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ARROW®

Arrowg+ard Blue Advance® Pressure Injectable Midline Catheter Product

Rx only.

Product Description:

The Arrowg+ard Blue Advance® catheters are processed with an external surface treatment that uses the antimicrobial chlorhexidine acetate on the catheter body and juncture hub nose, as well as an internal lumen impregnation utilizing an antimicrobial combination of chlorhexidine acetate and chlorhexidine base for the catheter body, juncture hub, extension line(s) and extension line hub(s). A maximum total amount of chlorhexidine applied to various French sizes and lengths of catheters could range up to 18.6 mg.

Characterization of Chlorhexidine:

Chlorhexidine is characterized as having a broad antimicrobial activity spectrum, including bacteriostatic and bactericidal effects on gram-positive bacteria, gram-negative bacteria and fungi. Whether chlorhexidine is bacteriostatic or bactericidal depends largely on the concentration of the agent and the susceptibility of specific organisms. Chlorhexidine ($C_{26}H_{38}Cl_2N_{10}O_2$) is demonstrated to be stable at pH levels consistent with body surfaces and tissues, but also continues to show stability at lower or higher pH levels as well to ensure infused chemotherapy or other IV fluids are not impacted. Chlorhexidine also has been shown to be effective against viruses with a lipid component in their coats or with an outer envelope, but these properties have not been evaluated with this product. The antithrombogenic effect of the Arrowg+ard Blue Advance Technology on catheters appears to be a function of thrombin inhibition by chlorhexidine via intrinsic and common pathways of blood coagulation, causing delayed blood clotting response and thrombus accumulation on catheter surface.

Chlorhexidine is a cationic compound. Its positively charged molecules are strongly attracted to the negative charges present on microbial surfaces. The outer membrane of gram-negative bacteria, cell wall of gram-positive bacteria or cytoplasmic membrane of yeasts then becomes weakened from increased permeability caused by chlorhexidine being adsorbed onto the cell surface. Chlorhexidine exhibits bacteriostatic effects at low concentrations due to the release of substances characterized by low molecular weights (i.e., phosphorus and potassium ions) from the cell. This damage is enough to inhibit bacterial cell function. Bactericidal activity of chlorhexidine occurs at higher concentrations by causing precipitation of proteins and nucleic acids.

Chlorhexidine is poorly absorbed from the gastrointestinal tract. In human and animal studies, the average plasma level peaked at 0.206 µg/g in humans 30 minutes after ingesting 300 mg of chlorhexidine. Excretion occurred primarily through the feces (about 90%), and less than 1% was excreted in urine. Chlorhexidine is metabolized in the same manner as most other foreign substances. The majority will be excreted without being metabolized.

Preclinical biocompatibility studies support the conclusion that there is a negligible risk of adverse effects from the Arrowg+ard Blue Advance antimicrobial/antithrombogenic catheters.

Indications for Use:

The Arrowg+ard Blue Advance Pressure Injectable Midline Catheter with antimicrobial and antithrombogenic technology is indicated for short-term (< 30 days) peripheral access to the venous system for intravenous therapy, blood sampling, infusion, and pressure injection of contrast media. The maximum pressure of pressure injector equipment used with the Arrow Antimicrobial and Antithrombogenic Pressure Injectable Midline Catheter may not exceed 300 psi (2068.4kPa). The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.

Arrowg+ard Blue Advance Technology on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization and thrombus accumulation on catheter surfaces. Antimicrobial and antithrombogenic effectiveness was evaluated using *in vitro* and *in vivo* test methods and no correlation between these testing methods and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections or vein thrombosis.

Contraindications:

The Arrowg+ard Blue Advance Pressure Injectable Midline is contraindicated for patients with known hypersensitivity to chlorhexidine.

Hypersensitivity Potential:

Benefits of the use of this catheter should be weighed against any possible risk. Hypersensitivity reactions are a concern with antimicrobial catheters and can be serious and even life-threatening.

Clinical Benefits to be Expected:

Following insertion of the Arrow pressure-injectable midline catheter, at least:

- 88% of patients may expect their devices to be successfully accessed for blood sampling
- 98% of patients may expect successful peripheral intravenous therapy through their midline catheter
- 99% of patients may expect successful pressure injection of contrast media through their midline catheter

Pre-Clinical Evaluations:

Arrowg+ard Blue Advance Technology has demonstrated reduction in colonization on catheter surfaces by gram-positive and gram-negative bacteria, and yeast in *in vitro* and *in vivo* studies for up to 30 days for external surface and *in vitro* studies for up to 30 days for fluid pathway.

In addition, Arrowg+ard Blue Advance Technology has also demonstrated reduction in thrombus accumulation on catheter surfaces for up to 30 days in *in vivo* testing. *In vitro* testing has exhibited reduction in platelet adhesion on catheter surface and catheter occlusion.

