

Pack Control

3M Sterilization Assurance Products



Quality control for the
sterilization process
from the inside



Pack Control

Pack Control uses chemical indicators inside every pack, allowing end users clear, unambiguous and immediate analysis to identify if the sterilant used in the sterilization process has penetrated the pack successfully. Pack Control is the step of the 3M Sterilization Assurance Programme that monitors sterilization exposure conditions – through the use of chemical indicators – inside individual packs of instrument trays, peel pouches, wrapped fabric packs, and specialised procedure sets, etc. The chemical indicators are placed inside each pack to detect whether the sterilant used in the sterilization process has penetrated the packs successfully to defined levels. Pack Control serves as a companion tool to Load Control where the overall sterilization process is monitored by a biological or chemical indicator, which may or may not be placed in a process challenge device.

What must happen inside the Packs

The contents of each pack must be exposed to several critical parameters of the sterilization process.

These critical parameters are:

Steam Sterilization

- Saturated steam
- Time
- Temperature

EO Gas Sterilization

- EO gas concentration
- Relative Humidity (RH%)
- Time
- Temperature

Why must packs be monitored individually?

Even though biological indicators used during the Load Control step may have indicated that proper sterilization conditions exist, 'local' problems which can occur due to human error or mechanical malfunction within any sterilizer could present problems to individual packs.

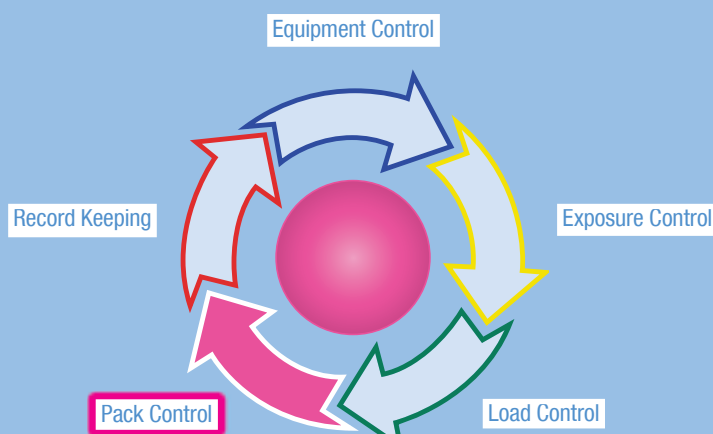
Examples of such problems are given below.

- *Air pockets and/or residual air can stay in a pack because of: a faulty vacuum system, air in the lines, not condensable gases from the steam supply.*
- *The pack itself is too dense or too large.*
- *The load is packed incorrectly or too tightly in the sterilizer.*
- *The packs are wrapped with a sterilant impermeable material.*
- *There is inadequate prehumidification of packs prior to EO sterilization or inadequate moisture injection during the EO sterilization cycle.*
- *An inappropriate cycle (i.e. incorrect time or temperature) is chosen for the load contents.*

Any one of these isolated equipment, loading and/or operator error problems could compromise the transfer of sufficient sterilization conditions from the sterilizer chamber to the inside of each pack. This is why the monitoring of individual packs – Pack Control – is a critical step in the 3M Sterilization Assurance Programme.

The Chain of total Assurance 3M Sterilization Assurance Programme

The 3M Sterilization Assurance Programme is a comprehensive and prudent approach to sterilization monitoring procedures and methods that you can count on to reduce the risk of unnoticed sterilization failure. The Programme consists of five separate, but interrelated processes, which monitor every aspect of the sterilization cycle and help you establish, manage and maintain a consistent protocol for sterilization in your facility.



A full line of 3M™ Comply™ Chemical Indicators

Just as live spores in biological indicators provide the best test of sufficient sterilization conditions in Load Control, chemical indicators have the most value in Pack Control. The advantage of using 3M Comply chemical indicators in Pack Control is that they allow the user to single out individual packs which were not exposed to sufficient sterilization conditions. 3M Comply chemical indicators are designed to:

- Detect potential sterilization failure resulting from 'local' problems
- Detect the critical parameters necessary to assure proper sterilization process monitoring
- Give information on the quality of the sterilant
- Provide diagnostic capability

Categories of chemical indicators

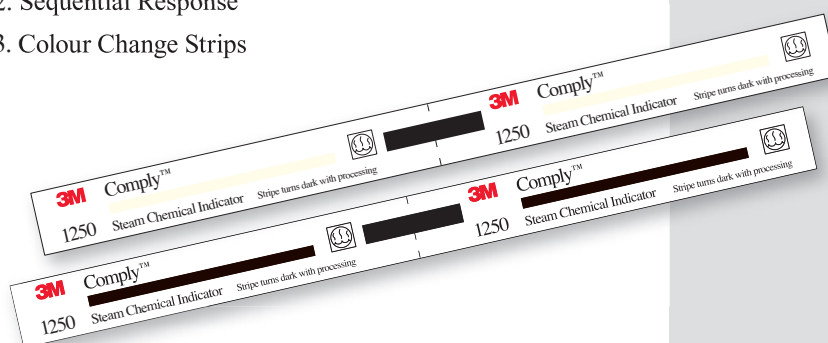
There are two basic categories of 3M Comply chemical indicators for the internal monitoring of packs:

