SPS medical
Sterilization Monitoring • Packaging • Testing Services

Technical Bulletin
SSI-100

STEAM*Plus*™
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, vacuum and flash), the STEAM*Plus* Integrator has documented performance equal to a biological indicator *plus* a safety margin. This margin is referred to as a Safety Zone and is illustrated in Figure 1.

Product 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 load 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

Technical Design
The base of the STEAM*Plus* Integrator is made of aluminum foil, 3 mils in thickness. A cavity embossed in the foil holds the temperature and steam-sensitive chemical. The foil also acts as a moisture barrier against steam during the sterilization cycle. The tablet is a temperature and steam-sensitive chemical which is designed to melt when subjected to a steam environment.

As moisture penetrates the polymeric cover film, 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 *B. stearothermophilus* spores as illustrated in Figure 1.

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

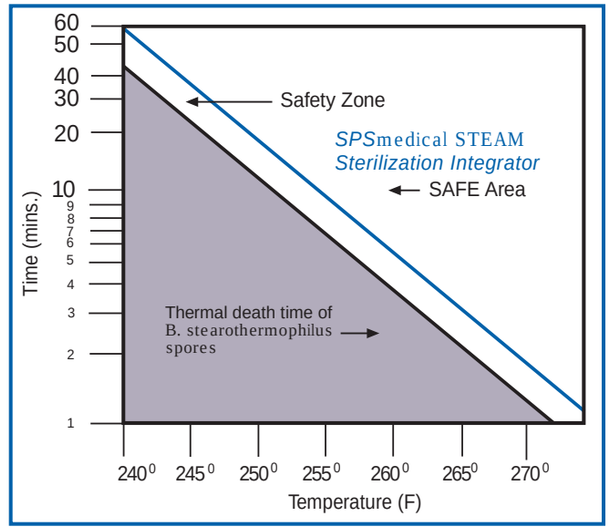

Figure 1

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. Four temperature points between 245°F and 270°F were tested for at least four separate time periods. This testing resulted in the following mean (average) times to produce a SAFE reading for each of the four temperatures tested:

245°F @ 35.0 minutes
250°F @ 18.5 minutes
260°F @ 5.5 minutes
270°F @ 1.9 minutes

The performance of the STEAM*Plus* Integrator in comparison with the performance of *B. 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.

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. Records are kept on each lot of raw materials and a production Lot No. is stamped on each STEAM*Plus* Integrator for traceability.

How To Use The STEAM*Plus*™ Steam Sterilization Integrator

1. Place a STEAM*Plus* Integrator in every load (i.e. middle of the load or inside the densest pack).
2. Process the load according to the sterilizer manufacturer's instructions.
3. After processing, remove the STEAM*Plus* Integrator and release the load if the dark bar has entered the blue SAFE area.

Special Note:

If the dark bar has not entered into the blue SAFE area, DO NOT release the load. Proper sterilization has NOT been achieved and the items in the load should be reprocessed. Prior to reprocessing the load, be sure to check the sterilizer for proper use and function.

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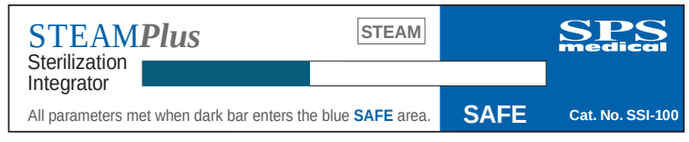
UNPROCESSED

PASS

FAIL



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