

# **Monitoring Frequency:**

For optimum control of hospital sterilized goods, we recommend that **EZTest** biological indicators be used to monitor every sterilizer load. The JCHA and AAMI require a BI to monitor each sterilizer load containing implantable products. Monitoring use is the responsibility of each institution or end user.

### **Instructions for Use:**

CAUTION: After sterilization, the contents of the **EZTest** biological indicator are hot and under pressure. Always allow to cool at least 10 minutes. Failure to cool at least 10 minutes may cause the glass ampoule to burst and may result in injury from hot liquid.

**NOTE:** Should one observe yellow media in the biological indicator upon removal from the product box, this unit should be killed and discarded.

## A. Exposure:

- 1. Remove an appropriate number of **EZTest** units from the box.
- 2. Identify the indicators by labeling pertinent process information.
- 3. It is recommended that at least two BI's be used per cycle.
- 4. Place the EZTest biological indicators in a horizontal position with representative materials to be sterilized. These materials should be located in the "worst case" (least lethal location) in the load.
- 5. Select the appropriate cycle and process the load.

NOTE: If a Flash cycle is selected the goods should be unwrapped. If the come up time is less than one minute, a three minute exposure cycle may have to be extended to four minutes to ensure that the BI is killed.

- 6. Remove from the sterilizer and allow to cool for at least 10 minutes.
- 7. Retrieve the **EZTest** biological indicators from the test load.
- The chemical indicator on the label changes from blue to black when exposed to steam. This
  distinguishes exposed from unexposed units. NOTE: a black color does not indicate acceptable
  sterilization.

#### **B.** Incubation:

Any microbiological incubator that is adjusted for 55 to 60°C will satisfy the incubation conditions for the **EZTest**. To activate the media, place the indicator in an upright position in a plastic crusher. Gently squeeze the crusher to break the glass ampoule. Place the activated indicator in the incubator rack, and incubate immediately.

### C. Interpretation:

- 1. Examine the indicator at regular intervals for any color change (i.e. 8, 12, 18 and 24 hours). The appearance of a yellow color indicates bacterial growth. No color change indicates adequate sterilization.
- Act on a positive test (a color change of yellow) as soon as the color change is noted. Notify appropriate
  hospital personnel (i.e. Infection Control). Always retest the sterilizer with several EZTest biological
  indicators throughout the test load. EZTest biological indicators can be subcultured if identification of
  positive growth is desired. Recommended subculturing procedure techniques are available upon request
  from Mesa Labs.
- 3. The incubation time is 24 hours (meets the US FDA/RIT protocol).
- 4. Record the results.
- 5. Dispose of all used **EZTest** biological indicators in accordance with your institution's policy. Incinerate or autoclave any positive cultures at 250°F (121°C) for not less than 30 minutes.

# **Use of Controls:**

- A. As a positive growth control, place an activated, un-sterilized **EZTest** biological indicator in each incubator on a daily basis.
- B. Examine the positive indicator at regular intervals (i.e. 4, 8, 12, 18 and 24 hours). The yellow color is evidence of bacterial growth. Record the results. Remove all positive indicators as the yellow color is noticed, and dispose of as mentioned above.
- C. If the positive control does not grow, do not use the units from this box. Contact Mesa Labs.

#### Storage:

- A. Store **EZTest** biological indicators at room temperature. Do not desiccate.
- B. Do not store these indicators near sterilants or other chemicals.
- C. **EZTest** biological indicators have a 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 autoclaving at 121°C for not less than 30 minutes.