BI-O.K.™ Self-Contained Biological Indicators

A biological indicator for use in monitoring ethylene oxide gas sterilizers

Basic Principle

The CDC recommends that EO sterilization procedures and EO sterilizers be monitored on a routine basis[1]. Typically this consists of monitoring each load with biological indicators[2,3]. Correct test performance requires a biological indicator (spore strips or self-contained system) and a chemical indicator be placed in the center of a standardized challenge pack. The recommended pack consists of a biological indicator placed in a plastic syringe with the needle end open (tip guard removed).

The syringe and a chemical indicator are placed in a cotton towel, which is then placed in one peel pouch or wrapper[2]. The test pack is placed in the center of a sterilization load.

Following the cycle, the test pack is opened and the chemical indicator is examined for correct exposure. The biological indicator is removed from the pack and processed according to the manufacturer's instructions.

Instructions

1. Prepare a recommended test pack using one biological indicator and a chemical indicator.
2. Place pack in the center of normally loaded EO gas sterilizer.
3. Run a normal sterilization cycle.
4. Remove the load from the sterilizer. (The biological indicator may be retrieved and processed immediately or it may be processed at the end of load aeration. Check with your institution's policy on handling materials after ethylene oxide sterilization.)
5. Open the pack, remove the biological indicator and chemical indicator.
6. Examine chemical indicator for correct exposure. If the indicator change is incorrect/incomplete the test must be repeated with a new pack. The sterilizer and/or the cycle used should be examined.
7. Label the vial with the date, as well as the load and sterilizer number.
8. Activate the BI-O.K.™ indicator by holding it in a vertical position. Compress the sides of the vial by using a manual crushing device to break the glass media ampule. Alternatively, use a dry block incubator designed to activate vials of this type and size. Refer to the incubator manufacturer's instructions.
9. A positive (unsterilized) control from the same lot as the sterilized indicator should be used each time a sterilization test is performed. A positive control must be run a minimum of once a week.
10. Incubate the control and test units at 37 ± 2°C and examine at regular intervals for a total of 48 hours incubation.

Interpretation

1. Appearance of a color change from red to yellow is evidence of bacterial growth. All control vials should show this red to yellow color change within 48 hours. All test (EO exposed) vials should remain red.
2. If test vials demonstrate a positive test, respond to this sterilization failure immediately according to the policies of your institution.
3. Record all information and results. File as a permanent record.

Limitations

Not for use in biological monitoring of steam sterilizers.

Storage

Store BI-O.K.™ indicators under normal room conditions (15-30°C; 59-86°F) 40-70% relative humidity. Store away from sterilants and other chemicals.

Disposal

Dispose of used biological indicators according to your institution's policy (usually autoclaving at 250°F for at least 15 minutes).

References

1. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Update: May 2019.
2. ANSI/AAMI ST41:2008/(R)2018. Ethylene Oxide Sterilization In Health Care Facilities: Safety And Effectiveness. AAMI, Arlington, VA 2018.
3. AORN. Guideline for Sterilization. In: Guidelines for Perioperative Practice. 2018.

Propper Manufacturing Company Inc. • 36-04 Skillman Ave., Long Island City, NY 11101 • tel (718) 392-6650 • fax (718) 482-8909 • www.proppermfg.com

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