

B/T Sure Biological Indicators



Introduction and Theory

B/T Sure Steam is a self-contained biological indicator for use in monitoring the efficacy of steam sterilization cycles. They are easy to use and require no sophisticated laboratory testing or analysis.

The B/T Sure vials consist of bacterial spores (*Bacillus Stearothermophilus*) inoculated onto a paper carrier, which is placed into a thermoplastic vial that serves as a culture tube. A small glass ampule containing sterile culture medium and color indicator are also contained in the vials. The culture medium is filled into the glass ampule and flame sealed. The sealed glass ampules are sized to be placed into the plastic vial body with the spore paper. Following manufacture, the ampules are exposed to a steam processing cycle to render them sterile. The ampule is an "onion skin" glass, which 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 added to it, which appears purple. Properly incubated, the medium changes to yellow when viable spores are present. If the medium remains purple, the spores did not grow, which means they are not viable. Therefore, if the sterilization process was effective, the medium will remain purple. If the process was not effective, the spores will turn medium cloudy and yellow. NOTE: If any ampules show signs of a visual color change prior to use, these should be autoclaved and discarded.

Monitoring Frequency

For optimum control of sterilized goods, we recommend that you continue your current monitoring process. If you do not have a process in place, please reference the state guidelines or CDC and/or OSAP recommendations on monitoring sterilized goods.

Instructions for Use

Exposure:

- 1) Remove an appropriate number of B/T Sure units from the box
- 2) Identify the indicators by labeling with pertinent process information
- 3) Place a B/T Sure biological indicator in a suitable test pack. The test pack refers to placing the indicator in the pouch with instruments or in the cassette, so that you confirm it was sterilized all the way through which is representative of the load
- 4) Place this test pack in the most challenging area of the sterilizer, generally on the bottom shelf near the door over the drain. NOTE: If a test pack is not being used, the B/T Sure should be oriented in a horizontal position during load processing.
- 5) Sterilize the load as usual
- 6) Remove from the sterilizer and allow the pack including indicator to cool for a sufficient time, at least 10 minutes.
- 7) Retrieve the B/T Sure indicator from the load.
- 8) The chemical indicator on the label changes from blue to black when exposed to steam. This distinguishes exposed from unexposed. NOTE: a black color does not indicate acceptable sterilization.

Incubation

Any microbiological incubator or dry block heater that is set for 55-60°C will satisfy the incubation conditions for the B/T Sure. To activate the media, place the indicator in an upright positioning in the plastic crusher

supplied. Gently squeeze the crusher to break the glass ampoule. Place the activated indicator in the incubator or dry block heater immediately.

Reading the Results

- 1) Examine the indicator at regular intervals for any color change (i.e. 18 hours, 24 hours). The appearance of a yellow color indicates bacterial growth. No color change indicates adequate sterilization.
- 2) Act on a positive test (a color change of yellow) as soon as the color change is noted. Notify appropriate personnel (i.e. infection control). Always retest the sterilizer with several B/T Sure biological indicators throughout the test load. B/T Sure biological indicators can be sub cultured if identification of positive growth is desired. Recommended sub culturing procedure techniques are available upon request.
- 3) The recommended incubation time is 24 hours.
- 4) Record the results.
- 5) Dispose of all used B/T Sure indicators in accordance with your office policy. Incinerate or autoclave any positive cultures at 250°F (121°C) for not less than 30 minutes.

Use of Controls

As a positive growth control, place an activated, unsterilized B/T Sure biological indicator in each incubator on a daily basis. Examine the positive indicator at regular intervals. The yellow color is noticed, and dispose of as mentioned above. NOTE: If the positive control does not grow, do not use the units from this box. Contact Thermo technical support 866-984-3766.

Storage

Store the B/T Sure biological indicators at controlled room temperature conditions (15°C to 30°C (59-86°F)) and 20 to 70 percent relative humidity. Do not store these indicators near sterilants or other chemicals. B/T Sure biological indicators have an 18-month shelf life, which is clearly designated, on each box. Rotate your stock accordingly. NOTE: Do not use after

expiration date printed on package. Dispose of expired indicators by incinerating or autoclaving at 121°C for not less than 30 minutes.

Ordering information:

Catalog Number List	Description	Quantity
AY759X1	B/T Sure Biological Indicators	5 per pack
AY759X3	B/T Sure Biological Indicators	100 per pack