

SporView[®] 10 Steam Self-Contained BI

For use in biologically monitoring gravity displacement and dynamic-air-removal steam sterilizers.

Description

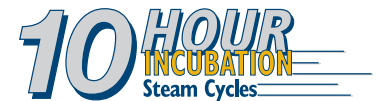
Each SporView[®] 10 Self-Contained Steam BI (SCBI) contains *Geobacillus stearothermophilus* spores and growth media along with a chemical indicator label printed with lot and expiration date. After processing, the SCBI is activated and then incubated at 55-60°C, with a final incubation of 10 hours. Special Note: Each lot of culture medium is validated for growth promotion capabilities per USP guidelines. Media growth promotion has been validated for growth of the *G. stearothermophilus* organism after exposure to a steam cycle of 132°C for 10 minutes exposure time.

Frequency of Use

ANSI/AAMI standards recommend steam sterilizers be biologically monitored at least weekly, preferably daily and every load with an implant. CDC guidelines recommend BI testing at least weekly and every load with an implant.

Features & Benefits

- Available for use over a broad range of cycle parameters as cleared by the FDA and indicated on each product's certification - *reduces inventory and operator error*
- Inexpensive dry block incubator with built-in activator - *save time and money*
- Spore growth of a test BI is observable in as little as 2 1/2 hrs. with 10 hr. final incubation - *fast results*
- Media growth promotion has been validated per USP for growth of the target organism after exposure to a steam cycle of 132°C for 10 minutes exposure time - *ensures confidence of media recovery and BI test results*



ORDERING INFORMATION

Cat. No.	Description	Packaging
SVT-050	SporView [®] 10 Self-Contained Steam BI	50/bx
SVT-504	SporView [®] 10 Self-Contained Steam BI, 50/bx	4bx/cs
RN-025	Record Notebook	each
NDB-060	55°C – 60°C Dry Block Incubator - 11mm	each

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Extended Cycles Validation

INTRODUCTION

Proper sterilization of instruments and materials is a critical aspect of infection control. For hospital steam sterilizers, biological indicators containing *Geobacillus stearothermophilus* spores offer the highest level of sterility assurance and are recommended to be used to monitor steam sterilizers daily, and every load with a medical implant. In recent years, steam sterilization cycle times have begun to increase beyond the standard pre-vacuum cycle of 270°F for 4 minutes exposure time. Extended cycles are due primarily to an increase in the weight and/or complexity of instrument sets, particularly orthopedic instruments. Culture medium packaged inside self-contained biological indicators (SCBIs) is typically validated for only standard sterilization cycle times. The purpose of this study was to evaluate the affect of extended steam sterilization cycles on the growth promotion of culture medium inside the SporView® 10 Steam SCBI. Failure of the culture medium to detect low numbers of viable spores during incubation could lead to false negative results and subsequently, the release of *non-sterile* loads. Multiple lots of SporView® 10 Steam SCBIs were used in this validation study.

JUSTIFICATION

Section 12.4 of the ANSI/AAMI/ISO 14161:2000 standard for Biological Indicators states... “Selection of a suitable culturing medium requires consideration of many variables, such as pH of the culturing medium and the presence of inhibitory substances such as salts, pH indicators, or antibiotics. Other substances in the culturing medium can affect the recovery of sterilizing agent-stressed test organisms. Users should not over process the culture medium, as extended sterilization can induce changes that can affect its growth promoting properties. The ability of the culturing medium to promote the growth of low numbers of microorganisms should be demonstrated.”

United States Pharmacopeia (USP) has an established procedure for testing culture medium. This testing requires inoculating the medium with less than 100 spores of a test organism, and then incubating at the appropriate incubation temperature for a specified time. Performing this test assures that the culture medium is capable of supporting growth of low numbers of microorganisms.

TEST EQUIPMENT and SAMPLES

Pre-vacuum Steam Sterilizer
Dry Block Incubator, 11mm
Laboratory Laminar Flow Hood
SPSmedical SporView® 10 Steam SCBIs

METHODS

A Bowie-Dick type test was performed each day in an empty chamber to document proper air removal prior to testing in the pre-vacuum steam sterilizer. Eleven (11) test SCBIs from each lot were labeled 1-11 for traceability purposes. All test SCBIs were placed inside a perforated instrument tray, wrapped with disposable sterilization wrap and secured with steam indicator tape. The sterilizer was set for an extended hospital pre-vacuum cycle of 270°F for 10 minutes exposure time, with 20 minutes dry time. The tray was placed on the lowest shelf over the drain and processed. Upon cycle completion, the tray was removed from the sterilizer and allowed to cool for thirty (30) minutes. Upon opening the tray, one (1) processed SCBI was removed, activated and incubated as a negative control. The remaining SCBIs were placed inside a laminar flow hood and each inoculated with approximately fifty (50) spores from suspension. Following inoculation with viable spores, the SCBIs were activated and then incubated along with one (1) unprocessed SCBI from each lot. The unprocessed SCBI served as a positive control to verify the spores were indeed viable at time of use and the incubator was functioning properly. The inoculated SCBIs were incubated at 55 – 60°C for 10 hrs, per their instructions for use.

TEST RESULTS

Results demonstrated that all SporView® 10 Steam SCBIs tested supported growth of a low number of spores per the USP recommended growth promotion procedure. Growth was documented by a yellow color change in the culture medium within 10 hrs incubation at 55 – 60°C.

For additional information, contact Customer Service at (800) 722-1529, Fax: (585) 359-0167 or E-mail: info@SPSmedical.com.