



Disposable EO Biological Test Pack with Instant Readout Integrator

REF BI 102

Directions For Use

INDICATIONS FOR USE

SteriTec Disposable EO Biological Test Pack with Instant Readout Integrator is designed specifically for biological testing of EO Gas sterilizers. The pack consists of a self-contained biological indicator containing *Bacillus Atrophaeus* spores inside a small package of porous and non-porous material, simulating the biological test pack as defined in AAMI ST41.

INSTRUCTIONS FOR USE

1. Load the sterilizer as normal
2. Place the Biological Test Pack in the most challenging area of the sterilizer.
3. Process the load, normal cycle
4. Post sterilization, perform either of the following:
 - a. Remove the test pack from the sterilization load and transfer the load to the aerator.
 - b. If hospital policy requires, leave the test pack with the load, but examine the integrator card through the pouch while transferring to the aerator.
5. Open the pouch, remove the plastic cylinder, and remove the end cap from the cylinder. Slide the self-contained biological indicator from the cylinder. Activate the biological indicator and incubate as described below.

BIOLOGICAL INDICATOR TESTING PROCEDURE

1. **Activation of the Biological Indicator:** Hold the biological indicator in a vertical orientation and carefully crush the inner glass media ampule by compressing the sides of the plastic body. Place the activated indicator in a microbiological incubator rack, and incubate immediately.
2. **Incubation period:** Recommended incubation for 48 hours at 35-39° C.

INTERPRETATION

Instant Readout Integrator: An integrator card, printed with a chemical integrator, is contained within the test pack to demonstrate that the test pack has been exposed to proper sterilization conditions. If the chemical indicator is yellow, it has not been exposed to a sufficient ethylene oxide sterilization process. If the indicator is brown, the pack has been exposed to proper ethylene oxide sterilization conditions; therefore biological kill should be achieved. Record data on the Integrator card.

Biological Indicator: Examine the biological indicator at regular intervals (i.e. 18, 24, 36, 48 hours) for signs of color change. If indicator growth media changes to YELLOW, the biological spores have survived and the load is NOT sterile.

Use of Controls: Five (5) EZTest biological indicators are supplied with each case of test packs for use as controls. Activate and incubate an unexposed control indicator with every sixth test pack run. Examine the control indicator at 18 and 24 hours. A yellow color indicates bacterial growth. Record the results. Dispose of indicators in accordance with your institution's policy for handling microbial waste. It is recommended to discard a biological indicator as soon as signs of biological growth are indicated. You may wish to autoclave any positive indicators at 250° F /121° C for at least 30 minutes.

SAFETY PRECAUTIONS

- Do not store Biological Indicators near sterilants or other chemicals.
- Do not use Biological Indicators after expiration date listed on packs. Dispose of expired Biological Indicators as outlined above.

STORAGE

Store at normal room temperature 50° - 100°F (10° - 38°C) 20-70% R.H.

EXPIRY DATE

The expiry date is printed on the product packaging.

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