



GENERAL DESCRIPTION

The Spordi Strip NA008/NA010 Biological Indicator (BI) consists of a filter paper strip inoculated with *Bacillus atrophaeus*, NRRL#B4418 and *Geobacillus stearothermophilus*, strain 7953 and enclosed in a glassine envelope. The strips are produced under controlled conditions to meet the suggested performance parameters published in the United States Pharmacopeia (USP). The Spordi Strip NA010 BI is identical to the Spordi Strip NA008 BI except for the quantity per box. Spordi NA010 BI has 100 biological indicators per box and Spordi NA008 BI has 500 biological indicators per box.

APPLICATION

The Spordi Strip NA008/NA010 BI is used to validate and re-qualify ethylene oxide (EO) gas, dry heat or steam sterilizers and to monitor the effectiveness of common EO gas, dry heat or steam sterilizing processes.

FEATURES

Dual species spore strip
One product for EO, dry heat or steam
Lot number and expiration on each glassine envelope and data card
Easy-peel glassine pouch
Packaged in plastic boxes; two sizes available

BENEFITS

May be used for EO, dry heat or steam sterilization
Inventory reduction and error prevention
Traceable results and valuable documentation
Facilitates aseptic transfer
Conveniently sized boxes 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: 1.0×10^6 to 5.0×10^6 colony forming units (cfu)/strip

Species: *Geobacillus stearothermophilus*, strain 7953

Mean population recovery: 1.0×10^4 to 5.0×10^4 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 Most Probable Number (MPN) method with a 600 ± 30 mg/L ethylene oxide concentration, 54°C (129°F) $\pm 1^\circ\text{C}$, 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) $\pm 2^\circ\text{C}$ exposure temperature.

D-value for saturated steam (D₁₂₁): 1.5 - 2.5 minutes

D₁₂₁ is determined by MPN methods utilizing 121°C (250°F) $\pm 0.5^\circ\text{C}$ 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 following EO or dry heat sterilizer cycle: 30-35°C (86-95°F)

Incubation temperature following a steam sterilizer cycle: 55-60°C (131-140°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.

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

Quantity: 500 per box, Spordi Strip NA008 Biological Indicator
100 per box, Spordi Strip NA010 Biological Indicator

DIRECTIONS FOR USE

After sterilization (and aeration, if required according to the sterilizer manufacturer's instructions) has been completed, remove the Spordi Strip NA008/NA010 BI from the test pack. Aseptically open the glassine envelope. This can be 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) if the strips were exposed to a gas or dry heat sterilization cycle. Incubate the tubes at 55-60°C (131-140°F) if the strips were exposed to a steam sterilization cycle. The duration of incubation should be 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 Spordi Strip box for detailed use directions.

STORAGE CONDITIONS

The Spordi Strip NA008/NA010 Biological Indicators 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 Per Box	Reorder Number
Spordi Strip NA008 Biological Indicator	500	NA008
Spordi Strip NA010 Biological Indicator (NA010 is identical to NA008 except for the quantity per box.)	100	NA010

For further information, please contact:

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