STERIS®

SPORDEX® VHP® NA330 – E6 INOCULATED STAINLESS-STEEL COUPONS
E6 BIOLOGICAL INDICATOR FOR HYDROGEN PEROXIDE VAPOR
TECHNICAL DATA

GENERAL DESCRIPTION

The Spordex VHP NA330 Biological Indicator (BI) uses a stainless-steel carrier which is nonpermeable to hydrogen peroxide (H_2O_2) vapor. The stainless-steel coupon is inoculated with a single-spore species (*Geobacillus stearothermophilus*, ATCC 7953) and enclosed in a Tyvek® (DuPont) envelope. The Tyvek envelope is porous to H_2O_2 vapor. The coupons are produced under controlled conditions to meet the suggested performance parameters published in the U.S. Pharmacopeia.

APPLICATION

The Spordex E6 Inoculated Stainless-Steel BI is recommended for validation and routine monitoring of H_2O_2 vapor sterilization processes.

FEATURES

Certificate of Performance with certified population, species, lot number and expiration.

Single Species, E6 *Geobacillus stearothermophilus*

Spore coupon material nonpermeable to H_2O_2 vapor

Inoculated side of coupon is facing print side of Tyvek envelope

A hole near one end of coupon for hanging exposures

TECHNICAL PROPERTIES

Primary Packaging	Tyvek envelope approximately 2-1/2 x 1-1/2" (64 x 38 mm)
Spore Carrier	Stainless-steel coupon approximately 3/8 x 11/16 x 1/8" (9 x 16 x 3 mm)
Species	*Geobacillus stearothermophilus*, ATCC 7953
Mean Population Recovery	1.0×10^6 to 5.0×10^6
Purity	Bacterial contaminates less than 1% of labeled population; this is detection limit using pour plate method with an aliquot that yields at least 100 colony forming units (CFU).
Packaged	100 inoculated coupons per box

DIRECTIONS FOR USE

Allow refrigerated Spordex VHP NA330 – Stainless-Steel E6 BIs to equilibrate to room temperature prior to testing (approximately one hour). The Stainless-Steel E6 BI may be exposed packaged or aseptically removed, hung by wire and exposed unpackaged.

Packaged Exposure

Place the packaged BIs into the areas of the enclosure considered to be the most difficult to be sterilized by H_2O_2 vapor. Operate the biodecontamination unit per the manufacturer's recommendations. ***Note: Do not cover the printed side of the Tyvek envelope***. At the end of the exposure cycle, remove the BIs and deliver them with the unexposed control BI from the same lot to the laboratory for culturing.

Optimally, all culturing should be conducted at a laminar flow clean air bench. Aseptic technique should be employed. It is recommended that exposed BIs be cultured within two hours after exposure. Open the Tyvek envelope by cutting the package with cold sterile scissors. Carefully transfer the spore coupon to a tube of sterile soybean casein digest broth (SCDB). Withdraw the spore coupon with cold sterile forceps and drop into the media. Assure coupon is completely submerged in the media by agitating the tube. Incubate the tube/coupon at 55-60°C (131-140°F) for seven days.

Unpackaged Exposure

Place the unpackaged BIs into the areas of the enclosure considered to be the most difficult to be sterilized by H_2O_2 vapor. Operate the biodecontamination unit per the manufacturer's recommendations. ***Note: Aseptic technique must be employed during transfer of unpackaged coupons or contamination may result.*** At completion of exposure cycle, remove the BIs and deliver them with the unexposed control BI from the same lot to the laboratory for culturing.

Optimally, all culturing should be conducted at a laminar flow clean air bench. Aseptic technique should be employed. It is recommended that exposed BIs be cultured within two hours after exposure. Carefully transfer the spore coupon to a tube of sterile soybean casein digest broth (SCDB). Withdraw the spore coupon with cold sterile forceps and drop into the media. Assure 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.

If sterilization of the Spordex VHP NA330 – Stainless-Steel E6 BI was achieved, no turbidity will be present after incubation. If the media begins to show turbidity, then sterility has not been achieved.

See the instruction card enclosed in the Spordex VHP NA330 – Stainless-Steel E6 BI box for detailed use instructions.

STORAGE CONDITIONS

Spordex VHP NA330 – Stainless-Steel E6 BI should be stored at 2-8°C (36-46°F). Do not freeze. Avoid contact with, or storage near, sterilants or chemicals; for example, any oxidizing or reducing agents such as formaldehyde, bleach, ammonia, etc. Do not use after the expiration date printed on the packaging.

ORDERING INFORMATION

Description	Quantity per Box	Reorder Number
Spordex VHP NA330 BI - Stainless-Steel E6	100	NA330
Other VHP Consumable Products		
Spordex VHP NA300P BI – E5 Polyflex	100	NA300P
VHP Chemical Indicator – NB305	100	NB305
VHP Spore Suspension	10 mL	NA304
Spordex Culture Media	100	NA114

For further information, please contact:

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