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Technical Bulletin

STEAM*Plus*™ Class 5 Steam Sterilization Integrator

Introduction

The STEAM*Plus* Sterilization Integrator is an "advanced technology" medical device that provides a simple, accurate method of assuring that proper conditions for sterilization have been met during a sterilizer cycle. Certified for use with all Steam processes (gravity, prevacuum and flash), the STEAM*Plus* has documented performance equivalent to a biological indicator.

Description

The STEAM*Plus* Sterilization Integrator is engineered to integrate the three (3) critical variables of sterilization: time, temperature, and saturated steam. This information is displayed in a precise, easy-to-read format. When the dark bar enters the blue SAFE area, sterilization criteria has been met. If the dark bar does not reach the blue SAFE area, proper conditions for sterilization have not been achieved and the processed items should not be released.

Some common causes of sterilization failure are:

- overloading the chamber
- air pockets within the sterilizer
- packs wrapped too tightly
- malfunction of the timing mechanism
- error in the temperature setting
- load configuration
- poor steam quality

Technical Design

The STEAM*Plus* Integrator is made of aluminum foil, which holds the temperature and steam-sensitive chemical which is designed to melt when subjected to a steam environment. The foil also acts as a moisture barrier against steam during the sterilization cycle.

As moisture penetrates the integrator, it lowers the melting point of the chemical. When melting occurs, the liquid chemical is soaked up by the paper wick and, as time elapses, moves along the scale. The rate of melt produced is a function of both the moisture-vapor transmission rate of the cover film and the melting point depression of the chemical. The combination of these two factors provides a rate of melt at various temperatures which parallels the thermal death time of *Geobacillus stearothermophilus* spores as illustrated in Figure 1.

Note: Figure 1 represents sterilization cycle time only and does not include come-up or down time.

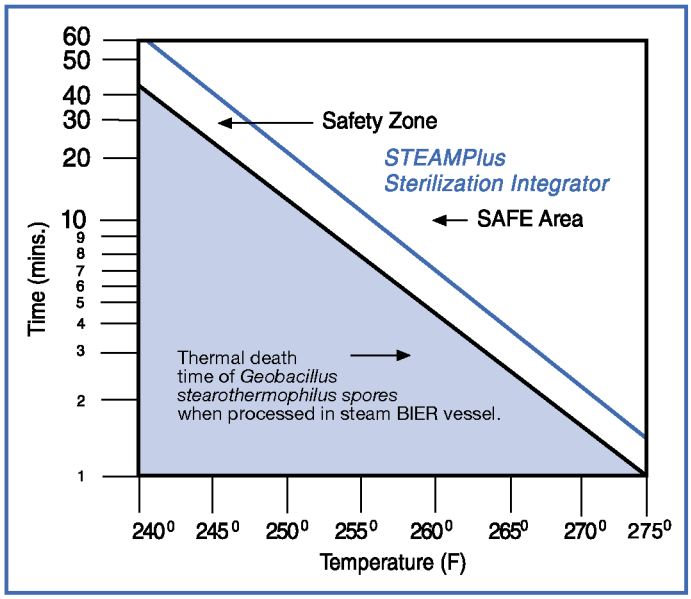

Figure 1

Performance Characteristics

The STEAM*Plus* Integrator was tested at various time and temperature intervals in saturated Steam in order to estimate the time required at each temperature for the STEAM*Plus* Integrator to produce a SAFE reading. Five temperature points between 245°F and 275°F were tested for at least five separate time periods. This testing resulted in the following mean (average) times to produce a SAFE reading for each of the five temperatures tested:

245°F/118°C @ 40.0 minutes
250°F/121°C @ 21.0 minutes
260°F/127°C @ 7.1 minutes
270°F/132°C @ 2.3 minutes
275°F/135°C @ 1.5 minutes

The performance of the STEAM*Plus* Integrator in comparison with the performance of *Geobacillus stearothermophilus* spores, plus a slight safety margin, is shown above in Figure 1. This margin of safety, which spans the entire spectrum of normal Steam sterilization temperatures, provides added assurance that once the dark bar enters the blue SAFE area, sterilization has indeed occurred. The STEAM*Plus* Sterilization Integrator meets Class 5 performance claims of AAMI ST-60 and ISO 11140-1:2005. Note: The FDA does not currently recognize Class 1-6 in ISO 11140-1:2005.

Quality Control

When tested in a Steam BIER (Biological Indicator-Evaluator Resistometer) vessel for 1 minute at 270°F (132°C), the STEAM*Plus* Integrator is designed to not register in the blue SAFE area. Conversely, when tested at 270°F (132°C) for 3.0 minutes, the STEAM*Plus* Integrator is designed to register in the blue SAFE area, thus signifying sterilization has been achieved. A production lot number & expiration date is printed on each device for traceability.