SELF CONTAINED BIOLOGICAL INDICATORS (SCBIs)
For monitoring Steam Sterilisation processes.



Excelsior Code: SCS-05E & SCS-06E

Product Description

Self-Contained Biological Indicators (SCBIs) for monitoring Steam processes consist of:

- A polypropylene cap
- A polycarbonate vial
- A crushable media ampoule which contains modified Tryptic Soy Broth (TSB) with a pH indicator . The modified TSB will transition from the initial purple colour to yellow and/or demonstrate turbidity in the presence of bacterial growth.
- An inoculated carrier (disc) of *Geobacillus stearothermophilus* (Cell Line 7953) with a population level of 10^5 or 10^6.

Indications for Use

The SCBIs may be utilised to monitor Steam sterilisation processes at 121°C to 140°C. Extended exposure to temperatures above 150°C may impact the integrity of the product. The SCBIs are ideal for monitoring non-liquid steam sterilisation cycles. The SCBIs are labelled for industrial use only.

Instructions for Use

Exposure: SCBI's may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or SCBIs in most difficult location to sterilise, as outlined in your specific sterilisation validation protocol or according to standard operating procedure. Run the cycle.

After sterilisation or exposure, remove SCBIs or product from steriliser

SCBIs may be held at room temperature for up to 72 hours post-exposure prior to activation without any impact to the performance. If the processed SCBIs are not activated within 72 hours of exposure, the cycle should be repeated.

Activation: Press the white cap of the unit down until an audible clip is heard and the glass media ampoule contained within is crushed. Ensure that the disc is immersed in the growth medium. Activate one SCBI which has not been exposed in a sterilisation process as a Positive Control.

Incubation: Place the processed, activated SCBI and the Positive Control in a vertical position in an incubator at 55°C to 65°C for a minimum of 10 hours.

Monitoring: Examine the SCBIs and record observations. All positive SCBIs should be disposed of immediately. Do not continue to incubate a positive SCBI. Continued growth may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and result in colour reversion that is visibly darker than a sterile unit. These should be considered as positive for growth (turbidity will be present).

For unexpected positives, it is recommended that a Gram stain be performed. Gram positive rods are Indicative for the indicator organism.

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Interpretation: Control SCBI: The Positive Control SCBI should exhibit a colour change to yellow and/or demonstrate turbidity. If the Positive Control as does not show signs of growth, consider the test invalid.

Test SCBI: A passing sterilisation cycle is indicated by no signs of turbidity and the purple colour not transitioning to yellow. A failed sterilisation cycle is indicated by turbidity and/or a colour change to yellow.

Chemical Indicator (CI): The chemical indicating strip (along the bottom of the SCBI label) should transition from pink to dark brown when exposed to a Steam process. Lack of colour change or a partial change in colour of the CI does not necessarily indicate failure. The CI does not prove efficacy of sterilisation; the biological result should be used to gauge efficacy of the sterilisation cycle.

Physical Properties

Process	Steam
Dimensions	9 mm x 48 mm
Packaging	50 per box
Chemical Indicator	Each SCBI contains a CI strip on the vial label. The CI should transition from pink to dark brown when exposed to a steam process.

Monitoring Frequency

For greatest control of sterilised goods, it is recommended that one or more SCBIs be included with every load.

Performance Characteristics

Population	≥ 1.0 x 10^5 or 10^6 per disc.
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	*D* value at 121°C ± 0.5°C ≥ 1.5 minutes The Steam *D* value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA). Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA. *z* value ≥ 6°C Determined based on three temperatures in the range of 110°C to 138°C. Excelsior Scientific typically utilises *D* values determined at 110°C, 121°C and 130°C for *z* value calculation.
Post-Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value Survival Time: All SCBIs result in growth at the certified survival time Kill Time: All SCBIs result in no growth at the certified kill time

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Compliance

ISO 11138-1 Sterilization of health care products – Biological Indicators- Part 1:General Requirements

ISO 11138-3 sterilisation of healthcare products—Biological Indicators – Part 3 for moist heat sterilization processes.

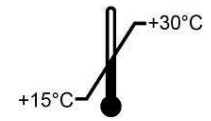
USP <55> Biological Indicators— Resistance Performance Tests

Excelsior Scientific has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled "Population Verification for mini strips (2mm x 10mm), Discs (Steel, paper & glass fibre), Threads, Wires and Coupons" to ensure consistent methodologies are being utilised when performing verification testing.

USP Biological/Official Monographs

USP Biological Indicator for Steam Sterilization, Self-Contained

Storage and Shelf Life

	15°C to 30°C		Keep away from Sunlight
	20% to 80% Relative Humidity		Keep dry
	Do not freeze		Protect from heat, radioactive sources & sterilising agents
Shelf Life	The shelf life of the SCBI is based on the shorter of two individual components (the media ampoule and inoculated carrier), which have independent expiration periods. This is usually 24 months from the date of manufacture.		
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the SCBIs. Do not use damaged SCBIs or SCBIs which demonstrate turbidity or have transitioned to a yellow colour. Do not use after expiration date. Do not refrigerate. The SCBIs contain live cultures and should be handled with care.		

Disposal

Autoclave for not less than 30 minutes at 121°C or per validated disposal cycle prior to discard.

For additional product information:
Please visit us at
www.excelsiorscientific.com
Email us at sales@excelsiorscientific.com

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