

Getinge Assured

Steam Sterilization Indicator

Indications for Use

The Getinge Assured Steam Sterilization Indicator strips are designed for use in steam sterilizers operating at 132°C to 135°C (270°F to 276°F) to give a visible indication that sterilization conditions have been met.

Color Change

During proper steam sterilization, the check mark changes to black.

Instructions for Use

1. Place a Getinge Assured Steam Sterilization indicator in each pack, peel-pouch or tray for sterilization. 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 the sterilization cycle, verify the check mark has turned to black.
4. If indicator is light blue, it suggests inadequate sterilization conditions and item(s) must be re-sterilized with new indicator strip(s).
5. Steam Sterilization indicator strips must not be used in place of a biological indicator, but can be used in conjunction with a standard infection control monitoring protocol such as that described by the AAMI Standards and Recommended practices: Good Hospital Practice: Sterilization and Sterility Assurance.

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 check marks are not blue in color prior to exposure to steam sterilization processing

Storage

- Store at normal room temperature 50° - 86°F (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

Indicators should be used only with instruments that have been thoroughly rinsed and dried following the washing process. Some detergents containing solvents, surfactants (propylene glycol) and/or plasticizers can lead to ink transfer if these residuals are left behind on the instrumentation and subsequently exposed to wet steam conditions. Care should be taken to ensure that the sterilizer is producing high quality steam so the indicators do not become overly wet during steam sterilization and to better facilitate the sterilization process. Steam that is too wet can lead to wet packs after sterilization and compromise sterility.

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 Getinge Assured Steam Sterilization Indicator meets FDA requirements for process indicator status.