Product Description
The 3M™ Comply™ Cold SteriLog™ Glutaraldehyde Monitors are semiquantitative chemical indicator strips designed for monitoring the minimum effective concentration (MEC) of glutaraldehyde established by the manufacturer of a specific cold disinfecting and sterilizing solution. The strips are constructed of a black outlined paper pad attached to a plastic strip, which is used for dipping the pad into the solution. The black outlined paper pad (i.e., glutaraldehyde monitor) is composed of two reactive ingredients: sodium sulfite and glycine. If the monitor (i.e., paper pad) indicates that the solution is not at or above the established MEC level (i.e., chemical reaction yields white), then the glutaraldehyde solution must be discarded. If the monitor (i.e., paper pad) indicates that the solution is at or above the established MEC level (i.e., chemical reaction is uniform yellow), the solution may be used/reused.

The Comply™ glutaraldehyde monitors cannot be used to validate the sterilization or disinfection process or to determine whether the activator was added to the glutaraldehyde solution. Do not use the glutaraldehyde solutions beyond the manufacturer’s expiration date regardless of the result of the monitor.

Monitoring Frequency
Glutaraldehyde solutions should be tested before each use prior to immersing medical devices into the solution to ensure that the solution is still at or above its MEC. If the solution is not at or above its MEC, discard the solution, as it is no longer effective.

Indications for Use
Each Comply™ glutaraldehyde monitor is designed for use with specific solutions.

<table>
<thead>
<tr>
<th>Cat. #</th>
<th>Monitor</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>3983MM</td>
<td>1.5%</td>
<td>Cidex™ Activated Dialdehyde Solution, Rapicide™ High Level Disinfectant and Sterilant</td>
</tr>
<tr>
<td>3987</td>
<td>1.8%</td>
<td>Aldahol® 1.8 High-Level Disinfectant</td>
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</tbody>
</table>

Contraindications
Do not use Comply™ glutaraldehyde monitors with any other glutaraldehyde solutions than those listed above.

Precautions
• Do not remove desiccant from the bottle.
• Do not store strips outside of bottle.
• Do not use strips 120 days after opening the bottle.

Directions for Use
1. Remove one monitor from the bottle. Re-close the bottle tightly.
2. Dip the entire paper pad end of the monitor into the mixed, activated, glutaraldehyde solution and withdraw immediately. Do not leave the pad in the solution or stir the pad in the solution. This could wash the reagents in the pad off the strip and cause a false fail result (i.e., no yellow color change or white spots).
3. Remove the excess solution from the pad by touching the long side edge of the monitor on a paper towel. Do not blot with the pad face down or shake the test strip. This could remove the reagents and solution from the pad and cause a false fail result (i.e., no yellow color change or white spots).
4. Lay the monitor across the bottle cap so it is balanced.
5. Wait 5 minutes for color development. Waiting less than 5 minutes could result in a color change that will be incomplete and be interpreted incorrectly. Do not read the pad after 8 minutes because the color will gradually fade making interpretation difficult.
6. Any shade of uniform yellow color on the pad indicates an effective solution. If any white color remains on the pad, the solution is ineffective and should be discarded.

Storage/Shelf Life
Store Comply™ glutaraldehyde monitors in original container, in a dry area (<50% relative humidity) at room temperature (15-30°C [59-86°F]). Keep the cap tightly closed. The bottle contains a desiccant which must not be removed. If the storage conditions are not followed, the active agent will change. An orange and not a yellow color will appear as a result. This is an invalid test.

Once the container is opened, the shelf life is reduced to 120 days. Record the date opened on the bottle under “date opened:” to ensure that the monitors are not used beyond the 120 days.

Disposal
Dispose of used or expired strips according to federal, state, and local laws.

Optional Performance Test for Monitors Procedure
Available upon request: In the US contact the 3M Sterilization Tech Line 1-800-441-1922 option 2. Outside of the US, contact your local 3M office.

Performance Characteristics
The accuracy and sensitivity of each Comply™ glutaraldehyde monitor is ±0.25%. The precision for each monitor for its stated specification is ±0.1%.

Explanation of Symbols
- Use by date
- Batch code
- Manufacturer
- Date of manufacture