



GENERAL DESCRIPTION

The Spordex Strip Biological Indicator (BI) is 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).

APPLICATION

The Spordex Strip BI is used to validate and re-qualify ethylene oxide (EO) gas or dry heat sterilizers and to monitor the effectiveness of common ethylene oxide 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
Help to protect the product integrity

TECHNICAL PROPERTIES

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

Spore carrier: filter paper strip approximately 38 x 6 mm (1-1/2 x 1/4")

Species: *Bacillus atrophaeus*, NRRL #B4418

Mean population recovery: 1.0×10^5 to 5.0×10^5 cfu/strip

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, 50-70% relative humidity (RH) and an Oxyfume® 2000 sterilant¹ blend.

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.

The D-value is reproducible only when the biological indicator 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 section.

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. 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 biological indicators during the incubation period. A color change from red to yellow and/or the presence of turbidity indicates microbiological growth. See the instruction card enclosed in the Spordex Strip box for detailed use directions.

1. Oxyfume® 2000 is a registered trademark of Honeywell.

STORAGE CONDITIONS

The Spordex Strip BIs should be stored at a temperature of 2-24°C (36-75°F) and a relative humidity 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	Quantity	Reorder Number
Spordex Strip E5 Biological Indicator	500 per box	NA032
Spordex Strip E4 Biological Indicator	500 per box	NA031
Spordex Strip E8 Biological Indicator	500 per box	NA034
Spordex Strip E7 Biological Indicator	500 per box	NA033
Spordex Strip E3 Biological Indicator	500 per box	NA112

For further information, please contact:

STERIS[®] STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-444-9009
www.steris.com

