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## SPORE WIRES For Monitoring Ethylene Oxide (EO)

Crosstex Codes: SWN-06 and SWN-06P

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### Product Description

Inoculated Carrier Spore Wires for monitoring EO processes consist of:

- An inoculated carrier, 40 mm x 1.5 mm steel wire, of *Bacillus atrophaeus* (Cell Line 9372)
- Primary packaging in bulk (SWN-06) or a glassine envelope (SWN-06P)

### Intended Use

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

### Instructions for Use

Place Spore Wires (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 Wires 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 Wires or product from sterilizer.

Aseptically remove the Spore Wires 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 Wire 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 Wires, the Positive Control and the Negative Control as outlined in the following table:

Media Type	Incubation Temperature	Minimum Incubation Time
SCDB	30°C to 40°C	7 days
GMBTB-100		72 hours

**Monitoring:** Examine the Spore Wires 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**

Process	EO
Wire Dimensions	40 mm x 1.5 mm
Glassine Dimensions	SWN-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 Wires be included with every load.

**Performance Characteristics**

Population	1.0 to 5.0 x 10 <sup>6</sup> per Spore Wire
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>
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 Wires result in growth at the certified survival time</p> <p>Kill Time: All Spore Wires result in no growth at the certified kill time</p>

**Compliance**

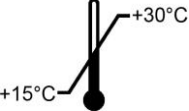





ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements

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
<b>Shelf Life</b>	12 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 Wires. Do not use damaged Spore Wires. Do not use after the expiration date. The Spore Wires 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.