

BIOLOGICAL INDICATOR SPORE STRIPS For Monitoring Ethylene Oxide (EO)

Excelsior Code: STN-02E, STN-03E, STN-04E, STN-05E , STN-06E
STN-07E & STN-08E



Product Description

Biological indicator Spore Strips for monitoring EO processes consist of:

- An inoculated carrier, 6mm x 30mm strip of *Bacillus atrophaeus* (Cell Line 9372)
- Primary packaging in a glassine envelope

Indications for Use

The Spore Strips are utilised to monitor EO sterilisation process efficacy. The Spore Strips are labelled for industrial use only.

Instructions for Use

Place Spore Strips (a minimum of 10 per exposure is recommended) inside representative materials to be sterilised or within the chamber directly. Package or wrap product as usual, if applicable.

Locate the test packages or Spore Strips in areas most difficult to sterilise, as outlined in your specific sterilisation validation protocol (usually four corners front, four corners rear, centre-centre and centre-top) or according to standard operating procedure. Run the cycle.

After sterilisation or exposure, remove Spore Strips or product from steriliser



Spore Strips may be held at room temperature up to 96 hours post-exposure prior to transfer without any impact to the performance. If the processed Spore Strips are not transferred to growth medium within 96 hours of exposure, the cycle should be repeated

Aseptically transfer the Spore Strip from the primary packaging and transfer to 10-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, Excelsior code GMBTB-100E may be used in place of the SCDB.

Transfer one Spore Strip which has not been exposed in a sterilisation 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 Strips, the Positive Control and the Negative Control in an incubator set at 30°C to 40°C.

Spore Strips cultured in SCDB should be incubated for a minimum of 7 days or per a validated reduced incubation period.

Spore Strips cultured in modified growth medium SCDB Excelsior code GMBTB-100E should be incubated for a minimum of 48 hours.

Monitoring: Examine the Spore Strips daily during incubation. Record observations.

Interpretation:

Where SCDB (standard or unmodified) was used:

Tubes which demonstrate turbidity with cream/orange coloured pellicle are considered positive for growth of *Bacillus atrophaeus*. Tubes which remain clear and without formation of pellicle are considered negative for growth.

Where modified media, Excelsior code GMBTB-100E was used:

Tubes which transition in colour from green to yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain green in colour 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 indicative for the indicator organism.

Positive Control: Tube should demonstrate turbidity with a cream/orange coloured pellicle or demonstrate a colour transition from green to yellow where modified media has been utilised. 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 media should remain clear and green in colour where modified medium was utilised. If the Negative Control results in growth, there is a potential for false positives

Physical Properties

Process	EO
Strip Dimensions	6mm x 30 mm
Glassine Dimensions	Envelope : 30mm x 38mm
Packaging	100 / pack

Monitoring Frequency

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

Performance Characteristics

Population	$\geq 1.0 \times 10^x$ per Strip where x= the population level of the Spore Strip
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
EO Resistance	<p><i>D</i> value at $54^\circ\text{C} \pm 1^\circ\text{C}$, $600 \text{ mg/L} \pm 30 \text{ mg/L}$, $60\% \text{ RH} \pm 10\% \text{ RH}$ ≥ 2.0 minutes</p> <p>The EO <i>D</i> value range is based on the requirements outlined in the USP, ISO 11138-2. The EO <i>D</i> value is determined using 100% EO.</p> <p>Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1</p>
Post Market Criteria	<p>Population: 50% to 300% of certified population</p> <p><i>D</i> value: $\pm 20\%$ of the certified <i>D</i> value</p> <p>Survival Time: All Spore Strips result in growth at the certified survival time</p> <p>Kill Time: All Spore Strips 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 STN-06E, STN-07E and STN-08E:

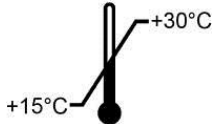





-ISO 11138-2 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

USP <55> Biological Indicators – Resistance Performance Tests

Excelsior Scientific has a validated method for Total Viable Spore Count. Please inquire for the Technical data sheet entitled “Population Verification for Biological Indicator Strips” to ensure consistent methodologies when performing verification testing.

USP Biological/Official Monographs

Storage and Shelf Life

	<p>15°C to 30°C</p>		<p>Keep away from sunlight</p>
	<p>20% to 80% 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>Normal fluctuation and excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Strips. Long term exposure (>3 Months) at relative humidity levels below 30% may impact the resistance of the STN-06E. Do not use damaged Spore Strips. Do not use after the expiration date. The Spore Strips 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.