

SporAmpule™

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*Monitoring
your autoclave
couldn't be easier
with the convenient
SporAmpule™.*



Certified for all steam sterilization processes. No crushing or other activating steps. Simply process, incubate, and record results.



Easy to use!

Process one or more SporAmpules™, by SPS Medical, along with your normal load, then incubate at 55-60°C. for 48 hours and observe for a color change. **No activation, crushing, or additional culture media** is required with this hermetically sealed product. Because SporAmpule™ is a completely sealed system, there is no chance of contamination.

Sterilization failure is noted when spore growth occurs (purple to yellow color change and visible turbidity) with a processed SporAmpule™. An unprocessed SporAmpule™ should always be incubated as a control.

Certified Performance.

Each SporAmpule™ contains spores of *Geobacillus stearothermophilus* suspended in their own culture media in a hermetically sealed glass ampule.

A "Certificate of Performance" stating spore population, Z- value, D-value, and expiration date is included with every shipment. 18 month shelf-life.

SporAmpule™	20/Box	BST20
SporAmpule™	100/Box	BST100



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Santa Maria, CA Tacoma, WA Salt lake City, UT Phoenix, AZ Lima, OH

Cat. No. **BST-20** Qty: 20 Vials
Cat. No. **BST-100** Qty: 100 Vials

Organism: *Geobacillus stearothermophilus*
ATCC No. 7953

SPORAMPULE® Biological Indicator

The SporAmpule is a self-contained biological indicator for use with steam and washer/sterilizer processes. Each SporAmpule contains *Geobacillus stearothermophilus* spores suspended in a culture medium containing bromocresol purple acid indicator.

Monitoring Frequency

Per AAMI, ADA and CDC recommendations, Steam sterilizers should be biologically tested at least weekly, preferably daily and every load that contains an implant.

Instructions for Use

1. Place one or more SporAmpules in sterilizer as indicated in the sterilizer instruction manual.
2. Process the load according to the sterilizers manufacturer's instructions.
3. After processing, open sterilizer door and allow the load to cool before removing the SporAmpules.

Incubation

1. Incubate at 55–60°C for **48 hours** checking for spore growth (turbidity and/or color change from purple to yellow) at regular intervals (i.e. 12, 24, 36 hours). The SporAmpule design allows for extended incubation without fear of media evaporation.

Test Results

1. Record negative (no growth) results after full incubation in a Sterilizer Record Notebook. No color change in the purple media indicates proper sterilization.
2. Any positive (turbidity and/or color change from purple to yellow) result, should be reported immediately to a Supervisor and sterilizer taken out of service until resolved.

Use of Controls

1. As a control, an unprocessed SporAmpule (from the same lot) should incubated each time the sterilizer is tested.

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CERTIFICATION

Incubate: 55 - 60°C
Storage: 2 - 8°C
Disposal: Incinerate or autoclave at 121°C
for 30 minutes or longer

Lot No.	718
Exp. Date:	2022-03-11

Population per SporAmpule: 1.7×10^5 CFU* / 1.9 mL ampule
****D-value at 121.1°C:** 1.7 minutes
*****Z-value:** 8.0 °C (approximate, based on 118, 121.1, 124 & 132°C, exposure temperatures)

Performance Characteristics: (Based on USP Calculations)

PROCESS	TEMPERATURE	SURVIVES (+)	KILLED (-)
Steam (Saturated)	250°F (121.1 ± 0.5°C)	5.50 minutes	15.71 minutes

* Colony forming units

** The normal resistance of the SporAmpule; i.e., the time (in minutes) to reduce the spore population by 90%. D-value determined using Fraction Negative analysis (Spearman-Karber method) and is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here. The user should determine the suitability of the SporAmpule for the intended use.

*** The number of degrees (in Celcius) to change the D-value by a factor of 10.



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Rev. 02/18

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