Technical Data Sheet

BIOLOGICAL INDICATOR SPORE STRIPS
For Monitoring Steam Sterilization Processes

True Indicating Codes: SB5-06

Product Description

Biological indicator Spore Strips for monitoring low temperature steam processes consist of:

- Inoculated carrier, 6mm x 30mm Spore Strip of *Bacillus subtilis* Cell Line 35021 (formerly 5230) with known population and resistance
- Packaged in a glassine envelope with label

Indications for Use

The Spore Strips are utilized to monitor Steam sterilization process efficacy. *Bacillus subtilis* is typically used to monitor low temperature steam processes of 100°C -121°C. The Spore Strips are labelled for laboratory/industrial use only.

Process	Low Temperature Steam
Strip Dimensions	6 mm x 30 mm
Glassine Dimensions	30 mm x 38 mm
Quantity	100 / Pack

Physical Properties
Monitoring Frequency

For greatest control of sterilized goods, it is recommended that a minimum of ten (10) Spore Strips be included with every load.

Instructions for Use

Place Spore Strips (a minimum of 10 per exposure is recommended) inside representative materials to be sterilized. Package or wrap product as usual, if applicable.

Locate the test packages or Spore Strips in areas most difficult to sterilize, as outlined in your specific sterilization validation protocol (usually four corners front, four corners rear, center-center and center-top) or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove Spore Strips or test packages from the sterilizer.

Spore Strips may be held at room temperature up to 96 hours post-exposure prior to transfer without any impact to the performance. If the processed Spore Strips are not transferred to growth medium within 96 hours of exposure, the cycle should be repeated.

Aseptically remove the Spore Strip from the primary packaging and transfer to 5-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, True Indicating Product Code RGM-100 may be utilized in place of the SCDB.

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Transfer one Spore Strip which has not been exposed in a sterilization process as a Positive Control.

Incubation: At least one tube of culture medium (no Spore Strip) from the same lot should be incubated with the test series as a Negative Control. Incubate the cultured Spore Strips, the Positive Control and the Negative Control at 30°C to 35°C as outlined in the following table:

Sterilization Process	Media Type	Min. Incubation Time
Steam	SCDB	7 days
	RGM-100	72 Hours

Monitoring: Examine the Spore Strips daily during incubation. Record observations.

Interpretation:

Where SCDB (standard or unmodified) was utilized: Tubes which demonstrate turbidity with cream-colored sediment are considered positive for growth of *Bacillus subtilis.* Tubes which remain clear and without sediment are considered negative for growth.

Where modified media, True Indicating Product Code RGM-100, was utilized: Tubes which transition in color from Orange to Yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain Orange in color and do not demonstrate turbidity are considered negative for growth.

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

Positive Control: Tube(s) should demonstrate turbidity and cream-colored sediment or demonstrate a color transition from Orange to Yellow where modified media has been utilized. If the Positive Control does not result in growth, the exposure is considered invalid. Check the conditions during incubation and verify the capability of the medium to support growth.

Negative Control: Tube of media should remain clear and Orange in color where modified medium was utilized. If the Negative Control results in growth, there is a potential for false positive results.

Compliance

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

USP <55> Biological Indicators – Resistance Performance Tests

True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin outlining the recommended methodology.

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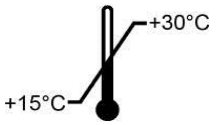
Population	≥1.0 x 10^6 per Strip
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	*D* value at 110°C ± 0.5°C ≥ 1.5 minute *D* value at 115°C ± 0.5°C ≥ 1.0 minute *D* value at 118°C ± 0.5°C ≥ 0.5 minute Survival - Kill Times Calculated based on the formulas 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 utilizes *D* values determined at 110°C, 115°C and 118°C for *z* value calculation.
Post Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value

Performance Characteristics

	15°C to 30°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep Dry
Shelf Life	30 months from the date of manufacture		Protect from heat and radioactive sources
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Strips. Do not use damaged Spore Strips. Do not use after the expiration date. The Spore Strips contain live cultures and should be handled with care.		

Storage and Shelf Life

Disposal

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

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