

3M Science.
Applied to Life.™

3M™ Comply™ SteriGage™ Chemical Integrators
For Steam Sterilization Cycles

Accurate results. Instantly.

Advanced integrator
technology that's
easy to read and use



Engineered to deliver immediate and accurate pack-by-pack steam sterilization assurance

Why is pack control important?

Internal pack monitoring verifies that the sterilant has penetrated to the point of placement in the pack and confirms that the specific exposure conditions have been met. By using internal chemical indicators you can detect “local” problems that sometimes occur due to human error, sterilizer malfunctions or sterilant quality problems. Even with a negative BI result, sometimes the sterilant may not penetrate individual packs.

What causes pack control failure?

Pack Control failure can be caused by a number of things:

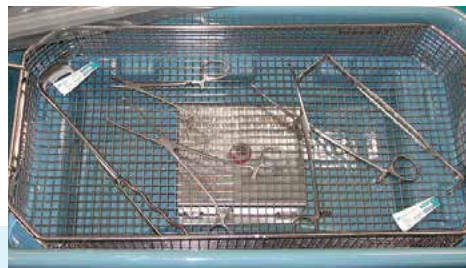
- There could be an air pocket in the steam sterilizer or a small leak in the vacuum system
- Poor quality or not enough sterilant
- The pack itself may be wrapped too densely
- The load is packed too tightly for the sterilant to penetrate

3M™ Comply™ SteriGage™ Chemical Integrators show whether each pack in a load has been exposed to the conditions necessary for sterilization to occur. SteriGage Chemical Integrators immediately detect failures resulting from equipment malfunction or human error in packing, loading or operation.

SteriGage Chemical Integrators provide precise results by detecting changes in all critical sterilization parameters before indicating an “ACCEPT” result. SteriGage Chemical Integrators in packs, trays, containers and peel pouches assure you that all the critical parameters for steam sterilization have been met.

- **“Accept” or “Reject” at a glance with moving front ink technology**
Requires no color change interpretation. Field tests show higher reading accuracy than color-change indicators.
- **For use in all FDA-cleared steam sterilization cycles: 250°F, 270°F, 273°F, and 275°F***
Eliminates the need to identify correct Type 6 cycle-specific emulating indicator and reduces your chemical indicator inventory.
- **Type 5 Integrating Indicator as defined by ISO 11140-1:2014**
SteriGage Chemical Integrator results correlate with a BI at three time/temperature relationships.
- **Helps prevent costly infections**
Identifies non-sterile instruments before they enter the sterile field.
- **Minimizes recalls and reprocessing**
Helps identify sterilization process failures by isolating individual pack problems.
- **Available with extender for easy retrieval from pack in the OR**
- **Not constructed with raw materials that are known to contain lead**

*For specific indications for use refer to the product IFU.



Examples of integrator placement in packs and trays

Place an integrator in the geometric center of each wrapped pack, peel pouch or unwrapped tray to be steam sterilized. In rigid containers, place an integrator in two opposite corners of each level. In multi-level wrapped containers supplied by the manufacturer, place an integrator in the center of each level.

The power of 3.

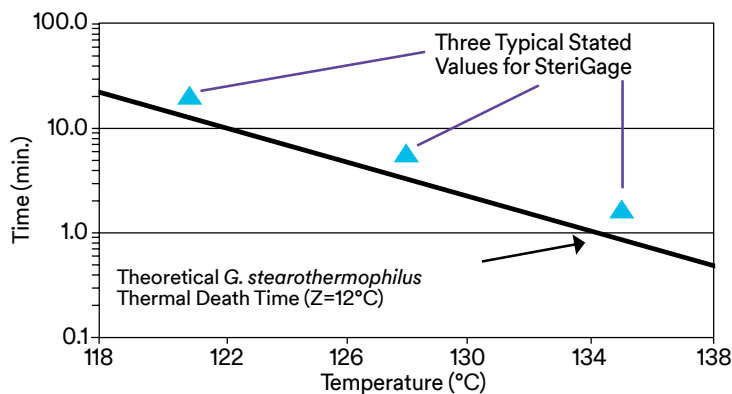
3M™ Comply™ SteriGage™ Chemical Integrators are designed to accurately integrate small changes in all critical sterilization parameters across the entire normal sterilization range in gravity and dynamic-air-removal steam sterilization processes. Their response must also approximate those of biological indicators (BIs) in ideal steam conditions.

