Cat. No. CSBI25
Qty: 25 Vials

Organism: *Geobacillus stearothermophilus*
ATCC No. 7953

ConFirm® 24

Self-Contained BI for **Steam** Sterilization

ConFirm 24 self-contained biological indicators are inoculated with viable *Geobacillus stearothermophilus* bacterial spores and are intended for monitoring the efficacy of saturated steam sterilization processes operating at 121°C and 132°C gravity displacement, 132°C flash gravity displacement and 121°C – 134°C prevacuum cycles. ConFirm 24 self-contained biological indicators are also appropriate for use in monitoring the efficacy of saturated steam prevacuum sterilization processes operating at 135°C for 3 minutes exposure time.

Due to varying sterilizer come-up times, it is recommended to extend the cycle time from 3 minutes to 4 minutes in order to achieve consistent kill when testing the gravity steam process at 270°F (132°C) in Flash Cycles.

ConFirm 24 biological indicators (BIs) meet the manufacturer's quality specifications and suggested performance parameters published in the current AAMI/ISO 11138 for steam gravity and dynamic-air-removal sterilization processes.

Monitoring Frequency

Per AAMI standards, BIs should be used for routine sterilizer efficacy monitoring at least weekly, but preferably daily, and with every load containing implants.

Instructions for Use

1.! Record the sterilizer number, load number and processing date on the BI label.
2.! Place one or more BIs inside an instrument tray, rigid container, peel pouch or process challenge device, e.g. AAMI challenge pack, whichever is representative of the load being processed.
3.! Test the most challenging area in the sterilizer as indicated in the sterilizer's instruction manual (i.e. the bottom shelf near the door, over the drain of a large sterilizer or in the middle shelf of a small sterilizer).
4.! Process the load according to the sterilizer manufacturer's instructions.
5.! Remove the BI and confirm the process indicator printed on the label has turned **brown/black**.
Caution: After processing, the BI is hot and under pressure. Always allow to cool for ten (10) minutes before crushing. Failure to do so could cause the glass ampule inside the BI vial to burst which may result in injury. For this reason, safety glasses should be worn when handling and crushing a processed BI.

Activation and Incubation

1.! Activate the processed BI within 8 hours after processing by gently crushing the inner glass media tube using a vial crusher.
2.! Incubate at 55 – 60°C for **24 hours** checking for spore growth (visual color change from purple to yellow) at regular intervals (i.e. 3, 5 and 8 hours). Growth of surviving spores has been observed in as little as 2.5 hours.

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 (growth indicated by purple to yellow color change) result, should be reported immediately to a Supervisor and the sterilizer taken out of service until resolved.
3.! The stability of positive growth as indicated by a yellow color change has been tested up to 48 hours.

Use of Controls

1. As a control, an unprocessed BI (from the same lot) should be activated using a vial crusher and incubated each day the sterilizer is tested.

CERTIFICATION

Disposal: Autoclave at 121ºC for 30 minutes or longer.

Purity: No evidence of contamination using standard plate count techniques.

Population[1]**:** 1.8 x 10^5 per 0.25 inch (6.4 mm) disc

Lot No. xxxx
Exp. Date: xx/xx/xxxx

Performance Characteristics:

PROCESS	TEMPERATURE	D-VALUE	SURVIVES (+)[4]	KILLED (-)[4]
Steam (Saturated)	250ºF (121.1 ± 0.5ºC)	2.2 minutes[2]	7.2 minutes	20.3 minutes
Steam (Saturated)	270ºF (132.2 ± 0.5ºC)	0.39 minutes[3]	1.3 minutes	3.6 minutes
Steam (Saturated)	273.2ºF (134 ± 0.5ºC)	0.30 minutes[3]	1.0 minutes	2.7 minutes
Steam (Saturated)	275ºF (135 ± 0.5ºC)	0.25 minutes[3]	0.9 minutes	2.3 minutes

[1]After a preliminary heat treatment of 95-100°C for 15 min.
[2]Determined at the time of manufacture using fraction negative procedures (e.g. Stumbo Murphy Cochran) in an AAMI/ISO compliant test vessel. The D-value is reproducible only under the exact conditions under which it was determined. Users may not necessarily obtain the same results. The manufacturer's D-value cannot be duplicated in a healthcare facility.
[3]Empirically derived data.
[4]Calculated using USP, AAMI and ISO survival and kill time formulas.

Storage: Store at controlled room temperature as defined by USP. Reference the USP for the complete definition.

Protect from light, chemicals and sterilants (e.g. Ethylene oxide), excessive heat and moisture. Optimal humidity range for long term storage is 20 to 70%. Do not desiccate.

Mfg. by: **Crosstex International, Inc. a Cantel Medical Company**
109 Inverness Drive East Unit F • Englewood, CO 80112 USA • (800) 819-3336 • www.crosstexbms.com

CSBI25/I/COA
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