3M™ Comply™ (SteriGage™) Steam Chemical Integrator

Dynamics of Steam Sterilization

Steam sterilization has been used for over 100 years. Decades of research have shown that the integrity of a steam sterilization process is the function of three basic parameters: time, temperature and the presence of saturated steam. All three are critical for effective steam sterilization.

The importance of saturated steam is demonstrated when dry heat sterilization is compared with steam sterilization. The use of steam allows faster sterilization than dry heat. For example, dry heat sterilization requires a sterilization time of 60 minutes at 320°F (160°C), while steam sterilization at the same temperature would take less than a minute.[1] Clearly, steam hastens the kill time of living organisms by many orders of magnitude and is generally preferable to dry heat.

Once a saturated steam environment is obtained, the independent variables of time and temperature can be determined by the following formula:[2]

$$t = F_0 \times 10^{(250-T)/Z}$$

Where

t = time for 100% kill at temperature T
T = processing temperature
F_0 = kill time for *Geobacillus stearothermophilus* with a z-value of 18°F (10°C) and D-value of 1 minute at 250˚F (121˚C)
z = rise in temperature required to increase the rate of kill by a factor of 10 (usually about 18˚F (10˚C))

Interpretation of this formula shows that the relationship of processing time (t) versus temperature (T) can be plotted as a logarithmic function. Expressed differently, it means that a small fluctuation in the temperature results in a large change in the actual processing time required for 100% kill. Figure 1 shows the thermal death time at different temperatures for 1 million live spores of *Geobacillus stearothermophilus*.[3] This curve can be expressed mathematically by the following formula which shows that it takes 12 minutes to kill 1 million living spores in a 250°F (121°C) steam sterilization cycle.

$$t = (12)10^{(250-T)/18}$$

Where
F_0 = 12 min for *G. stearothermophilus*
z = 18°F (10°C) for *G. stearothermophilus*

In order to show the high sensitivity of kill time to temperature, the above formula can be solved for 247°F (119°C).

Integrating Indicator vs. Biological Death Curve

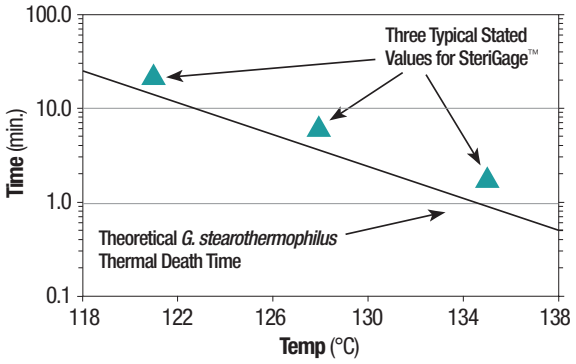


Figure 1. Graph comparing three typical Stated Values of 3M™ Comply™ SteriGage™ Chemical Integrators with the theoretical death curve of *Geobacillus stearothermophilus* spores

$$t = (12)10^{(250-247)/18}$$
$$t = (12)10^{(0.167)} = (12)(1.47)$$
$$t = 17.6 \text{ minutes}$$

In theory, therefore, if the inside temperature of a sterilizer were actually operating at 247°F (119°C) instead of 250°F (121°C), a time of 17.6 minutes would be required to kill the 1 million spores of *G. stearothermophilus* at 247°F (119°C) versus the 12 minutes needed to kill the spores at 250°F (121°C).

This interdependence of time and temperature (in saturated steam) is an important relationship which should be understood by all personnel responsible for providing sterility assurance for steam sterilized items. Consider the ramifications if a sterilizer operator inadvertently set the processing temperature at 247°F (119°C) instead of 250°F (121°C). Or, if the load was processed at 247°F (119°C) as a result of a minor malfunction of the sterilizer (e.g., air pocket or small air leak), a slight calibration error in the temperature monitoring system, incorrect loading or packaging.

Because even small decreases in temperature during steam sterilization may significantly increase the time necessary for 100% kill, an accurate means of monitoring internal sterilizer and pack conditions are essential.

Pack and Load Control

The dynamics of steam prove the need for accurate monitoring of internal sterilization conditions. Pack control is the use of chemical indicators for the internal monitoring of packs, trays, containers, and peel pouches. Internal chemical indicators should be used inside each type of packaging to address the potential for interference with proper steam sterilization conditions in all of these types of packaging.[4,5,6]

Several problems can occur in the packaging and loading of individual packs that can inhibit air removal and steam penetration which leads to a lower temperature. Packing problems include:

- Incorrect packaging or container system chosen for the cycle parameters;
- Incorrect preparation of the container for use (i.e., filters and valves or appropriate bottom tray);
- Placing a folded peel pouch inside another peel pouch;
- Placing a peel pouch inside of an instrument tray or container system;
- Preparing textile packs that are too dense to sterilize in the cycle parameters chosen.

Loading problems include:

- Stacking container systems (if not recommended by the manufacturer);
- Laying peel pouches flat instead of on edge;
- Improperly placing peel pouches on edge (plastic sides not facing all in one direction);
- Turning instrument trays on edge;
- Laying fabric packs or basins flat;
- Placing packages too close to each other impeding air removal and sterilant penetration around and through the load.

