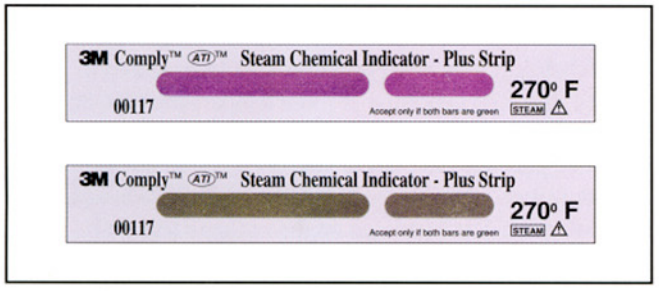
Technical Information Sheet

3M™ Comply™ Steam Chemical Indicator-Plus Strips



Pack Control

The dynamics of steam sterilization proves the need for monitoring of the sterilization process conditions. Load control is the process in which a load is monitored and released based on the result of a biological indicator (BI) in a test pack. Pack control monitoring, recommended by organizations such as AAMI and AORN, consists of monitoring individual packs based on readouts from chemical indicators from inside each pack.

As stated by AAMI and AORN, problems can occur with equipment malfunctions or in packaging and loading of packs into sterilizers. These problems can inhibit air removal and steam penetration. Examples of equipment malfunctions include a localized air leak due to a faulty door gasket or a poorly operating steam trap. Examples of packaging problems include stacking peel pouches and packs that are too heavy or dense.

As discussed above, small reductions in time or 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 temperature and/or time exposure. Chemical indicators used inside each pack to monitor time, temperature and/or steam exposure conditions are one of the many tools used to help provide sterilization assurance and identify problems in the sterilization process.

Product Description

The 3M™ Comply™ 00117/00118 and 00119 Steam Chemical Indicator-Plus Strips are single-use devices that verify sterilizing conditions of time, temperature and steam penetration inside the pack. Comply 00117/00118 can be used for pack control monitoring of 270˚F (132˚C) gravity and vacuum-assisted sterilizer cycles. Comply 00119 can be used for pack control monitoring of 250˚F (121˚C) gravity and vacuum-assisted sterilizer cycles.

The Comply steam indicator-plus strips consist of two indicator ink strips that turn color from purple to green in sequence (left strip first, then right strip). Incomplete color change (some purple still present) of one or both strips indicates that the conditions necessary for sterilization have not been met. This pack should be reprocessed and the cause of the sterilization failure in this pack should be investigated. A clear plastic coating over the ink strips allows steam penetration yet prevents the ink from transferring to items that are being sterilized.

Comply 00117/00118/00119 steam chemical indicator-plus strips should not be used to monitor dry heat, ethylene oxide or other low temperature sterilization processes.

Technical Design and Performance Characteristics

Each indicator consists of a convenient, individual, disposable paper strip with two exclusive sequential indicator bars that are extremely sensitive to steam sterilizing conditions. A special clear plastic protective coating over the ink bars prevents the ink from touching items being sterilized.

The accurate chemical formulation of the inks makes the indicator sensitive to the three factors necessary for sterilization—the correct combination of time, temperature and saturated steam. Inks only begin to react and change color when steam is present. The indicators complete their color change progressively from purple to green only after sufficient time has passed.

Comply Steam Indicator-Plus Strips 00117/00118

- Indicator changes color from purple to green in saturated steam at 270˚F (132˚C) as follows:

  First area (left bar)–within one minute

  Second area (right bar)–within three minutes

Comply Steam Indicator-Plus Strip 00119

- Indicator bar changes from purple to green in saturated steam at 250˚F (121˚C) as follows:

  First area (left bar)–within 10 minutes

  Second area (right bar)–within 18 minutes

Chemical Indicator Classification

Comply 00117/00118/00119 steam indicator-plus strips meet the general requirements of EN-867-1:1997 European Standard for Class D: "Multi-variable" indicators.

Instructions for Use

1. Place a Comply 00117/00118/00119 steam indicator-plus strip in the center of each pack, peel pouch or tray to be sterilized. For a rigid container, place a strip in each corner, in two opposing/diagonal corners or in the area determined by product testing to be the greatest challenge.
2. When using the long strip 00118, place the end of the strip with two indicator strips in the center of the pack and position the other end so that it extends slightly beyond the inner contents of the pack.
3. Process the load according to established procedures. (Note: Comply 00117/00118 are for 270˚F gravity and vacuum-assisted cycles and Comply 00119 is for 250˚F gravity and vacuum-assisted cycles).
4. After processing, remove the steam indicator strips and observe the color change.

