

SPORDEX VH202 BIOLOGICAL INDICATOR

Biological Indicator



APPLICATION

STERIS's Spordex VH202 Biological Indicator (NA333) is a hydrogen peroxide vapor Biological Indicator (BI) designed for use with STERIS VHP® Biodecontamination Units using STERIS's VHP Process Technology and Vaprox® Hydrogen Peroxide Sterilant or Vaprox® 59 Hydrogen Peroxide Sterilant.

DESCRIPTION

Spordex BI uses a stainless-steel carrier inoculated with an E6 (6-log) population of *Geobacillus stearothermophilus* spores. The inoculated carrier is placed in a Tyvek®¹ envelope.

The Spordex envelope also includes the lot number, expiration date and reorder number.

Spordex Biological Indicator is also shipped with:

- Hole in Tyvek envelope for hanging
- Instructions For Use (IFU)
- Certificate of Performance



DIRECTIONS FOR USE

STERIS's VHP Process Technology uses Spordex BI (NA333) to determine biodecontamination efficacy. This Process utilizes hydrogen peroxide vapor as a broad-spectrum antimicrobial without condensation of the active ingredient onto surfaces.

Note: When using STERIS VHP Biodecontamination Units with Vaprox Hydrogen Peroxide Sterilant or Vaprox 59 Hydrogen Peroxide Sterilant in the United States of America (USA), the term biodecontamination referred to in this document is defined as sterilization of exposed porous and non-porous surfaces in a pre-cleaned, dry, sealed enclosure. Any reference to biodecontamination as it relates to the use of this equipment in the USA does not impart additional claims of effectiveness beyond that approved in the USA Environmental Protection Agency (EPA) registered labeling of Vaprox Hydrogen Peroxide Sterilant (EPA Reg. No. 58779-4) or Vaprox 59 Hydrogen Peroxide Sterilant (EPA Reg. No. 1043-123).

Before using Spordex BIs, check expiration date printed on the Tyvek envelope. Follow IFU shipped with product.

Per Fumigation Management Plan (FMP), place Spordex BIs within Enclosure. After Biodecontamination Cycle completion, collect Spordex BIs. Aseptically transfer Spordex BI to STERIS's Spordex Biological Indicator Media product. (Refer to IFU for Spordex VH202 Biological Indicator (NA333) and pertinent Spordex Biological Indicator Media for additional information and application instructions.

Note: STERIS recommends performing all transfers in a laminar clean air bench or a clean and dust-free area, with as near static air circulation as is possible.

Incubate Spordex BIs at 131 - 140°F (55 - 60°C) for seven days. Observe the test tubes daily during the incubation period:

- If the presence of turbidity, and/or media color change (purple to yellow) is present, bacterial growth is present.
- If no turbidity and/or media color change, bacterial growth is not present.

Record the results per the FMP.

Before disposing, treat as appropriate for standard microbiological waste, non-pathogenic species.

STANDARDS

BI culture is traceable to a recognized culture collection identified in USP and ISO 11138.

STERILITY ASSURANCE PRODUCTS

Spordex® Biological Indicator Media (NA114) — Trypticase Soy Bean broth (TSB) culture media designed for use with Spordex biological indicators.

Spordex® Biological Indicator Media (NA117) — TSB culture media designed for use with Spordex biological indicators.

1. Tyvek is a registered trademark of E.I. du Pont de Nemours and Company

NOTES

1. STERIS Life Sciences recommends allowing Spordex BI to normalize to Enclosure conditions for a minimum of one hour prior to use.
2. Do not use after expiration date.
3. STERIS Life Sciences recommends maintaining a record of results.
4. Users of Vaprox Hydrogen Peroxide Sterilant and Vaprox 59 Hydrogen Peroxide Sterilant are required to take and pass the Vaprox Hydrogen Peroxide Sterilant Training and Certification Course (www.sterislifesciences.com). US ONLY
5. Not for use in reprocessing of medical devices used for human applications.

ENGINEERING DATA

Shelf Life: 9 months

Size: 65mm x 30mm

Species: *Geobacillus stearothermophilus* (ATCC 12980)

Mean Population: 1.0 to 5.0 x 10⁶ CFU

Selections Checked Below Apply To This Equipment

NA333 - Spordex BI - 1 Box (100 Indicators)

NA114 - Spordex BI Media - 1 Box (100 Test Tubes)

NA117 - Spordex BI Media - 1 Box (100 Test Tubes)

Item:	
Locations:	

For Further Information, contact:



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The base language of this document is ENGLISH. Any translations must be made from the base language document.

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D-Value (Typical): 0.6 to 2.0 min. @ 2.0 mg/L H₂O₂

Spore Carrier:

Envelope: Tyvek

Disc: 304 Stainless Steel

Storage Conditions:

Do not store near Sterilants, oxidizing agents or reducing agents. Do not freeze.

Temperature: 36 - 46°F (2 - 8°C)

Relative Humidity: <50%

Note: Remove any appropriate number of BIs from storage approximately one hour before use.

Note: Storage conditions during shipping should be 36-104°F (2 - 40°C)

Disposal:

Positive biological indicators or unused/expired biological indicators should be processed in a steam sterilizer at 250°F (121°C) for 30 minutes and then disposed of as non-pathogenic waste or incinerated.