

Directions for Use

Famos Self Contained Biological Indicator for Steam

Reference: 15.100.419

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1. General information

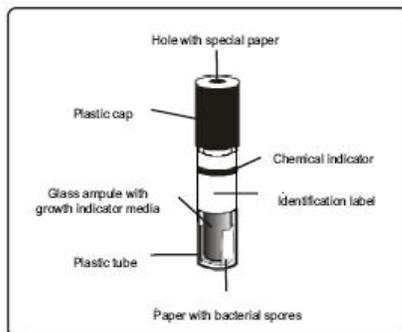
Biological indicator is specifically designed for the monitoring of vacuum assisted steam sterilization processes at 121°C-134°C and for steam sterilization cycle at 121°C-123°C in a gravity displacement air.

If sterilization process was not successful, the indicator media will change to yellow after incubation at 56±2°C, thus indicating the presence of live *Geobacillus stearothermophilus* spores.

If the sterilization process was successful, the indicator media will remain the same colour after incubation. The final readout should be made after 24 hours of incubation at 56±2°C.

2. Composition

Each tube contains a population of *Geobacillus stearothermophilus* ATCC 7953 spores soaked on a strip of paper. It also has a growth indicator media of purple colour contained in the glass ampoule.



3. Directions for use

1. Identify the SCBI STEAM indicator by writing the sterilizer number (in case it has more than one), load number, and processing date on the indicator label.

2. Pack the SCBI STEAM along with materials to be sterilized in an appropriated package according to recommended sterilization practices. Place this package in those areas which a priori you consider most inaccessible for sterilizing agent (high temperature steam). Generally a problematic area is the centre of the load and near the drain or door seals.

3. Sterilize as usual.

4. After the sterilization process has finished, you can;

A: Open the sterilizer door; remove SCBI STEAM from sterilization package for incubation

B: Aerate the package containing the SCBI STEAM with the rest of the load and wait until cool down.

Precaution! Wear safety glasses and gloves when the SCBI STEAM is removed from the sterilized package. Do not crush or handle the SCBI STEAM excessively, since this might cause the glass ampoule to burst.

5. Check the chemical indicator on the label of SCBI STEAM. A colour change from green to grey/violet confirms that the biological indicator has been exposed to steam at 121°C or more.

Important: this colour change does not indicate that the process was sufficient to achieve sterility. If the chemical indicator is unchanged, check the sterilization process.

6. Crush the glass ampoule contained in the SCBI STEAM and incubates at 56±2°C. See the instructions for use at your incubator

Important: Use a non-sterilized SCBI STEAM as positive control each time a processed SCBI STEAM is incubated. The positive control ensure that correct incubation conditions were met.

7. Incubate the processed SCBI STEAM and the indicator used as positive control for a maximum of 24 hours at 56±2°C. Reading should be made at convenient intervals of 8 hours. A colour change from purple to yellow of the growth indicator media means a sterilization process failure has occurred.

If after 24 hours there is no colour change in the processed indicators, a final negative result is made (the sterilization process was acceptable). The positive control indicator should show a purple to yellow colour change for the result to be valid. Record the positive ones and discard them immediately as it is shown below.

Warning! Do not use the sterilizer until the SCBI STEAM test results are negative.

4. Storage

Store the SCBI STEAM in a dark place and temperatures between 10-40°C, 20- 80% relative humidity. Do not freeze. Do not store these biological indicators near sterilizing agents or other chemical products

For further instructions and information a product safety data sheet available upon request.

5. Important considerations

You should use at least two SCBI STEAM biological indicators to monitor each steam sterilization cycle.

6. Warning!

Do not use this SCBI STEAM for monitoring gravity steam sterilization cycle at 132°C-135°C, or ethylene oxide, dry heat, chemical vapour, radiation or other sterilization processes.

Do not re-use the SCBI STEAM.

7. Disposal

Dispose of used SCBI STEAM according to your country's healthcare and safety regulations. The positive SCBI STEAM can be sterilized at 121°C for at least 30 minutes or at 132°C for 10 minutes in a gravity displacement steam sterilizer, or at 132°C for 4 minutes in a vacuum assisted steam sterilizer.

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