Technical Data Sheet

SELF CONTAINED BIOLOGICAL INDICATORS (SCBIs) For Monitoring Steam Processes

True Indicating Codes: SCST-05 and SCST-06

Product Description

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

- A polycarbonate vial and a polypropylene cap
- A crushable media ampoule 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 or 10^6.

Physical Properties

Process	Steam
Dimensions	9.5 mm x 48 mm
Packaging	50 per box
Chemical Indicator	Each SCBI 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 SCBIs be included with every load.

Indications for Use

The SCBIs 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 SCBIs are ideal for monitoring non -liquid steam sterilization cycles and are labeled for laboratory/industrial use only.

Instructions for Use

Exposure: SCBI's may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or SCBIs 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 SCBIs or product from sterilizer.

SCBIs 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 SCBIs are not activated within 72 hours of exposure, the cycle should be repeated.

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Activation: Depress the cap in a downward motion until an audible clip is heard and the glass media ampule contained within is crushed. Ensure that the disc is immersed in the growth medium. Activate one SCBI which has not been exposed in a sterilization process as a Positive Control.

Incubation: Place the processed, activated SCBI and the Positive Control in a vertical position in an incubator at 55°C to 65°C for a minimum of 24 hours. The SCBIs may be incubated for up to 7 days when the cap has been completely seated on the vial.

Monitoring: Examine the SCBIs and record observations.

Where SCBIs have been activated and sealed with the cap, evaporation of the growth medium will be delayed in comparison to Traditional Mini SCBI configurations. Evaporation causes the medium in positive SCBIs to revert from Yellow back to Purple; this will not occur unless incubated for greater than 7 days.

Interpretation: Control SCBI: The Positive Control SCBI 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 SCBI: 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.

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

True Indicating has a validated method for Total Viable Spore Count. 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.

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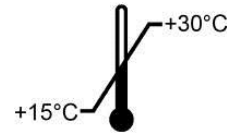
Performance Characteristics

Population	≥ 1.0 x 10^5 or 10^6 per disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	*D* value at 121°C ± 0.5°C ≥ 1.5 minutes 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). Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA. *z* value ≥ 6°C Determined based on three temperatures in the range of 110°C to 138°C. True Indicating typically utilises *D* values determined at 110°C, 121°C and 130°C for *z* value calculation.
Post-Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value Survival Time: All SCBIs result in growth at the certified survival time Kill Time: All SCBIs result in no growth at the certified kill time

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 SCBI 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 SCBIs. Do not use damaged SCBIs or SCBIs which demonstrate turbidity or have transitioned to a Yellow color. Do not use after expiration date. Do not refrigerate. The SCBIs contain live cultures and should be handled with care.		

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