



BIOLOGICAL INDICATOR SPORE STRIPS For Monitoring Radiation

Crosstex Codes: PM-102, PM-103, PM-104, PM-105, PM-106, PM-107 and PM-108

Product Description

Biological Indicator Spore Strips for monitoring Radiation processes consist of:

- An inoculated carrier, 7 mm x 38 mm (1.5" x 0.281") strip, of *Bacillus pumilus* (Cell Line 27142)
- Primary packaging in a white glassine pouch

Intended Use

The Spore Strips may be utilized to monitor Radiation sterilization process efficacy. The Spore Strips are labeled For Industrial Use Only.

Instructions for Use

Place Spore Strips (a minimum of 10 per exposure is recommended) inside representative materials to be sterilized or within the chamber directly. Package or wrap product as usual, if applicable.

Locate the test packages or Spore Strips 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 Strips or product from sterilizer.

Aseptically remove the Spore Strip from the primary packaging and transfer to Soybean Casein Digest Broth (SCDB).

Transfer one Spore Strip 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. Place the cultured Spore Strips, the Positive Control and the Negative Control in an incubator set at 30°C to 35°C.

Incubate for a minimum of seven days or per a validated reduced incubation period.

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

Interpretation:

Tubes which demonstrate turbidity with a lacy cream colored pellicle are considered positive for growth of *Bacillus pumilus*. Tubes which remain clear and without pellicle formation 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 a lacy, cream colored 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 medium should remain clear. If the Negative Control results in growth, there is a potential for false positives.

Physical Properties

Process	Radiation (Gamma and E-Beam)
Strip Dimensions	7 mm x 38 mm (1.5" x 0.281")
Glassine Dimensions	25 mm x 75 mm
Packaging	100/Box

Monitoring Frequency

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

Performance Characteristics

Population	1.0 to 5.0 x 10 ^x per strip, where x = the population level of the Spore Strip
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Radiation Resistance	<i>D</i> value (Cobalt-60) 0.10 to 0.20 Mrads (1.0 to 2.0 kGy)
Post-Market Criteria	Population: 50% to 300% of certified population <i>D</i> value: ± 20% of the certified <i>D</i> value

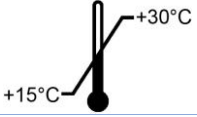

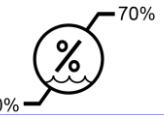



Compliance

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

USP <55> Biological Indicators – Resistance Performance Tests

Crosstex has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled *Population Verification of Paper Carrier Biological Indicators* to ensure consistent methodologies are being utilized when performing verification testing.

Storage and Shelf Life

	20°C to 25°C average Excursions 15°C to 30°C allowed		Keep away from sunlight
	20% to 70% 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 Strips. Do not use damaged Spore Strips. Do not use after the expiration date. The Spore Strips 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.