INOCULATED CARRIER SPORE WIRES
For Monitoring Ethylene Oxide (EO)

True Indicating Code: WA-06

Product Description

Inoculated carrier Spore Wires for monitoring EO processes consist of:

- An inoculated carrier, 38mm x 1.5mm Wire of *Bacillus atrophaeus* Cell Line 9372
- Primary packaging is in glassine envelopes for WA-06.

Indications for Use

The Spore Wires are designed to be placed directly into a device and utilized to monitor EO process efficacy. The Spore Wires can be used for equipment or process validation and routine monitoring. Spore Wires are labeled for laboratory/ industrial use only.

Physical Properties

Process	EO
Wire Dimensions	38 mm x 1.5 mm
Glassine Dimensions	30 mm x 38 mm (WA-06)
Packaging	100 / Pack

Monitoring Frequency

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

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 Wire or product from sterilizer.

Aseptically transfer the Spore Wire to 5-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, True Indicating Code GGM-100, may be utilised in place of the SCDB.

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

Transfer one Spore Wire which has not been exposed in a sterilization process as a Positive Control.

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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 at 30°C to 40°C as outlined in the following table:

Sterilization Process	Media Type	Min. Incubation Time
EO	SCDB	7 Days
	GGM-100	48 Hours

Monitoring: Examine the Spore Wires daily, whenever possible during incubation. Record observations.

Interpretation:

Where SCDB (standard or unmodified) was utilized: 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, True Indicating Code GGM-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 indicative for the indicator organism.

Positive Control: Tube(s) 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(s) of media should remain clear. If the Negative Control results in growth, there is a potential for false positives in the Culture Spore Wires.

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

True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin which outlines the recommended methodology.

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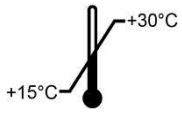
Performance Characteristics

Population	≥1.0 x 10^6 per Wire
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.
Post Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value Survival Time: All Spore Wires result in growth at the certified survival time Kill Time: All Spore Wires result in no growth at the certified kill time

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep Dry
Shelf Life	30 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 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.		

Disposal

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

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