STEAMPlus™ Type 5 Steam Sterilization Integrator

EN

REF SSI-100 / SSI-1000

INSTRUCTIONS FOR USE

Indication for Use:

The integrating indicator is designed to chemically react over time with the critical parameters of a steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Standard Steam Sterilization Cycles		
Cycle Type	**Exposure Temperature**	**Exposure Time**
Dynamic Air Removal	270°F (132°C)	4 minutes
	270°F (132°C)	5 minutes
	270°F (132°C)	6 minutes
	270°F (132°C)	7 minutes
	270°F (132°C)	8 minutes
	270°F (132°C)	9 minutes
	270°F (132°C)	10 minutes
	273°F (134°C)	4 minutes
	275°F (135°C)	3 minutes
Gravity	250°F (121°C)	30 minutes
	270°F (132°C)	15 minutes
	275°F (135°C)	10 minutes
Immediate Use Steam Sterilization (IUSS) Cycles		
Dynamic Air Removal	270°F (132°C)	4 minutes
	275°F (135°C)	3 minutes
Gravity	270°F (132°C)	3 minutes
	270°F (132°C)	10 minutes
	275°F (135°C)	3 minutes
	275°F (135°C)	10 minutes

DeviceDescription/PerformanceCharacteristics:

The STEAMPlus™ Integrating Indicator is used in each pack to be sterilized to indicate exposure to specified critical parameters of steam sterilization. It meets the performance specifications for a Type 5 integrating indicator as defined in ANSI/AAMI/ISO 11140-1:2014.

Each strip consists of aluminum foil base adhered to label face stock that has been coated with a polypropylene film. A steam sensitive chemical containing a dark colored dye is held within a well located at one end of the foil. A wicking strip leads from the well to the opposite side of the strip and during the steam sterilization cycle, steam penetrates the polypropylene film and comes in contact with the steam sensitive chemical. The steam sensitive chemical requires all the critical parameters of steam (Steam, Temperature and Time) to melt and wick along the filter paper carrying the dark dye with it. This is made visible through the window. The integrator strip indicates that the specified critical parameters of steam sterilization have been achieved when the dark colored steam sensitive chemical containing dye reaches the "PASS" window.

The STEAMPlus™ Integrating Indicator and its packaging are manufactured in the absence of lead or other heavy metals. It is also manufactured without natural rubber latex and dry natural rubber.

Instructions for Use:

Wrapped items, Rigid Sterilization Containers and Sterilization Pouches

1. Place an integrator strip(s) inside each pack, pouch, container, tray or other containment device, in the area(s) of greatest challenge to the sterilant but not directly beneath an item of great metal mass.

NOTE: Place an indicator strip on each level of multi-level trays or cassettes.

NOTE: If the packaging is opaque, use an external process indicator.

2. Follow the containment devices instructions for use to prepare for steam sterilization.
3. Upon completion of the cycle, follow department procedure for load release.

NOTE: Confirmation of the integrator strip result should take place at time of pack use.

4. Prior to use of the items within the pack, aseptically remove the integrator strip(s) and observe the location of the dark bar within the integrators window.

   a.) The integrator demonstrates passing results when the dark bar has completely travelled through the "FAIL" area or window and has entered the "PASS" area.

NOTE: Variability in the color of the dark bar is normal and acceptable as long as the dark color is visible in the "PASS" area.

   b.) The integrator demonstrates failing results when the dark bar is not visible in the "PASS" area. Follow departmental procedures for investigating suspected sterilization failures.

5. See Reference Guide for examples of pass and fail results.

Immediate Use Steam Sterilization:

1. Place the integrator strip in the center of each configuration (tray, protective case, flash approved rigid sterilization container) to undergo immediate use steam sterilization.
2. Follow the containment device's instructions for immediate use steam sterilization.
3. Upon completion of the sterilization cycle, review the printout for appropriate sterilization parameters. Remove the immediate use sterilized item(s).

CAUTION: THE CONTAINMENT DEVICE WILL BE HOT. USE THERMAL PROTECTIVE GLOVES.

4. Prior to use of the items within the pack, aseptically remove the integrator strip(s) and observe the location of the dark bar within the integrators window.

   a.) The integrator demonstrates passing results when the dark bar has completely travelled through the "FAIL" area or window and has entered the "PASS" area.

   b.) The integrator demonstrates failing results when the dark bar is not visible in the "PASS" area. Follow departmental procedures for investigating suspected sterilization failures.

5. See Reference Guide for examples of pass and fail results.

Storage Conditions:

Before use, store all STEAMPlus™ Integrating Indicators in their original closed zipper bag at room temperature. Do not store integrator strips near heat, moisture, oxidizing agents, acids/alkalis or cleaning/disinfecting agents.

The endpoint color of exposed integrator strips is stable for 36 months when stored away from light at room temperature.

Expiration Date:

Do not use beyond the expiration date printed on the integrator strip. The expiration date is printed starting with the four digit year followed by the two digit month ending with the two digit day.

Example: 20200509 expires the year 2020 on May 9th.

Performance Limitations:

- This product is for single use only. Do not reuse partially processed integrator strips.
- The STEAMPlus™ Integrating Indicator is part of a quality control system for sterility assurance. They cannot be used as a sole means for validating the sterilization process.
- All personnel involved must be trained in the proper use of the integrator strips and a system for reporting failures must be established.
- If there are any problems interpreting the results from the product, contact HuFriedyGroup or your local HuFriedyGroup representative.

Safety Precautions:

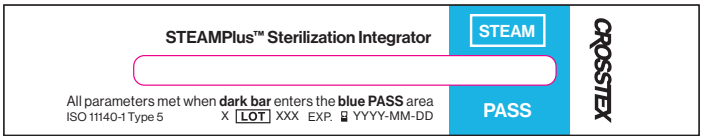
This device contains a steam sensitive chemical and indicator dye that is safe under normal conditions of use. This device is not intended for human consumption.

Disposal:

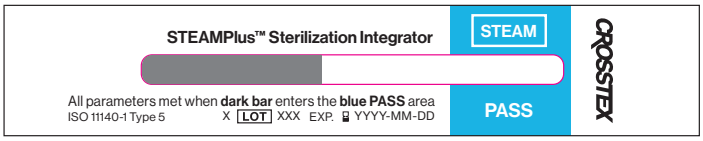
This product is manufactured in the absence of lead and other heavy metals and may be disposed of as regular waste.

Reference Guide:

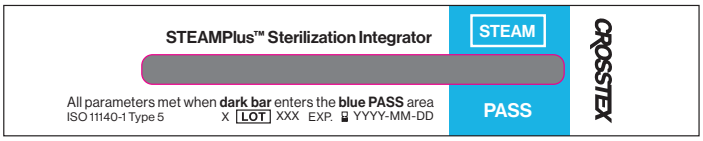
Unexposed

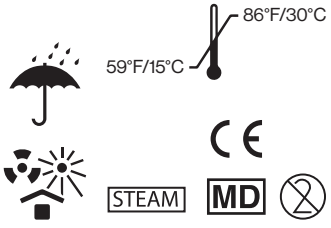


Fail



Pass





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In case of any serious incident that has occurred and involves our devices within the European Union, please report it to Hu-Friedy Mfg. Co., LLC and your national competent authority of the member state.

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