



# ARROW<sup>g</sup>ard Blue PLUS<sup>®</sup> Antimicrobial Catheter Technology Information

## Introduction

Infection is the leading complication associated with intravascular devices. The National Nosocomial Infection Surveillance System (NNIS) tracks central line-associated bloodstream infection (BSI) rates in adult and pediatric intensive care units from 300 participating hospitals. This report gives a benchmark for other hospitals. Approximately 90% of catheter-related bloodstream infections (CRBSIs) occur with central lines. (Maki, 1997) Mortality attributable to CRBSIs has been reported to be between 4% to 20% resulting in prolonged hospitalization (mean 7 days) and increased hospital costs. (Pittet, 1994)

## Rationale for Antimicrobial Catheters Pathogenesis of Catheter-Related Bloodstream Infections:

Vascular catheter infections develop for many reasons, but begin when a catheter becomes colonized by microorganisms entering through one of two routes, or both: 1) colonization of outside of catheter, or 2) colonization of inside of catheter. Colonization of outside of catheter can occur from skin microorganisms, contiguous infections, or hematogenous seeding of catheter from a distant site. Colonization of inside of catheter can happen through introduction of microorganisms through catheter hub or contamination of infusion fluid. (Sherertz, 1997)

## Product Description:

The ARROW<sup>g</sup>ard Blue PLUS<sup>®</sup> antimicrobial catheter is a central venous catheter (CVC) with an external surface treatment using the antimicrobials chlorhexidine acetate and silver sulfadiazine on the catheter body and juncture hub nose, plus 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). For a 20 cm catheter, average total amount of chlorhexidine, silver, and sulfadiazine applied to entire catheter is 9.3 mg, 0.63 mg and 1.50 mg, respectively.

The ARROW<sup>g</sup>ard Blue PLUS<sup>®</sup> antimicrobial catheter has demonstrated efficacy against *Candida albicans*, *Enterococcus faecalis*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Staphylococcus epidermidis*.

## Intended Use:

### ARROW<sup>g</sup>ard Blue PLUS<sup>®</sup> Central Venous Catheter:

- The ARROW<sup>g</sup>ard Blue PLUS<sup>®</sup> catheter permits venous access to central circulation by way of subclavian, jugular, and femoral veins.
- The ARROW<sup>g</sup>ard technology is intended to provide protection against catheter-related bloodstream infections (CRBSIs). It is not intended to be used as a treatment for existing infections nor is it indicated for long-term use (> 30 days). Clinical effectiveness of the ARROW<sup>g</sup>ard Blue PLUS<sup>®</sup> catheter in preventing CRBSIs compared to the original ARROW<sup>g</sup>ard Blue<sup>®</sup> catheter has not been studied.

## Indications for Use:

### ARROW<sup>g</sup>ard Blue PLUS<sup>®</sup> Central Venous Catheter:

- The ARROW<sup>g</sup>ard Blue PLUS<sup>®</sup> antimicrobial catheter is indicated to provide short-term (< 30 days) central venous access for treatment of diseases or conditions requiring central venous access.
- The catheter is not intended to be used as a treatment for existing infections nor as a substitute for a tunneled catheter in those patients requiring long-term therapy.
- One clinical study indicates antimicrobial properties of the catheter may not be effective when it is used to administer TPN.

## Contraindications:

Use of ARROW<sup>g</sup>ard Blue PLUS<sup>®</sup> antimicrobial catheter technology is contraindicated for patients with known hypersensitivity to chlorhexidine, silver sulfadiazine and/or sulfa drugs.

## Special Patient Populations:

Controlled studies of this product have not been conducted in pregnant women, pediatric or neonatal patients, and patients with known sulfonamide hypersensitivity, erythema multiforme, Stevens-Johnson syndrome and glucose-6-phosphate dehydrogenase deficiency. Benefits of use of this catheter should be weighed against any possible risk.

## Hypersensitivity Potential:

Hypersensitivity reactions are a concern with antimicrobial catheters in that they can be very serious and even life-threatening. Since antimicrobial catheters were introduced into the market, there have been reports of hypersensitivity occurrences. This may affect your patient population, especially if your patient is of Japanese origin.

