



INOCULATED CARRIER SPORE DISCS For Monitoring Steam

Crosstex Codes: BS-105D and BS-106D

Product Description

Inoculated Carrier Spore Discs for monitoring Steam processes consist of:

- An inoculated carrier, 6 mm disc, of *Geobacillus stearothermophilus* (Cell Line 7953)
- Primary packaging in bulk

Intended Use

The Spore Discs are designed to be placed directly into a device and utilized to monitor Steam sterilization process efficacy. The Spore Discs are labeled For Industrial Use Only.

Instructions for Use

Place Spore Discs (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 Discs 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 Discs or product from sterilizer.

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

Transfer one Spore Disc 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 Discs, the Positive Control and the Negative Control in an incubator set at 55°C to 60°C.

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

Spore Discs cultured in modified growth medium, Crosstex Code GMBCP-100, should be incubated at 55°C to 60°C for a minimum of 24 hours.

Monitoring: Examine the Spore Discs 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 *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
Disc Diameter	6 mm
Packaging	100/Box

Monitoring Frequency

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

Performance Characteristics

Population	1.0 to 5.0 x 10 ^x per disc where x = the log population of the Spore Disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	<p><i>D</i> value at 121°C ± 0.5°C 1.5 to 3.0 minutes</p> <p>The Steam <i>D</i> value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA).</p> <p>Survival – Kill Times Calculated based on the formulas outlined in the USP, ISO 11138-1 and guidance issued by the FDA.</p> <p><i>z</i> value ≥6°C</p> <p>The <i>z</i> value is based on <i>D</i> values at three temperatures in the range of 110°C to 130°C. Crosstex typically utilizes <i>D</i> values determined at 118°C, 121°C and 126°C.</p>
Post-Market Criteria	<p>Population: 50% to 300% of certified population</p> <p><i>D</i> value: ± 20% of the certified <i>D</i> value</p> <p>Survival Time: All Spore Discs result in growth at the certified survival time</p> <p>Kill Time: All Spore Discs result in no growth at the certified kill time</p>

Compliance

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

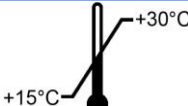





ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

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.

Storage and Shelf Life

	<p>20°C to 25°C average Excursions 15°C to 30°C allowed</p>		<p>Keep away from sunlight</p>
	<p>20% to 70% Relative Humidity</p>		<p>Keep dry</p>
<p>Shelf Life</p>	<p>24 Months from the date of manufacture</p>		<p>Protect from heat and radioactive sources</p>
	<p>Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Discs. Do not use damaged Spore Discs. Do not use after the expiration date. The Spore Discs 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.