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RESEARCH ARTICLE

Hydrogen Peroxide Vapor Penetration into Small Cavities during Low-Temperature Decontamination Cycles

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Abstract

Introduction The suitability of vapor-phase hydrogen peroxide for the decontamination of different-sized narrow cavities and complex geometrical structures were investigated in this paper.

Methods A cavity test block was used, and cavities made from different materials were tested with variable entrance heights and cavity depths. At the end of each cavity, biological indicators were exposed as a microbiological challenge for vapor-phase hydrogen peroxide penetration. Within this study, the test block with the biological indicators was subjected to different decontamination cycles in a production isolator. Inoculation level, cycle length, hydrogen peroxide, and water concentration were varied.

Results The ratio of cavity entrance height to depth was found to be critical for decontamination success by biological indicators exposed inside the cavities. The higher the ratio, the more spores could be inactivated. Inactivation is also effected by exposure time and hydrogen peroxide concentration.

Conclusion The results indicate that the entrance height of the cavities should not be smaller than 6 mm and the cavity depth should not exceed 30 mm. If smaller cavities cannot be avoided, high peroxide concentration (800 ppm) and prolonged cycle times were shown to significantly enhance the penetration into dead-ended cavities under diffusive conditions.

Keywords Cavity · Crevice · Dead leg · Decontamination · Gap · *Geobacillus stearothermophilus* · Hole · Hydrogen peroxide · Inactivation · Interstice · Lumen · MPN · Penetration · Pharmaceutical isolator · Vapor · VPHP

Introduction

A wide range of low-temperature sterilization methods using gaseous sterilants are currently under application in the pharmaceutical and medicinal sector. For example, ethylene oxide, formaldehyde, hydrogen peroxide vapor, and gas plasma are used to sterilize heat-sensitive equipment and facilities [1]. It is well-known that complex geometries such as gaps, crevices, cavities, dead-ended tubes, and narrow intrusions present the most difficult challenges for these sterilization processes [2–4]. In general, the penetration of the sterilant into narrow cavities occurs via the combined mechanisms of diffusion and convection [5].

Published literature on the subject of penetration into small cavities for low-temperature sterilization methods mainly concentrates on the investigation of reusable and non-heat-resistant medical equipment which is not autoclavable. These devices, e.g., endoscopes, often include

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