ARROWgård Blue® 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 infections (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 (CRBSI) occur with central lines. (Maki, 1997) Mortality attributable to CRBSIs has been reported to be between 4% to 20% with 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 ARROWgård Blue® antimicrobial catheter consists of an Arrow® standard polyurethane catheter with Blue FlexTip®, plus an external surface treatment using antimicrobials, chlorhexidine acetate and silver sulfadiazine.
- Significant antimicrobial activity associated with the Arrow® catheter has been demonstrated using zone of inhibition bioassays against the following organisms:
  - *Klebsiella pneumoniae*
  - *Candida albicans*
  - *Escherichia coli*
  - *Pseudomonas aeruginosa*
  - *Staphylococcus aureus*
  - *Staphylococcus epidermidis*

Intended Use:
The ARROWgård technology is intended to provide protection against catheter-related bloodstream infections. It is not intended to be used as a treatment for existing infections nor is it indicated for long-term use (> 30 days).

Indications for Use:
The ARROWgård Blue® antimicrobial catheter is indicated to provide short-term (< 30 days) central venous access for the treatment of diseases or conditions requiring central venous access.

Contraindications:
Use of the ARROWgård Blue® antimicrobial catheter technology is contraindicated for patients with known hypersensitivity to chlorhexidine acetate, 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.

<table>
<thead>
<tr>
<th>Antimicrobial Catheter Size</th>
<th>Minimum Safe Infant Weight</th>
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<tr>
<td>4 Fr.</td>
<td>≥ 2.0 kg</td>
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<tr>
<td>5 Fr.</td>
<td>≥ 2.5 kg</td>
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<tr>
<td>5.5 Fr.</td>
<td>≥ 3.0 kg</td>
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This product has not been cleared for pediatric use by the FDA in the United States.

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:

- A prospective randomized clinical trial of 403 catheter insertions in adult patients in a medical-surgical ICU showed antimicrobial catheters were 50% less likely to be colonized than control catheters (p=0.003) and 80% less likely to produce catheter-related bacteremia (p=0.02).

- Complete data was obtained for 403 catheters (195 control catheters and 208 antimicrobial catheters) in 158 patients. Control catheters removed from patients who were receiving systemic antibiotic therapy occasionally showed low-level surface activity that was unrelated to length of time catheter had been in place (mean zone of inhibition ± SD, 1.7 ± 2.8 mm); in contrast, antimicrobial catheters uniformly showed residual surface activity (mean zone of inhibition, 5.4 ± 2.2 mm; P < 0.002), which declined after prolonged periods in situ. Antimicrobial activity was seen with antimicrobial catheters that had been in place for as long as 15 days.


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 ARROWgård Technology refer to Arrow International, Inc. website: www.arrowintl.com