



Arrowg+ard Blue Advance® Technology Information

Refer to enclosed product Instructions for Use (IFU) for specific indications, additional Warnings and Precautions, procedural technique(s) and potential complications associated with catheter insertion procedures.

Product Description:

Arrowg+ard Blue Advance® catheters are processed with an external surface treatment that uses 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 22.2 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 ($C_{26}H_{38}C_{12}N_{10}O_4$) 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:

Arrowg+ard Blue Advance treatment 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 on catheter surfaces. Antimicrobial 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.

Contraindications:

The Arrowg+ard Blue Advance antimicrobial/antithrombogenic catheter is contraindicated for patients with known hypersensitivity to chlorhexidine.

Warning:

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.

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.

Pre-Clinical Evaluations:

Arrow+ard Blue Advance catheters have demonstrated microbial colonization reduction against gram-positive, gram-negative 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, Arrow+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.

Store product per conditions indicated on product label.

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, Inc. website: www.teleflex.com