
BIOLOGICAL INDICATOR SPORE STRIPS For Monitoring Steam Formaldehyde

Crosstex Codes: STSF-05 and STSF-06



Product Description

Biological Indicator Spore Strips for monitoring Steam Formaldehyde 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 to monitor Steam Formaldehyde sterilization process efficacy. The Spore Strips are labeled For Industrial Use Only.

Instructions for Use

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 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 product from sterilizer.

Aseptically remove the Spore Strip from the primary packaging and transfer to Soybean Casein Digest Broth (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 65°C.

Incubate for a minimum of seven days or per a validated reduced incubation period.

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



Interpretation: 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.

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. 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. If the Negative Control results in growth, there is a potential for false positives.

Physical Properties

| | |
|--------------------|------------------------------|
| Process | Steam Formaldehyde |
| Strip Dimension | 7 mm x 38 mm (1.5" x 0.281") |
| Glassine Dimension | 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.

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. |
| Post-Market Criteria | Population: 50% to 300% of certified population |

Compliance

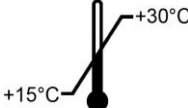

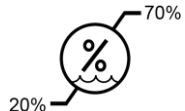



ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements

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.

Crosstex International, Inc. | Industrial Markets

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Storage and Shelf Life

| | | | |
|---|--|---|---|
|  | 15°C to 30°C |  | Keep away from sunlight |
|  | 20% to 70% Relative Humidity |  | Keep dry |
| <p>Shelf Life</p> | 30 Months from the date of manufacture |  | Protect from heat and radioactive sources |
|  | <p>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.</p> | | |

Disposal

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