STEEL SPORE DISCS
For Monitoring Vaporised Hydrogen Peroxide (VH_2O_2)

Excelsior Code: SDN-06E & TTN-06E

Product Description

Biological indicator Steel Spore Discs for monitoring VH_2O_2 processes consist of:

- An inoculated carrier, 6mm steel disc of *Bacillus atrophaeus* (Cell Line 9372) with a population level of 10^6
- Primary packaging in Tyvek®/Mylar® pouches (SDN-06E) or Tyvek® pouches (TTN-06E)

Indications for Use

The Spore Discs are utilised to monitor VH_2O_2 sterilisation process efficacy. The Spore Discs are labelled for industrial use only.

Instructions for Use

Place Spore Discs (a minimum of 10 per exposure is recommended) inside representative materials to be sterilised. Package or wrap product as usual, if applicable.

Locate the test packages or Spore Discs in areas most difficult to sterilise, as outlined in your specific ster-ilisation validation protocol (usually four corners front, four corners rear, centre-centre and centre-top) or according to standard operating procedure. Run the cycle.

After sterilisation or exposure, remove Spore Discs or product from steriliser

Within four (4) hours post-exposure, aseptically transfer the Spore Discs from the primary packaging and transfer to 10-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, Excelsior code GMBTB-100E may be used in place of the SCDB.

Transfer one Spore Disc which has not been exposed in a sterilisation 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 the Negative Control in an incubator set at 30°C to 40°C.

Spore Strips cultured in SCDB should be incubated for a minimum of 7 days or per a validated reduced incubation period.

Spore Discs cultured in modified growth medium SCDB Excelsior code GMBTB-100E should be incubated for a minimum of 48 hours.

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

Interpretation:

Where SCDB (standard or unmodified) was used:
Tubes which demonstrate turbidity with cream/orange coloured pellicle are considered positive for growth of *Bacillus atrophaeus.* Tubes which remain clear and without pellicle are considered negative for growth.

Where modified media, Excelsior code GMBTB-100E was used:
Tubes which transition in colour from green to yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain green in colour 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 should demonstrate turbidity with a cream/orange coloured pellicle or demonstrate a colour transition from green to yellow where modified media has been utilised. 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 and green in colour where modified medium was utilised. If the Negative Control results in growth, there is a potential for false positives .

Physical Properties

Process	Plasma / VH_2O_2
Disc Dimensions	6 mm
Glassine Dimensions	SDN-06E: 57mm x 70mm TTN-06E: 28.5mm x 63.5mm
Packaging	100 / Pack

Monitoring Frequency

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

Performance Characteristics

Population	$\geq$1.0 x 10^6 per Disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
VH_2O_2 Resistance	*D* value at 50°C ± 5°C , 2.5 mg/L $\geq$1.0 minutes
Post Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value

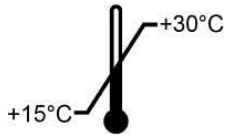
Compliance

ISO 11138-1 Sterilization of health care products – Biological Indicators- Part 1: General Requirements

USP <55> Biological Indicators – Resistance Performance Tests

Excelsior Scientific has a validated method for Total Viable Spore Count. Please inquire for the Technical data sheet entitled “Population Verification for Biological Indicator Mini Strips (2mm x 10mm), Discs (Paper and glass fiber) Discs and Coupons” to ensure consistent methodologies when performing verification testing.

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% relative humidity		Keep Dry
Shelf Life	12 months from the date of manufacture		Protect from heat and radioactive sources
	Normal fluctuation and excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Discs. Do not use after the expiration date. The Spore Discs 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.

For additional product information:
Please visit us at
www.excelsiorscientific.com
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