TRUE INDICATING PRODUCTS

Certificate of Analysis

This lot of product meets the accepted performance criteria recommended in the USP, ISO 11138-1 and ISO 11138-3.

Product Name: Self-Contained Biological Indicator (SCBI)

For use in Monitoring: Steam

Organism: *Geobacillus stearothermophilus*

Derived from: ATCC® 7953

LOT S732-0

REF MSCST-05

Quantity 100 SCBIs

2020-09-21

2022-09-21

Performance Characteristics		
Population: 3.4 x 10^5 per 6 mm disc		
D value	Survival	Kill
Steam 121°C: 2.1 minutes	7.5 minutes	20.0 minutes
Steam 132°C: 0.3 minutes	1.1 minutes	2.8 minutes
Steam 135°C: 0.2 minutes	0.7 minutes	1.9 minutes
The *D* value(s) were determined per the fraction negative method and are reproducible only when exposed and cultured under the exact conditions used to obtain results reported above. The user would not necessarily obtain the same results, therefore, should determine the suitability for their particular use. Survival-kill times calculated using USP and ISO survival time and kill time formulae.		
z value: 8.4°C	Based on D value determinations at 121°C, 132°C, and 135°C	

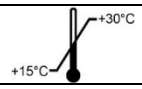
Recovery: After exposure to the sterilization process, activate the SCBI by pressing on the sides of the unit applying sufficient pressure to break the media ampule. Ensure the Spore Disc is immersed in the growth medium. Incubate at 55°-65°C for a minimum of 10 hours. Incubate an unexposed SCBI which has been activated as a Positive Control.

Examine SCBIs for growth as frequently as possible. SCBIs which are positive for growth of *Geobacillus stearothermophilus* will transition from Purple to Yellow and/or display a cream-colored sediment. If the Positive Control does not yield a Yellow color and/or turbidity, the test is not valid and the incubation conditions should be verified.

Remove SCBIs which are positive for growth (Yellow and/or turbid) from incubation promptly. Continued incubation of the SCBIs will cause the growth medium to evaporate and lead to the color of positive units to revert from Yellow back to a dark Purple color.

SCBIs which are negative for growth will remain clear and Purple in color. Negative SCBIs (Clear and Purple after incubation) indicate the cycle/process was effective.

Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the biological indicator.

Storage and Shelf Life			
	Room Temperature (15°-30°C)		Keep away from sunlight
	20% to 80% Relative Humidity		Protect from heat, radioactive sources, and sterilizing agents
Shelf Life	24 Months Product is labeled with the shorter expiration date of the two components with individual expiry periods: the Media Ampule and the Spore Disc.		

Disposal: Autoclave, steam at 121˚C for not less than 30 minutes, or incinerate (standard microbial waste; non-pathogenic species).

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Quality Approval

August 24, 2022

Date

Manufactured by: True Indicating LLC 946 Kane St, Suite A Toledo, Ohio 43612 www.trueindicating.com
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MSCST-05 True Indicating Self-Contained Biological Indicator (SCBI)

Important:

The following instructions provides the necessary information for an end user to understand the directions for use. Always refer to the directions which are provided with the product and adhere to any and all warnings and cautions.

WARNING:

There is a glass ampule inside the plastic vial of the biological indicator.

- Crushing or excessive handling of the biological indicator before cooling may cause the glass ampule to burst.
- Do not use your fingers to crush the glass ampule.

Indications for Use: The True Indicating SCBI is intended for monitoring the efficacy of saturated steam sterilization processes. The True Indicating SCBI has a validated Reduced Incubation Time (RIT) of 10 hours and may be used in the following steam sterilization cycles: 121ºC, 30 minutes (Gravity), 132°C, 4 minutes (Pre-Vacuum) and 135ºC, 3 minutes (Pre-Vacuum).

Common Steps:

SCBIs are designed to monitor Steam sterilization efficacy at stated values of 121°C for ≥ 30 minutes (Gravity Cycle), 132°C for ≥ 4 minutes (Pre-Vacuum), and 135°C for ≥ 3 minutes (Pre-Vacuum). Exposure to temperatures above 137°C may impact the integrity of the product. The SCBIs are ideal for monitoring non-liquid steam sterilization cycles within full, partial, or empty chambers. The SCBIs can be exposed with porous, nonporous, or mixed loads.

Exposure:

SCBIs may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate 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/exposure, remove SCBIs from sterilizer. The 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 SCBIs should be discarded and the cycle should be repeated.

SCBI Activation:

Depress the sides of the vial in an inward motion until an audible click is heard and the glass media ampule contained within the SCBI 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 on a daily basis, following local procedures.

SCBI Incubation:

Place the processed, activated SCBI and the Positive Control in a vertical position in an incubator at 55° - 65°C for a minimum of 10 hours. It is not recommended to incubate the SCBI beyond 72 hours without covering its cap to prevent evaporation of the media. The media will evaporate from the SCBI if incubated longer than 72 hours, making the test invalid if not evaluated prior.

Monitoring: Examine the SCBIs and record observations.

SCBI Interpretation:

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.

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

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

Storage:

Best stored in the original box under normal room conditions: 15-30°C, 20-80% relative humidity. Do not store these biological indicators near sterilants or other chemicals.

Disposal:

Dispose of used SCBIs according to your healthcare facility's policy. Autoclave, steam at 121°C for at least 30 minutes, or incinerate (standard microbial waste; non-pathogenic species).

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