CROSSTEX®
A CANTEL MEDICAL COMPANY

SPORE WIRES
For Monitoring Steam

Crosstex Code: SWS-06

Product Description

Spore Wires for monitoring Steam processes consist of:

- An inoculated carrier, 40 mm x 1.5 mm steel wire, of *Geobacillus stearothermophilus* (Cell Line 7953)
- Primary packaging in bulk

Intended Use

The Spore Wires are designed to be placed directly into a device and utilized to monitor Steam 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 GMBCP-100, may be utilized in place of the SCDB.

Transfer 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	55°C to 65°C	7 days
GMBCP-100	58°C to 62°C	24 hours

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

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Interpretation:

Where SCDB (standard or unmodified) was utilized:
Tubes which demonstrate turbidity with cream colored sediment are considered positive for growth of *Geobacillus stearothermophilus*. Tubes which remain clear and without sediment are considered negative for growth.

Where modified medium, Crosstex Code GMBCP-100, was utilized:
Tubes which transition in color from purple to yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain purple 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 and cream colored sediment or demonstrate a color transition from purple to yellow where modified medium has been utilized. 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 and purple where modified medium was utilized. If the Negative Control results in growth, there is a potential for false positives.

Physical Properties

Process	Steam
Wire Dimensions	40 mm x 1.5 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.

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Performance Characteristics

Population	1.0 to 5.0 x 10^6 per wire
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 to 3.0 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 formulas outlined in the USP, ISO 11138-1 and guidance issued by the FDA. *z* value ≥6°C The *z* value is based on *D* values at three temperatures in the range of 110°C to 130°C. Crosstex typically utilizes *D* values determined at 118°C, 121°C and 126°C.
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

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 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.

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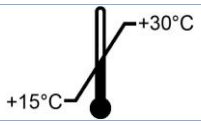
Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 70% Relative Humidity		Keep dry
Shelf Life	19 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 121ºC or per other validated disposal cycle prior to discard.

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