

ExpoSure™ Biological Indicator

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

The ExpoSure™ Biological Indicator is intended to be used as a standard method for frequent monitoring of the following STERRAD® Sterilizer Systems used in Healthcare facilities:

- STERRAD® 50
- STERRAD® 100S
- STERRAD® 200
- STERRAD® NX® (Advanced & Standard)
- STERRAD® 100NX® (STANDARD, FLEX, DUO, and EXPRESS)

PLACEMENT AND PACKAGING:

Place the ExpoSure™ BI in a Tyvek® pouch and place the pouch in the most challenging area for the sterilant to reach. This is typically on the shelf close to the rear of the sterilizer.

Note: Ensure that the ExpoSure™ BI is at room temperature before use and that the color of the media in the BI is purple prior to use in sterilizer.

BIOLOGICAL TEST:

- Set up the biological incubator at 55°C to 60°C according to manufacturer's instructions, allowing appropriate time for the incubator to heat up.
- Immediately after the STERRAD® Sterilization Cycle, remove the BI from the sterilizer. It is recommended that gloves be worn when handling BIs as peroxide burns can result if the media ampule is broken (follow the instructions found in "Other Considerations-A" below)
 - Check the chemical indicator* for color change to blue. See Interpretation of Results.
 - Press the cap down until firmly seated in order to seal the vial.
 - Using only the supplied tube crusher, squeeze the vial until the media ampule has been crushed.
Note: Do not crush the media ampule by hand as this may result in personal injury.
 - Keep the vial in a vertical position after the ampule has been crushed.
Note: Care should be taken not to puncture the vial in the crushing process in order to avoid false positive test results due to contamination entering the punctured vial.
- Incubate the processed vial at 55°C to 60°C in the biological indicator incubator.
Note: Any positive BI, including positive control BI and any biological indicator from a cancelled cycle, should be autoclaved for at least 30 minutes at 121°C (250°F) or follow your facility's procedure.

A new BI should be used in the next cycle.

USE OF CONTROLS:

- Use a positive control with each sterilization cycle. Crush an unprocessed ExpoSure™ vial and place in the same incubator used for the processed vial. The positive control should be from the same lot of ExpoSure™ as the processed biological indicator.
- A negative control ExpoSure™ vial is one from the same lot which has not been processed in a sterilizer and has not been crushed. When needed, a negative control can be used for comparison to the exposed test vial and the positive control vial.

READOUT OF RESULTS:

- Observe each vial for color change from purple to or toward yellow and/or for turbidity of the media. Record results after 24 hours of incubation.
- Discard all vials immediately after final reading including the positive control vial. To discard any positive vial, refer to NOTE in Section C in Biological Test.
Note: For easier color comparison, observe the vials against a white background.

INTERPRETATION OF RESULTS:

- Compare the processed ExpoSure™ vial with the positive control vial.
 - The *absence* of a color change and/or turbidity in the processed ExpoSure™ vial (i.e. the media remains purple as compared directly to a negative control) indicates that the sterilization conditions were achieved in the STERRAD® Sterilizer.
 - If the processed ExpoSure™ vial changes color from purple to yellow (as in the positive control vial), and/or exhibits turbidity, this indicates that conditions necessary to achieve sterilization in the STERRAD® Sterilizer have not been met.
- If a positive result is observed
 - Follow the current facility policy and procedures for a failed sterilization cycle regarding retrieval of unused instruments and notification of the physicians(s).
 - Repeat the sterilization cycle with a second ExpoSure™ BI.
- If the second ExpoSure™ BI is negative, run a third ExpoSure™ BI to confirm sterilizer performance. If two consecutive positive results are observed in the processed ExpoSure™ vials:
 - Follow current facility policy and procedures for a failed sterilization cycle regarding retrieval of unused instruments and notification of the physicians(s).
- The Chemical Indicator on the label changes color to blue when exposed to hydrogen peroxide during the cycle in the STERRAD® Sterilizer.
- When examining biological indicators for recoverable test organisms, the methods and conditions, which are prescribed in this section shall be applied, or if alternate methods are used, those methods shall be validated.
- In the rare event that media completely evaporates during the incubation period, the results are invalid for this individual sample.
- Always confirm negative results by direct color comparison to the negative control and by observing for turbidity. Any color not matching the negative control (purple) or indicating turbidity **is positive**.

STORAGE OF ExpoSure™ Biological Indicator:

- Store at 2°C to 25°C (36°F to 77°F) and ≤ 60% relative humidity. Ensure that the ExpoSure™ BI is at room temperature before use.
- 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.
- Do not use beyond labeled expiration date.

OTHER CONSIDERATIONS

- Check the integrity of the media ampule prior to, and after STERRAD® Processing. If a broken ampule is found before processing, use another ExpoSure™ BI. If a broken ampule is found after processing, reprocess the same load with another ExpoSure™ BI. To discard the broken ampule, refer to NOTE in Section C in Biological Test.
- To enable the sterilant, hydrogen peroxide, to get into the ExpoSure™ vial,
 - Do not place tape or labels over the holes in the cap of the ExpoSure™ BI prior to processing.
 - Do not push the cap down prior to processing.
- Do not use ExpoSure™ BI if media in the ampule is yellow and/or the chemical indicator on the label is blue prior to the sterilization cycle.
- Refer to the STERRAD® System's Operator's Manual for proper loading of the sterilizer.
- ExpoSure™ results should not be interpreted by anyone with eyesight impairment or color blindness.