INOCULATED CARRIER SPORE THREADS
For Monitoring Ethylene Oxide (EO and Dry Heat)

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

Product Description

Inoculated carrier spore threads for monitoring EO and Dry Heat processes consist of:

- An inoculated carrier, 30mm x 0.1mm thread of *Bacillus atrophaeus* (Cell Line 9372)
- Primary packaging either in bulk (THN-06E) or in glassine envelopes (THN-06PE)

Indications for Use

The Spore Threads are designed to be placed directly into a device and utilised to monitor EO and Dry Heat 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 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 Threads or product from steriliser

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

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.

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. Incubate the cultured Spore Threads, the Positive Control and the Negative Control at 30°C to 40°C as outlined in the following table:

Sterilisation Process	Media Type	Min. Incubation Time
EO/ Dry Heat	SCDB	7 Days
EO	GMBTB-100E	48 Hours
Dry Heat	GMBTB-100E	48 Hours

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

Interpretation:

Where SCDB (standard or unmodified) was utilised:
Tubes which demonstrate turbidity with a cream/orange pellicle are considered positive for growth of *Bacillus atrophaeus*. Tubes which remain clear and without pellicle are considered negative for growth.

Where modified media, Excelsior Code GMBTB-100E, was utilised:
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 pellicle. 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. If the Negative Control results in growth, there is a potential for false positives

Physical Properties

Process	EO & Dry Heat
Thread Dimensions	30mm x 0.1 mm
Glassine Dimensions	THN-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.

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Performance Characteristics

Population	≥1.0 x 10^6 per thread
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
EO Resistance	*D* value at 54°C ± 1°C , 600 mg/L ± 30 mg/L, 60% RH ± 10% RH ≥ 2.0 minutes The EO *D* value range is based on the requirements outlined in the USP, ISO 11138-2. The EO *D* Value is determined using 100% EO Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1.
Dry Heat Resistance	*D* value at 160°C ± 1°C ≥ 2.0 minutes The Dry Heat *D* value range is based on the requirements outlined in the USP, Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1. Z value ≥ 20°C Determined based on *D* values at three temperatures in the range of 150°C to 180°C. Excelsior typically uses *D* values determined at 150°C, 160°C and 180°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

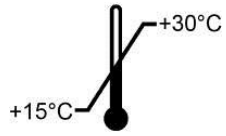
Compliance

ISO 11138-1 Sterilization of health care products – Biological Indicators- Part 1: General Requirements
ISO 11138-2 Sterilization of health care products – Biological Indicators- Part 2: biological indicators for ethylene oxide sterilization processes
ISO 11138-4 Sterilization of health care products – Biological Indicators- Part 4: biological indicators for 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 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

	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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