

Technical Report

MesaStrip 5230 Low Temperature Steam

I. Introduction

MesaStrip 5230 is a biological indicator used in monitoring the efficacy of Low Temperature Steam sterilization processes. MesaStrip consists of 10^6 *Bacillus subtilis* 5230 strain 35021 spores inoculated onto a 6mm x 25 mm paper spore strip, packaged in a 27mm x 73mm glassine envelope. The glassine envelope serves as a microbial barrier which protects the spore strip from post sterilization contamination.

II. Storage

MesaStrip 5230 should be stored at room temperature. The strips should not be stored near sterilants or other chemicals. Do not desiccate.

III. Shelf Life

MesaStrip 5230 for Low Temperature Steam 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 MesaStrips 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.

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V. Incubation and Readout Time

The recommended incubation for MesaStrip 5230 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

Steam resistance assessment testing is performed by exposing MesaStrip BIs in a Steam resistometer conforming to ANSI/AAMI/ISO 18472:2018. Exposure conditions are at 115°C ± 0.5°C, 118°C ± 0.5°C and 121°C ± 0.5°C. D-value is determined using the paper carrier packaged in glassine, cultured in Difco™ Soybean Casein Digest Broth, and calculated using the Fraction Negative method.

Z-value is calculated using 115°C, 118°C and 121°C D-values.

Survival and Kill times are empirically derived data.

VIII. Population Determination

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

IX. Compliance

MesaStrip 5230 is manufactured in compliance with Mesa Laboratories' quality standards, USP, ISO 11138-1:2017 and ISO 11138-2:2017 guidelines, with the exception of the Survival/Kill data.