

Technical Report

Spore Strip Ethylene Oxide and Dry Heat

I. Introduction

Spore Strip is a biological indicator used in monitoring the efficacy of Ethylene Oxide (EO) or Dry Heat sterilization processes. Spore Strip consists of 10^6 *Bacillus atrophaeus* strain 9372 spores inoculated onto a 6mm x 38 mm paper spore strip, packaged in a 25mm x 70mm glassine envelope. The glassine envelope serves as a microbial barrier which protects the spore strip from post sterilization contamination.

II. Storage

Spore Strip should be stored cool at 15 - 27°C and 30 – 70% RH, away from sterilizing agents, direct sunlight and all other forms of UV light. Do not refrigerate.

III. Shelf Life

Spore Strip for EO and Dry Heat sterilization has a 24-month shelf life from the date of manufacture when stored at recommended conditions.

Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes or per site procedures.

IV. Use

1. Identify the spore strips by labeling pertinent process or load location information. Place inside the product or product package and place in the most difficult location to sterilize. Refer to the manufacturer's operating manual for guidelines.

NOTE: Inspect each strip prior to use for the following:

- Damage that has left an opening in the glassine envelope
- Separation along the edge of the glassine envelope
- The presence of a strip in the glassine envelope
- Two strips in one glassine envelope

Dispose of any damaged or questionable units per site procedure.

2. Place a sufficient number of Spore Strips throughout the load to be sterilized.
3. Expose the load to the validated sterilization cycle.
4. Following the exposure, remove the spore strips and transfer them to the laboratory for culturing.
5. In the laboratory, using strict aseptic technique and working in a clean, dust free room and within confines of a laminar flow hood, transfer each spore strip into a tube containing soybean casein digest broth.
6. The tubes should be placed in the incubator immediately after the strips are cultured.

Technical Report

Spore Strip Ethylene Oxide and Dry Heat

V. Incubation and Readout Time

The recommended incubation for Spore Strip for EO and Dry Heat is not less than seven days at 30 - 35°C. Placement in an optimized growth environment which maintains the correct incubation temperature is necessary to gain accurate results.

VI. Interpretation

The appearance of turbid medium or the formation of sediment indicates bacterial growth and a positive result. Clear medium indicates no growth and that the spores were killed in the sterilization process.

Act on a positive test as soon as it is noted. Carefully review sterilizer process records to ensure that all physical process parameters are within specifications. Always ensure that loading configuration and product and package specifications are in agreement with the sterilization validation process. Positive units may be subcultured if identification of positive growth is desired.

A positive control should be prepared periodically or at least weekly. Many users perform a positive and negative control for each cycle tested. The positive control typically turns turbid within 24 to 48 hours of incubation. As soon as the control turns positive, it should be appropriately recorded, autoclaved and discarded. The positive control is intended to confirm viable spores are present on the spore strip and the culture media will support growth of the test organism.

A positive control that has not grown is a serious problem. Fortunately, the causes are few: a grossly malfunctioning incubator; inadvertent sterilization of the positive control strip; or inadvertent sterilization of the entire box of indicators due to improper storage.

A negative control (a tube incubated without a spore strip) tests the medium for contamination. It should show no signs of growth.

VII. Performance Characteristics

EO resistance assessment testing is performed by exposing MesaStrip BIs in an EO resistometer conforming to ANSI/AAMI/ISO 18472:2018. Exposure conditions are 600 mg/L \pm 30 mg/L EO, 54°C and 60% \pm 10% RH. D-value is determined using the paper carrier packaged in glassine, cultured in Mesa Modified Tryptic Soy Broth with Bromocresol Purple, and calculated using the Fraction Negative method.

Survival and Kill times are calculated per the equations in ISO 11138-1, Annex E, using a population value and a D-value rounded to four decimal places.

Dry Heat resistance assessment testing is performed by exposing MesaStrip BIs in a Dry Heat resistometer conforming to ANSI/AAMI/ISO 18472:2018. Exposure conditions are 160°C \pm 2.5°C. Additional D-value assessment at 150°C \pm 2.5°C and 170°C \pm 2.5°C are performed for calculation of z-value. D-value is determined using the paper carrier packaged in glassine, cultured in Mesa Modified Tryptic Soy Broth with Bromocresol Purple, and calculated using the Fraction Negative method.

Dry Heat z-value is calculated using 150°C, 160°C and 170°C D-values.

Survival and Kill times at 160°C are calculated per the equations in ISO 11138-1, Annex E, using a population value and a D-value rounded to four decimal places.

Technical Report

Spore Strip Ethylene Oxide and Dry Heat

VIII. Population Determination

Detailed population assay instructions, TS-403 Paper, Quartz, & Cotton Thread Carrier Products, are available on Mesa's website.

IX. Compliance

Spore Strip for Ethylene Oxide and Dry Heat is manufactured in compliance with Mesa Laboratories' quality standards, USP, ISO 11138-1:2017, ISO 11138-2:2017 and ISO 11138-4 guidelines with the exceptions of Dry Heat D-value.