



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

Crosstex Codes: THN-06 and THN-06P

Product Description

Spore Threads for monitoring EO and Dry Heat processes consist of:

- An inoculated carrier, 25 mm x 0.1 mm thread, of *Bacillus atrophaeus* (Cell Line 9372)
- Primary packaging in bulk (THN-06) or a glassine envelope (THN-06P)

Intended Use

The Spore Threads are designed to be placed directly into a device and utilized to monitor EO and Dry Heat process efficacy. The Spore Threads are labeled For Industrial Use Only.

Instructions for Use

Place Spore Threads (a minimum of 10 per exposure is recommended) inside representative materials to be sterilized. 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 sterilization validation protocol (usually four corners front, four corners rear, center-center and center-top) or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove Spore Threads or product from sterilizer.

Aseptically remove the Spore Threads from the primary packaging, if applicable, and transfer to Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, Crosstex code GMBTB-100, may be utilized in place of the SCDB.

Transfer a minimum of one Spore Thread which has not been exposed in a sterilization 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:

Sterilization Process	Media Type	Minimum Incubation Time
EO / Dry Heat	SCDB	7 days
EO	GMBTB-100	72 hours
Dry Heat	GMBTB-100	48 hours

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



Interpretation:

Where SCDB (standard or unmodified) was utilized:

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

Where modified media, Crosstex Code GMBTB-100, was utilized:

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

Positive Control: Tube should demonstrate turbidity with an 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 should remain clear. If the Negative Control results in growth, there is a potential for false positives.

Physical Properties

Processes	EO and Dry Heat
Thread Dimensions	25 mm x 0.1 mm
Glassine Dimensions	THN-06P: 25 mm x 50 mm
Packaging	100/Box

Monitoring Frequency

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

Performance Characteristics

Population	1.0 to 5.0 x 10 ⁶ per Spore Thread
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
EO Resistance	<p><i>D</i> value at 54°C ± 1°C, 600 mg/L ± 30 mg/L, 60% RH ± 10% RH 2.5 to 5.8 minutes</p> <p>The EO <i>D</i> value range is based on the requirements outlined in the USP and ISO 11138-2. The EO <i>D</i> value is determined using 100% EO.</p> <p>Survival – Kill Times Calculated based on the formulas outlined in the USP and ISO 11138-1.</p>
Dry Heat Resistance	<p><i>D</i> value at 160°C ± 1°C 1.0 to 3.0 minutes</p> <p>The Dry Heat <i>D</i> value range is based on the requirements outlined in the USP.</p> <p>Survival – Kill Times Calculated based on the formulas outlined in the USP and ISO 11138-1.</p> <p><i>z</i> value ≥20°C</p> <p>Determined based on <i>D</i> values at three temperatures in the range of 150°C to 180°C. Crosstex typically utilizes <i>D</i> values determined at 150°C, 160°C and 170°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 Threads result in growth at the certified survival time</p> <p>Kill Time: All Spore Threads 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

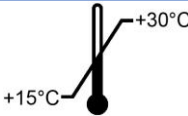





ISO 11138-2 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

USP <55> Biological Indicators – Resistance Performance Tests

USP Biological/Official Monographs

Crosstex has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled *Population Verification of Threads, Glass Fiber Discs and Steel Carriers* to ensure consistent methodologies are being utilized when performing verification testing.

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 70% Relative Humidity		Keep dry
<p>Shelf Life</p>	24 Months from the date of manufacture		Protect from heat and radioactive sources
	<p>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.</p>		

Disposal

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