INOCULATED CARRIER SPORE THREADS
For Monitoring Steam Sterilisation Processes

Excelsior Code: THS-06E & THS-06PE

Product Description

Inoculated carrier spore threads for monitoring steam processes consist of:

- An inoculated carrier, 30mm x 0.1mm thread of *Geobacillus stearothermophilus* (Cell Line 7953)
- Primary packaging either in bulk (THS-06E) or in glassine envelopes (THS-06PE)

Indications for Use

The Spore Threads are designed to be placed directly into a device and utilised to monitor Steam sterilisation process efficacy. The Spore Threads are labelled for industrial use only.

Instructions for Use

Place Spore Threads (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 Threads in areas most difficult to sterilize, 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 Threads or product from steriliser

Spore threads 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 Threads are not transferred to growth medium within 96 hours of exposure, the cycle should be repeated.

Aseptically transfer the Spore Threads to 10-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, Excelsior Code GMBCP-100E, may be utilised in place of the SCDB.

Transfer one Spore Thread 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 Threads, the Positive Control and the Negative Control in an incubator set at 55°C to 65°C.

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

Spore Threads cultured in modified growth medium, Excelsior GMBCP-100E, should be incubated for a minimum of 24 hours.

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

Interpretation:

Where SCDB (standard or unmodified) was utilised:
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 utilised:
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 where modified medium was utilised. If the Negative Control results in growth, there is a potential for false positives

Physical Properties

Process	Steam
Thread Dimensions	30mm x 0.1 mm
Glassine Dimensions	THS-05PE / THS-06PE: 30mm x 38mm
Packaging	100 / Pack

Monitoring Frequency

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

Compliance

ISO 11138-1 Sterilization of health care products – Biological Indicators- Part 1: General Requirements
ISO 11138-3 Sterilization of health care products – Biological Indicators- Part 3: biological indicators for moist heat 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 Mini Strips (2 mm x 10 mm), Threads (steel, paper and glass fibre), Threads, Wires and Coupons” to ensure consistent methodologies are being utilised when performing verification testing.

USP Biological/Official Monographs
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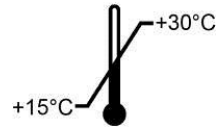
Population	≥1.0 x 10^6 per thread
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	*D* value at 121°C ± 0.5°C ≥1.5 minutes The Steam *D* value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA). Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA. *z* value ≥ 6°C Determined based on three temperatures in the range of 110°C to 130°C. Excelsior 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 *D* value: ± 20% of the certified *D* value Survival Time: All Spore Threads result in growth at the certified survival time Kill Time: All Spore Threads result in no growth at the certified kill time

Performance Characteristics

	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 Threads. Do not use damaged Spore Threads. Do not use after the expiration date. The Spore Threads contain live cultures and should be handled with care.		

Storage and Shelf Life 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
Email us at sales@excelsiorscientific.com

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