

Getinge Assured MI

Steam Migrating Integrator Strip

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Indications for Use

The Getinge Assured MI Steam Migrating Integrator Strip is an internal pack integrating indicator designed to react to critical process parameters of a steam sterilization cycle within a stated tolerance. The integrating indicator is intended to be placed in each pack, pouch, tray or container to function as an independent monitor of critical parameters for the following sterilization cycles:

Steam Sterilization Cycles:

- 250°F/121°C, 30 minutes Gravity
- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 275°F/135°C, 3 minutes Dynamic Air Removal
- 275°F/135°C, 10 minutes Gravity

Steam Sterilization Cycles (IUSS):

- 270°F/132°C, 4 minutes Dynamic Air Removal IUSS
- 270°F/132°C, 3 minutes Gravity IUSS
- 270°F/132°C, 10 minutes Gravity IUSS
- 275°F/135°C, 3 minutes Dynamic Air Removal IUSS
- 275°F/135°C, 3 minutes Gravity IUSS
- 275°F/135°C, 10 minutes Gravity IUSS

Device description

The Getinge Assured MI Steam Migrating Integrator Strip is used in each pack to be sterilized to monitor exposure to critical process parameters of steam sterilization. The Getinge Assured MI meets the performance specifications for a Type 5 integrating indicator as defined ANSI/AAMI/ISO 11140-1:2014. It consists of a paper wick and a steam sensitive chemical pellet containing blue colored dye. A pellet is held within a pocket located at one end of an aluminum foil base. The foil base is adhered to label material that has been bonded with a film. During steam sterilization, the integrating indicator pellet will migrate into the PASS zone when the specified critical parameters of steam sterilization have been met.

Instructions for Use

1. Place Getinge Assured MI Steam Migrating Integrator strip(s) in each pack, pouch, container, tray or other containment device to be steam sterilized in an area of greatest challenge to sterilization. Do not place directly beneath items of heavy metal mass.
2. Sterilize goods as recommended by manufacturer.
3. Adequate sterilization conditions are reached when the blue bar has completely traveled through the FAIL window and has entered the PASS window. Follow departmental procedures for load release.
4. If the blue bar does not reach the PASS window, reprocessing is required. Follow departmental procedures for investigating possible sterilization failures.

Immediate Use Steam Sterilization

1. Place a Getinge Assured MI Steam Migrating Integrator Strip in the center of each containment device or flash approved rigid sterilization container.
2. Follow the containment devices' instructions for immediate use steam sterilization.
3. Upon completion of the sterilization cycle, remove the flash sterilized items.
4. Prior to use of the items within the pack, remove the indicator strip and observe the location of the blue bar. Adequate sterilization conditions are reached when the blue bar has completely traveled through the FAIL window and has entered the PASS window.
5. If the blue bar does not reach the PASS window, reprocessing is required.

Color Change

During steam sterilization, the chemical pellet melts and migrates as a blue color along the paper wick. The migration is visible through a window marked FAIL or PASS. Variability in the color of the blue bar is normal and acceptable as long as blue color is visible in the "PASS" window. Exposed indicators are stable for up to 12 months.

- 1 Unexposed
- 2 Pass
- 3 Fail

Stated Values

Reference the stated values listed in the table on the product label. The table lists the time and temperature for the integrators contained in the package to reach their endpoint when tested in a steam resistometer* under highly controlled conditions with saturated steam.

*Resistometer end point times may be different than standard steam sterilizer endpoint times.

Safety Precautions

This device is composed of an indicator tablet and dye that is safe under normal conditions of use. This device is not intended for human consumption. Care should be taken when loads are removed from sterilizer, as contents will be hot.

Storage

Store indicators in provided sealed packaging at room temperature 10°-30°C and 10-60% Relative Humidity, away from light, moisture and oxidizing agents.

Stability

The indicator will remain stable following exposure to steam sterilization for 12 months when stored at above storage conditions.

Expiry Date

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

Interfering Substances or Conditions

There are no actively known interfering substances or conditions that could affect the intended use of the indicator; however product should not be exposed to oxidizers, alkaline or acidic conditions, or cleaning and/or disinfection chemicals.

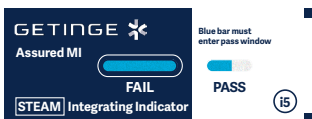
Release of Toxic Substances

The integrator releases no known toxic substances in sufficient quantities to cause a health hazard and can be disposed of as regular waste. The integrator is not manufactured with lead, heavy metals or latex.

Declaration of Conformity

The Getinge Assured MI Steam Migrating Integrator Strip conforms to ISO 11140- 1, Type 5 and FDA requirements for integrator status.

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This is an example of one type of fail