MRI Safety Information:

The Midline 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 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. **Remove catheter immediately if catheter-related adverse reactions occur after catheter placement.**

   Note: Perform sensitivity testing to confirm allergy to catheter antimicrobial agents if adverse reaction occurs.
4. **Clinicians must be aware of clinical conditions that may limit use of Midlines including but not limited to:**
   - dermatitis
   - cellulitis and burns at or about the insertion site
   - previous ipsilateral venous thrombosis
   - radiation therapy at or about insertion site
   - contractures
   - mastectomy
   - potential use for AV fistula
5. **Clinicians must be aware of the potential for entrapment of 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.**
6. **Clinician should refer to institutional policies and procedures to determine appropriate therapies for a peripheral access device.**
7. **Air embolism can occur if air is allowed to enter a vascular access device or vein.**

Do not leave open needles, sheaths, or uncapped, unclamped catheters in venous puncture site. Use only securely tightened Luer-Lock connectors with any vascular access device to help guard against inadvertent disconnection.

8. **Clinicians should be aware that slide clamps may be inadvertently removed.**
9. **Use only lumen(s) labeled "Pressure Injectable" for pressure injection to reduce risk of catheter failure and/or patient complications. Refer to Arrow pressure injection label for pressure injection information.**
10. **Clinicians must be aware of complications/undesirable side-effects associated with Midlines including, but not limited to:**
    - anaphylaxis
    - air embolism
    - catheter embolism
    - bleeding/hemorrhage
    - bacteremia
    - venous thrombosis
    - hematoma
    - vessel erosion
    - exit site infection
    - nerve injury/damage
    - catheter tip malposition
    - catheter occlusion
    - septicemia
    - inadvertent arterial puncture
    - fibrin sheath formation
    - phlebitis
    - thrombophlebitis
    - infiltration
    - extravasation
    - cellulitis
11. **Do not apply excessive force in placing or removing catheter or guidewire. Excessive force can cause catheter component damage or breakage. If placement damage is suspected or withdrawal cannot be easily accomplished, radiographic visualization should be obtained and further consultation requested.**
12. **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.**
13. **Do not use excessive force when introducing guidewire, peel-away sheath over tissue dilator, or tissue dilator as this can lead to vessel perforation and bleeding, or component damage.**

Precautions:

1. **Do not alter the catheter except as instructed. Do not alter the 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. **If the package is damaged or unintentionally opened before use do not use the device. Dispose of the device.**
5. **Storage conditions for these devices require that they are kept dry and out of direct sunlight.**
6. **Verify midline catheter placement by radiographic visualization when advancing catheter in smaller patients, or in such a manner that tip location may be advanced beyond the shoulder.**
7. **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 before applying dressing.**
    - **Do not allow kit components to come into contact with alcohol.**
8. **Ensure catheter patency prior to use, including prior to pressure injection. Do not use syringes smaller than 10 mL to reduce risk of intraluminal leakage or catheter rupture. Power injector equipment may not prevent overpressurizing an occluded or partially occluded catheter.**
9. **Continuous vesicant therapies, Parenteral Nutrition or infusates with an extreme pH or osmolarity are inappropriate for delivery through a peripheral vein or a midline catheter.**

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. Prepare clean skin with appropriate antiseptic agent and allow to dry.
2. Drape puncture site.
3. Apply sterile probe cover (where provided).
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).

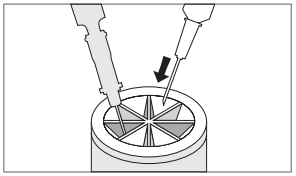

Figure 1

- 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.**

Trim Catheter if Required:

⚠ **Warning: Infusion of incompatible drugs through adjacent exit ports may cause precipitation and/or occlusion.**

6. Retract contamination guard.
7. Use centimeter marks on catheter body to trim catheter to desired length based on patient size and desired point of insertion.

Catheter Trimmer (where provided):

A catheter trimmer is a one-time use trimming device.

- Insert catheter into hole on trimmer to desired cut location.
- Depress blade to cut catheter.

8. Cut catheter straight across (90° to catheter cross-section) using trimming device (where provided) to maintain a blunt tip.
9. Inspect cut surface for clean cut and no loose material.

Flush Catheter:

10. Flush each lumen with sterile normal saline for injection to establish patency and prime lumen(s).
11. Clamp or attach Luer-Lock connector(s) to extension line(s) to contain saline within lumen(s).

