Technical Report

ExpoSure®

I. Introduction

ExpoSure is a self-contained biological indicator (SCBI) for use in monitoring the efficacy of the following STERRAD® sterilization cycles:

- STERRAD® 50
- STERRAD® 100S (Short & Long[1])
- STERRAD® 200 (Short & Long[1])
- STERRAD® NX® (Advanced & Standard)
- STERRAD® 100NX® (STANDARD, FLEX, DUO, and EXPRESS)

ExpoSure is easy to use; no sophisticated laboratory testing or analysis is required. ExpoSure units consist of 10^6 bacterial spores of *Geobacillus stearothermophilus* 7953, inoculated onto a 7mm Quartz fiber disc which is placed into a thermoplastic vial that serves as a culture tube. A small glass ampoule containing sterile culture medium and pH color indicator is also contained in the vial. A Tyvek® disc filter is placed over the top of the culture tube to prevent contamination, and a cap is set over the top with a gap to allow sterilant penetration through the two side holes. A label on the outside of the vial includes a chemical indicator that serves as a visual indicator of whether or not the unit has been exposed to hydrogen peroxide vapor.

II. Storage

ExpoSure should be stored at 2°C to 25°C (36°F to 77°F) and ≤ 60% relative humidity (RH). Do not store near any sterilizer, sources of ethylene oxide, hydrogen peroxide, acids, alkalis or volatile antimicrobials such as glutaraldehyde or formaldehyde, STERRAD Cassettes, or any other oxidizers. Do not store in direct sunlight or any other form of UV light.

III. Shelf Life

ExpoSure has a 12-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. Medium

The culture medium, consisting of a proprietary formulated soybean casein digest base, is filled into glass ampoules and flame sealed. Following manufacture, the ampoules are exposed to a steam processing cycle to render them sterile and growth promotion is performed using less than 100 spores of *Geobacillus stearothermophilus* 7953. The sealed ampoules are of a convenient size to be placed into the plastic body with the spore disc. The ampoule is an 'onion skin' glass that allows it to be easily crushed when the plastic body is compressed. This provides the spores with a nutrient medium for growth.

The culture medium has a pH indicator (Bromocresol purple) added to it, which appears purple. After activation (when the plastic body is compressed) and an appropriate incubation period, if the

[1] "Long" applies to industrial cycles only

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spores grow the medium changes to yellow which means viable spores were present and acid is being produced. If the medium remains purple, the spores did not grow indicating they were killed in the sterilization process. Therefore, if the sterilization process was not effective, the spores will grow and turn the medium cloudy and yellow. If any ampoules show signs of a visual color change, or turbidity, prior to use, they should be autoclaved and discarded.

V. Use

1. Remove an appropriate number of ExpoSure from the box.

2. Ensure the Exposure SCBIs are at room temperature before use.

3. Ensure each cap is in a raised position to allow the sterilant access to the interior of the vial.

4. Place the SCBIs to be sterilized in a Tyvek pouch and then place in the “worst case” (least lethal) location in the load.

5. Process the load as usual.

6. Retrieve the ExpoSure SCBIs from the sterilizer load.

7. Remove the SCBIs from the Tyvek pouch as soon as it is removed from the load to eliminate the effects from potential residual sterilant inside the pouch.

8. Press the cap down on the SCBIs to prevent media evaporation.

9. The chemical indicator on the label changes to or toward blue when exposed to hydrogen peroxide. The purpose of the chemical indicator is to distinguish exposed from unexposed units. A blue color does not indicate acceptable sterilization.

10. To culture the disc in an ExpoSure SCBI, place the indicator in an upright position and compress the plastic vial with the provided crushing device to break the glass ampoule. This will allow the growth medium to come in contact with the spore disc. Ensure that the spore disc is completely saturated with the culture medium. Do not allow the culture medium to come into contact with the filter in the cap at any time

    NOTE: The medium ampoule contained in ExpoSure is made from thin walled glass that is designed to break easily during culturing/activation. For this reason, the ampoule can be damaged in shipping or in handling (placement in a load, product or process challenge device, or removal from a load, product or process challenge device). Inspection of ExpoSure units both prior to use in a sterilization process and after the process is critical because damaged units may produce inaccurate results.

    Inspect each ExpoSure unit for:

    - Indication of a damaged ampoule including low medium fill volume, wet or dried medium inside vial, cap filter appearing wet or discolored or spore disc appearing wet.

    - Missing or damaged components including cap, cap filter, spore disc, medium ampoule and plastic vial.

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Dispose of any damaged or questionable units per site procedure. Results obtained from damaged units should be considered suspect.

VI. Incubation and Readout Time

The recommended incubation for ExpoSure is not less than 24 hours at 55° – 60°C.

Exposure should be placed in the incubator immediately after activation. Placement in an optimized growth environment which maintains the correct incubation temperature is necessary to gain accurate results.

Mesa Labs' I1410 dry bath incubator is a small, convenient, tabletop incubator capable of maintaining the correct incubation temperature for ExpoSure SCBIs.

The incubation time of ExpoSure was validated according to the guidelines set forth in Attachment II of the *Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions*, issued October 4, 2007 by the Food and Drug Administration (FDA) Center of Devices and Radiological Health (CDRH). The CDRH reduced incubation time (RIT) protocol for validation of RIT may or may not meet each user's requirements for regulatory compliance. Users should therefore confirm regulatory requirements for reduced incubation time or incubate for 7 days.

VII. Interpretation

After the incubation period, the ExpoSure SCBIs should be examined for color change to or towards yellow and/or turbidity. ***ANY*** color change or turbidity observed in the exposed SCBI that is not present in a negative control SCBI (a negative control is a sample from the same lot, but one that has not been processed in a sterilizer or crushed) indicates that conditions necessary to achieve sterilization were not met. In this event, follow your facility policies and procedures for a failed sterilization cycle. A positive test (any color or turbidity change when compared to the negative control) can be acted on as soon as the color change is noted.

If after 24 hours the media color remains purple and there is no turbidity in the sample, this indicates that conditions necessary to achieve sterilization were met.

A positive control (a unit from the lot that has been crushed, but not exposed to a sterilization cycle) should be incubated for each cycle tested, or at least once per week. As soon as a control turns yellow, it should be appropriately recorded and then autoclaved and discarded. The control serves as visual evidence that the lot being used contains viable spores on the carrier. Positive controls are not to be used as a "color standard" to compare test results. Incubating the positive controls for longer than 24 hours is not recommended. A positive control that does not change color and is truly a negative result due to lack of growth is a serious issue. Some potential situations that may cause this are: a malfunctioning incubator; inadvertent sterilization of the control sample; inadvertent sterilization of the box of indicators (due to improper storage).

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VIII. Resistance Performance Characteristics

Hydrogen peroxide resistance assessment testing is performed by exposing ExpoSure SCBIs in a hydrogen peroxide resistometer conforming to ANSI/AAMI/ISO 18472:2018. Exposure conditions are 2.5 mg/L at 50°C. D-value is determined using the Fraction Negative method.

IX. Population Determination

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

X. Compliance

ExpoSure is manufactured in compliance with Mesa Laboratories' quality standards, USP and ISO 11138-1:2017 guidelines.

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