit of 325 psi on high pressure injector equipment or catheter's maximum recommended flow rate for corresponding injectate viscosity to reduce risk of catheter failure.**
2. **Pressure limit settings on high pressure injector equipment may not prevent over-pressurizing an occluded or partially occluded catheter, which may cause catheter failure.**
3. **Follow the contrast media manufacturer's specified instructions for use, contraindications, warnings, and precautions.**
4. **The single flow rate on venous placement label is the maximum recommended flow rate for high pressure injection using injectate of 11.8 centipoise (cP) viscosity. For higher viscosity media or a high pressure injector setting lower than 325 psi, this flow rate may not be achievable.**
5. **Due to variations in add-on devices, tubing, injectate temperature and pressure limit settings, the maximum pressure injection flow rates may not be achievable.**

⚠ *Arterial Use Warnings*

Warnings:

1. **Practitioners must be aware of complications associated with arterial catheterization including but not limited to: septicemia, vessel wall perforation, intravascular thrombosis and embolization, hematoma, arterial spasm, tissue necrosis, hemorrhage, peripheral ischemia and infarction, peripheral nerve injury, air embolism, site infection, and cellulitis.**

2. **Practitioners must ascertain that definite evidence of adequate collateral ulnar flow exists prior to radial artery catheterization.**
3. **In brachial artery catheterization, collateral flow cannot be guaranteed. Therefore, intravascular thrombosis can compromise circulation and result in patient injury.**
4. **Accidental infusions of drugs or therapeutics or pressure injection into an arterial system may result in severe patient injury or death.**

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

Use Sterile Technique.

A Suggested Procedure:

Prepare for Insertion:

1. Select most appropriate insertion site.
   - Use of ultrasound has been shown to increase success with catheter placement. For upper arm insertion, ultrasound is recommended.
   - Selecting a vessel with an appropriate subcutaneous depth optimizes the success of peripheral catheter placement.
   - Select a vessel less than 2 cm from the surface of the skin, to ensure adequate catheter length within the vessel.
2. Prep and drape anticipated insertion site per institutional policies and procedures.
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.

Preparation of the Device

4. Check that extension line clamp is not engaged and vent plug is secure (refer to Figure 1).
5. Remove needle guard by lifting the top tab of the needle guard (refer to Figure 2).

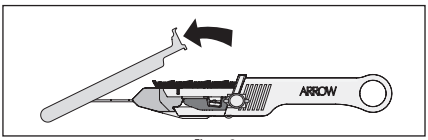

Figure 2

6. Prepare catheter by breaking the seal adhesion.
   - Retract the guidewire slider to the 2 cm mark (refer to Figure 3 step 1).
   - Advance the catheter forward slightly, no more than 3mm, using the juncture hub advancer (refer to Figure 3 step 2).

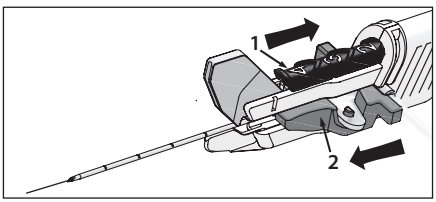

Figure 3

- Using the juncture hub advancer return catheter to original position. Ensure catheter is fully seated in the device and needle tip is visible (refer to Figure 4 step 1).
- Advance the guidewire slider to original position (refer to Figure 4 step 2).

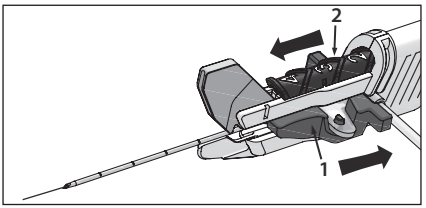

Figure 4

- Ensure the "0" mark on the guidewire slider is visible (refer to Figure 5).

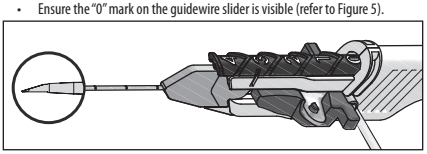

Figure 5

⚠ **Precaution: Prior to insertion, distal tip of catheter must be fully retracted past needle bevel or catheter tip damage may occur (refer to Figure 5).**

⚠ **Precaution: Prior to insertion, guidewire must be fully retracted into needle or blood flashback may be inhibited.**

⚠ **Warning: Do not advance tip of catheter past tip of needle to prevent catheter tip shear.**

NOTE: Do not prime catheter prior to insertion.

Insert Catheter System:

7. Access chosen vessel using a continuous, controlled, slow, forward motion.
   - Observe blood flashback through the catheter.
   - When appropriate, utilizing lower insertion angles during vessel access ensures the success of peripheral catheter placement.
8. Carefully advance as needed to ensure needle bevel is seated within the vessel (refer to Figure 6).

