Direction for use (DFU SCBI STEAM 01.2013 version C)

This direction for use is applicable for the following Sterintech products:

107.001.0100 SCBI for STEAM

Sterintech Self Contained Biological Indicator (SCBI) for STEAM

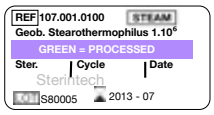
Introduction

The SCBI STEAM is developed for testing pre-vacuum steam sterilizers. Based upon a color change of the media inside the SCBI at the moment that sterilization was not effective the SCBI is an ultimate aid in quality management systems. SCBI's are considered the most reliable test for checking sterility levels.

The SCBI consists of a strip inoculated with a population of spores ATCC 7953 Geobacillus Stearothermophilus as well as a growth indicator media (enclosed in a glass ampoule) which is signaling after incubation whether the sterilization cycle was effective by its color. Original color of the growth indicator media is purple.

How to use the SCBI STEAM

I. The SCBI Label is providing space to write down sterilizer number, cycle and date.



II. Place the SCBI or SCBI's together with the to sterilize load in a suitable package in accordance with your working instructions. Ideally the pack should be placed in the area where penetration by the STEAM sterilant is most difficult.

III. Start the sterilization cycle.

IV. After completion of the sterilization cycle you should cool down the complete load in accordance with your working instructions and safety guidelines.

V.At completion of the cooling down time you can take out the pack and prepare the SCBI for incubation.

VI.Protective clothing, goggles and gloves are recommended to wear during handling SCBI's . Handle the ampoule with care in order not to break the glass of the ampoule.

VII. On the SCBI's label a class 1 process indicator is printed to make a distinct between used and unused SCBI's. Exposed SCBI do have a process indicator which is **Green**. The process indicator is not giving any information about the effectiveness of the cycle however.

VIII.Before incubation can start one have to break the glass ampoule inside of the SCBI. Incubates at 60±2°C with any dry bed incubator.

IX. It is recommended to incubate one positive (non-sterilized) SCBI together with the exposed SCBI's. The positive SCBI will give an indication that the right incubation temperature and time has reached. The incubation time for STEAM SCBI's is 24 hours for the given temperature.

X.Every 8 hours the color change of the growth media should take place to early detect failures of the sterilizer. When the growth media changes color from purple into yellow it means that living bacillus are present i.e. the sterilization cycle was not effective.

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XI.Only after 24 hours you can do your final reading and evaluation. If non of the SCBI is giving a positive result except for the positive SCBI (which was not sterilized) the sterilizer load can be released.

XII.Positive SCBI's should be disposed adequately.

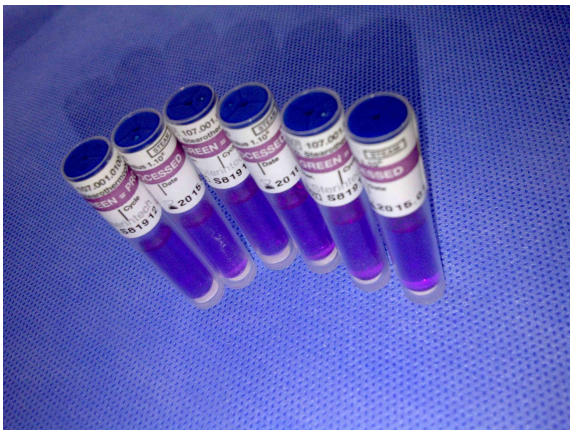
Warnings and recommendations

We recommend to use always two (2) SCBI's for monitoring your steam sterilization cycle.

The steam sterilizer should not be used until the SCBI is showing a negative result.

Storage conditions and disposal

The storage conditions are mentioned on the carton box in which the SCBI's are delivered.



For further instructions and information a technical data file is available.

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In this Technical data file you may find information about disposal of positive SCBI's and safety pre-cautions which should be applied while working with the SCBI.

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Certificate of Analysis

Ref.No.: 107.001.0100
Product: Self-Contained Biological Indicator for STEAM

Organism: **Geobacillus Stearothermophilus**

Lot: S81733
Man.Date: 06-2013
Expiry Date: 06-2015

Derived from: ATCC Cell Line 7953
Population: 6.2 x 10E6 per SCBI

Resistance Characteristics:

D-Value (121°C): 1,9 minutes

The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results as stated above.

Calculations based upon ISO 11138-1:

Steam Survival: 9,2 minutes
Steam Kill: 20,5 minutes
Z-value: 14,5°C (based on 119°C, 121°C and 130 °C exposures)

Storage conditions: (see box label)

Storage Temp.: 15 - 30 °C (DO NOT FREEZE)
Keep away from: Sterilizing agents, direct sunlight and UV Light.

Disposal:

Sterilize at 121 °C for not less than 30 minutes or incinerate

DO NOT USE AFTER EXPIRY DATE !!!

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