



SELF-CONTAINED BIOLOGICAL INDICATORS (SCBIs) SPORE AMPULES WITH NEGATIVE CONTROLS For Monitoring Liquid Steam Processes



True Indicating Code: AT-0610

Product Description

Spore Ampules are SCBIs consisting of a hermetically sealed glass ampule which contains modified Tryptic Soy Broth (TSB) with a pH indicator and *Geobacillus stearothermophilus* Cell Line 7953 with a population level of 10^6 . The modified TSB will transition from the initial Purple color to Yellow and/or demonstrate turbidity in the presence of bacterial growth.

Negative Control Ampules are manufactured with the modified TSB from the same lot as the Spore Ampules providing a consistent Purple color prior to and post-incubation. Each Negative Control Ampule contains a glass bead to ensure they are easily distinguishable from the Spore Ampules.

Indications for Use

Spore Ampules may be utilized to monitor Steam sterilization processes at 121°C to 137°C and are ideal for monitoring liquid steam sterilization cycles but may also be utilized in monitoring dry loads. Spore Ampules and Negative Controls are labeled for laboratory/industrial use only.

Physical Properties

Process	Steam
Dimensions	47 mm x 10.6 mm
Packaging	50 Spore Ampules + 10 Negative Control Ampules per box
Volume	1mL

Monitoring Frequency

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

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.



Handle Spore Ampules with care as the contents are extremely hot post-exposure. Always employ proper PPE when handling hot materials; remove Spore Ampules from sterilizer as quickly as safely possible post-exposure. 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.

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.





Technical Data Sheet

Controls: A Negative Control Ampule should be used in conjunction with the Spore Ampules. 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 60°C to 65°C for a minimum of 48 hours.

Monitoring: Examine the Spore Ampules daily, whenever possible during incubation. Record observations. All positive Spore Ampules should be disposed of immediately. Do not continue to incubate a positive Spore Ampule. Continued incubation of positive Ampules may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and result in color reversion that is visibly darker (Dark Purple-Brown) than a sterile unit. These should be considered as positive for growth (turbidity and sediment in the Ampule will be present).

Interpretation: Negative Control: The Negative Control Ampule should remain Purple and not exhibit a color change to Yellow and/or demonstrate turbidity. Utilize the Negative Control as a color comparison for the exposed Spore Ampules.

Positive Control: 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 throughout the incubation period.

Test Spore Ampules: A passing sterilization cycle is indicated by a Test Spore Ampule remaining Purple in color and is free from turbidity. A failed sterilization cycle is indicated by turbidity and/or a color change to Yellow.

Compliance

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

ISO 11138-3 sterilization of healthcare products—Biological indicators — Part 3: Biological indicators for moist heat sterilization processes.

USP <55> Biological Indicators— Resistance Performance Tests

True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin which outlines the recommended methodology.

Disposal

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





Technical Data Sheet

Performance Characteristics

Population	≥ 1.0 x 10 ⁶ per 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 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 formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA.</p> <p><i>z</i> value ≥ 6°C</p> <p>Determined based on three temperatures in the range of 110°C to 138°C. True Indicating typically utilizes <i>D</i> values determined at 118°C, 121°C and 130°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 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>

Storage and Shelf Life

	Refrigerate at 2°C to 8°C		Keep away from Sunlight
	Do not freeze		Protect from heat, radioactive sources and sterilizing agents
Shelf Life	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.		

