

Steel Spore Disc Biological Indicators

Vaporized Hydrogen Peroxide (VH₂O₂)

Bacillus atrophaeus - Cell Line 9372 Monitoring

An inoculated carrier, 6 mm steel disc, of *Bacillus atrophaeus* (Cell Line 9372) with a population level of 10³, 10⁴, 10⁵ or 10⁶. These Biological Indicators (BIs) for use in monitoring Vaporized Hydrogen Peroxide (VH₂O₂) sterilization processes. The BIs are designed for monitoring processes whether placed directly into the chamber, positioned in areas of a device which are the most difficult to sterilize or distributed throughout rooms and isolators. Steel Spore Discs are 6 mm in diameter and are available packaged in easy-to-access Tyvek®/Tyvek® pouches (Please inquire for bulk & other packaging)



Standard Features

- Convenient shelf packages of 100 units per box
- Products are accompanied by a Certificate of Analysis and are certified with population, purity, and resistance characteristics (D value, survival and kill where applicable)
- ISO 11138-1 Compliant

Intended Use

The Spore Discs are utilized to monitor VH₂O₂ sterilization process efficacy. The Spore Discs are labeled For Industrial Use Only.

Instructions for Use

Place Spore Discs (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 Discs 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 Discs or product from sterilizer.

Aseptically transfer the Spore Discs to Soybean Casein Digest Broth (SCDB).

Transfer one Spore Disc 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 Discs, the Positive Control and a Negative Control (tube of media) in an incubator set at 30°C to 40°C.

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

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

Interpretation

Tubes which demonstrate turbidity with an orange-colored pellicle are considered positive for growth of *Bacillus atrophaeus*. 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(s) should demonstrate turbidity with an orange-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: Tubes of media should remain clear. If the Negative Control results in growth, there is a potential for false positives.

Technical Data

Physical Properties			
Process	VH ₂ O ₂		
Disc Diameter	6 mm		
Pouch Dimensions	29 mm x 75 mm		
Packaging	100/Box		
Performance Characteristics			
Population	1.0 to 5.0 x 10 ^x per disc, where x = the population level of the Spore Disc		
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.		
VH ₂ O ₂ Resistance	D value at 55°C ± 5°C, 2.3 mg/L 1.0 to 3.0 minutes		
Post-Market Criteria	Population: 50% to 300% of certified population D value: ± 20% of the certified D value		
Monitoring Frequency			
For greatest control of sterilized goods, it is recommended that a minimum of ten (10) Spore Discs be included with every load.			
Compliance			
ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements USP <55> Biological Indicators – Resistance Performance Tests			
Disposal			
Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.			
Storage and Shelf Life			
Temperature	15°C to 30°C	Sunlight	Keep away from sunlight
Relative Humidity	20% to 70%	Moisture	Keep dry
Shelf Life	12 Months from the date of manufacture	Radioactivity	Protect from heat and radioactive sources
Caution	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Discs. Do not use damaged Spore Discs. Do not use after the expiration date. The Spore Discs contain live cultures and should be handled.		

Ordering Information

Part Number	Description	Quantity
3031308	<i>Bacillus atrophaeus</i> Cell Line 9372, Stainless Steel Disc each 6 mm in Diameter, Individually Packaged in Tyvek® Tyvek® Pouches, 100 per box, 103 population level, ISO 11138 and USP compliant where applicable	100
3031309	<i>Bacillus atrophaeus</i> Cell Line 9372, Stainless Steel Disc each 6 mm in Diameter, Individually Packaged in Tyvek®/ Tyvek® Pouches, 100 per box, 104 population level, ISO 11138 and USP compliant where applicable	100
3031310	<i>Bacillus atrophaeus</i> Cell Line 9372, Stainless Steel Disc each 6 mm in Diameter, Individually Packaged in Tyvek®/ Tyvek® Pouches, 100 per box, 105 population level, ISO 11138 and USP compliant where applicable	100
3031311	<i>Bacillus atrophaeus</i> Cell Line 9372, Stainless Steel Disc each 6 mm in Diameter, Individually Packaged in Tyvek®/ Tyvek® Pouches, 100 per box, 106 population level, ISO 11138 and USP compliant where applicable	100

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