



## SPORE COUPONS For Monitoring Vaporized Hydrogen Peroxide (VH<sub>2</sub>O<sub>2</sub>)

Crosstex Code: CPN-06

### Product Description

Spore Coupons for monitoring VH<sub>2</sub>O<sub>2</sub> processes consist of:

- An inoculated carrier, 34 mm x 7 mm x 0.9 mm steel coupon, of *Bacillus atrophaeus* (Cell Line 9372) with a population level of 10<sup>6</sup>
- Primary packaging in a Tyvek<sup>®</sup>/Mylar<sup>®</sup> pouch

### Intended Use

The Spore Coupons are utilized to monitor VH<sub>2</sub>O<sub>2</sub> sterilization process efficacy. Spore Coupons are labeled For Industrial Use Only.

### Instructions for Use

Place Spore Coupons (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 Coupons 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 Coupons or product from sterilizer.

Aseptically remove the Spore Coupons 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 Coupon 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 Coupons, the Positive Control and the Negative Control at 30°C to 40°C as outlined in the following table:

Media Type	Minimum Incubation Time
SCDB	7 days
GMBTB-100	48 hours

**Monitoring:** Examine the Spore Coupons 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 or demonstrate a color transition from green to yellow where modified media 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 of media should remain clear. If the Negative Control results in growth, there is a potential for false positives.

**Physical Properties**

Process	VH <sub>2</sub> O <sub>2</sub>
Coupon Dimensions	34 mm x 7 mm x 0.9 mm
Pouch Dimensions	57 mm x 70 mm
Packaging	100/Box

**Monitoring Frequency**

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

**Performance Characteristics**

Population	1.0 to 5.0 x 10 <sup>6</sup> per coupon
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
VH <sub>2</sub> O <sub>2</sub> Resistance	<i>D</i> value at 2.3 mg/L ± 0.4mg/L, 50°C ± 0.5°C 1.0 to 3.0 minutes
Post-Market Criteria	Population: 50% to 300% of certified population <i>D</i> value: ± 20% of the certified <i>D</i> value

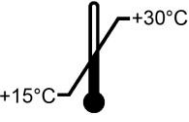

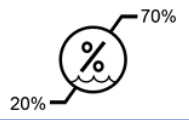



**Compliance**

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 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
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Coupons. Do not use damaged Spore Coupons. Do not use after the expiration date. The Spore Coupons 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.

Tyvek<sup>®</sup> and Mylar<sup>®</sup> are registered trademarks of E.I. du Pont de Nemours and Company.