

GENERAL DESCRIPTION

The Spordex® Self-Contained Biological Indicator (SCBI) Ampoule (NA500) is for use in monitoring common steam sterilization processes. The Spordex SCBI Ampoule (NA500) is manufactured and tested in accordance with ISO 11138.

Each indicator is completely self-contained, combining a spore species (*Geobacillus stearothermophilus*) and a specifically modified soybean casein digest growth medium with pH indicators in a glass ampoule. Following incubation, a vivid color change from red/pink to bright yellow and/or turbidity gives unmistakable evidence of microbial growth. If no microbial growth occurs, the media remains red/pink and without turbidity.

The ampoule has been validated for a 48-hour reduced incubation time to shorten holding time for product release. (All testing for the reduced incubation time has been performed according to the Guidance for Industry and FDA staff-Biological Indicator (BI) Premarket Notification [510 (k)] Submissions.) Incubation for up to seven days is possible, if desired.

APPLICATION

The Spordex SCBI Ampoules (NA500) are designed for use in monitoring the effectiveness of common steam sterilization processes and are able to be submerged in liquids for sterilization verification of liquid loads. The Spordex SCBI Ampoule (NA500) is for pharmaceutical industry applications and is not approved for use in hospital and healthcare facilities in the United States.

FEATURES	BENEFITS
<i>Geobacillus stearothermophilus</i> single species E6 population.....	E6 population meets the current ISO/AAMI/EN requirement of 6-log reduction
Manufactured and tested in accordance with ISO 11138.....	Allows for harmonization of biological indicators between global customer sites
Manufactured to meet the current USP.....	Compliance with current guidelines
Reduced incubation time.....	A 48-hour reduced incubation time study has been performed to shorten holding time for product release
Closed system within ampoule.....	Prevents contamination of contents; media does not evaporate
Vivid color change of pH indicator during incubation to indicate microbial growth.....	pH indicator makes positives easier to identify
Complete system is self-contained, including spores, media, and pH indicator.....	Reduces chances for false positives from aseptic transfer technique

TECHNICAL PROPERTIES

Spore carrier: Soybean casein digest growth medium with pH indicators, glass ampoule

Species: *Geobacillus stearothermophilus*

Mean population recovery: 1.0×10^6 to 5.0×10^6

pH indicators: Phenol red

Growth media: specially modified soybean casein digest growth medium

D-value for saturated steam (D_{121}): >1.5 minutes

– D_{121} is determined with a $121^\circ\text{C} \pm 0.5^\circ\text{C}$ exposure temperature utilizing a prevacuum cycle.

Incubation temperature: 55-59°C (131-138°F)

Shelf life: 12 months from time of manufacture. The expiration date is printed on the certification card that accompanies the Spordex SCBI Ampoule (NA500).

Quantity: 100 count box

DIRECTIONS FOR USE

The Spordex SCBI Ampoule (NA500) should not be used after the expiration date. Place the Spordex SCBI Ampoule (NA500) inside the representative liquid or directly inside the steam sterilizer according to the applicable standard operating procedure (SOP). Package or wrap the product to be sterilized according to the SOP. Run the sterilization cycle in the autoclave.

After cycle completion and while dressed in appropriate personal protective equipment (PPE) according to the applicable SOP, allow the Spordex SCBI Ampoule (NA500) to cool down before handling.

No activation is required for the Spordex SCBI Ampoule (NA500). Incubate the Spordex SCBI Ampoule (NA500) upright at 55°C to 59°C for a minimum of 48 hours if using STERIS Verify® Incubators. If not, incubate for 7 days, or according to the applicable SOP. Monitor the Spordex SCBI Ampoules (NA500) daily during incubation.

Interpretation:

A passing result (no biological growth) is indicated by no color change and/or no turbidity. The Spordex SCBI Ampoule (NA500) remains red/pink and liquid is clear. A failing result (biological growth) is indicated by a color change to yellow and/or demonstration of turbidity.

Controls:

One or more positive controls should be included in each test series. This requires incubation of a Spordex SCBI Ampoule (NA500) that has not been exposed to the steam sterilization cycle. Biological growth (turbidity) and/or a color change indicates that the Spordex SCBI Ampoules (NA500) are viable. No growth or color change indicates that the Spordex SCBI Ampoules (NA500) are no longer viable.

Following incubation, dispose of positive cultures the same as with other microbiological waste; non-pathogenic species, e.g., steam autoclave 121°C for not less than 30 minutes or use other suitable means.

A specially designed incubator is available for use with the Spordex SCBI Ampoule (NA500). Please contact STERIS for more information.

STORAGE CONDITIONS

Spordex SCBI Ampoules (NA500) should be stored at refrigeration temperature 2-8°C (36-46°F) as defined by the United States Pharmacopeia. Avoid contact with, or storage near, sterilants or chemicals; e.g., any oxidizing or reducing agents such as formaldehyde, bleach, ammonia, etc. Do not use after the expiration date printed on the packaging.

DISPOSAL

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

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.

ORDERING INFORMATION

Description	Quantity Per Box	Reorder Number
Spordex Self-Contained Biological Indicator Ampoules for Steam	100	NA500

For further information, please contact:



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