Risk of Misinterpreting Hydrogen Peroxide Indicator Colors for Vapor Sterilization: Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) has become aware of the potential for health care facility staff that reprocess and sterilize medical devices to misinterpret the indicators used to validate the sterilization of medical devices because there is no standard indicator color to indicate a sterilized device.

Health care facilities alerted the FDA that, among manufacturers of hydrogen peroxide vapor sterilization systems:

- The 3M Comply Hydrogen Peroxide Chemical Indicator 1248 uses blue to indicate an unprocessed device and pink to indicate a sterilized device.
- The Aesculap MD334 Process Indicator Card uses pink/magenta to indicate an unprocessed device and blue to indicate a sterilized device.

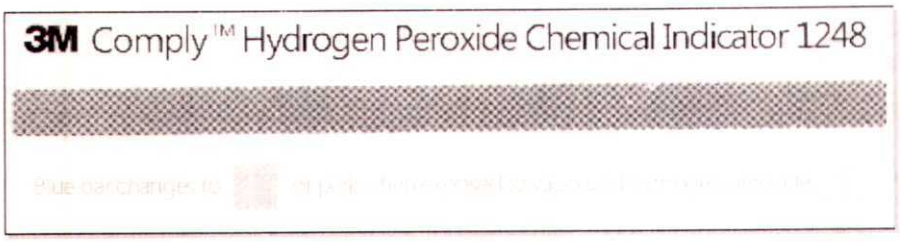
There have been no injuries reported to the FDA associated with the use of these indicators.

Recommendations

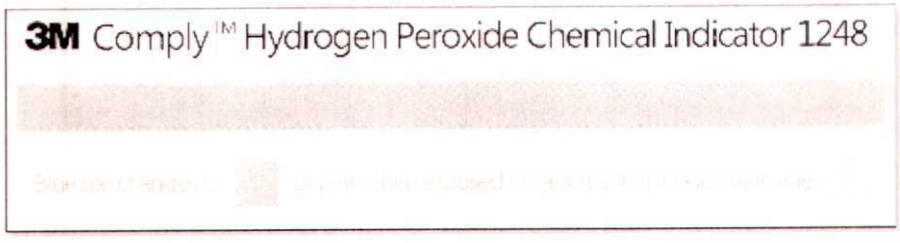
The FDA recommends health care facilities and reprocessing staff:

- Review the manufacturer's instructions for the particular indicator bar or card being used and know the significance of the indicator colors.
- Enhance staff training on the indicators for all sterilization systems employed in the facility and reinforce that training with prominently displayed visual reminders such as the examples below:

Unprocessed Chemical Indicator

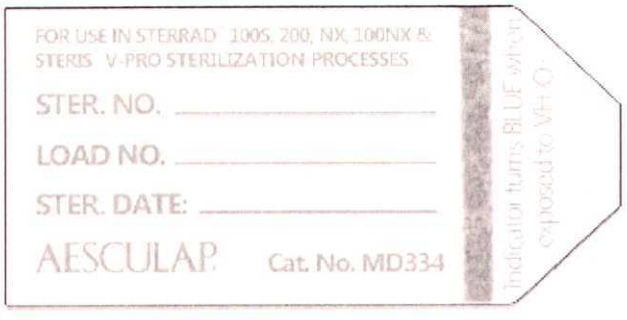


Processed Chemical Indicator



The 3M Comply Hydrogen Peroxide Chemical Indicator 1248 Card uses blue to indicate unprocessed and pink to indicate processed.

Unprocessed Card



Containerized

Processed Card

Containerized

The Aesculap MD334 Process Indicator Card uses pink/magenta to indicate unprocessed and blue to indicate processed.

Background

During the COVID-19 pandemic, health care facilities are rapidly adopting conservation practices, including decontaminating disposable compatible N95 and N95-equivalent respirators for single-user reuse. Reprocessing staff may be using sterilization systems for the first time or concurrently using sterilization systems from different manufacturers. If staff assume that all manufacturers use the same color code to validate sterilization, they may mistakenly release contaminated devices for reuse.

There is no standard color to indicate validated sterilization. Each manufacturer has developed its own color scheme to validate the sterilization process, and the colors vary among manufacturers even though many are validated for the same cycle conditions.

FDA Actions

The FDA is collaborating with manufacturers of sterilization systems to improve product labeling and explore standardization for colors used to indicate sterilization. The FDA will continue to keep health care providers, manufacturers, and the public informed of new or additional information.

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Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with any sterilization indicators.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user organizations must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by organizations that are subject to the FDA's user facility reporting requirements (https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities#3) should follow the reporting procedures established by their organizations.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (DICE) (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice).