Living Assurance for the Sterilization Process

What do industry experts and agencies say about Biological Indicators...

“Biological indicators (BIs) are the most accepted means of monitoring the sterilization process because they directly determine whether the most resistant microorganisms (e.g., Geobacillus or Bacillus species) are present rather than merely determine whether the physical and chemical conditions necessary for sterilization are met. Because spores used in BIs are more resistant and present in greater numbers than are the common microbial contaminants found on patient care equipment, an inactivated BI indicates that other potential pathogens in the load have also been killed.”

“Because chemical indicators do not prove sterilization has been achieved, a biological indicator (i.e., spore test) is required.”

CDC: Centers for Disease Control and Prevention
Sterilization Monitoring – FAQs – Infection Control in Dental Settings
www.cdc.gov

“Infection Control and Hospital Epidemiology Vol 17 no.7 423 July 1996
Comparison of a Rapid Readout Biological Indicator for Steam Sterilization With Four Conventional Biological Indicators and Five Chemical Indicators
Authors: William A. Rutala, PhD, MPH; Suzanne M. Jones, MPH; David J. Weber, MD, MPH

“Biological indicators are recognized by most authorities as being the closest to ideal monitors of the sterilization process, because, unlike chemical indicators, they measure the sterilization process directly by using the most resistant microorganism (Bacillus spores), not merely testing the physical and chemical conditions necessary for sterilization.”

CDC: Centers for Disease Control and Prevention
Authors: William A. Rutala, PhD, MPH; David J. Weber, MD, MPH and the Healthcare Infection Control Practices Advisory Committee (HICPAC)

“Biological indicators are the only process indicators that directly monitor the lethality of a given sterilization process. Spores used to monitor a sterilization process have demonstrated resistance to the sterilizing agent and are more resistant than the bioburden found on medical devices...

...daily use of biological indicators allows earlier discovery of equipment malfunctions or procedural errors and thus minimizes the extent of patient surveillance and product recall needed in the event of a positive biological indicator. Each load should be monitored if it contains implantable objects. If feasible, implantable items should not be used until the results of spore tests are known to be negative.”

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“Only the biological indicators performed consistently in all of the sterilizer conditions evaluated. Both the fluorescent readout and the growth readout of the self-contained biological indicators were able to detect the sub-optimal or failure conditions at a greater frequency than any of the chemical integrators.”

American Journal of Infection Control June 2005 Volume 33, Number 5
Performance of various steam sterilization indicators under optimum and sub-optimum exposure conditions
Authors: Philip M. Schneider, Robert R. Reich, Steven S. Kirckof, and William G. Foltz
Guest Editor: William A. Rutala, PhD, MPH

“The BI is used to test the effectiveness of the sterilization process by assessing the microbial lethality of the process. A Chemical Indicator (CI) indicates that the medical device has been exposed to one or more process conditions, and unless the CI integrates ALL process conditions, it is not an adequate test for assessing the effectiveness of the process.”

FDA
Guidance on Premarket Notification (510(K)) Submissions for Sterilizers Intended for Use in Health Care Facilities
Infection Control Devices Branch Division of General and Restorative Devices
March 1993

“Regardless of their design, chemical monitors cannot be used in lieu of biological indicators and instrumented measurement of temperature/pressure/time during the validation of a steam sterilization process.”