Type 5 Chemical Integrators – such as 3M™ Comply™ SteriGage™ Chemical Integrators – are required to correlate with a BI at three time/temperature relationships: 121°C/250°F, 135°C/275°F and at least one temperature in between, such as 128°C/263°F. In addition, the stated value at 121°C/250°F must be greater than 16.5 minutes. This requirement ensures that chemical integrators do not change too quickly or inappropriately at these lower temperatures.

SteriGage Chemical Integrators monitor three critical steam sterilization parameters:

- Time
- Temperature
- Steam penetration

Integrating Indicator versus Biological Death Curve



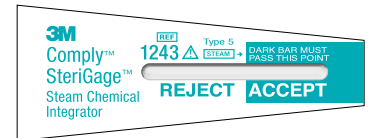
Can SteriGage Chemical Integrator technology also be used for load control?

By providing immediate results on sterilization process performance, an Integrating Indicator Process Challenge Device (PCD) may be used to monitor non-implant loads and serve as a monitoring bridge between loads that are monitored with a Biological Indicator PCD. The 3M™ Comply™ SteriGage™ Steam Chemical Integrator Test Pack presents a challenge to the sterilization process equivalent to the AAMI recommended towel pack. After processing, the integrator is retrieved from the PCD and the easy-to-read Accept or Reject result confirms whether the parameters for sterilization were met before the load is released.

If you are not monitoring every steam sterilization load with a BI PCD, consider using the Comply SteriGage Steam Chemical Integrator Test Pack in conjunction with the 3M™ Attest™ Super Rapid or Rapid 5 Steam Plus Test Pack as outlined in the chart at right. In this way, you will have information on sterilization process performance for all of your loads.

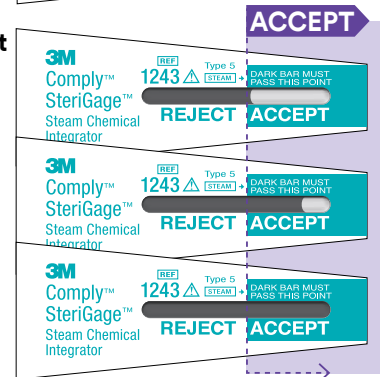
3M™ Comply™ SteriGage™ Chemical Integrators are easy to read – helping eliminate guesswork

Unprocessed



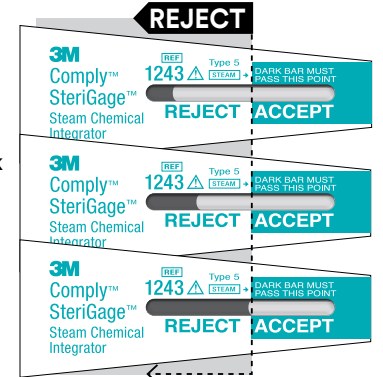
Processed – Accept

The color bar has reached the **ACCEPT** window in all three samples shown here, indicating that the necessary conditions for sterilization have been met. **If the color bar crosses into the ACCEPT region, it is considered a pass.**



Processed – Reject

The color bar is in the **REJECT** window, indicating that the necessary conditions for sterilization have not been met. The pack should be reprocessed and the cause of sterilization failure should be investigated. **If the color bar is in the REJECT region or right on the line, it is considered a fail.**



Recommended Applications

3M™ Attest™ Super Rapid or Rapid 5 Steam Plus Test Pack	3M™ Comply™ SteriGage™ Steam Chemical Integrator Test Pack
All loads containing implants	All other loads not monitored by Attest Test Packs
Routine sterilizer efficacy testing	
Sterilizer qualification testing	



