

About the Sterizone VP4

The Sterizone VP4 is a medical device sterilizer which uses dual sterilants; vaporized hydrogen peroxide (H₂O₂) and ozone (O₃), in a multiphase process, at low temperature. It is intended for use in terminal sterilization of cleaned, rinsed, and dried metal and non-metal reusable medical devices in health care facilities. The single pre-set cycle of the Sterizone VP4 uses hydrogen peroxide and ozone.

Recommendations for processing FFR in the Sterizone VP4 Sterilizer during the COVID-19 Public Health Emergency

It is not recommended to reprocess and reuse FFRs with any method, and healthcare workers should utilize new FFRs whenever possible. When there is a shortage of FFR, however, healthcare facilities may elect to reprocess them using sterilizers such as the Sterizone VP4. When utilizing the Sterizone VP4 in such a manner, healthcare facilities should follow the instructions and recommendations from this document.

Instructions for MDRD workers

Decontamination of N95 respirators with the Sterizone VP4 sterilizer...page 2 - 3

Instructions for MDRD workers

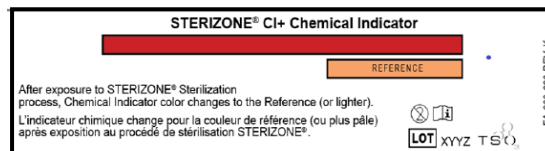
Decontamination of N95 respirators with the Sterizone VP4 sterilizer



- Due to incompatibility, the Sterizone VP4 is not authorized for use with respirators containing cellulose-based or paper materials, natural rubber, or latex.
- Do not decontaminate a respirator that is damaged, soiled, wet or contain excessive moisture.

The following are Stryker suggestions and recommendations. Please follow your facility's policies.

1. Inspect respirators prior to decontamination and discard visibly damaged soiled, wet respirators.
2. Package each respirator individually in a Tyvek Pouch identified to the user.
3. Ensure that a STERIZONE CI+ chemical indicator is contained within each pouch, as shown below.



4. Make sure both ends of the Tyvek pouches are sealed.
5. Place the pouches onto the loading rack. Using two pouch holders on the bottom shelf will help maximizing the rack capacity, as shown below. Up to 20 respirators can be processed in a sterilization load.



Note: Pouches should not overlap each other. Load temperature should be between 20-26°C (68-78°F).

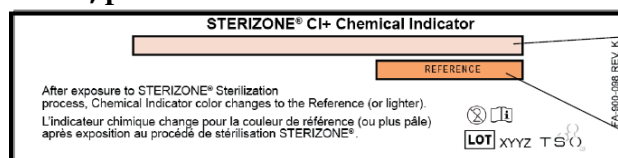
6. When running consecutive cycles, ensure the loading rack and pouch holders are cooled down between cycle (\approx 15 minutes) back to a

temperature between 20 - 26°C (68 - 78 F).

7. Place a Test Pack¹ containing a STERIZONE BI+ Self-contained Biological Indicator² and a STERIZONE CI+ Chemical Indicator³ on the top shelf of the loading rack, as per recommendation of the STERIZONE VP4 Sterilizer User Manual⁴.



8. Initiate a cycle and once cycle is completed verify successful completion, following the STERIZONE VP4 Sterilizer User Manual.
9. Once cycle is complete, inspect each mask and discard any damaged ones.
10. Check that the indicator color stripe of the CI+, contained in each package, to ensure it is a lighter color than the reference stripe. If the color is darker than the reference, return respirator to decontamination. If the respirator has 2 tick marks, please discard.



11. Keep respirators in Tyvek pouches until next use.
12. Send respirators for distribution.

Note: Respirator must air out for **24 hours** before it is sent back to the user.

¹ MA-900-066, STERIZONE® VP4 Test Pack Kit Accessories Instruction for Use.

² MA-900-043, STERIZONE® BI+ Self-Contained Biological Indicator Instructions for Use.

³ MA-900-044, STERIZONE® CI+ Chemical Indicator Instructions for Use.

⁴ MA-200-049, User Manual VP4 STERIZONE® Sterilizer, CA.