

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



# Accurate Results. Instantly.

Advanced integrator technology  
that's easy to read and use

- “Accept” or “Reject” at a glance with moving front ink technology
- For use in all FDA-cleared steam sterilization cycles
- Class 5 Integrating Indicator as defined by ANSI/AAMI/ISO 11140-1:2005 (R)2010 and EN ISO 11140-1:2009
- Not constructed with raw materials that are known to contain lead

Lead  
the Way

**3M**

## 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**  
Requires no color change interpretation. Field tests show higher reading accuracy than color-change indicators.
- **For use in steam sterilization cycles at 250°F, 270°F, 273°F, and 275°F.\***  
Eliminates the need to identify correct Class 6 cycle-specific emulating indicator and reduces your chemical indicator inventory.
- **Class 5 Integrating Indicator as defined by ANSI/AAMI/ISO 11140-1:2005 (R)2010 and EN ISO 11140-1:2009**  
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**

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

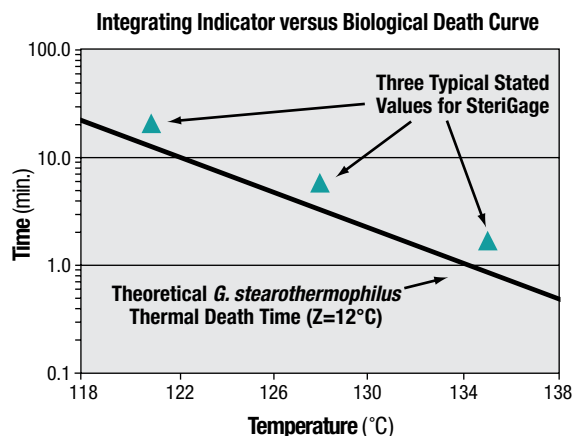
# The Power of 3

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.

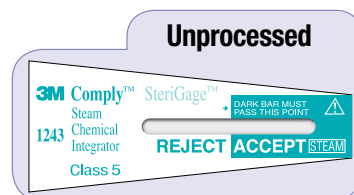
Class 5 Chemical Integrators – such as 3M™ Comply™ SteriGage™ Chemical Integrators – are required to correlate with a BI at three time/temperature relationships: 121°C/250°F, 135°C/275°F and at least one temperature in between, such as 128°C/263°F. In addition, the stated value at 121°C/250°F must be 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

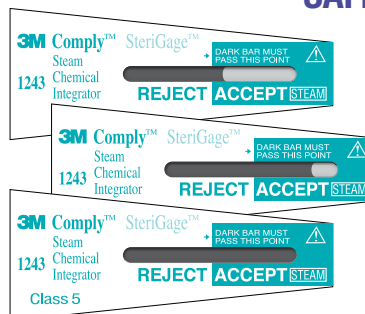


3M™ Comply™ SteriGage™ Chemical Integrators are easy to read – help eliminate guesswork



## Processed

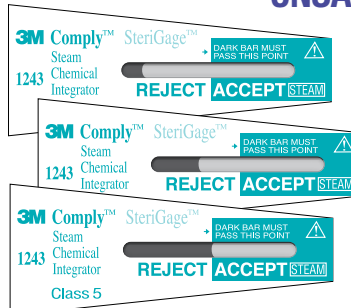
**SAFE**



## Processed - SAFE

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

**UNSAFE**



## Processed - UNSAFE

If the bar does not reach the "ACCEPT" area, or is right on the line, 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.

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

By providing immediate results on sterilization process performance, a Class 5 Integrating Indicator Process Challenge Device (PCD) may be used to monitor nonimplant 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 test packs. 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™ 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.



## Recommended Applications

**3M™ Attest™  
Super Rapid or Rapid 5 Steam  
Plus Test Pack**

All loads containing implants  
Routine sterilizer efficacy testing  
Sterilizer qualification testing

**3M™ Comply™ SteriGage™  
Steam Chemical Integrator  
Test Pack**

All other loads not monitored  
by Attest Test Packs

## 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™ Sterilization Integrator Load Record Cards for Record Keeping	1 each/bag	100 bags/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/infectionprevention](http://www.3M.com/infectionprevention)

#### Medical Division

**3M Canada**  
Post Office Box 5757  
London, Ontario N6A 4T1  
Canada  
1 800 563-2921

Please recycle. Printed in USA.  
Issued: 11/14 © 3M 2014.  
All rights reserved. 10142HB  
70-2011-5594-5

3M, Comply and SteriGage  
are trademarks of 3M.  
Used under license by  
3M subsidiaries and affiliates.