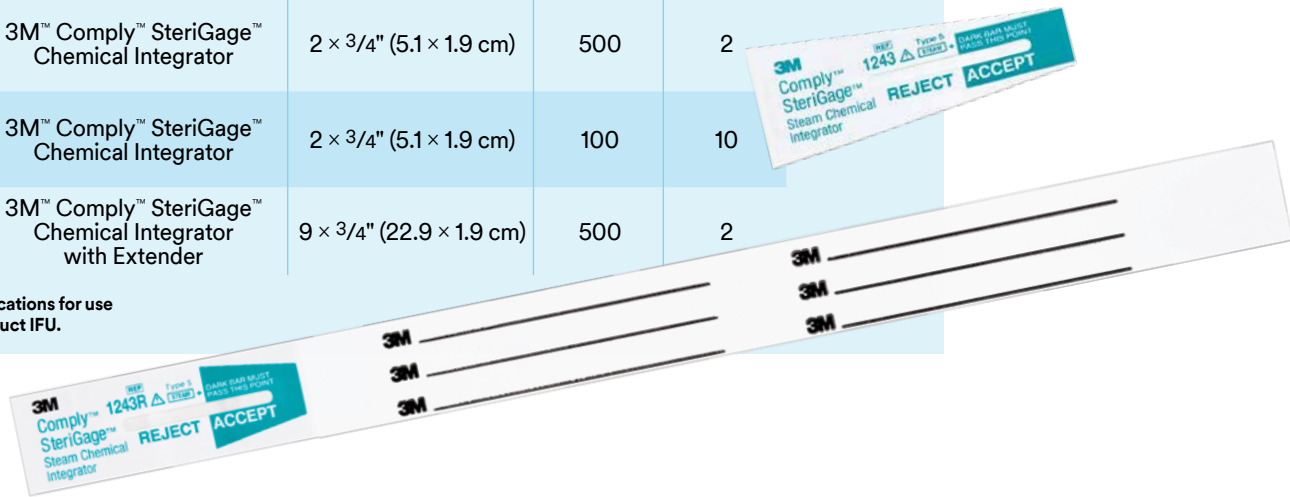
Ordering Information

3M™ Comply™ SteriGage™ Chemical Integrators for Pack Control

For use in steam sterilization cycles at 250°F, 270°F, 273°F, and 275°F.*

Catalog Number	Product Name	Size	Items/Bag	Bags/Case
1243A	3M™ Comply™ SteriGage™ Chemical Integrator	2 × 3/4" (5.1 × 1.9 cm)	500	2
1243B	3M™ Comply™ SteriGage™ Chemical Integrator	2 × 3/4" (5.1 × 1.9 cm)	100	10
1243RE	3M™ Comply™ SteriGage™ Chemical Integrator with Extender	9 × 3/4" (22.9 × 1.9 cm)	500	2

*For specific indications for use refer to the product IFU.



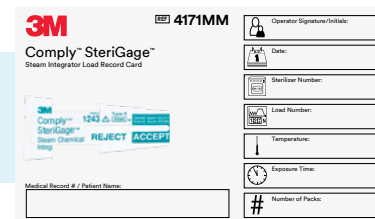
3M™ Comply™ SteriGage™ Steam Chemical Integrator Test Pack for Load Control

Catalog Number	Product Name	Items/Bag	Boxes/Case
41360	3M™ Comply™ SteriGage™ Steam Chemical Integrator Test Pack	4 each/bag	4 bags/box 4 boxes/case



3M™ Comply™ SteriGage™ Sterilization Integrator Load Record Cards for Record Keeping

Catalog Number	Product Name	Items/Bag	Boxes/Case
4171MM	3M™ Comply™ SteriGage™ Load Record Cards for Record Keeping	100 each/box	1 box/case



Infection Prevention Division
3M Health Care
2510 Conway Avenue
St. Paul, MN 55144-1000
USA
1-800-228-3957
www.3M.com/medical

Please recycle. Printed in USA.
Issued: 6/16 © 3M 2016.
All rights reserved. 11470HB
70-2011-5594-5

3M, Attest, Comply and SteriGage are trademarks of 3M.