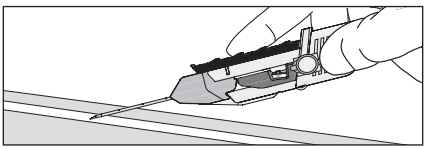

Figure 6

NOTE: Rate of blood flashback may slow at catheter hub before flowing to the extension line. Blood flashback indicates the needle bevel is in the vessel.

9. Stabilize position of needle/handle and carefully advance guidewire into vessel by pulling guidewire slider back into handle (refer to Figure 7).
   - The guidewire slider has centimeter markings to indicate how far the guidewire is advanced past bevel of needle.

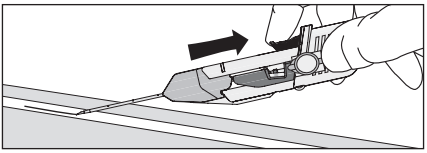

Figure 7

10. Fully advance guidewire.
    - Guidewire should advance smoothly without resistance.
    - The guidewire is fully advanced, when the guidewire slider is completely moved backward into the device.

⚠ **Precaution: Do not advance guidewire unless the needle is confirmed to be in the vessel.**

⚠ **Precaution: Do not force guidewire if resistance is encountered during advancement.**

⚠ **Precaution: Blood flashback may slow or stop upon guidewire advancement.**

⚠ **Warning: Do not retract guidewire through needle while in vessel to reduce risk of guidewire damage and embolization. If it is necessary to withdraw guidewire once deployed, needle and guidewire should be removed as a unit.**

11. Holding device stationary, advance the catheter over guidewire into vessel (refer to Figure 8).
    - Advance catheter using a continuous, controlled, slow, forward motion using juncture hub advancer.
    - Catheter should advance smoothly without resistance.
    - It is recommended to maintain needle/handle stability while advancing catheter.
    - Centimeter markings on the catheter body indicate the length of the catheter inserted.

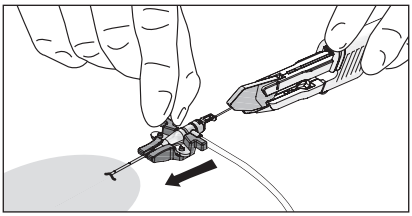

Figure 8

12. Fully advance catheter until the juncture hub advancer nose is against the insertion site.
    - The final mark on the catheter should be against the insertion site. This allows 5 mm between insertion site and nose of catheter juncture hub to facilitate dressing.

⚠ **Precaution: Do not advance the catheter unless the guidewire is fully advanced.**

⚠ **Precaution: Always keep handle stationary while threading catheter.**

⚠ **Precaution: Do not force catheter if resistance is encountered during advancement.**

13. Holding catheter stationary, withdraw needle/guidewire out of catheter.
    - The needle protection will be automatically activated once the needle exits catheter hub.
    - Visually confirm needle tip is enclosed in the needle protection, once the needle/guidewire moves out of the catheter completely (refer to Figure 9).

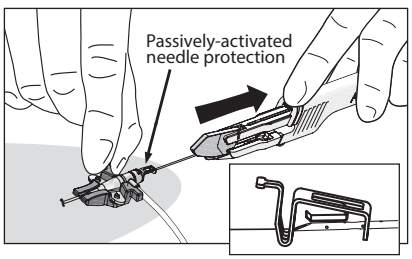

Figure 9

⚠ **Precaution: Do not attempt to advance needle back into catheter after catheter is partially threaded off needle to reduce risk of catheter damage.**

⚠ **Precaution: Do not attempt to remove needle protection assembly from needle.**

NOTE: Needle protection is activated when the needle tip locks in the needle protector.

⚠ **Warning: If resistance is met, do not apply excessive force in removing the needle/guidewire. Remove system as a unit.**

Complete Insertion:

14. Upon removal of handle, ensure guidewire is intact.
    - Slowly retract guidewire into needle before disposal.
    - When guidewire slider "0" mark is visible, tip of guidewire should be positioned within the needle tip.
15. Remove juncture hub advancer from catheter.
    - Gently lift the catheter while holding the juncture hub advancer (see Figure 10).
    - Once disengaged, remove the juncture hub advancer and discard.

⚠ **Precaution: Do not raise the catheter beyond 90° relative to the skin to avoid catheter kinking and damage.**

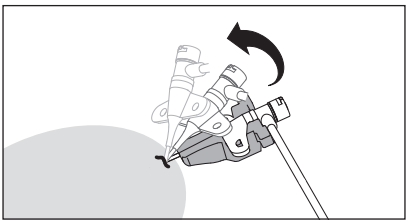

Figure 10

16. Engage the extension line clamp and remove the vent plug from catheter extension line Luer hub by pulling in a straight line.

