



## SELF-CONTAINED BIOLOGICAL INDICATORS For Monitoring Ethylene Oxide (EO)

Crosstex Code: SCE-06

### Product Description

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

- A polycarbonate vial and cap
- A crushable media ampule which contains modified Trypticase<sup>®</sup> Soy Broth (TSB) with a pH indicator. The modified TSB will transition from the initial green color to yellow and/or demonstrate turbidity in the presence of bacterial growth
- An inoculated carrier (disc) of *Bacillus atrophaeus* (Cell Line 9372) with a population level of 10<sup>6</sup>

### Intended Use

The SCBIs may be utilized to monitor EO sterilization process efficacy. The SCBIs are labeled For Industrial Use Only.

### Instructions for Use

**Exposure:** SCBIs may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate SCBIs or product in areas most difficult to sterilize, as outlined in a sterilization validation protocol (usually four corners front, four corners rear, center-center and center-top) or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove SCBIs or product from sterilizer.

**Activation:** Press the white cap of the unit down until the glass media ampule contained within the vial is crushed. Ensure that the disc is immersed in the growth medium. Activate one SCBI which has not been exposed in a sterilization process as a Positive Control.

**Incubation:** Place the processed, activated SCBIs and the Positive Control SCBI in a vertical position in an incubator set at 30°C to 40°C for a minimum of 48 hours.

**Monitoring:** Examine the SCBIs daily during incubation. 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 color 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 characteristic of the indicator organism.

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

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

Chemical Indicator (CI): The chemical indicating strip (along the bottom of the SCBI label) should transition from violet to green when exposed to an EO process. Lack of color change or a partial change in color of the CI does not necessarily indicate failure. The CI does not prove efficacy of sterilization; the biological result should be used to gauge efficacy of the sterilization cycle.

**Physical Properties**

Process	EO
Dimensions	13 mm x 61 mm
Packaging	50/Box
Chemical Indicator	Each SCBI contains a CI strip on the vial label. The CI should transition from violet to green when exposed to an EO process.

**Monitoring Frequency**

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

**Performance Characteristics**

Population	1.0 to 5.0 x 10 <sup>6</sup> per disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
EO Resistance	<i>D</i> value at 54°C ± 1°C, 600 mg/L ± 30 mg/L, 60% RH ± 10% RH 2.5 to 5.8 minutes The EO <i>D</i> value range is based on <i>D</i> values at the requirements outlined in the USP and ISO 11138-2. The EO <i>D</i> value is determined using 100% EO. Survival – Kill Times Calculated based on the formulas outlined in the USP and ISO 11138-1
Post-Market Criteria	Population: 50% to 300% of certified population <i>D</i> value: ± 20% of the certified <i>D</i> 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

**Compliance**

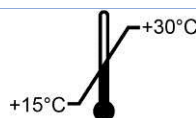

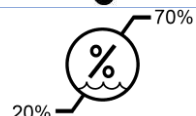




ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements

ISO 11138-2 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

USP <55> Biological Indicators – Resistance Performance Tests

Crosstex has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled *Population Verification for Paper Carrier Biological Indicators* to ensure consistent methodologies are being utilized when performing verification testing.

**Storage and Shelf Life**

	15°C to 30°C		Keep away from sunlight
	20% to 70% Relative Humidity		Keep dry
	Do not freeze		Protect from heat, radioactive sources, & sterilizing agents
<p><b>Shelf Life</b></p>	The shelf life of the SCBIs is based on the shorter of the two individual components (the media ampule and inoculated carrier), which have independent expiration periods.		
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the SCBIs. Do not use damaged SCBIs. 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 other validated disposal cycle prior to discard.

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