



GENERAL DESCRIPTION

The Spordi Disc NA094 carrier consists of filter paper disc inoculated with spores of *Bacillus atrophaeus*, NRRL#B4418 and *Geobacillus stearothermophilus*, strain 7953. The discs are produced under controlled conditions to meet the suggested performance parameters published in the current U.S. Pharmacopeia. Spordi NA094 carrier has 1,000 discs per box.

APPLICATION

The Spordi Disc NA094 carrier is used to validate and re-qualify ethylene oxide (EO) gas or steam sterilizers. Because of the small size of discs, they may be used to determine the worst-case position of a sterilization load that does not accommodate spore strips.

FEATURES

Dual species spore disc
One product for EO or steam
No primary packaging

Packaged in plastic boxes;
two sizes available
Lot number and expiration on the box

BENEFITS

May be used for EO or steam sterilization
Inventory reduction and error prevention
Small size for placement in product (or simulated product) areas with limited space
Conveniently sized boxes help to protect the product integrity
Traceable results and valuable documentation

TECHNICAL PROPERTIES

Spore carrier: filter paper disc approximately 6.3 mm (1/4") diameter

Species: *Bacillus atrophaeus*, NRRL#B4418

Mean population recovery: 1.0×10^6 to 5.0×10^6 colony forming units (cfu)/disc

Species: *Geobacillus stearothermophilus*, strain 7953

Mean population recovery: 1.0×10^4 to 5.0×10^4 cfu/disc

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% R.H. and an Oxyfume® 2000 sterilant¹ blend.

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 data card that accompanies the box.

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

DIRECTIONS FOR USE

After sterilization (and aeration, if required according to the sterilizer manufacturer's instructions) has been completed, aseptically remove the Spordi Disc NA094 carrier from the test pack or device. Aseptically transfer each disc 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 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.

STORAGE CONDITIONS

The Spordi Disc NA094 carrier 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 remove the outer wrapper of the box until the discs are to be used. 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 Disc NA094	1,000	NA094

For further information, please contact:

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