



MINI SELF CONTAINED BIOLOGICAL INDICATORS (MSCBIs) For Monitoring Steam Processes

REF No.: AMAMSCST-05G

Product Description

Mini Self-Contained Biological Indicators (MSCBIs) for monitoring Steam processes consist of:

- A polypropylene vial and cap
- A crushable media ampule which contains modified Tryptic Soy Broth (TSB) with a pH indicator. The modified TSB will transition from the initial Purple color to Yellow and/or demonstrate turbidity in the presence of bacterial growth.
- An inoculated carrier (disc) of *Geobacillus stearothermophilus* Cell Line 7953 with a population level of 10^5 .

Physical Properties

Process	Steam
Dimensions	8.3 mm x 46 mm
Packaging	100 per box
Chemical Indicator	Each MSCBI contains a Chemical Indicator (CI) on the vial label. The CI should transition from Pink to Brown when exposed to a steam process.

Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one or more MSCBIs be included with every load.

Indications for Use

The MSCBIs may be utilized to monitor Steam sterilization processes efficacy at 121°C to 140°C. Exposure to temperatures above 145°C will impact the integrity of the product. The MSCBIs are ideal for monitoring non-liquid steam sterilization cycles. MSCST-05 may be used for monitoring sterilization efficacy in health-care, dental and laboratory/industrial applications (reference K200970).

Instructions for Use

Exposure: MSCBI's may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or MSCBIs in most difficult location to sterilize, as outlined in your specific sterilization validation protocol or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove MSCBIs or product from sterilizer.



MSCBIs may be held at room temperature for up to 72 hours post-exposure prior to activation without any impact to the performance. If the processed MSCBIs are not activated within 72 hours of exposure, the cycle should be repeated.

Activation: Squeeze the sides of the unit until an audible click is heard and the glass media ampule contained within is crushed. Ensure that the disc is immersed in the growth medium. Activate one MSCBI which has not been exposed in a sterilization process as a Positive Control.

Incubation: Place the processed, activated MSCBI and the Positive Control in a vertical position in an incubator at 55°C to 65°C for a minimum of 10 hours.

Monitoring: Examine the MSCBIs and record observations. All positive MSCBIs should be disposed of immediately. Do not continue to incubate a positive MSCBI. Continued incubation may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and result in color reversion that is visibly darker than a sterile unit. These should be considered as positive for growth (turbidity will be present).

Interpretation: Control MSCBI: The Positive Control MSCBI should exhibit a color change to Yellow and/or demonstrate turbidity. If the Positive Control as does not show signs of growth, consider the test invalid.

Test MSCBI: A passing sterilization cycle is indicated by no signs of turbidity and the Purple color remaining and not transitioning to Yellow. A failed sterilization cycle is indicated by turbidity and/or a color change to Yellow.

Chemical Indicator (CI): The chemical indicating strip should transition from Pink to Brown when exposed to a Steam process. Lack of color change or a partial change in color of the CI does not necessarily indicate failure. The CI does not prove efficacy of sterilization; the biological result should be used to gauge efficacy of the sterilization cycle.

For unexpected positives, it is recommended that a Gram stain be performed. Gram positive rods are indicative for the indicator organism.

Compliance

ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1:General requirements

ISO 11138-3 Sterilization of healthcare products – Biological indicators – Part 3 Biological indicators for moist heat sterilization processes.

USP <55> Biological Indicators – Resistance Performance Tests

The method for Total Viable Spore Count has been validated. Please inquire for the Technical Bulletin which outlines the recommended methodology.

USP Biological/Official Monographs

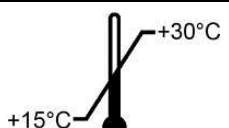




Disposal

Autoclave for not less than 30 minutes at 121°C or per validated disposal cycle prior to discard.

Performance Characteristics

Population	$\geq 1.0 \times 10^5$ per disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	<p>D value at $121^\circ\text{C} \pm 0.5^\circ\text{C}$ ≥ 1.5 minutes</p> <p>D value at $132^\circ\text{C} \pm 0.5^\circ\text{C}$ ≥ 10 seconds</p> <p>D value at $135^\circ\text{C} \pm 0.5^\circ\text{C}$ ≥ 8 seconds</p> <p>The Steam D value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA).</p> <p>Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA.</p> <p>z value $\geq 10^\circ\text{C}$</p> <p>Determined based on three temperatures in the range of 110°C to 138°C. The manufacturer typically utilizes D values determined at 121°C, 132°C and 135°C for z value calculation.</p>
Post-Market Criteria	<p>Population: 50% to 300% of certified population</p> <p>D value: $\pm 20\%$ of the certified D value</p> <p>Survival Time: All MSCBIs result in growth at the certified survival time</p> <p>Kill Time: All MSCBIs result in no growth at the certified kill time</p>

Storage and Shelf Life

	15°C to 30°C		Protect from heat, radioactive sources and sterilizing agents
	20% to 80% Relative Humidity		Do not freeze
Shelf Life	The shelf life of the MSCBI is based on the shorter of two individual components (the media ampoule and inoculated carrier), which have independent expiration periods. This is usually 24 months from the date of manufacture.		
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the MSCBIs. Do not use damaged MSCBIs or MSCBIs which demonstrate turbidity or have transitioned to a Yellow color. Do not use after expiration date. Do not refrigerate. The MSCBIs contain live cultures and should be handled with care.		