

Steri-Vapeur 18

CI 117

Indications for Use

The Steri-Vapeur 18 emulators are designed for use in steam sterilizers operating at 134°C for 4 minutes and 18 minutes. When used as directed, the Steri-Vapeur 18 gives visual confirmation that sterilization conditions were met at the location in the sterilizer chamber.

Color Change

During proper steam sterilization, the two indicators change from purple to green.

Stated Values (As determined in a steam sterilization resistometer)

18 MIN	4 MIN
19 minutes at 134°C	4 minutes at 134°C

Instructions for Use

1. Place a Steri-Vapeur 18 in each pack, peel pouch, or tray to be steam sterilized. Place indicator at a location in the package considered most difficult for steam to reach. For larger packs, place strips at several locations in pack.
2. Sterilize package as recommended by manufacturer.
3. Following steam processing, verify that the indicators have changed color from purple to green.
 - a. If the first spot turns green, standard sterilization conditions have been met.
 - b. If both the first and second spots turn green, this indicates that an extended sterilization cycle has been performed.
4. If the 4 minute 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 the 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 between 10°- 30°C and 10-60% 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 strip 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 Steri-Vapeur 18 emulator conforms to all applicable portions ISO 11140-1 Type 4 & 6 indicators.