- Multi-parameter indicators – respond to at least two of the critical sterilization parameters at defined levels
- Integrating indicators – are of a higher classification and performance because they are designed to respond to all of the critical parameters

Design Type

Multi-parameter and integrating indicators come in three basic design types:

1. Moving-Front Integrators
2. Sequential Response
3. Colour Change Strips



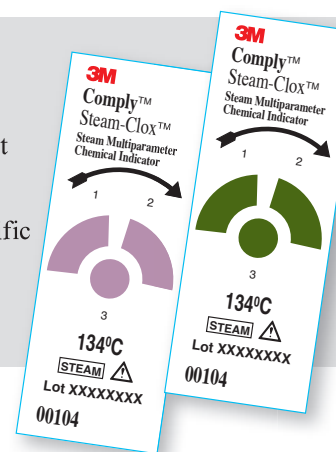
Moving-Front Chemical Indicators

Moving-front indicators are the more sophisticated monitors: they use both physical and chemical processes to control performance. An additional advantage with Moving-Front Integrators is their unambiguous readout that requires no interpretation. As the sterilization process proceeds, the indicator readout develops as a dark colour 'moving-front' and passes all the way to the 'ACCEPT' window or stops at the 'REJECT' window.



Sequential Response Indicators

Sequential response indicators react sequentially to the parameters of sterilization, providing both a specific time/temperature reaction and also an evaluation of the sterilant.



Colour Change Chemical Indicators

The most common group of chemical indicators uses a colour strip design. These sterilization monitors utilise chemical coatings on the indicators which are formulated to change colour only after exposure to certain specific conditions in the sterilization cycle.

3M™ Comply™ Range of Chemical

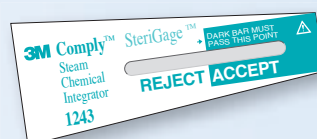
Choosing a Chemical Indicator – The categories tabled below will help you make your choice as 3

Class 5 Integrator

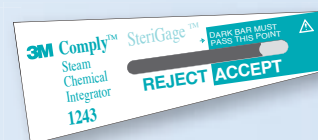
3M Comply (SteriGage) Steam Chemical Integrator

Characteristics:

- Parallels the response of a biological indicator strip to the sterilization process
- Moving-front indicators – easiest chemical indicators to read because of the distinct 'Accept' or 'Reject' readout – no need for interpretation
- Small, convenient size for packs, trays and peel pouches, also available with extenders for large packs



Unexposed



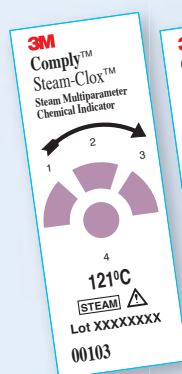
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Class 4 Multi-Parameter Indicator

3M Comply (Steam-Clox) Steam Multi-Parameter Chemical Indicators and 3M Comply Steam Chemical Indicator-Plus Strips

Characteristics:

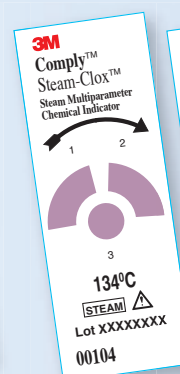
- Sequential colour change
- Colour change indicators which have a slower timed response
- Provide diagnostic information
- Cycle specific types



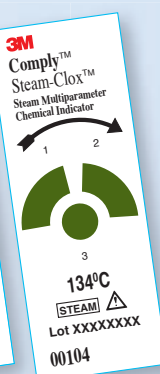
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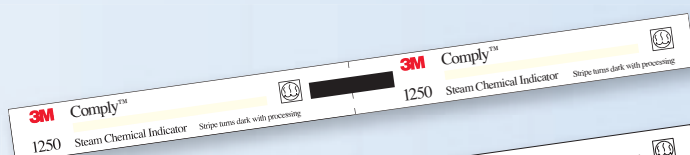


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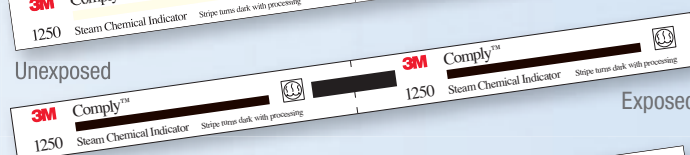
The colour stripe 3M Comply Steam, Chemical Indicator Strip and 3M Comply EO Chemical Indicator Strip

