MediPros®

Class 5 MediCheck™ Sterilization Integrating Indicator

Introduction

A steam sterilization process is the function of three basic parameters: time, temperature and the presence of saturated steam.

This Class 5 MediCheck™ Sterilization Integrating Indicator consisting of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked REJECT or ACCEPT. The extent of migration depends on steam, time, and temperature. A small decreases in temperature during steam sterilization may significantly increase the time necessary for 100% kill, an accurate means of monitoring internal sterilizer and pack conditions are essential.

Once a saturated steam environment is obtained, the independent variables of time and temperature can be determined by the following formula:

$t = Fo \times 10^{(250-T)/Z}$ Where

t = time for 100% kill at temperature T

T = processing temperature

Fo= kill time for *Geobacillus stearothermophilus* with a z-value of 18°F (10°C) and D-value of 1 minute at 250˚F (121˚C)

z = rise in temperature required to increase the rate of kill by a factor of 10 (usually about 18˚F (10˚C)) Interpretation of this formula shows that the relationship of processing time (t) versus temperature (T) can be plotted as a logarithmic function. Expressed differently, it means that a small fluctuation in the temperature results in a large change in the actual processing time required for 100% kill.

Control and Check

The dynamics of steam prove the need for accurate monitoring of internal sterilization conditions. Pack control is the use of chemical indicators for the internal monitoring of packs, trays, containers, and peel pouches. Internal chemical indicators should be used inside each type of packaging to address the potential for interference with proper steam sterilization conditions in all of these types of packaging.

Several problems can occur in the packaging and loading of individual packs that can inhibit air removal and steam penetration which leads to a lower temperature. Packing problems include:

- Incorrect packaging or container system chosen for the cycle parameters;
- Incorrect preparation of the container for use (i.e., filters and valves or appropriate bottom tray);
- Placing a folded peel pouch inside another pouch;
- Placing a peel pouch inside of an instrument tray or container system;
- Preparing textile packs that are too dense to sterilize in the cycle parameters chosen.

Loading problems include:

- Stacking container systems (if not recommended by the manufacturer);
- Laying peel pouches flat instead of on edge;
- Improperly placing peel pouches on edge (plastic sides not facing all in one direction);
- Turning instrument trays on edge;
- Laying fabric packs or basins flat;
- Placing packages too close to each other impeding air removal and sterilant penetration around and through the load.

Malfunctioning equipment can also result in insufficient sterilization conditions inside of packaging as the result of:

- Incomplete air removal;
- Inadequate cycle temperature;
- Insufficient time at temperature;

• Poor steam quality and quantity.

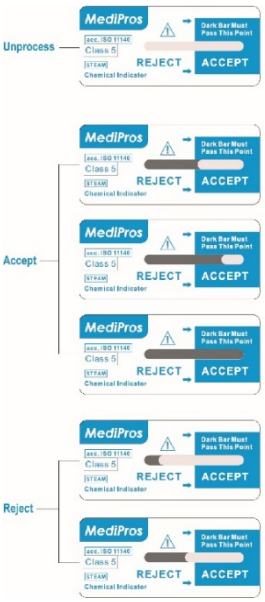
As discussed above, small reductions in time at temperature can reduce the margin of safety with steam processing. Problems that limit air removal or steam penetration in individual packs will have the effect of reducing the effective time at temperature. Class 5 MediCheck™ Integrating Integrators that meet the ISO 11140-1:2005 *Sterilization of healthcare products-*
Chemical Indicators-Part 1: *General requirements* used inside each pack to monitor time, temperature and steam exposure conditions can provide the necessary sterilization assurance on a pack-to-pack basis.

To confirm that MediCheck™ Integrating Integrators meet the Class 5 Integrating Indicator performance requirements of ISO 11140 - 1:2005.

Performance Characteristics

The MediCheck™ Integrating Integrators has been tested at various time and temperature intervals in saturated steam in a test vessel (called a resistometer) to determine compliance to the chemical indicator standards listed in the Chemical Indicator Classification section above. To meet the Class 5 Integrating Indicator performance standards, the MediCheck™ Integrating Integrators must have a response that correlates to the performance of a BI at three temperatures (121°C/250°F, 135°C/275°F, and one or more temperatures in between, such as 128°C/263°F). These responses are called Stated Values. Stated Values are “values of a critical variable at which the indicator is designed to reach its endpoint as defined by the manufacturer.” In addition, the Stated Value at 121°C/250°F must be >16.5 minutes. This is the most important Stated Value and was added to ensure that chemical indicators labeled for use in 132°C/270°F do not change too quickly or inappropriately at these lower temperatures. All of these performance requirements must be met to ensure that the CI can detect improper sterilization conditions inside of each pack/container.

Instructions For Use



1. To preserve as much package area as possible for folding and resealing, use scissors on the marked area at the top of the foil package to make the initial opening. Reseal the package by folding the opened end over at least two times.
2. Place a MediCheck™ Integrating Integrators in each pack, peel pouch, container system or tray to be steam sterilized in the area determined to be the least accessible to steam penetration. Position the unattached end of the extender so that it extends slightly beyond the inner contents of the pack. This will permit integrator retrieval without touching the pack contents.
3. Process the load according to established procedures. If using an integrator with extender, after processing, grasp the extender between the thumb and forefinger to remove the integrator from the inner pack.

After processing, the dark color should have entered the ACCEPT window of the MediCheck™ Integrating Integrators. If the dark color has not entered the ACCEPT window, this indicates a REJECT result which means that the items in the pack, peel pouch, container system, or tray were not exposed to sufficient steam sterilization conditions. These items should be returned for reprocessing.

Storage and Shelf Life

• Store unopened and resealed packages at 40-60% relative humidity condition at room temperature [15-30ºC (59-86 ºF)]. Store away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/disinfecting agents.

• After use, the indicator will not change visually within 6 months when stored at above conditions.

• MediCheck™ Integrating Integrators contained in an unopened package have a 5 year shelf life from the date of manufacture when stored at recommended conditions. The expiration date is printed on the package label.