STERIS
Life Sciences

SPORDEX® VH2O2 BIOLOGICAL INDICATOR

APPLICATION

STERIS's Spordex VH2O2 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* (ATCC 12980) 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

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

STANDARDS

Spordex VH2O2 Biological Indicator complies with the following standard:

- **USP guidelines**

DIRECTIONS FOR USE

STERIS's VHP Process Technology uses Spordex BI (NA333) to determine biodecontamination[1] efficacy. This Process utilizes hydrogen peroxide vapor as a broad-spectrum anti-microbial without condensation of the active ingredient onto surfaces.

[1] *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.[2] 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).*

[2] *Contained area to be biodecontaminated (e.g., rooms, facilities and equipment).*

(Typical - details may vary.)

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[3] product.

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.

NOTE: A 24-hour Reduced Incubation Time (RIT) is available when used with Spordex Biological Indicator Media (NA117). Sufficient growth media is provided for incubation up to seven days if desired.

Record the results per the FMP.

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

[3] *Refer to IFU for Spordex VH2O2 Biological Indicator (NA333) and pertinent Spordex Biological Indicator Media for additional information and application instructions.*

STERILITY ASSURANCE PRODUCTS

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

Ordering Information

- ❑ 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 _____

Location(s)_____

_____

Spordex® Biological Indicator Media (NA117) – TSB culture media designed for use with Spordex biological indicators 24-Hour Reduced Incubation Time (RIT) capable when used with Spordex® VH2O2 Biological Indicators (NA333).

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.

CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.

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

ENGINEERING DATA

Shelf Life:	9 Months
Species:	*Geobacillus stearothermophilus,* ATCC 12980
Mean Population:	1.0 to 5.0 x 10^6
D-Value (Typical):	0.6 to 2.0 min. @ 2.0 mg/L

Spore Carrier:

Envelope:	Tyvek
Disc:	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: Move BIs from storage to ambient conditions ≥ 1 hour before use.

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.

For Further Information, contact:

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