

SPORE AMPOULES

For monitoring Steam Sterilisation processes.



Excelsior Code: SA1-50-04E, SA1-50-05E & SA1-50-06E

Product Description

Spore Ampoules are Self-Contained Biological Indicators for monitoring Steam processes consisting of a hermetically sealed glass ampoule which contains modified Tryptic 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 colour to yellow and/or demonstrate turbidity in the presence of bacterial growth.

Indications for Use

The Spore Ampoules may be utilized to monitor Steam sterilisation processes at 121°C to 137°C. The Spore Ampoules are ideal for monitoring liquid steam sterilisation cycles but may also be utilised in monitoring dry loads. Spore Ampoules are labelled for industrial use only.

Instructions for Use

Exposure: Spore Ampoules 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 Ampoules in most difficult location to sterilise, as outlined in your specific sterilisation validation protocol or according to standard operating procedure. Run the cycle.



Handle Spore Ampoules with care as contents are extremely hot. Once Spore Ampoules are cooled and able to be handled, remove from steriliser immediately. Leaving the Spore Ampoules in the steriliser post-exposure may have a negative impact on the product's performance. As such, Spore Ampoules left in the chamber for extended periods of time (24 hours) post-exposure should be discarded.

After sterilisation or exposure, remove Spore Ampoules or product from steriliser. Allow product or Spore Ampoules to cool to the touch. No activation is required.

Controls: A Negative Control ampoule, Excelsior Code SA1-NC-10E, may be used in conjunction with the Spore Ampoules, where a negative control is required. If a Positive Control is needed, label one unprocessed Spore Ampoule as "Positive Control".

Incubation: Place the processed Spore Ampoules, the Negative Control and the Positive Control in a vertical position in an incubator at 55°C to 65°C for a minimum of 48 hours.

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

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

Interpretation: Negative Control (Excelsior Code SA1-NC-10E): The Negative Control Ampoule should not exhibit a colour change to yellow and/or demonstrate turbidity. Utilise the Negative Control as a colour comparison for the exposed Spore Ampoules, where applicable.

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

Test Spore Ampoules: A passing sterilisation cycle is indicated by a test Spore Ampoule which retains its original purple colour and is free from turbidity. A failed sterilisation cycle is indicated by turbidity and/or a colour change to yellow.

Physical Properties

Process	Steam
Dimensions	58 mm x 10.6mm
Packaging	50 per box
Volume	1mL

Monitoring Frequency

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

Performance Characteristics

Population	≥ 1.0 x 10 ^x per ampoule, where x is the population level of the spore ampoule.
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. Excelsior Scientific typically utilises <i>D</i> values determined at 110°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 Ampoules result in growth at the certified survival time</p> <p>Kill Time: All Spore Ampoules 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 Excelsior codes SA1-50-05E & SA1-50-06E: ISO 11138-3 sterilisation of healthcare products— Biological Indicators for moist heat sterilization processes.

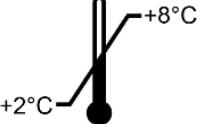




USP <55> Biological Indicators— Resistance Performance Tests

Excelsior Scientific has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled “Population Verification for Spore Ampoules” to ensure consistent methodologies are being utilised when performing verification testing.

USP Biological/Official Monographs

USP Biological Indicator for Steam Sterilization, Self-Contained

Storage and Shelf Life

	Refrigerate at 2°C to 8°C		Keep away from Sunlight
	Do not freeze		Protect from heat, radioactive sources & sterilising agents
Shelf Life	24 months from the date of manufacture.		
	Do not use damaged Spore Ampoules or Spore Ampoules which demonstrate turbidity or have transitioned to a yellow colour. Do not use after expiration date. The Spore Ampoules 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.