

Variations in the Resistance of Biological Indicators Used to Assess Sterilization



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Biological indicators (BI) are routinely used within the pharmaceutical, food, and medical devices industries to monitor the efficacy of various sterilization processes. These processes include dry heat, ethylene oxide, hydrogen peroxide, moist heat (steam sterilization), chlorine dioxide, and peracetic acid. Biological indicators (or 'bio-indicators') are preparations of a specific microorganism with high resistance towards particular sterilization methods.

More specifically, biological indicators are "standardized" preparations of specific microorganisms with known characteristics (a defined population, purity, and resistance characteristic) (1). The microorganisms used to prepare biological indicators are those capable of forming endospores; ultimately, the microorganism is used in the "spore state" (to do otherwise would be a failure to present the microorganism in the state of greatest resistance to the sterilization device). A biological indicator is prepared by depositing bacterial spores from a spore crop onto a carrier such as filter paper or a medium contained within an ampoule (importantly, it is the microorganism *plus* the carrier that forms the 'biological indicator'). Destruction of the spores is indicative of the probability of sterility (2), and the outcome is used to make assessments about the level of sterility assurance that can be achieved.

Sometimes, unexplained results occur when using biological indicators. This could be attributable to a failure of the sterilization process or, perhaps, due to a mishandling of the biological indicator. Other reasons could be traced to issues of resistance and variations with the biological indicator itself. This paper discusses the "phenomenon of resistance."

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