BIOLOGICAL INDICATOR SPORE STRIPS
For Monitoring Steam

Crosstex Codes: BS-102, BS-103, BS-104, BS-105, BS-106, BS-107, BS-108



Product Description

Biological Indicator Spore Strips for monitoring Steam processes consist of:

- An inoculated carrier, 7 mm x 38 mm (1.5" x 0.281") strip, of *Geobacillus stearothermophilus* (Cell Line 7953)
- Primary packaging in a white glassine pouch

Intended Use

The Spore Strips may be utilized for routine Steam sterilization process efficacy monitoring, sterilizer qualification testing after installation, relocation, malfunctions, major repairs and sterilization process failures for both Healthcare and Industrial applications. Crosstex Codes BS-102, BS-103 and BS-104 are labeled For Industrial Use Only.

Instructions for Use – Industrial Settings

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

Locate the 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 product from sterilizer.

Aseptically remove the Spore Strip from the primary packaging and transfer to Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, Crosstex Code GMBCP-100, may be utilized in place of the SCDB.

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

Incubation: At least one unused tube of culture medium 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 55°C to 60°C.

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

Spore Strips cultured in modified growth medium, Crosstex Code GMBCP-100, should be incubated for a minimum of 24 hours.

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

Crosstex International, Inc. | Industrial Markets
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Interpretation:
Where SCDB (standard or unmodified) was utilized:
Tubes which demonstrate turbidity with cream colored sediment are considered positive for growth of *Geobacillus stearothermophilus*. Tubes which remain clear and without sediment are considered negative for growth.

Where modified medium, Crosstex Code GMBCP-100, was utilized:
Tubes which transition in color from purple to yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain purple 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 characteristic of the indicator organism.

Positive Control: Tube should demonstrate turbidity and cream colored sediment or demonstrate a color transition from purple to yellow where modified medium 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 medium should remain clear and purple where modified medium was utilized. If the Negative Control results in growth, there is a potential for false positives.

Physical Properties

Process	Steam
Strip Dimensions	7 mm x 38 mm (1.5” x 0.281”)
Glassine Dimensions	25 mm x 75 mm
Packaging	100/Box

Monitoring Frequency

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

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Performance Characteristics

Population	1.0 to 5.0 x 10^x per strip where x = the population level of the Spore Strip
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 to 3.0 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 formulas outlined in the USP, ISO 11138-1 and guidance issued by the FDA. *z* value ≥6°C The *z* value is based on *D* values at three temperatures in the range of 110°C to 130°C. Crosstex typically utilizes *D* values determined at 118°C, 121°C and 126°C.
Post-Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value Survival Time: All Spore Strips result in growth at the certified survival time Kill Time: All Spore Strips result in no growth at the certified kill time

Compliance

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

For Crosstex Codes BS-105, BS-106, BS-107 and BS-108: ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

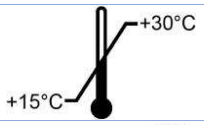
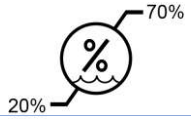
USP <55> Biological Indicators – Resistance Performance Tests

USP Biological/Official Monographs

Crosstex has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled *Population Verification of Paper Carrier Biological Indicators* to ensure consistent methodologies are being utilized when performing verification testing.

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Storage and Shelf Life

	20°C to 25°C average Excursions 15°C to 30°C allowed		Keep away from sunlight
	20% to 70% 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 121ºC or per other validated disposal cycle prior to discard.

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