BI-O.K.® steam test-pak™

A disposable test pack with biological indicator for use in monitoring prevacuum and gravity autoclaves.

Basic Principle:

The current recommended practices on steam sterilization and sterility assurance in health care facilities suggest that steam autoclaves be monitored for performance on a routine basis[1,2]. Typically this consists of weekly monitoring with biological indicators. However, daily monitoring is recommended. Biological indicators should also be used for sterilizer qualification testing after sterilizer installation, relocation, malfunctions, major repairs, and after sterilization process failures.

Correct test performance requires a biological indicator (spore strip or self-contained system) and a chemical indicator be placed in the center of a standardized 16-towel challenge pack (Process Challenge Device, or PCD).

Propper BI-O.K.® Test-Pak™ is equivalent to the 16-towel pack in challenging steam cycles[3]. It can be used as a convenient replacement for the hospital prepared fabric towel pack in biological monitoring. The AAMI/ISO compliant[4] self-contained biological indicator is provided in the hollow chamber at the center of the pack. The test is carried out in the same way as testing with a 16-towel challenge pack. The BI-O.K.® Test-Pak™ comes complete with a record keeping card which has a pre-printed chemical indicator and can reliably monitor gravity displacement and pre-vacuum steam sterilizers at 250ºF and 270ºF.

Instructions:

1. Place the pack correct side up on the bottom shelf near the door of a normally loaded steam autoclave.
2. Run a normal sterilization cycle.
3. Remove the pack from the autoclave. Caution: Pack and contents may be hot. Glass ampoule containing B.I. may burst if crushed or handled excessively before cooling. Personnel should use gloves and safety glasses. Observe the process indicator on the front of the pack. A white to dark color change indicates that the pack has been processed. Open pack and remove the biological indicator and record card.
4. Examine chemical indicator on record card for correct exposure. If the color change is incorrect/incomplete the test must be repeated with a new pack. The sterilizer and/or the cycle used should be examined.
5. Allow the BI-O.K.® vial to cool.
6. Identify the vial by load, sterilizer and date.
7. 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 ampoule. Alternatively, use a dry block incubator designed to activate vials of this type and size.
8. A positive (unautoclaved) control from the same lot as the autoclaved indicator should be used each time a sterilization test is performed. A positive control should be run a minimum of once a week.
9. Incubate the control and test units at 55-60ºC and examine at regular intervals for a total of 24 hours incubation.

Interpretation:

1. A color change from purple to yellow is evidence of bacterial growth. All control vials should show such purple to yellow color change within 24 hours. All test (autoclaved) vials should remain purple.
2. If test vials demonstrate a positive test, react to this sterilization failure immediately according to the policies of your institution.
3. Record all information and results on the Record Card. File as a permanent record.

Limitations:

1. Use once and discard. Since exposure of steam will change the permeability characteristics of the materials used in the BI-O.K.® Test-Pak™, reuse will invalidate subsequent test results.
2. Not for use in biological monitoring of ethylene oxide sterilizers.
3. Not for use in immediate use cycles.

Storage:

Store BI-O.K.® Test-Paks™ under normal room conditions (15-30ºC; 59-86ºF, 35-60% relative humidity). Store away from sterilants and other chemicals.

Disposal:

Dispose of used biological indicators according to your institution's policy (usually autoclaving at 250ºF for at least 30 minutes.)

References:

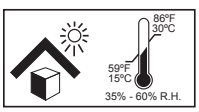
1. ANSI/AAMI ST-79:2010. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. AAMI, Arlington, VA 2010.
2. Perioperative Standards and Recommended Practices, AORN, 2008.
3. Propper FDA 510k K903024. BI-O.K. ® Steam Test-Pak™
4. ANSI/AAMI/ISO 11138-1:2006. Sterilization of health care products – Biological indicator systems – Part 3: Biological indicators for moist heat sterilization. AAMI, Arlington, VA 2006.

Explanation of symbols

= The date of manufacture

LOT = The lot number

= The expiration date



Reorder No:
269205 - 20 packs with **5** controls
269210 - 20 packs with **10** controls
269220 - 20 packs with **20** controls

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