Malfunctioning equipment can also result in insufficient sterilization conditions inside of packaging as the result of:

- Incomplete air removal;
- Inadequate cycle temperature;
- Insufficient time at temperature;
- Poor steam quality and quantity.

As discussed above, small reductions in time at temperature can reduce the margin of safety with steam processing. Problems that limit air removal or steam penetration in individual packs will have the effect of reducing the effective time at temperature. Class 5 Integrating Integrators that meet the ANSI/AAMI/ISO 11140-1:2005 *Sterilization of healthcare products-Chemical Indicators-Part 1*: *General requirements* used inside each pack to monitor time, temperature and steam exposure conditions can provide the necessary sterilization assurance on a pack-to-pack basis.[7]

Load control is the process by which a load is monitored and released based on the result of a Biological Indicator (BI) in a process challenge device (PCD). A BI PCD should be used, preferably every day the sterilizer is used, for routine sterilizer efficacy testing. BI PCDs are also recommended for sterilizer qualification testing.[5,7] A BI PCD that includes a Class 5 Integrating Indicator should be used to monitor each implant load. The load should be quarantined until the results of the BI testing are available.[5,7] In nonimplant loads a PCD containing a Class 5 Integrating Indicator may be used to release the load.

Using a BI in each load will ensure that all of the required testing is performed, will ensure patient safety by using a consistent method to release each load, will reduce the cost of recall, and will reduce the chance that a non-sterile medical device is released for use.

Product Description

3M™ Comply™ SteriGage™ 1243A, 1243B, and 1243E Steam Chemical Integrators are chemical indicators consisting of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked REJECT or ACCEPT. The extent of migration depends on steam, time, and temperature.

This product is also available with an extender strip affixed to one end of a Comply SteriGage 1243 Steam Chemical Integrator and is labeled as Comply SteriGage 1243E Steam Chemical Integrator. The affixed extender is a 19 cm (7.5 in) long by 1 cm (0.375 in) wide rigid, paperboard strip that serves as a handle to retrieve processed integrators from inner packs.

Indications for Use

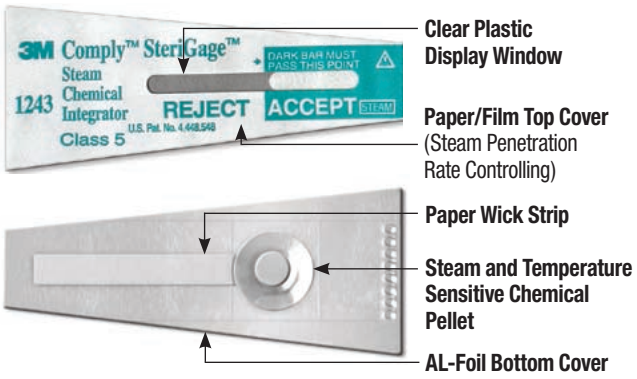
Use Comply SteriGage 1243A, 1243B, and 1243E Steam Chemical Integrators for pack control monitoring of all 118-138ºC (245-280ºF) steam sterilization cycles.

Contraindications

None.

Precautions

Do not use Comply SteriGage 1243A, 1243B, or 1243E Steam Chemical Integrators to monitor dry heat, ethylene oxide, or other low temperature sterilization processes.



Technical Design

The 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrator is made of four functional components. These components are arranged in a sandwich configuration held together with a temperature-resistant, pressure-sensitive adhesive: (See above)

1. Steam and temperature sensitive chemical pellet
2. Paper strip (for chemical wicking)
3. Steam penetration rate controlling paper/film top cover
4. Aluminum foil bottom cover

The base of the Comply SteriGage 1243 Steam Chemical Integrator is made of aluminum foil 3 mils thick which acts as a moisture barrier against steam penetration during sterilizing. A cavity embossed in the foil holds the temperature and steam sensitive chemical pellet. The pellet has a dry heat melting point of 285°F (139°C). However, it is designed to melt at lower temperatures when subjected to a steam environment. The moisture of steam depresses the melting point down to the actual sterilization temperature. If the melting point of the pellet was lower than the desired sterilization temperature, steam penetration would not be required and the device would be capable of reaching the ACCEPT area without the necessary presence of steam. The top cover of the Comply SteriGage 1243 Steam Chemical Integrator is a paper/polymeric film which allows steam to penetrate at a certain rate. As steam penetrates the polymeric cover film, it lowers the melting point of the chemical causing the tablet to begin melting.

When melting occurs, the liquid chemical is soaked up by the paper wick and, as time elapses, moves along the scale. The more the chemical melts, the farther the color front advances towards the ACCEPT area of the display window. This is called a moving-front technology. The rate of chemical pellet melting is a function of both the moisture-vapor transmission rate of the cover film and the melting point depression of the chemical pellet. The combination of these two factors provides a rate of melting at various temperatures which closely follows the spore death curve of *G. stearothermophilus* (proven to be the best challenge in a steam sterilization process) (see Figure 1).