⚠ **Warning: Do not clamp extension line in close proximity of the extension line hub to reduce the risk of component damage.**

Gain Initial Venous Access:

12. Apply tourniquet and replace sterile gloves.

Echogenic Needle (where provided):

An echogenic needle is used to allow access to the vascular system for introduction of a guidewire to facilitate catheter placement. The needle tip is enhanced for approximately 1 cm for clinician to identify exact needle tip location when puncturing the vessel under ultrasound.

Protected Needle/Safety Needle (where provided):

A protected needle/safety needle should be used in accordance with manufacturer's instructions for use.

13. Insert introducer needle or catheter/needle into vein.
14. Check for non-pulsatile flow.

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

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

⚠ **Precaution: Do not reinsert needle into introducer catheter (where provided) to reduce risk of catheter embolus.**

Insert 33 or 45 cm Guidewire (Access Wire):

Arrow Advancer (where provided):

Arrow Advancer is used to introduce guidewire into a needle:

- Using thumb, retract guidewire tip. Place tip of Arrow Advancer – with guidewire retracted – into introducer needle (refer to Figure 2).

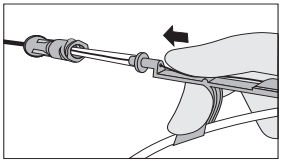

Figure 2

15. Advance guidewire into introducer needle.

⚠ **Warning: Do not insert stiff end of guidewire into vessel as this may result in vessel damage.**

16. Raise thumb and pull Arrow Advancer approximately 4 - 8 cm away from introducer needle. Lower thumb onto Arrow Advancer and while maintaining a firm grip on guidewire, push assembly into needle to further advance guidewire. Continue until guidewire reaches desired depth.

⚠ **Precaution: Maintain firm grip on guidewire at all times. Keep sufficient guidewire length exposed for handling purposes. A non-controlled guidewire can lead to wire embolus.**

⚠ **Warning: Do not withdraw guidewire against needle bevel to reduce risk of possible severing or damaging of guidewire.**

17. Remove introducer needle (or catheter) while holding guidewire in place.

Place Peel-Away Sheath:

18. Ensure dilator is in position and locked to hub of sheath.
19. Thread peel-away sheath/dilator assembly over guidewire.
20. Grasping near skin, advance peel-away sheath/dilator assembly over guidewire with slight twisting motion to a depth sufficient to enter vessel.
21. If necessary, enlarge cutaneous puncture site with cutting edge of scalpel, positioned away from guidewire.

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

⚠ **Warning: Do not cut guidewire with scalpel.**

- Position cutting edge of scalpel away from guidewire.
- Engage safety and/or locking feature of scalpel (where provided) when not in use to reduce the risk of sharps injury.

⚠ **Precaution: Do not withdraw dilator until sheath is well within vessel to reduce risk of damage to sheath tip.**

⚠ **Precaution: Sufficient guidewire length must remain exposed at hub end of sheath to maintain a firm grip on guidewire.**

22. Check peel-away sheath placement by holding sheath in place, twisting dilator hub counterclockwise to release dilator hub from sheath hub, withdraw guidewire and dilator sufficiently to allow blood flow.
23. Holding sheath in place, remove guidewire and dilator as a unit (refer to Figure 3).

⚠ **Warning: Do not apply undue force on guidewire to reduce risk of possible breakage.**

⚠ **Warning: Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.**

24. Quickly occlude sheath end upon removal of dilator and guidewire to reduce risk of air entry.

⚠ **Warning: Do not leave open dilators or sheaths uncapped in venous puncture site. Air embolism can occur if air is allowed to enter a vascular access device or vein.**

25. Verify entire guidewire is intact upon removal.

Advance Catheter:

26. Retract contamination guard.
27. Insert catheter through peel-away sheath to final indwelling position.
    - Retract and/or gently flush while advancing catheter if resistance is met.
28. Withdraw peel-away sheath over catheter until sheath hub and connected portion of sheath is free from venipuncture site. Grasp tabs of peel-away sheath and pull away from the catheter (refer to Figure 4), while withdrawing from vessel until sheath splits down its entire length.

⚠ **Precaution: Avoid tearing sheath at insertion site which opens surrounding tissue creating a gap between catheter and dermis.**

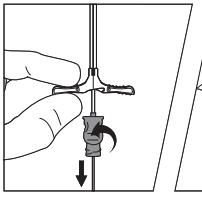

Figure 3

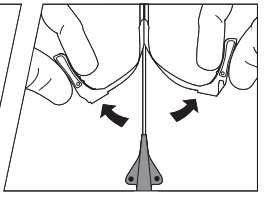

Figure 4

29. If catheter migrated during sheath removal, re-advance catheter to final indwelling position.

Complete Catheter Insertion:

30. Check lumen patency by attaching a syringe to each extension line and aspirate until free flow of venous blood is observed.
31. Flush lumen(s) to completely clear blood from catheter.
32. Connect all extension line(s) to appropriate Luer-Lock connector(s) as required. Unused port(s) may be "locked" through Luer-Lock connector(s) using standard institutional policies and procedures.
    - Clamp(s) are provided on extension line(s) to occlude flow through each lumen during line and Luer-lock connector changes.

