

Technical Bulletin

STEAMPlus™ Class 5 Steam Sterilization Integrator

Introduction

The STEAMPlus 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 STEAMPlus 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 STEAM*Plus* Sterilization Integrator meets Class 5 performance claims of AAMI ST-60 and ISO 11140-1:2005. Note: The FDA does not recognize Class 3, 4 or 5 in ISO 11140-1:2005.

How to Use the STEAMPlus™ **Steam Sterilization Integrator**

- 1. Place a STEAMPlus Integrator inside each pack or 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. 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.

FAIL

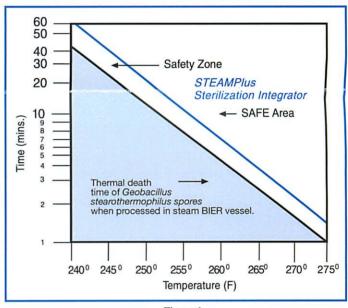


Figure 1

The STEAMPlus 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 eliminate the release of non-sterile items.

Cat. No.	Description STEAM <i>Plus</i> ™ Class 5 Sterilization Integrator		Qty
SSI-100			100/pk
	UNPROCESSED	STEAMPlus STERILIZATION INTEGRATOR All parameters met when dan's but enters the blue SAFE area CLASS 5/050 11140-1 2000S	
	PASS	STEAMPlus STERILIZATION INTEGRATOR All parameters and when dark but enters the blue SAFE area CLASS 9/50 1140-1200 [[[07]] EXY X	

STEAMPIUS STERILIZATION INTEGRATOR