

MCKESSON

STER-ALL® Performance

Self-Contained BI for Steam Sterilization

Steam self-contained biological indicators are inoculated with viable *Geobacillus stearothermophilus* bacterial spores and are intended for monitoring the efficacy of saturated steam sterilization processes operating at 121°C and 132°C gravity displacement, 132°C flash gravity displacement and 121°C – 134°C prevacuum cycles. Steam self-contained biological indicators are also appropriate for use in monitoring the efficacy of saturated steam prevacuum sterilization processes operating at 135°C for 3 minutes exposure time.

Due to varying sterilizer come-up times, it is recommended to extend the cycle time from 3 minutes to 4 minutes in order to achieve consistent kill when testing the gravity steam process at 270°F (132°C) in Flash Cycles.

Steam biological indicators (BIs) meet the suggested performance parameters published in the current USP and AAMI/ISO 11138 for steam gravity and dynamic-air-removal sterilization processes. Culture media is tryptic soy broth validated for growth promotion capabilities per USP guidelines. Media growth promotion has been validated for extended steam cycles operating at 132°C for 20 minutes exposure time.

Monitoring Frequency

Per AAMI standards, Steam sterilizers should be biologically tested at least weekly, preferably daily and every load that contains an implant.

Instructions for Use

1. Record the sterilizer number, load number and processing date on the BI label.
2. Place one or more BIs inside an instrument tray, rigid container, peel pouch or process challenge device, e.g. AAMI challenge pack, whichever is representative of the load being processed.
3. Test the most challenging area in the sterilizer as indicated in the sterilizer's instruction manual (i.e. the bottom shelf near the door, over the drain of a large sterilizer or in the middle shelf of a small sterilizer).
4. Process the load according to the sterilizer manufacturer's instructions.
5. Remove the BI and confirm the chemical indicator printed on the label has turned brown.
Caution: After processing, the BI is hot and under pressure. Always allow to cool for ten (10) minutes before crushing. Failure to do so could cause the glass ampule inside the BI vial to burst which may result in injury. For this reason, safety glasses should be worn when handling and crushing a processed BI.

Activation and Incubation

1. Activate the processed BI within 8 hours after processing by gently crushing the inner glass media tube using a vial crusher.
2. Incubate at 55 – 60°C for 24 hours checking for spore growth (visual color change from purple to yellow) at regular intervals (i.e. 3, 5 and 8 hours). Growth of surviving spores has been documented in as little as 2 1/2 hours.

Test Results

1. Record negative (no growth) results after full incubation in a Sterilizer Record Notebook. No color change in the purple media indicates proper sterilization.
2. Any positive (growth indicated by purple to yellow color change) result, should be reported immediately to a Supervisor and the sterilizer taken out of service until resolved.
3. The stability of positive growth as indicated by a yellow color change has been tested up to 48 hours.

Use of Controls

1. As a control, an unprocessed BI (from the same lot) should be gently crushed using a vial crusher and incubated each day the sterilizer is tested.