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## **INOCULATED CARRIER SPORE DISCS**

### **For Monitoring Ethylene Oxide (EO) and Dry Heat**

**Crosstex Code: BG-106D**

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#### **Product Description**

Inoculated Carrier Spore Discs for monitoring EO and Dry Heat processes consist of:

- An inoculated carrier, 6 mm disc, of *Bacillus atrophaeus* (Cell Line 9372)
- Primary packaging in bulk

#### **Intended Use**

The Spore Discs are designed to be placed directly into a device and utilized to monitor EO and Dry Heat 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).

Transfer a minimum of 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 30°C to 37°C.

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

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

**Interpretation:** Tubes which demonstrate turbidity with an orange pellicle are considered positive for growth of *Bacillus atrophaeus*. Tubes which remain clear and without pellicle formation 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 with an orange pellicle. 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. If the Negative Control results in growth, there is a potential for false positives.

### Physical Properties

Process	EO and Dry Heat
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 <sup>6</sup> per disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
EO Resistance	<p><i>D</i> value at 54°C ± 1°C, 600 mg/L ± 30 mg/L, 60% RH ± 10% RH 2.5 to 5.8 minutes</p> <p>The EO <i>D</i> value range is based on the requirements outlined in the USP and ISO 11138-2. The EO <i>D</i> value is determined using 100% EO.</p> <p>Survival – Kill Times Calculated based on the formulas outlined in the USP and ISO 11138-1.</p>
Dry Heat Resistance	<p><i>D</i> value at 160°C ± 1°C 1.0 to 3.0 minutes</p> <p>The Dry Heat <i>D</i> value range is based on the requirements outlined in the USP.</p> <p>Survival – Kill Times Calculated based on the formulas outlined in the USP and ISO 11138-1.</p> <p><i>z</i> value ≥20°C</p> <p>Determined based on <i>D</i> values at three temperatures in the range of 150°C to 180°C. Crosstex typically utilizes <i>D</i> values determined at 150°C, 160°C and 170°C for <i>z</i> value calculation.</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

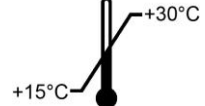





ISO 11138-2 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

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><b>Shelf Life</b></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.