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## GENERAL DESCRIPTION

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The Spordex VHP NA300P Biological Indicator (BI) uses a polyflex (polystyrene) carrier which is non-permeable to hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) vapor. Polyflex has been approved by the FDA for use as a primary packaging for dairy products. The polyflex disc is inoculated with a single spore species (*Geobacillus stearothermophilus*, ATCC 7953) and enclosed in a Tyvek®/clear Mylar® envelope<sup>1,2</sup>. The Tyvek® side of the envelope<sup>1</sup> is porous to H<sub>2</sub>O<sub>2</sub> vapor. The Mylar® portion of the envelope<sup>2</sup> is non-permeable to H<sub>2</sub>O<sub>2</sub> vapor. A small pink or green circle visible on the disc provides a visual assurance that the disc was inoculated and that the disc is correctly oriented in the envelope. The discs are produced under controlled conditions to meet the suggested performance parameters published in the United States Pharmacopeia (USP).

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## APPLICATION

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The Spordex VHP NA300P BI is recommended for validation and routine monitoring of H<sub>2</sub>O<sub>2</sub> vapor sterilization processes.

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### FEATURES

Single species, E5 *Geobacillus stearothermophilus*  
Spore disc is made of polyflex, which is non-permeable to H<sub>2</sub>O<sub>2</sub> vapor  
A small pink or green circle is visible on the disc  
Lot number and expiration on packaging

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### BENEFITS

Biological indicator for vapor hydrogen peroxide sterilization  
No H<sub>2</sub>O<sub>2</sub> residues on the carrier after a properly configured cycle  
Visual indication that disc was inoculated  
Traceable results and valuable documentation

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## TECHNICAL PROPERTIES

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**Primary packaging:** Tyvek®/Mylar® envelope<sup>1,2</sup> approximately 64 x 38 mm (2-1/2 x 1-1/2")

**Spore carrier:** polyflex (polystyrene) disc approximately 10 mm (3/8") in diameter

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

**Mean Population Recovery:** 1.0 x 10<sup>5</sup> to 5.0 x 10<sup>5</sup>

**Purity:** Bacterial contaminants less than 1% of the labeled population; this is the detection limit using the pour plate method with an aliquot that yields at least 100 colony forming units (cfu).

Resistance data for Spordex VHP NA300P BI in hydrogen peroxide vapor 2.0 ±0.5 mg/L

Survives: 1.5 minutes

Killed: 30 minutes

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## DIRECTIONS FOR USE

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Allow refrigerated Spordex VHP NA300P Biological Indicators to equilibrate to room temperature prior to testing (approximately one hour). Place the biological indicators into the areas of the enclosure considered to be the most difficult to be sterilized by hydrogen peroxide vapor. Operate the unit per the manufacturer's recommendation.

**NOTE: Do not cover the Tyvek® envelope<sup>1</sup> (white portion) of the BI. At the end of the cycle, remove the biological indicators and deliver them with the unexposed control BI from the same lot to the laboratory for culturing.**

Optimally, all tests involving culturing should be conducted at a laminar flow clean air bench. Aseptic technique should be observed. Open the Tyvek®/Mylar® envelope<sup>1,2</sup> by cutting the envelope with cold, sterile scissors. Carefully transfer the spore disc to a tube of sterile Soybean Casein Digest Broth (SCDB) as recommended by USPXXIII. Withdraw the spore disc with cold, sterile forceps and drop into the media. Ensure the disc is completely submerged in the media by agitating the tube. Incubate the tube/discs at 55-60°C (131-140°F) for seven days.

<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.

If sterilization of the Spordex VHP NA300P BI was achieved, no turbidity or precipitation is present after incubation. If the media begins to show turbidity or precipitation, then sterility is not achieved.

See the instruction card enclosed in the Spordex VHP NA300P BI box for detailed use directions.

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## STORAGE CONDITIONS

Spordex VHP NA300P BI should be stored at a temperature of 2-8°C (36-46°F) and a relative humidity of 30-80%. Do not freeze. Avoid contact with, or storage near, sterilants or chemicals; e.g., any oxidizing or reducing agents such as formaldehyde, bleach or ammonia. Do not use after the expiration date printed on the packaging.

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## 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.

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## ORDERING INFORMATION

Description	Quantity Per Box	Reorder Number
Spordex VHP NA300P BI	100	NA300P

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**For further information, please contact:**

**STERIS**<sup>®</sup>



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