⚠ **Warning: Open clamp prior to infusion through lumen to reduce risk of damage to extension line from excessive pressure.**

Secure Catheter:

33. Use catheter stabilization device and/or catheter clamp and fastener to secure catheter (where provided).
    - Use catheter hub as primary securement site.
    - Use catheter clamp and fastener as a secondary securement site as necessary.

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

Catheter Stabilization Device (where provided):

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

Catheter Clamp and Fastener (where provided):

A catheter clamp and fastener are used to secure catheter when an additional securement site other than the catheter hub is required for catheter stabilization.

- After necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter body making sure catheter surface is not moist to maintain proper securement.
- Snap rigid fastener onto catheter clamp.
- Secure catheter clamp and fastener as a unit to patient by using either catheter stabilization device, stapling or suturing. Both catheter clamp and fastener need to be secured to reduce risk of catheter migration (refer to Figure 5).

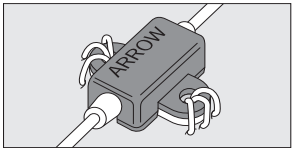

Figure 5

34. Ensure insertion site is dry before applying dressing per manufacturer's instructions.
35. Assess catheter tip placement to ensure catheter tip is at or below the axiliary line in compliance with institutional policies and procedures.
36. If catheter tip is malpositioned, assess the situation and replace the catheter or reposition according to institutional policies and procedures.
    - Secure catheter at 0 cm marking to facilitate antiseptic dressing.
    - Apply catheter label distal to luer connection on extension line (where provided).

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).

Catheter Patency:

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

Pressure Injection Instructions - Use sterile technique.

1. Identify lumen for pressure injection.
2. Check for catheter patency:
   - Attach 10 mL syringe filled with sterile normal saline.
   - Aspirate catheter for adequate blood return.
   - Vigorously flush catheter.

⚠ **Warning: Ensure patency of each lumen of catheter prior to pressure injection to minimize the risk of catheter failure and/or patient complications.**

3. Detach syringe and needleless connector (where applicable).
4. Attach pressure injection administration set tubing to appropriate extension line of catheter according to manufacturer's recommendations.

⚠ **Precaution: Do not exceed maximum pressure of 300 psi on power injector equipment to reduce risk of catheter failure and/or tip displacement.**

⚠ **Precaution: Do not exceed ten (10) injections or catheter's maximum recommended flow rate located on product labeling and catheter luer hub to minimize the risk of catheter failure and/or tip displacement.**

⚠ **Warning: Discontinue pressure injections at first sign of extravasation or catheter deformation. Follow institutional policies and procedures for appropriate medical intervention.**

⚠ **Precaution: Warm contrast media to body temperature prior to pressure injection to minimize the risk of catheter failure.**

⚠ **Precaution: Pressure limit settings on injector equipment may not prevent over pressurizing an occluded or partially occluded catheter.**

⚠ **Precaution: Use appropriate administration set tubing between catheter and pressure injector equipment to minimize the risk of catheter failure.**

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

5. Inject contrast media in accordance with institutional policies and procedures.
6. Aseptically disconnect catheter lumen from pressure injector equipment.
7. Aspirate, then flush catheter lumen using 10 mL syringe or larger filled with sterile normal saline.
8. Disconnect syringe and replace with sterile needleless connector or injection cap on catheter extension line.

Catheter Removal Instructions:

1. Position patient as clinically indicated to reduce risk of potential air embolus.
2. Remove dressing.
3. Release catheter and remove from catheter securement device(s).
4. Remove catheter by slowly pulling it parallel to skin. If resistance is met while removing catheter **STOP**

⚠ **Precaution: Catheter should not be forcibly removed, doing so may result in catheter breakage and embolization. Follow institutional policies and procedures for difficult to remove catheter.**

5. Apply direct pressure to site until hemostasis is achieved followed by an ointment-based occlusive dressing.

⚠ **Warning: Residual catheter track remains an air entry point until site is epithelialized. Occlusive dressing should remain in place for at least 24 hours or until site appears epithelialized.**

6. Document catheter removal procedure including confirmation that entire catheter length and tip has been removed per institutional policies and procedures.

For reference literature concerning patient assessment, clinician education, insertion techniques 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	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	Store below 25°C (77°F). Avoid excessive heat above 30°C (86°F)	MR safe
								
Catalogue number	Lot number	Use by	Manufacturer	Date of manufacture				

"Rx only" is used within this labeling to communicate the following statement as presented in the FDA CFR : Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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