

GENERAL DESCRIPTION

The Spordex Disc carrier is produced from filter paper inoculated with a single spore species (*Bacillus atrophaeus*, NRRL#B4418). The discs are produced under controlled conditions to meet the suggested performance parameters published in the current United States Pharmacopeia (USP).

APPLICATION

The Spordex Disc carrier is used to validate and re-qualify ethylene oxide (EO) gas 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

Bacillus atrophaeus single species populations available ranging from E3 to E8

Tested in accordance with International Standards Organization (ISO) 11138-2 and EN 866-2

No primary packaging

Packaged in plastic boxes; two sizes available

Lot number and expiration on the box

BENEFITS

Flexibility of use with various sterility level requirements

Allows for harmonization of biological indicators between global Customer sites

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: 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 Most Probable Number (MPN) and Survivor Curve (SC) methods 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.

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 data card that accompanies the box.

DIRECTIONS FOR USE

After sterilization and aeration processing have been completed according to sterilizer manufacturer's instructions, aseptically remove the Spordex Disc carrier from the test pack or device. Aseptically transfer each disc to a tube of sterile Spordex Culture Media NA114 carrier. 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.

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

STORAGE CONDITIONS

The Spordex Discs 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
Spordex E6 Disc NA075	1,000	NA075
Spordex E6 Disc NA130	100	NA130
Spordex E7 Disc NA105	1,000	NA105
Spordex E8 Disc NA082	1,000	NA082
Spordex E3 Disc NA120	1,000	NA120

(NA130 is identical to NA075 except for the quantity per box.)

For further information, please contact:

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