

## **Technical Bulletin**

### **STEAM***Plus*<sup>™</sup> 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. For use with all Steam processes (gravity, prevacuum and flash), the STEAM*Plus* has documented performance equivalent to a biological indicator.

#### **Description**

The STEAMPlus 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. The STEAMPlus Sterilization Integrator has been tested to the AAMI ST-60 and ISO 11140-1:2005 standards performance requirements. Note: The FDA does not recognize Class 3, 4 or 5 indicators as defined in ISO 11140-1:2005.

# How to Use the STEAM*Plus*<sup>™</sup> Steam Sterilization Integrator

- Place a STEAMPlus Integrator (at least once daily) inside a load (i.e. middle of the load or inside the densest pack).
  A STEAMPlus Integrator should be used in every load containing an implantable device.
- 2. Process the load according to the sterilizer manufacturer's instructions.
- 3. Release the load if the dark bar on the STEAMPlus Integrator has entered the blue SAFE area. If the dark bar has not entered into the blue SAFE area, DO NOT release the load.

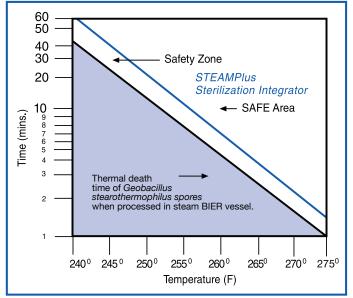


Figure 1

The STEAM*Plus* Integrator is not to replace the weekly use of a biological indicator, but instead is intended to give users immediate notification of whether all critical parameters of steam sterilization have been met. This knowledge is intended to help reduce the release of non-sterile items.

#### **ORDERING INFORMATION**

Cat. No.	Description STEAMPlus <sup>™</sup> Class 5 Sterilization Integrator		<b>Qty</b> 100/pk
SSI-100			
	UNPROCESSED	STEAMPlus STERILIZATION INTEGRATOR STEAM	
	PASS	All parameters met when dark bar enters the blue SAFE area CLASS #E0 11140-12005	
	FAIL	All parameters met when dark bar enters the blas SAFE area CLASS 5450 11140-12005	

STEAMPlus is a trademark of SPSmedical Supply Corp.