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## GENERAL DESCRIPTION

The Spordex VHP Suspension consists of a vial containing a certified population of bacterial spores in an aqueous solution. Spordex VHP Suspensions contain a single spore species *Geobacillus stearothermophilus*, ATCC 7953. Spordex VHP Suspensions have a concentration of E7 per 0.1 mL.

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## APPLICATION

The Spordex VHP Suspension for hydrogen peroxide vapor is used to validate, re-qualify and monitor hydrogen peroxide vapor sterilization processes.

The Spordex VHP Suspension may be used for the following applications:

- to directly inoculate the product to determine the worst-case location in a device that does not accommodate a spore strip or spore disc.
- to directly inoculate the product in the places least accessible to the sterilization agent.
- to manufacture biological indicators utilizing carriers simulating the product being sterilized.

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## FEATURES

Single species *Geobacillus stearothermophilus* population available E7 per 0.1 mL

Lot number and expiration on each vial

Certification card in each package

Dispensed via inoculation

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## BENEFITS

Flexibility of use with various sterility assurance level requirements

Traceable results and valuable documentation

Certification of product integrity

Can be used to inoculate small carriers and locations which cannot accommodate strips or discs

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## TECHNICAL PROPERTIES

**Species:** *Geobacillus stearothermophilus* (ATCC 7953)

**Suspension:** Bacterial spores in aqueous solution, 10 mL of spore suspension per vial

**Population:**  $1 \times 10^7$  per 0.1 mL to  $5 \times 10^7$  per 0.1 mL

**Resistance data for Spordex VHP Suspensions when inoculated on polyflex and exposed to a  $2.0 \pm 0.5$  mg/L concentration of hydrogen peroxide vapor:**

100% Survival: 1.5 minutes

100% Kill: 30 minutes

NOTE: The resistance data was determined utilizing a La Calhène isolator and VHP® 1000 Generator, when the Spordex VHP Suspension was inoculated onto polyflex carriers (with a population greater than  $1 \times 10^5$  per disc). The inoculated carriers were enclosed in a Mylar®/Tyvek® envelope<sup>1,2</sup>.

**Incubation temperature:** 55-60°C (131-140°F)

**Shelf life:** 18 months from time of manufacture. The expiration date is printed on the certification card that accompanies the Spordex Suspension.

**Quantity:** 10 mL per vial

<sup>1</sup> Tyvek® is a registered trademark of DuPont for spunbonded olefin.

<sup>2</sup> Mylar® is a registered trademark of DuPont for a clear polyester film.

## DIRECTIONS FOR USE

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The spore suspension must be vortexed a minimum of five minutes. Use a  $1 \times 10^7$  per 0.1 mL to achieve a  $1 \times 10^6$  spore population of *Geobacillus stearothermophilus* per carrier. With a calibrated micropipeter, inoculate 10 microliters to center of each carrier. If the suspension runs off the carrier, replace the carrier and repeat the inoculation. Allow inoculated coupons to completely air dry under laminar flow hood conditions. The recommended practice is to place the multiple inoculated carriers in an area of the chamber or enclosure considered to be the most difficult to sterilize. **NOTE: Do not place the inoculated side of the coupon face down or against any surfaces. Operate the hydrogen peroxide vapor unit in accordance with the manufacturer's recommendation.**

The microbiologist or technician should observe aseptic technique while culturing.

Carefully transfer the carrier to a tube of sterile Soybean Casein Digest Broth (SCDB) as recommended by the United States Pharmacopeia (USP). Do not contact any non-sterile surfaces prior to or during transfer of coupon to sterile media vial.

Incubate at 55-60°C (131-140°F) for seven days. Examine the culture media during the incubation period for the evidence of microbiological growth: turbidity or sedimentation. See the instruction card enclosed in the Spordex Suspension box for detailed use-directions.

## STORAGE CONDITIONS

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Store refrigerated between 2-8°C (36-46°F). Avoid contact with, or storage near, sterilants or chemicals; e.g., any oxidizing or reducing agents such as formaldehyde, bleach or ammonia. Do not remove the outer wrapper until suspension is to be used. Do not use after the expiration date printed on the packaging.

## DISPOSAL

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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

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### 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

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Population of <i>Geobacillus stearothermophilus</i>	Quantity Per Vial	Reorder Number
Spordex Suspension E7 per 0.1 mL	10 mL	NA304

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### For further information, please contact:

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