

INTEGRATING INDICATOR STRIP - LABEL
For Monitoring Steam Processes
ISO 11140-1 TYPE 5

True Indicating Code: CSPN-15

Code Dutscher : **633338**

Product Description

True Indicating Integrating Indicator strips contain no lead or other toxic heavy metals. The Indicator Strips monitor whether sterilization conditions were met at the point of placement of the strip. The Indicator Strips are intended for use in steam sterilizers operating at 121°C and up to 135°C. Type 5 integrating indicators react to all critical variables (time, temperature and moisture) and reach an end point indicating exposure to sterilization conditions as defined by True Indicating stated values.

Physical Properties

Process	Steam
Indicator Strip Dimensions	19 mm x 64 mm (0.75” x 2.5”)
Packaging	250 Strips / Package
Chemical Indicator	Initial Color: Pink Signal Color: Dark The word “NOT” will be completely concealed when proper conditions have been met

Indications for Use

Type 5 Integrating indicator stated values

- 121°C, 16.5 minutes (pre-vacuum)
- 135°C, ≥1.2 minutes (pre-vacuum)

Instructions for Use

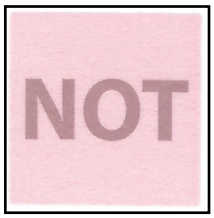
Use as a strip or label in each pack, peel pouch or tray intended for steam sterilization. Process packages/ items as instructed in the autoclave/sterilizer validation or manual.

Upon exposure to steam, the Indicator will transition from a shade of Pink to Dark. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from Pink to Dark and the word “NOT” being completely concealed provides indication of effective steam sterilization conditions. If the signal color is not achieved this may suggest ideal exposure conditions were not met. Review the exposure conditions and investigate the sterilizer malfunction.

The chemical reaction which causes the color transition is a steam specific reaction and is irreversible.

Performance Characteristics

Result Availability	Immediately following exposure to high temperature steam processes

Unexposed	Ineffective Cycle	Exposed to steam 121°C, 16.5 minutes
		

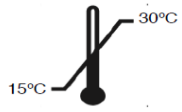
Colors shown are representations of unexposed, ineffective and exposed signal colors but may vary from actual use.

Color Transition is dependent upon load configuration, cycle parameters and may vary. A color transition from the Initial color to a shade of the signal color which results in the word “NOT” being completely concealed is considered an acceptable transition. If the word “NOT” remains visible, check cycle parameters and equipment function.

Compliance

ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1:General requirements for Type 5 Integrating Indicators

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep Dry
Shelf Life	3 years from the date of manufacture. The date of manufacture is based on the day the indicating ink is applied to the substrate. The remaining shelf life upon receipt will be shorter than 3 years		Do not reuse
	Keep away from sterilants. Do not use damaged indicators or indicators which have transitioned to Dark. Do not use after expiration date.		

Disposal

Discard as general waste.