



Class 5 Sterilization Integrator Double Window 134 °C - 3.5 min.

Ref Code: C-1603

Product Description

Type 5 Steam Integrators can be used inside each load to monitor time, temperature and steam exposure conditions and can provide the necessary sterilization assurance. Type 5 integrator mimics the ability of a biological indicator at three separate points during the sterilization process because it will monitor both time and temperature without requiring incubation as does a biological indicator.

The Integrator consists of a paper wick and steam and temperature-sensitive chemical pellet contained in a foil laminate. The chemical pellet melts and migrates as a dark color along with the paper wick. The migration is visible through a window marked as REJECT or ACCEPT.

Physical Parameters

Process	Steam
Dimensions	2,0 cm x 5,0 cm
Packaging	100 integrators / pack 250 integrators / pack 500 integrators / pack
Chemical Integrator	Initial color: White Filter Signal color: Dark/Black Filter %100 Toxic Heavy Metals Free

Intended Use

The integrators are for use in all Steam sterilization processes.

Class 5/Type 5 Process Integrator Requirements



- 134 °C 3,5 min. – 121 °C 15 min.

Instructions for Use

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

Process the packages/items as instructed in the sterilizer validation or manual. Upon exposure, the integrator will transition from white filter to dark/black filter. 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.

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





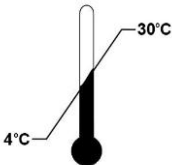
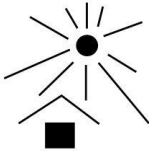
The signal color achieved from exposure to steam may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For a Type 5 Process Integrators, any color change produced during exposure to steam which is close to signal color is considered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

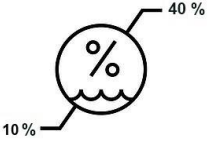


Compliance

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 5 years from the date of manufacture</p>
	<p>Keep away from sterilants.</p> <p>Do not use damaged Integrators or Integrators 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.