Answering the Antimicrobial Question

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Due to recent changes regarding the reimbursement (or lack thereof) for treatment of secondary infections that patients sometimes acquire during a hospital stay, great interest has developed in finding technologies to reduce and ultimately eliminate these problems. This article looks at how one material supplier specialist is addressing the challenge.

Evonik's Cyrolite Protect is offered in a transparent green tint in order to distinguish and identify it from the standard transparent blue tint of the Cyrolite product lines.

Patients entering hospitals for a wide array of medical treatments and procedures face the potential prospect of developing a secondary infection during their stay. Previously, secondary infections obtained by patients that extended their time spent in the hospital and added additional costs would be paid for by the patient's insurance carrier. However, insurance companies no longer pay for the expenses related to secondary infections, meaning the hospitals must absorb this added patient cost, leading directly to a reduction in their bottom line. Therefore, the desire to reduce secondary infections is two-fold—maintaining the health of both the patient and the hospital's financial statement. One method now being used in the fight against secondary infections is the use of medical devices produced from materials exhibiting antimicrobial capabilities.

By definition, an antimicrobial agent is one that is capable of destroying or inhibiting the growth of microorganisms. Antimicrobial products are used for secondary infection management or to inhibit bacterial growth. The FDA's draft guidance for 510(k) submission with antimicrobial additives was initially issued on July 19, 2007 and last updated on September 14, 2010. The FDA states that medical devices that reduce or prevent device-related infections or reduce or inhibit microbial colonization on a medical device may be appropriate reasons to use an antimicrobial agent in a medical device. However, the FDA states that "Your rationale should compare the potential impact of the antimicrobial agent on the emergence of resistant microbial strains to the anticipated benefit of the antimicrobial agent on the device."

In order to evaluate the effectiveness of the potential antimicrobial systems being analyzed, the JIS Z 2801 Test Method was used to test the "kill rate" or efficacy capability of the system against the targeted organisms. A general review of the JIS Z 2801 test method is as follows:

- Each test sample is inoculated with a suspension of the test organism. The inoculum is held in contact with the test sample using a sterile polyethylene film. All test samples are inoculated in triplicate, with an additional three replicates of the control.
- The bacterial population on three control replicates is evaluated immediately following inoculation. This is assumed to be the initial population on all test samples (i.e., the population at zero hours).
- The remaining samples are incubated for the test period (typically 24 hours) at 35°C, at which time, the bacterial population is evaluated.
- A comparison of the bacterial population at the beginning and end of the test period is made and presented in tabular form.
- The test result (the value of antimicrobial activity) is the logarithmic number of the reduction rate (i.e. the ratio between the number of viable cells of bacteria on the control and on the treated sample after incubation for 24 hours).

The JIS Z 2801 standard requires values of antimicrobial activity no less than 2.0 for antimicrobial efficacy of the product. Values over 2.0 may be applicable subject to agreement between the thermoplastic manufacturer and its customers.

In an effort to address the expanding market for antimicrobial medical device applications, the leading suppliers of thermoplastic materials initiated a wide array of developmental research projects targeting this area. As a leading supplier of specially formulated acrylic-based products to the medical market for more than 35 years, Evonik Cyro [1] has offered its proprietary line of Cyrolite acrylic-based multipolymer compounds—impact-resistant thermoplastic molding compounds based on methacrylate.

Evonik Cyro's first task in the area of antimicrobial product development was to survey a number of targeted medical device manufacturers and identify key microorganisms that lead to secondary infections in hospital environments.

Following extensive discussions with these medical device manufacturers, the following four microorganisms and their areas of concern were identified:

- *Staphylococcus aureus*—common cause of staph infections
- *Pseudomonas aeruginosa*—naturally resistant to penicillin
- *Staphylococcus epidermidis*—infection risk for compromised immune systems
- *Klebsiella pneumoniae*—respiratory patient risk

With the medical device manufacturers recognizing the JIS Z 2801 test method for antimicrobial evaluation and the four targeting microorganisms identified, Evonik Cyro clarified the test duration required for medical devices. While the standard time duration of 24 hours is incorporated into the JIS Z 2801 test method, the additional time duration of 96 hours was identified as a product need representing the longest duration a medical device utilized in a I.V. dispenser would be used.

Understanding the needs of medical device manufacturers in the area of antimicrobial capabilities, test method, and duration, the next critical step for Evonik Cyro was to conduct a detailed review of antimicrobial technologies available for thermoplastic materials. Following a lengthy analysis of antimicrobial systems and their effectiveness, and considering other issues, such as environmental concerns, Evonik Cyro selected a proprietary silver-based system that could be incorporated into its Cyrolite acrylic-based multipolymer compounds. Incorporated into the resin, the silver ions were slowly released in the presence of moisture and demonstrated efficacy against the targeted microorganisms after both 24 and 96 hours, as required by the medical device manufacturers. Many additives, including silver, do have a perceived negative impact in one or more material performance characteristics. When incorporating silver into acrylic-based products, a reduction in light transmission and an increase in haze are observed versus the excellent visual characteristics typically seen with acrylic-based products. However, the contact clarity and appearance found with these products offsets those concerns as the medical device manufacturers are able to obtain a visual image of the fluids passing thru their components.

In addition to the product needs identified by the medical device manufacturers, it is critical that Evonik Cyro meets the requirements for products specifically designed for FDA regulated Class I or Class II medical devices covered by 510(k) submission. Understanding the medical device market from years of service and supply, Evonik Cyro also identified the need to supply a polymer that passed the Class VI United States Pharmacopoeia tests for determining the suitability of a plastic material intended for use in fabricating containers or accessories thereto, for parenteral preparations.

Cyrolite Protect acrylic-based multipolymer compound displays the characteristics of toughness; transparency; bondablility to PVC tubing; resistance to gamma, e-beam, and ETO sterilization; easy processing; and chemical resistance. Of greater importance, the compound provides antimicrobial capabilities against the four identified microorganisms as tested against the JIS Z 2801 protocol for both the 24-

and 96-hour time periods. Cyrolite Protect is specifically designed for FDA regulated Class I or Class II medical devices covered by 510(k) submission and has a Device Master File Number available to its customers upon request.

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