

Title The effect of pressure differential and secondary packaging on microbial penetration of a sterile medical device tray

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Abstract

The method involved aseptically filling sealed, sterile device packages with a known volume of an appropriate growth medium, exposing the packages to an aerosolized microbial challenge, incubating the package and inspecting for growth. After creating and refining the test technique, the research explored the impact of pressure differential and secondary packaging with varying hole sizes on microbial penetration. The specific pressure differential examined simulates an aircraft descending from 8,000 feet or a ground shipment descending from the same elevation. Both pressure differential and hole size had a statistically significant effect on the microbial penetration of the sterile medical device test tray used in this study. The effect of secondary packaging on penetration rates and CFUs is currently being investigated