⚠ **Precaution: When removing vent plug, pull in a straight line and avoid twisting or applying lateral forces to prevent unwanted breakage of the vent plug.**

17. Attach needleless connector (venous use) or stopcock (arterial use) to 10 mL flush syringe.
18. Attach 10 mL normal saline syringe for injection, unclamp and aspirate to check for brisk free-flowing blood return, flush, and reengage extension line clamp.

NOTE: Inability to obtain blood return and/or flush indicates catheter is not in place.

Catheter Securement, Dressing and Labeling:

19. Secure catheter according to institutional policies and procedures.
    - Use catheter stabilization device in accordance with manufacturer's instructions for use (where provided).
20. Dress according to institutional policies, procedures, and practice guidelines.
21. Attach appropriate venous or arterial placement label to extension line.
22. Document insertion procedure.

⚠ **Precaution: 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.**

⚠ **Precaution: Avoid kinking when securing catheter to patient.**

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

⚠ **Warning: After insertion, use supplied labels to distinguish if the catheter was placed into a vein or an artery. Failure to do so creates a potential risk of catheter misuse which may result in severe patient injury or death.**

Care and Maintenance:

⚠ **Precaution: Never attempt to insert a needle or a blunt cannula into the seal in back of catheter hub (refer to Figure 11).**

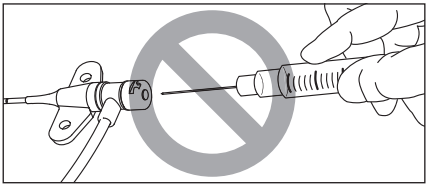

Figure 11

Dressing:

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

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.

Pressure Injection Instructions

Pressure injection information on product labeling provides assistance in making catheter-related decisions when pressure injecting with Arrow Endurance Extended Dwell Peripheral Catheter. The Arrow Endurance Catheter's indication for high pressure injection implies the catheter's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient.

⚠ **Warning: Do not pressure inject if catheter is placed into an artery. Pressure injection into an artery may result in severe patient injury or death.**

Use sterile technique.

1. Inspect catheter site and catheter to ensure there are no signs and/or symptoms of phlebitis, erythema or tenderness at site. Ensure that there are no kinks or bends in the catheter body and that the dressing is clean, dry and intact.
2. Remove needleless connector from extension line Luer hub if required. It may be acceptable to pressure inject through specifically labeled needleless connectors - refer to the needleless connector manufacturer's instructions for use.
3. Check for patency:
   - Attach a 10 mL syringe filled with normal saline for injection.
   - Flush catheter gently.
   - Check for brisk free-flowing blood return.
   - Vigorously flush catheter.

⚠ **Warning: Ensure catheter patency prior to pressure injection to reduce risk of catheter failure and/or patient complications. Inability to obtain brisk blood return or to flush easily indicates a possible problem with the catheter and catheter should not be used.**

4. Detach syringe.
5. Attach pressure injection administration set tubing to extension line Luer hub according to manufacturer's recommendations.

⚠ **Precaution: Do not exceed maximum pressure limit of 325 psi on high pressure injector equipment or catheter's maximum recommended flow rate for corresponding injectate viscosity to reduce risk of catheter failure.**

6. Inject contrast media in accordance with institutional policies and procedures.

⚠ **Precaution: Follow the contrast media manufacturer's specified instructions for use, contraindications, warnings, and precautions.**

7. Disconnect catheter from high pressure injector equipment.
8. Flush catheter using a 10 mL syringe filled with normal saline for injection.
9. Disconnect syringe and replace sterile needleless connector, as required, on catheter extension line Luer hub and flush per institutional policies and procedures.

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.
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.**

4. Apply digital pressure using a gauze pad at site until hemostasis is achieved.
5. Once hemostasis is achieved cover the site with a sterile occlusive dressing or per institutional policies and procedures.
6. Document catheter removal procedure including confirmation that entire catheter length has been removed per institutional policies and procedures.

Catheter Specification Testing Details

Refer to product labeling for catheter specifications. The following section explains how some catheter specifications were generated.

- Priming volumes are approximate and are done via direct connection to catheter hub (no needleless connector).
- Gravity flow rates were determined using room temperature water at 100 cm head height and represent approximate flow capabilities.
- Pump flow rates are determined at pump pressure of 10 psig and represent approximate flow capabilities.
- Maximum pressure injection flow rate is the maximum indicated flow rate for high pressure injection. Pressure injection flow rates are determined at injector pressure limit setting of 325 psi maximum, with 152 cm administration set tubing, and using injectate viscosities as identified on labeling.

For reference information concerning patient assessment, clinical education, potential complications, and specific techniques for 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	Contains hazardous substances	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	MR safe	Catalogue number
								
Lot number	Use by	Manufacturer	Date of manufacture	Electronic instructions for use	Unique device identifier			

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