Characteristics:

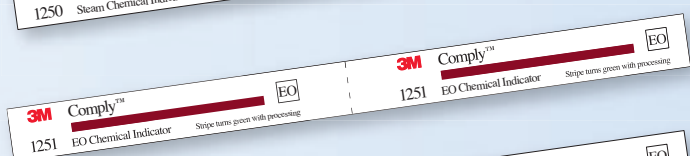
- Have a large portion of indicator ink for a greater area of monitoring in the pack
- Perforated – style strip allows full – or half length use for different pack sizes



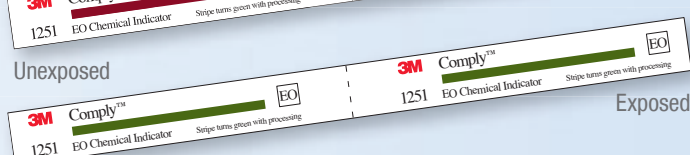
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Chemical Integrators and Indicators

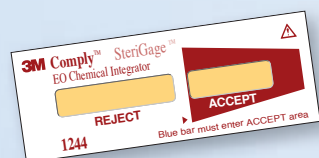
3M has a wide range of moving front, sequential response and colour change chemical indicators.

Integrator FDA

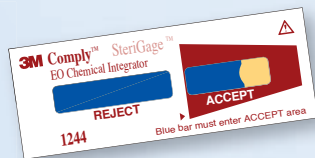
3M Comply (Thermalog) Steam Chemical Integrator, 3M Comply (SteriGage) EO Chemical Integrator and 3M Comply (Thermalog) EO Chemical Integrator

Characteristics:

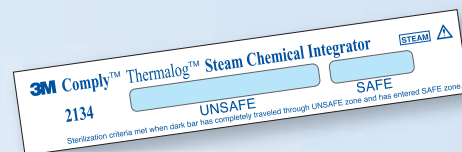
- Parallels the response of a biological indicator strip to the sterilization process
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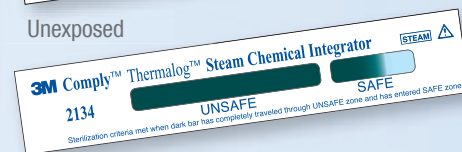
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Class 1 Exposure Indicator

The colour block 3M Comply Steam Chemical Indicator Strips, 3M Comply EO Chemical Indicator Strips, 3M Comply EO Chemical Indicator Strip, 3M Comply Dry Heat Chemical Indicator Strip and 3M Comply LTSF Chemical Indicator Strip

Characteristics:

- Colour change indicators
- Comes in two sizes



Unexposed



Exposed



Unexposed



Exposed

Ordering Information

A selection of products is listed below. Please contact your local 3M representative for our full product offering.

Cat No	Product Name	Items/Bag	Bags/Case
00103	3M™ Comply™ (Steam-Clox™) Steam Multi-Parameter Chemical Indicator (for use at 134°C)	250	20
00104	3M™ Comply™ (Steam-Clox™) Steam Multi-Parameter Chemical Indicator (for use at 121°C)	250	20
00107	3M™ Comply™ (ATI™) Steam Chemical Indicator Strip (Long)	250	20
00109	3M™ Comply™ (ATI™) Steam Chemical Indicator Strip (Short)	250	20
00109A	3M™ Comply™ (ATI™) Steam Chemical Indicator Strip (Short)	1000	4
00311	3M™ Comply™ (ATI™) Dry Heat Chemical Indicator Strip	250	10
1240E	3M™ Comply™ Integrator Extender	2500	2
1243A	3M™ Comply™ (SteriGage™) Steam Chemical Integrator	500	2
1243B	3M™ Comply™ (SteriGage™) Steam Chemical Integrator	100	10
1243E	3M™ Comply™ (SteriGage™) Steam Chemical Integrator with Extender	1000	1
1244A	3M™ Comply™ (SteriGage™) EO Chemical Integrator	500	2
1244B	3M™ Comply™ (SteriGage™) EO Chemical Integrator	100	10
1244E	3M™ Comply™ (SteriGage™) EO Chemical Integrator	1000	1
1250	3M™ Comply™ Steam Multi-Parameter Indicator Strip	240	8
1251	3M™ Comply™ EO Multi-Parameter Indicator Strip	240	4
1258	3M™ Comply™ Form Chemical Indicator Strip	240	4
2134MM	3M™ Comply™ (Thermalog™) Steam Chemical Integrator	250	8
2524MM	3M™ Comply™ (Thermalog™) EO Chemical Integrator	250	8



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