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# HYDROGEN PEROXIDE STERILIZATION AND CHEMICAL INDICATORS

**Chemical Indicators are important tools in the medical device sterilization process. Despite their importance, they are also a source of confusion and misunderstanding for many of their users and producers. Vaporized Hydrogen Peroxide Chemical Indicators are possibly the most misunderstood. This document attempts to clarify some of the confusion.**

## REVIEWING CHEMICAL INDICATORS

ISO11140-1 (2014) Type 1 Chemical Indicators (CI's) are Process Indicators. They are used to show that a device has been exposed to a proper sterilization cycle. This is not an assurance that the contents of the sterilization unit were sterilized, only that they have been exposed to a proper sterilization process.

Biological and Chemical indicators help assure that 1.) individual sterilizer conditions provide the necessary level of kill to achieve sterilization (Biological Indicators), and 2.) devices, in individual packages were exposed to these proper conditions (CI's).

CI's are commonly used for every device, or package, going through a sterilization process; they are often incorporated into pouches/reels, or onto labels and tags which are included with the device during processing. A sterilization indicator ink forms part of the CI providing a visual color change from the initial printed color to a different color after being exposed to a sterilization process. The ISO standard does not specify what the color change should be, only that there is a distinct visual difference between the 'before' (printed) and 'after' (signaled) sterilization cycle colors.

If there is not a color change, or if the color change is incomplete or different from that which the producer of the CI specifies, this is a failure and indicates something with the process may be wrong. If this happens, the system should be checked to identify the issue. This may include equipment malfunctions causing insufficient or non-uniform distribution of hydrogen peroxide, sterilizer overload, (i.e. too many devices in the unit), or some other function/parameter not being met.

Note: Many people think that an incorrect or incomplete signal color is a problem with the CI's. Most often, CI's uncover/identify a potential issue with the sterilizer, except for cases of CI's produced incorrectly or with low quality raw materials.

## VH2O2 CHEMICAL STERILIZATION

Hydrogen Peroxide Sterilization, Vaporized Hydrogen Peroxide, hydrogen peroxide gas sterilization, Hydrogen Peroxide Gas Plasma – are all different way of referring to a similar type of sterilization process.

At a high level, the process is:

i. Liquid $H_2O_2$ gets converted into a vapor
ii. The vapor fills the chamber, contacting all surface areas
iii. After the defined sterilization cycle, the vapor is converted into water and oxygen for safe discharge

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## Advantages of VH2O2 Chemical Sterilization:

VH2O2 Chemical Sterilization is a sterilization process offering many advantages. It is used for sterilization of devices which cannot tolerate exposure to high temperatures or high humidity levels. The emissions from this process are safe, easily disposed of and no special ventilation is required. The systems are comparatively simple to install and operate in hospital settings.

CI's for VH2O2 sterilization are covered by ISO standards, including ISO 11140-1:2014, which covers the use and performance of chemical indicators.

## Challenges of VH2O2 Chemical Sterilization:

Many companies now manufacture these sterilization units and each one is somewhat different. The devices placed in the sterilizer may impact the ability of the VH2O2 to circulate. Medical devices with enclosed volumes can trap the sterilant and prevent it from circulating freely. Excessively loading a sterilizer can have a similar effect.

When a sterilizer consistently delivers an appropriate volume of sterilant in the chamber and distributes it uniformly, the CI's will repeat the same/similar color change regardless of its placement in the chamber. To understand the color change in a specific sterilization unit, it is important to benchmark the unit with both CI's and BI's at initially installation, and periodically re-confirm it.

## Chemical Indicators and H2O2 Sterilization

The function of a CI is to provide visual confirmation that a device has been exposed to a proper sterilization process. The ISO 11140-1:2014 standard does not stipulate specific colors that the indicator must change from or to, only that there must be a visible change, after proper exposure, as defined by the manufacturer of the indicator.

This can be a challenge for manufacturers of $H_2O_2$ CI's. A common $H_2O_2$ CI color change is from red (print color) to yellow (signal color). Depending on the sterilization unit, a properly exposed indicator may change in one case to a bright yellow, and in another case to an orange/yellow color. Many sterilizers have both a full length, and a rapid/fast cycle. The color of a properly exposed indicator may also differ between these two cycles, even in the same sterilizer.

It is important for users to benchmark their systems to understand the specifics of the signal color change in their sterilizer/equipment. Once benchmarked, and a proper signal color understood, future signal colors that do not match expectations should lead to full review of the sterilizer itself, or the sterilizer load. For example, an overloaded sterilizer may prevent the proper amount and distribution of the $H_2O_2$ sterilant within the chamber.

Note: When benchmarking a sterilization system, it is important to use multiple indicators in various locations within the chamber. This should help determine if the sterilant distribution is uniform as non-uniform color changes of CI's in various areas may indicate potential issues with the equipment or the way the equipment is being used.

## For Additional Information Contact:

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