# BIOLOGICAL INDICATOR SPORE STRIPS
# For Monitoring Steam Sterilisation Processes


Excelsior Code: STS-02E, STS-03E, STS-04E, STS-05E & STS-06E

**Product Description**

Biological indicator Spore Strips for monitoring steam processes consist of:

- An inoculated carrier, 6mm x 30mm strip of *Geobacillus stearothermophilus* (Cell Line 7953)
- Primary packaging in glassine envelopes

**Indications for Use**

The Spore Strips are utilised to monitor Steam 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. 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 GMBCP-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 55°C to 65°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 GMBCP-100E should be incubated for a minimum of 24 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 coloured sediment are considered positive for growth of *Geobacillus stearothermophilus.* Tubes which remain clear and without sediment are considered negative for growth.

Where modified media, Excelsior code GMBCP-100E was used:
Tubes which transition in colour from purple to yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain purple 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 and cream coloured sediment or demonstrate a colour transition from purple 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 purple in colour where modified medium was utilised. If the Negative Control results in growth, there is a potential for false positives

**Physical Properties**

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|---|---|
| Process | Steam |
| 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**

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|---|---|
| Population | ≥ 1.0 x 10x 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. |
| Steam Resistance | *D* value at 121°C ± 0.5°C<br>≥ 1.5 minutes<br><br>The Steam *D* value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA).<br><br>Survival – Kill Times<br>Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA.<br><br>*z* value<br>≥ 6°C<br><br>Determined based on three temperatures in the range of 110°C to 138°C. Excelsior Scientific typically utilises *D* values determined at 110°C, 121°C and 130°C for *z* value calculation. |
| Post Market Criteria | Population: 50% to 300% of certified population<br><br>*D* value: ± 20% of the certified *D* value<br><br>Survival Time: All Spore Strips result in growth at the certified survival time<br><br>Kill Time: All Spore Strips result in no growth at the certified kill time |

**Compliance**

ISO 11138-1 Sterilization of health care products – Biological Indicators- Part 1: General Requirements

For Excelsior Codes STS-05E and STS-06E: 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

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**

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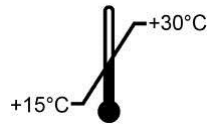
|---|---|---|---|
|  | 15°C to 30°C |  | Keep away from sunlight |
|  | 20% to 80% relative humidity |  | Keep Dry |
| Shelf Life | 24 months from the date of manufacture |  | Protect from heat and radioactive sources |
|  | Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Strips. 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. | | |

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

For additional product information:
Please visit us at
www.excelsiorscientific.com
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