

Integraph

CI 101

Indications for Use

The Integraph chemical integrators are designed for use in pre-vacuum steam sterilizers operating at 134°C for 3.5 minutes or longer and at 121°C for 12 minutes or longer. When used as directed, the Integraph gives visual confirmation that sterilization conditions were met at the location in the sterilizer chamber.

Color Change

During proper steam sterilization, the three indicators (check mark, long bar, and short bar) change from purple to green.

Stated Values (As determined in a steam sterilization resistometer)

Degrees	Check Mark Insufficient	Long Bar Correct	Short Bar Extended
134°C	3.25 minutes	4.75 minutes	11 minutes
132°C	3.75 minutes	5.5 minutes	12 minutes
121°C	8 minutes	12.5 minutes	30 minutes

Instructions for Use

- Place an Integraph strip in each pack, peel-pouch or tray for sterilization. Place strip at a location in the package considered most difficult for steam to reach. For larger packs, place strips at several locations in pack.
- Sterilize package as recommended by manufacturer.
- Following sterilization cycle, verify that the indicator check mark and long bar have turned from purple to green. The short bar will only change completely in sterilization cycles exceeding 10 minutes at 134°C or 30 minutes at 121°C.
- If the long bar indicator is not green, it suggests inadequate sterilization conditions and item(s) must be re-sterilized with new indicator strip(s).

Safety Precautions

- If there is any doubt about sterility of item, it must be considered NOT sterile
- Do not use any strips if indicator marks are not purple in color prior to exposure to steam sterilization processing
- Not recommended for use in a "flash" sterilization cycle

Storage

- Store at normal room temperature 10° – 38°C and 10-70% R.H.
- No special storage conditions are necessary after exposure to steam sterilization conditions
- Keep unexposed indicator strips in the sealed bag provided

Expiry Date

The expiry date is printed on the product packaging. Do not use after expiration date listed on the packaging.

LOT Number

A unique identification code, **LOT**, is printed on each indicator and packaging labels.

Interfering Substances or Conditions

There are no known interfering substances or conditions that could affect the intended use of the indicator or adversely affect the indicator performance.

Release of Toxic Substances

The indicator releases no known toxic substances in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process.

Declaration of Conformity

The Integraph integrator conforms to all applicable portions ISO 11140-1, Type 5 integrators.

DF-003 Rev. K



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