

Class 5 Laminated Indicator, Triple Indicators, 134 °C - 3.5 min.

Ref Code: C-1055

Product Description

Class 5 Laminated Indicators are cycle verification indicators that confirm the presence or absence of specific time and temperature parameters during a cycle and integrate all the critical parameters of the steam sterilization cycle. Laminated indicators can be placed inside each pack or pouch during sterilization of supplies or equipment in a validated pre-vacuum cycle. These laminated indicators can be used for routine monitoring of steam sterilization cycles. The indicators color transition from pink to dark brown/black.

Physical Parameters

Process	Steam
Dimensions	2,5 cm x 6,5 cm
Packaging	250 indicators / pack
Chemical Indicator	Initial color: Pink Signal color: Dark brown / Black %100 Toxic Heavy Metals Free

Intended Use

The indicators are for use in all Steam sterilization processes.

Class 5/Type 5 Process Indicator Requirements

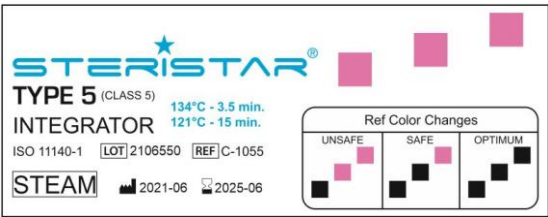
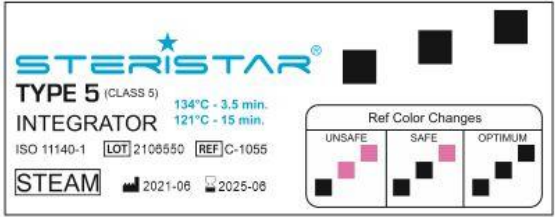
- 134 °C 3,5 min. – 121 °C 15 min.

Instructions for Use

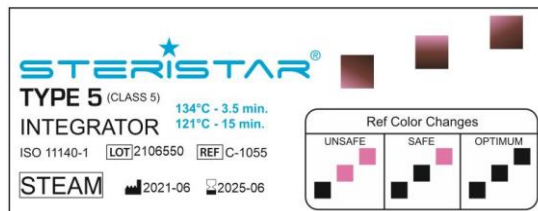
Use an indicator on each item, pack, peel pouch, or tray intended for steam sterilization. Place at a location considered most challenging for the steam penetration.

Process the packages/items as instructed in the sterilizer validation or manual. Upon exposure, the indicator will transition from pink to dark brown/black. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from pink to a shade of dark brown/black provides indication of exposure. If the signal color is not achieved immediately following exposure, allow the indicator to aerate for 1 minute. If the signal color is still not achieved, this suggests ideal sterilization conditions may not have been met.

Performance Characteristics

Results Availability:	Immediately following exposure to Steam processes.
Unexposed*	Exposed to 134°C 3,5 min. – 121 °C 15 min. *
	

Potential Fail Color



*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.

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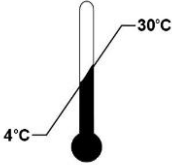
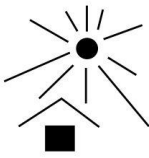
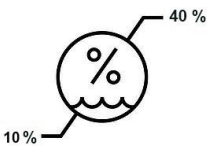


The signal color achieved from exposure to steam may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For a Type 5 Process Indicator, any color change produced during exposure to steam which is close to signal color is considered acceptable.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators

ISO 13485:2016 Medical devices - Quality management systems

Storage and Shelf Life

	<p>Do not reuse</p>		<p>Keep dry</p>
	<p>4°C to 30°C</p>		<p>Keep away from sunlight</p>
	<p>10% - 40% RH</p>		<p>Shelf life 4 years from the date of manufacture</p>
	<p>Keep away from sterilants.</p> <p>Do not use damaged Indicators or Indicators which have transitioned to green. Do not use after expiration date.</p> <p>Do not expose this product to Dry Heat, EO, H2O2 or any sterilization processes other than Steam,</p>		

Disposal

Discard as general waste.

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