*See the Warning section for additional information.*

## Clinical Evaluations:

### Clinical Study - France

A prospective, multi-center, randomized, double-blind clinical study of 397 patients performed at 14 university-affiliated hospital ICUs in France from June 1998 to January 2002 using ARROW<sup>†</sup>g<sup>‡</sup>ard Blue PLUS<sup>®</sup> antimicrobial catheters showed use of these catheters was associated with a strong trend toward reduction in infection rates of central venous catheters (colonization rate of 3.7% versus 13.1%, 3.6 versus 11 per 1000 catheter-days,  $p=0.01$ ) and CVC-related infection (bloodstream infection) in 4 versus 11 (2 versus 5.2 per 1000 catheter-days,  $p=0.10$ ).

Brun-Buisson C, Doyon F, Sollet J, Cochar J, et al. Prevention of intravascular catheter-related infection with newer chlorhexidine-silver sulfadiazine-coated catheters: a randomized controlled trial. *Intensive Care Medicine*. 2004;30:837-843.

### Clinical Study - Germany

A prospective, randomized, double-blind, controlled clinical study of 184 patients performed at the University Hospital of Heidelberg (Heidelberg, Germany) from January 2000 to September 2001 using ARROW<sup>†</sup>g<sup>‡</sup>ard Blue PLUS<sup>®</sup> antimicrobial catheters showed these catheters were effective in reducing the rate of significant bacterial growth on either the tip or subcutaneous segment (26%) compared to control catheters (49%). Incidence of catheter colonization was also significantly reduced (12% coated versus 33% uncoated). Number of bloodstream episodes in patients with CHSS catheter was lower than in patients provided with control catheter (3 versus 7 episodes,  $p=0.21$ ).

Ostendorf T, Meinhold A, Harter C, Salwender H, et al. Chlorhexidine and silver sulfadiazine coated central venous catheters in haematological patients – a double-blind, randomized, prospective, controlled trial. *Support Care Cancer*. 2005;13:993-1000.

## Clinical Study - United States

A prospective, multi-center, randomized, double-blind, controlled clinical study of 780 patients performed at 9 university-affiliated hospitals in the United States from July 1998 to June 2001 using ARROW<sup>†</sup>g<sup>‡</sup>ard Blue PLUS<sup>®</sup> antimicrobial catheters showed these catheters were less likely to be colonized at time of removal compared to control catheters (13.3 versus 24.1 colonized catheters per 1000 catheter-days,  $p<0.01$ ). Rate of definitive catheter-related bloodstream infection was 1.24 per 1000 catheter days (CI, 0.26 to 3.26 per 1000 catheter-days) for control group versus 0.42 per 1000 catheter days (CI, 0.01 to 2.34 per 1000 catheter-days) for ARROW<sup>†</sup>g<sup>‡</sup>ard Blue PLUS<sup>®</sup> catheter group ( $p=0.6$ ).

Rupp M, Lisco S, Lipsett P, Perl T, et al. Effect of a second-generation venous catheter impregnated with chlorhexidine and silver sulfadiazine on central catheter-related infections. *Annals of Internal Medicine*. October 18, 2005;143(8):570-581.

No adverse events were observed from ARROW<sup>†</sup>g<sup>‡</sup>ard Blue PLUS<sup>®</sup> catheters in any of the clinical studies.

## Studies of Drug Interactions:

The ARROW<sup>†</sup>g<sup>‡</sup>ard Blue PLUS<sup>®</sup> antimicrobial catheter has demonstrated no loss on delivery or interaction of internal lumen impregnation of chlorhexidine when infused with 82 various parenteral drugs tested for compatibility. (Xu, 2000)

## Warning:

- 1. Remove catheter immediately if adverse reactions occur after catheter placement. Chlorhexidine containing compounds have been used as topical disinfectants since the mid-1970's. An effective antimicrobial agent, chlorhexidine found use in many antiseptic skin creams, mouth rinses, cosmetic products, medical devices and disinfectants used to prepare the skin for a surgical procedure.**

**NOTE: Perform sensitivity testing to confirm allergy to catheter antimicrobial agents, if adverse reaction occurs.**

Store product per conditions indicated on product label.

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

For reference literature concerning ARROW<sup>†</sup>g<sup>‡</sup>ard Technology refer to Arrow International, Inc. website: [www.arrowintl.com](http://www.arrowintl.com)

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