Chemical Indicator Classification

Comply 1243 Steam Chemical Integrators meet the requirements of ANSI/AAMI/ISO 11140-1:2005 and EN/ISO 11140-1:2005 for Class 5 Integrating Indicators. These indicators are designed to monitor all three of the critical variables of the steam sterilization process (time, temperature and steam).

Third Party Testing

As part of our compliance process, 3M hired BSI, a leading global independent product testing services company, to confirm that 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrators meet the Class 5 Integrating Indicator performance requirements of ISO 11140-1:2005. Through rigorous product testing, BSI confirmed these products meet the performance requirements of ISO 11140-1:2005.
A copy of the BSI Declaration is available upon request from 3M.

Performance Characteristics

The Comply SteriGage 1243 Steam Chemical Integrator has been tested at various time and temperature intervals in saturated steam in a test vessel (called a resistometer) to determine compliance to the chemical indicator standards listed in the Chemical Indicator Classification section above. To meet the Class 5 Integrating Indicator performance standards, the Comply SteriGage 1243 Steam Chemical Integrator must have a response that correlates to the performance of a BI at three temperatures (121°C/250°F, 135°C/275°F, and one or more temperatures in between, such as 128°C/263°F).[7] These responses are called Stated Values. Stated Values are "values of a critical variable at which the indicator is designed to reach its endpoint as defined by the manufacturer."[7] In addition, the Stated Value at 121°C/250°F must be >16.5 minutes.[7] This is the most important Stated Value and was added to ensure that chemical indicators labeled for use in 132°C/270°F do not change too quickly or inappropriately at these lower temperatures. All of these performance requirements must be met to ensure that the CI can detect improper sterilization conditions inside of each pack/container. Figure 1 shows three typical Stated Values for the Comply SteriGage 1243 Steam Chemical Integrators.[8]

Instructions For Use

Placement and Processing

1. To preserve as much package area as possible for folding and resealing, use scissors on the marked area at the top of the foil package to make the initial opening. Remove only the number of Comply SteriGage 1243A, 1243B, or 1243E Steam Chemical Integrators needed. Reseal the package by folding the opened end over at least two times.
2. Place a Comply SteriGage 1243A or 1243B Steam Chemical Integrator in each pack, peel pouch, container system or tray to be steam sterilized in the area determined to be the least accessible to steam penetration. If using a Comply SteriGage 1243E Steam Chemical Integrator, position the unattached end of the extender so that it extends slightly beyond the inner contents of the pack. This will permit integrator retrieval without touching the pack contents.
3. Process the load according to established procedures. If using an integrator with extender, after processing, grasp the extender between the thumb and forefinger to remove the integrator from the inner pack.

Note: Refer to the package insert for a complete set of instructions.

How to Read the Comply Steam Chemical Integrator

Interpretation of Results

Unprocessed

Accept

When the color bar moves anywhere into the "ACCEPT" area, all the critical parameters of steam sterilization have been met.

Reject

If the bar does not reach the "ACCEPT" area, the necessary conditions for sterilization have not been met. The pack should be reprocessed and the cause of the sterilization process failure should be investigated.

After processing, the dark color should have entered the ACCEPT window of the 3M™ Comply™ SteriGage™ 1243A, 1243B, or 1243E Steam Chemical Integrator. If the dark color has not entered the ACCEPT window, this indicates a REJECT result which means that the items in the pack, peel pouch, container system, or tray were not exposed to sufficient steam sterilization conditions. These items should be returned for reprocessing.

Safety

The design of the Comply SteriGage 1243 Steam Chemical Integrator prevents the indicating chemicals from coming in contact with sterilized materials or handling personnel. The chemical, as a pellet before processing or a melted color front after processing, is contained in an envelope of impermeable top and bottom layers

Storage and Shelf Life

- Store unopened and resealed packages at 40-60% relative humidity condition at room temperature [15-30ºC (59-86ºF)]. Store away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/disinfecting agents.
- After use, the indicator will not change visually within 6 months when stored at above conditions.
- Comply 1243A, 1243B, and 1243E Steam Chemical Integrators contained in an unopened package have a 5 year shelf life from the date of manufacture when stored at recommended conditions. The expiration date is printed on the package label.

References

[1] Perkins, J.J., Principles and Methods of Sterilization In Health Sciences, ed 2, Springfield, IL, Charles C. Thomas, 1976.

[2] Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control, Technical Report No. 1 (Revised 2007), PDA Journal of Pharmaceutical Science and Technology, Supplement Vol. 61, No. S-1, 2007.

[3] International Standard. Sterilization of health care products-Biological indicators-Guidance for selection, use, and interpretation of results, ANSI/AAMI/ISO 14161:2000.

[4] Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79: 2008 in progress.

[5] The Association of periOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Settings, 2008.

[6] The Association of periOperative Registered Nurses (AORN) Recommended Practices for Selection and Use of Packaging Systems for Sterilization, 2008.

[7] Association for the Advancement of Medical Instrumentation. Sterilization of health care products-Chemical indicators-Part 1: General requirements, ANSI/AAMI/ISO 11140-1:2005.

[8] Data on file at 3M.

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