



### INSTRUCTIONS FOR USE

For 121°C steam sterilization cycles only. Store in a refrigerator at 2-8°C.  
DO NOT FREEZE.

#### Description:

This is intended for use in the monitoring of saturated steam sterilization cycles at 121°C. Each ampoule contains a spore suspension of *Geobacillus stearothermophilus* (#7953) within a growth medium also containing Bromocresol Purple to function as a pH indicator. The acid production associated with growth causes a change in color from purple to or toward yellow.

#### Frequency of Testing:

For greatest control of sterilized goods we recommend that our Biological Indicators be included with every load.

#### Precautions:

Ampoules should be purple and undamaged prior to use. Do not use after expiration date. Since ampoule contains live cultures, ampoules should be handled with care. Ampoule is not intended for flash sterilization processes. This is a single use product. Use of a unit in multiple cycles will invalidate the results and could potentially result in the release of non-sterile product.

#### Disposal:

Sterilize all positive and expired units prior to disposal.

#### Instructions for Use

1. **Exposure:** Place one or more Biological Indicators in the most difficult location to sterilize, usually near the drain or suspended in a volume of liquid. Run cycle.

**Caution:** After sterilization, handle ampoules with care. Contents of the ampoule are hot and under pressure. Failure to allow sufficient cooling time (10-15 minutes) may result in bursting of the ampoule.

2. **Incubation:** Place the processed ampoule in a vertical position in an incubator at 55-60°C. Mark a control ampoule as such and incubate along with processed ampoules to ensure spore viability. We recommends an incubation time of 48 hours.

3. **Monitoring:** Examine the ampoules daily during incubation. Record observations. All positive ampoules should be recorded and then disposed of immediately.

#### 4. Interpretation:

a. **Control:** The control ampoule should exhibit a color change to or toward yellow and/or turbidity. If the control ampoule does not show signs of growth, consider the test invalid.

b. **Test:** A failed sterilization cycle is indicated by turbidity and/or a change in color to or toward yellow. A test ampoule that retains its purple color indicates an adequate sterilization cycle.

#### Resistance Characteristics:

In saturated steam at 121°C:



**Survival Time (in minutes)** = not less than (labeled D-value) x [(log 10 labeled spore count) – 2]\*

**Kill Time (in minutes)** = not more than (labeled D-value) x [(log 10 labeled spore count) + 4]\*

\*These equations are taken from the current USP.