



# Technical Data Sheet

## INSTANT BIOLOGICAL INDICATORS (IBIs) For Monitoring Steam Processes

True Indicating Codes: ISCS-05 and ISCS-06

### Product Description

Instant Biological Indicators (IBIs) for monitoring Steam processes consists of two components which provide confirmation of sterilization efficacy:

- A Biological Tablet contained within the yellow silicone base manufactured with proprietary materials extracted from *Geobacillus stearothermophilus* spores.
- An Indicator Solution containing co-enzymes which react with the Biological Tablet post-exposure to provide a result within 30 seconds post-exposure.
- A polycarbonate vial and a polypropylene 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  $10^5$  or  $10^6$ .

### Physical Properties

Process	Steam at 121°, 132° and 134°C
Dimensions	14.5 mm x 53.5 mm
Packaging	25 per box
Chemical Indicator	Each ICBI contains a Chemical Indicator (CI) on the 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 IBI be included with every load.

### Indications for Use

The IBIs may be utilized to monitor Steam sterilization processes efficacy at 121°C to 135°C. Exposure to temperatures above 137°C may impact the integrity of the product. The IBIs are ideal for monitoring non-liquid steam sterilization cycles and are labeled for laboratory/industrial use only.

### Instructions for Use

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



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



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PRODUCTS

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**Biological Tablet and Indicator Solution:** Remove the yellow adhesive strip from the silicone base to expose the Tablet. Add 1-2 drops of Indicator Solution onto the tablet. After 30 seconds, record the color of the Tablet and then discard immediately per the disposal instructions. Repeat process for one IBI which has not been exposed as a Positive Control.

**SCBI Activation (Optional):** 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.

**SCBI 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 10 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.

**Interpretation:** Control Biological Tablet : The Positive Control should exhibit a color change to a shade of Red within 30 seconds.

Test Biological Tablet: A passing sterilization cycle is indicated by little to no color change within 30 seconds. A failed sterilization cycle is indicated by a color change to a shade of Red within 30 seconds.

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.

For an unexpected positive result in the SCBI, it is recommended that a Gram stain be performed. Gram

## 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.

## Disposal

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



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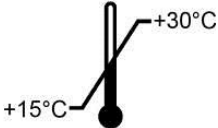






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## Performance Characteristics

Population	$\geq 1.0 \times 10^5$ or $10^6$ per Inoculated Carrier Spore Disc
Purity of Spore Disc	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	<p><math>D</math> value at <math>121^\circ\text{C} \pm 0.5^\circ\text{C}</math> <math>\geq 1.5</math> minutes</p> <p>The Steam <math>D</math> value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food &amp; 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><math>z</math> value <math>\geq 6^\circ\text{C}</math></p> <p>Determined based on three temperatures in the range of <math>110^\circ\text{C}</math> to <math>138^\circ\text{C}</math>.</p>
Post-Market Criteria	<p>Spore Disc Population: 50% to 300% of certified population</p> <p><math>D</math> value: <math>\pm 20\%</math> of the certified <math>D</math> value</p> <p>Survival Time: All IBIs result in a positive Biological Tablet or growth for the Spore Disc at the certified survival time</p> <p>Kill Time: All IBIs result in a negative Biological Tablet or no growth for the Spore Discs 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
<b>Shelf Life</b>	The shelf life of the IBI is based on the shorter of individual components (Biological Tablet, Indicator Solution, the media ampule and inoculated carrier), which have independent expiration periods. This is usually 12 months from the date of manufacture.		
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the IBIs. Do not use damaged IBIs or IBIs which demonstrate turbidity or have transitioned to a Yellow color. Do not use after expiration date. Do not refrigerate. The IBIs contain live cultures and should be handled with care.		

