



# Cleaning-coating technology reduces bacterial by-products on liners

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## INTRODUCTION

There are about two million amputees in the U.S. Approximately 1.7 million of these individuals use a prosthetic device. A common problem for amputees is irritation, odor and infections related to prosthetic liners. There are currently few options for the wearer beyond regular cleaning with soap and water and use of alcohol wipes. Compliance with good hygiene can also be an issue for some patients.

This paper deals with a liner coating applicator and technology designed to deep clean and coat silicone and gel-based products to improve comfort, decontaminate and reduce odors related to the skin and liner interface. The BI Medical (Coventry, Rhode Island) cleaning system has the unique ability to deliver a coating in liquid solvents, to ensure even coverage, adherence, and deep penetrance in prosthetic liner materials. The residual film consists of Titanium oxide, silicone and a metal-organic silver compound determined to be biocompatible with no cytotoxicity according to ISO 10993 testing (Jarrell, 2013). Prior testing used in the development of the technology showed antimicrobial activity of the residual film (Tran, 2015).

For this study the Japanese Industrial Standard (JIS) Z 2801, "Antibacterial Products – Test for Antibacterial Activity and Efficacy," was used to identify the efficacy of this coating technology against *Staphylococcus aureus* (Gram-positive) and *Pseudomonas aeruginosa* (Gram-negative) for two weeks after application of the cleaner/coating.

## METHOD

The JIS Z 2801 method was used which involved application of the coating chemistry using the products sponge tip applicator to 4x4 cm sections of thermoplastic liner material and allowed to dry. In a second set of testing, the chemistry was diluted with anhydrous isopropanol 1:4 to create a much thinner coating to simulate wear conditions.

Bacteria cultures for *Staphylococcus aureus* and *Pseudomonas aeruginosa* are individually applied to separate liner samples at greater than  $1 \times 10^5$  cells/cm<sup>2</sup> and tested for colony forming units (CFUs) at time zero and after 24 hours of contact time. This was controlled for and compared against non-coated samples of liner material inoculated at the same time to determine the comparable percentage and log reduction in bacteria achieved by the coated liner material. These tests were performed immediately after applying the coating, after 2 days and after 2 weeks to establish the long-term efficacy of the coating product. A 2 log or 99% reduction is passing.

## RESULTS

There was a dramatic reduction in both Gram-positive and Gram-negative bacteria for all coated samples. For the diluted chemistry coatings, this resulted in a > 4 log reduction of both bacteria types for all time points including two weeks. For the full strength coatings there was a >99.9997% reduction in *S. aureus* and >99.9998% reduction of *P. aeruginosa* two weeks after application of the coating compared to non-coated control samples.

## DISCUSSION

Technologies incorporating silver have been used in elastomeric liners and fabrics with good success. The limitation of these is the loss of activity over time. Liquid cleaning-coating solutions, such as the one tested, not only aid in the removal of embedded skin and sebaceous secretions, but replenish the coating and silver compounds which could otherwise be lost over the lifetime of a product.

Organic solvent based titanium dioxide and metalorganic silver forming coatings address the underlying issues related to the causes of liner odor and discomfort, which is related to bacteria.

## CONCLUSION

The BI Medical cleaning and coating technology greatly reduced bacterial by-products on liners according to the JIS Z 2801 method. For the full strength coatings there was a >99.9997% reduction in *Staphylococcus aureus* (Gram-positive) and >99.9998% reduction of *Pseudomonas aeruginosa* (Gram-negative) for two weeks after application of the coating compared to non-coated control samples.

## CLINICAL APPLICATIONS

Removal of bacterial by-products, prevention of odor and related discomfort from skin contacting liners with their underlying health implications is an important need recognized by the O&P community and their patients. BI Medical's cleaning and coating applicator chemistry addresses the root issues related to both Gram-positive and Gram-negative bacteria. Combining materials science and drug delivery based approaches to improving patient experience and hygiene at the skin interface are an important step for prosthetic advancement (Jarrell, 2010).

## REFERENCES

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American Academy of Orthotists & Prosthetists  
**44<sup>th</sup> Academy Annual Meeting &  
Scientific Symposium**  
February 14 – 17, 2018