



## BIOLOGICAL INDICATOR SPORE STRIPS For Monitoring Steam Sterilization Processes

True Indicating Codes: SB5-04, SB5-05 and SB5-06

### Product Description

Biological indicator Spore Strips for monitoring low temperature steam processes consist of an inoculated carrier, 6mm x 30mm Spore Strip of *Bacillus subtilis* Cell Line 35021 packaged in a glassine envelope.



### Indications for Use

The Spore Strips are utilised to monitor Steam sterilization process efficacy. *Bacillus subtilis* is typically used to monitor low temperature steam processes of 100°C -120°C. The Spore Strips are labelled for lab-industrial use only.

### Monitoring Frequency

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

### Instructions for Use

Place Spore Strips 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, centre-centre and centre-top) or according to standard operating procedure. Run the cycle.

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

Aseptically transfer the Spore Strip from the primary packaging and transfer to 5-15 mL of Soybean Casein Digest Broth (SCDB).

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

**Incubation:** At least one tube of SCDB (no Spore Strip) from the same lot should be incubated with the test series as a Negative Control. Place the cultured Spore Strips, the Positive Control and the Negative Control in an incubator set at 30°C to 35°C.

Spore Strips cultured in SCDB should be incubated for a minimum of 7 days or per a validated reduced incubation period.

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





# Technical Data Sheet

## Interpretation:

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.

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

Positive Control: Tube should demonstrate turbidity and cream colored sediment. 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 SCDB should remain clear with n visible signs of growth. If the Negative Control results in growth, there is a potential for false positives in the Spore Strip results.

## Physical Properties

Process	Steam
Strip Dimensions	6mm x 30 mm
Glassine Dimensions	30mm x 38mm
Quantity	100 / Pack
Secondary Packaging	Heat Sealed Pouch which is Re-sealable

## Performance Characteristics

Population	$\geq 1.0 \times 10^x$ per Strip where $x = \log$ of population
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	$D$ value at $110^\circ\text{C} \pm 0.5^\circ\text{C} \geq 1.5$ minute $D$ value at $115^\circ\text{C} \pm 0.5^\circ\text{C} \geq 1.0$ minute $D$ value at $118^\circ\text{C} \pm 0.5^\circ\text{C} \geq 0.5$ minute
Post Market Criteria	Population: 50% to 300% of certified population $D$ value: $\pm 20\%$ of the certified $D$ value

## Compliance

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

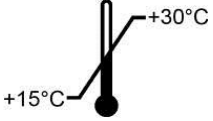





True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin outlining the recommended methodology.





# Technical Data Sheet

## Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep Dry
Shelf Life	24 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.		

## Disposal

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