How to Read the Comply Indicator-Plus Strips

Interpretation of Results

1. If the indicator areas have NOT changed color completely from purple to green (green color can range from light to dark) after processing, sterilization conditions have NOT been met.
2. If the color bars appear to be "washed out" with a grayish color and the plastic laminate is crinkled, this is evidence of wet steam or excessive condensation. Try to avoid placement of the indicator near metal items and avoid transferring hot/warm containers to a cool area. It is always best to allow drying and cool down in the sterilizer.
3. If the color bars turn a dark brown color, this is evidence of superheating within the sterilizer.

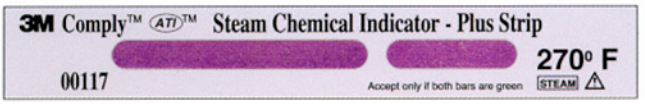
Storage and Shelf Life

Unopened and resealed packages containing Comply steam chemical indicator-plus strips should be stored in a dry (<50% RH) condition at room temperature [59–86˚F (15–30˚C)]. Comply indicator-plus strips contained in an unopened package have a five-year shelf life from the date of manufacture when stored at recommended conditions. The expiration date is printed on the package label.

Color Change Guide

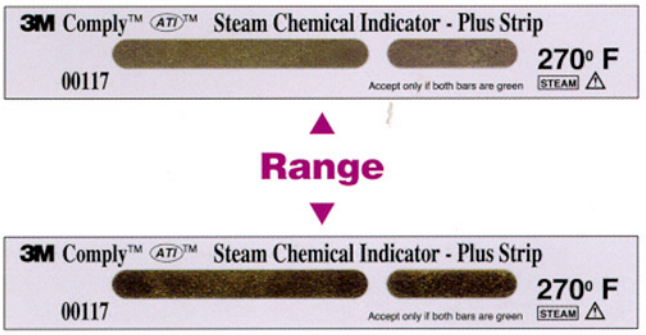
Unexposed

Superior purple ink technology and exclusive dual Sequential Indicator Bars tell precisely when the correct sterilization conditions have been met.



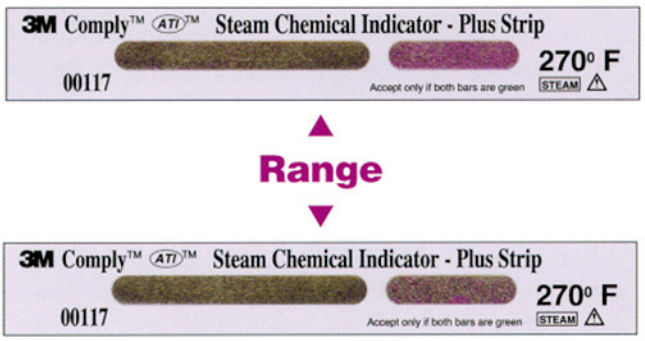
Normal Exposure

When *both* bars change color from purple to green, you are assured that the correct conditions of time, temperature, and saturated steam have been met. The color range of green as shown is normal and acceptable.



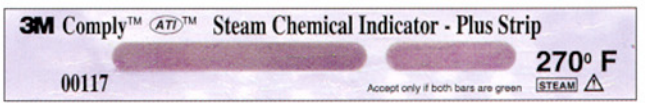
Insufficient Exposure

When only one bar changes from purple to green, exposure to sterilization conditions is insufficient and complete sterilization may not have taken place. The color range at right shows unacceptable conditions.



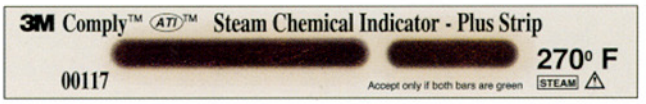
Wet Steam

Wet steam or excess condensate can prevent an acceptable color change from taking place. The color bars look pale and "washed out" and the plastic laminate crinkles and bubbles up. If exposure time is extended to compensate for wet steam, both bars will turn to an acceptable light green.



Superheated Steam

When the steam is superheated, the indicator bar turns dark brown.



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