

Biological Indicators for Monitoring Low Temperature Steam Sterilization

INSTRUCTIONS FOR USE

Sterilization:

- 1. Place **SterilAmp**[®] **II** inside representative liquid containers to be sterilized. Package or seal as usual. AAMI recommends a minimum of 10 BIs per cycle.
- 2. Locate test samples in areas of the load considered most difficult to sterilize or in convenient areas that have been validated. Identify test samples as to location in sterilizer.
- 3. After sterilizing, send **SterilAmp II** and products to test laboratory along with at least one non-sterilized **SterilAmp II** marked POSITIVE CONTROL.

Test Laboratory:

- 1. All **SterilAmp II** are fully self-contained BIs which do not require subculture.
- 2. Procedure:
 - a. **SterilAmp II** may be left in the sterilized container or transferred to a rack or container which allows visual observation during incubation.
 - b. Incubate **SterilAmp II** for three days at 35-39°C.
 - c. Observe daily for growth.

Yellow and/or turbid = growth = non-sterile

Red = no growth = sterile

SterilAmp II should show "no growth" if sterilization has been achieved.

If color change to yellow or presence of turbidity occurs in **SterilAmp II** cultures, it indicates that the spores have survived the sterilization process and are non-sterile.

Controls:

a. **Positive**: At least one positive control should be included in each test series. Incubate a non-sterilized **SterilAmp II** with test series. Color change from red to yellow or presence of turbidity indicates that the medium possesses suitable growth promoting qualities and that the **SterilAmp II** contains viable spores. If positive control does not grow, do not use the units from that package. Contact Mesa Labs.

Storage and Disposal:

- 1. Refrigerate at $2 8^{\circ}$ C. Protect from light.
- 2. Incinerate or autoclave at 121°C for not less than 30 minutes.
- 3. **SterilAmp II** biological indicators have a 15 shelf life which is clearly designated on each package. 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.