
GENERAL DESCRIPTION

The Spordex™ *Bacillus atrophaeus* Biological Indicator and Spordex™ Single Species Biological Indicator (BI) are produced from filter paper inoculated with a single spore species (*Bacillus atrophaeus*, NRRL #B4418) and enclosed in a glassine envelope. The strips are produced under controlled conditions to meet the suggested performance parameters published in the current United States Pharmacopeia (USP) and ISO 11138-2.

APPLICATION

The Spordex Strip BI is used to validate and requalify Ethylene Oxide (EO) gas or dry heat sterilizers and to monitor the effectiveness of common EO gas or dry heat sterilizing processes.

FEATURES

Bacillus atrophaeus single species population ranging from E3 to E8 colony forming units (CFU)/strip
Lot number and expiration on each glassine envelope and data card
Easy-peel glassine pouch
Packaged in plastic boxes

BENEFITS

Flexibility of use with various sterility level requirements
Traceable results and valuable documentation
Facilitates aseptic transfer
Helps to protect the product integrity

TECHNICAL PROPERTIES

Primary packaging: glassine envelope approximately 76 × 25 mm (3 × 1")

Spore carrier: filter paper strip approximately 38 × 6 mm (1½ × ¼")

Species: *Bacillus atrophaeus* (NRRL #B4418)

Mean population recovery: various (see Ordering Information)

Purity: Bacterial contaminants are less than 1% of labeled population; this is the detection limit using the pour plate method with an aliquot that yields at least 100 CFU.

D-value for ethylene oxide (D_{EO})*: 2.6-4.5 minutes

- D_{EO} is determined by a Most Probable Number (MPN) method with a 600±30 mg/L ethylene oxide concentration, 54°C (129°F) ±1°C and 50-70% Relative Humidity (RH) and using 100% EO Sterilant.

D-value for dry heat (D_{DH})*: 1.0-3.0 minutes

- D_{DH} is determined by MPN utilizing 160°C (320°F) ±2°C exposure temperature.

* NOTE: The D-value is reproducible only when the BI is exposed and cultured under the same conditions which were used by STERIS to determine the D-value.

Incubation temperature: 30-35°C (86-95°F)

Shelf life: 18 months from time of manufacture. The expiration date is printed on the glassine envelope and on the data card that accompanies the box.

Quantity: See Ordering Information

DIRECTIONS FOR USE

After sterilization and aeration processing has been completed according to the sterilizer manufacturer's instructions, remove the Spordex Strip BI from the test pack. Aseptically open the glassine envelope. This is accomplished by cutting the glassine with sterile scissors or peeling apart the glassine at the indicated end.

Aseptically transfer each strip from its envelope to a tube of sterile Spordex Culture Media NA114 or equivalent. Incubate the tubes at 30-35°C (86-95°F) for seven days or for a Customer-validated reduced incubation time. Examine the media containing the BI during the incubation period. A color change from red to yellow and/or media becoming turbid indicates microbiological growth.

See the instruction card enclosed in the Spordex Strip box for detailed use directions.

STORAGE CONDITIONS

The Spordex Strip BIs should be stored at a temperature of 2-24°C (36-75°F) and an RH of 30-80%. Avoid contact with, or storage near, sterilants or chemicals; e.g., any oxidizing or reducing agents such as formaldehyde, bleach, ammonia, etc. Do not use after the expiration date printed on the packaging.

DISPOSAL

Before discarding, treat as appropriate for standard microbiological waste, nonpathogenic species; e.g., steam autoclave at 121°C (250°F) for not less than 30 minutes, incinerate, or use other suitable means.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

ORDERING INFORMATION

Description	Population	Quantity	Reorder Number
Spordex Strip E5 Biological Indicator	1.0 × 10 ⁵ to 5.0 × 10 ⁵ CFU	500 per box	NA032
Spordex Strip E7 Biological Indicator	1.0 × 10 ⁷ to 5.0 × 10 ⁷ CFU	500 per box	NA033
Spordex Strip E8 Biological Indicator	1.0 × 10 ⁸ to 5.0 × 10 ⁸ CFU	500 per box	NA034
Spordex Strip E3 Biological Indicator	1.0 × 10 ³ to 5.0 × 10 ³ CFU	500 per box	NA112

For further information, please contact:



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