



## 1 mL SPORE AMPULES For Monitoring Steam

### Crosstex Codes:

SA1-15-04, SA1-50-04, SA1-15-05, SA1-50-05, SA1-15-06, SA1-50-06

### Product Description

1 mL Spore Ampules are Self-Contained Biological Indicators for monitoring Steam processes consisting of a hermetically sealed glass ampule which contains modified Trypticase<sup>®</sup> Soy Broth (TSB) with a pH indicator and *Geobacillus stearothermophilus* (Cell Line 7953) with a population level of  $10^4$ ,  $10^5$  or  $10^6$ . The modified TSB will transition from the initial purple color to yellow and/or demonstrate turbidity in the presence of bacterial growth.

### Intended Use

The Spore Ampules may be utilized to monitor Steam sterilization efficacy. The Spore Ampules are ideal for monitoring liquid steam sterilization cycles but may also be utilized in monitoring dry loads. Spore Ampules are labeled For Industrial Use Only.

### Instructions for Use

**Exposure:** Spore Ampules may be placed inside representative materials (containers of liquid) or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or Spore Ampules in most difficult location to sterilize, as outlined in your specific sterilization validation protocol or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove Spore Ampules or product from sterilizer. Allow product or Spore Ampules to cool to the touch. No activation is required.



Handle Spore Ampules with care as contents are extremely hot. Leaving the Spore Ampules in the sterilizer post-exposure may have a negative impact on the product's performance. As such, Spore Ampules left in the chamber for extended periods of time (>24 hours) post-exposure should be discarded.

**Controls:** A Negative Control ampule, Crosstex Code SA1-NC-10, may be used in conjunction with the Spore Ampules, where a negative control is required. If a Positive Control is needed, label one unprocessed Spore Ampule as "Positive Control".

**Incubation:** Place the processed Spore Ampules, the Negative Control and the Positive Control in a vertical position in an incubator at 58°C to 62°C for a minimum of 48 hours.

**Monitoring:** Examine the Spore Ampules daily during incubation. Record observations. All positive Spore Ampules should be disposed of immediately.

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

**Interpretation:** Negative Control (Crosstex Code SA1-NC-10): The Negative Control Ampule should not exhibit a color change to yellow and/or demonstrate turbidity. Utilize the Negative Control as a color comparison for the exposed Spore Ampules, where applicable.

Positive Control Spore Ampule: The Positive Control Spore Ampule should exhibit a color change to yellow and/or demonstrate turbidity. Utilize the Positive Control as a color comparison for the exposed Spore Ampules, where applicable. If the positive control does not demonstrate a yellow color and/or turbidity, the results for test Spore Ampules should not be considered valid. Verify incubation conditions were met.

Test Spore Ampules: A passing sterilization cycle is indicated by a test Spore Ampule which retains its original purple color and is free from turbidity. A failed sterilization cycle is indicated by turbidity and/or a color change to yellow.

### Physical Properties

Process	Steam
Dimensions	Approximately 58 mm x 10.8 mm
Packaging	15 or 50 per box depending on the product code
Volume	1 mL

### Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one or more Spore Ampules be included with every load.

## Performance Characteristics

Population	1.0 to 5.0 x 10 <sup>x</sup> per ampule, where x is the population level of the Spore Ampule
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 &amp; 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 Ampules result in growth at the certified survival time</p> <p>Kill Time: All Spore Ampules 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

For Crosstex Codes SA1-15-05, SA1-50-05, SA1-15-06 and SA1-50-06: ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

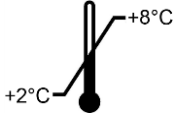




USP <55> Biological Indicators – Resistance Performance Tests

USP Biological/Official Monographs

USP Biological Indicator for Steam Sterilization, Self-Contained

Crosstex has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled *Population Verification of 1 mL Spore Ampules* to ensure consistent methodologies are being utilized when performing verification testing.

**Storage and Shelf Life**

	Refrigerate at 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat, radioactive sources, & sterilizing agents
<p><b>Shelf Life</b></p>	24 Months from the date of manufacture		
	Do not use damaged Spore Ampules or Spore Ampules which demonstrate turbidity or have transitioned to a yellow color. Do not use after expiration date. The Spore Ampules contain live cultures and should be handled with care.		

**Disposal**

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

Trypticase<sup>®</sup> is a registered trademark owned by Becton, Dickinson and Company.