

FACT SHEET FOR HEALTHCARE PERSONNEL

Stryker STERIZONE VP4 Sterilizer for Decontaminating Compatible N95 Respirators

January 21, 2021

Coronavirus
Disease 2019
(COVID-19)

You have been given a **decontaminated N95 respirator** that has been decontaminated using a decontamination system that is authorized to decontaminate compatible N95 respirators **for single-user reuse by healthcare personnel (HCP) in a healthcare setting** (i.e., the same respirator is returned for reuse to the same HCP following its decontamination) to help prevent HCP exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of decontaminated, compatible N95 respirators. These compatible N95 respirators have been decontaminated using the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle in the STERIZONE VP4 Sterilizer (hereafter referred to as "**decontaminated N95 respirators**" and "**STERIZONE VP4 Sterilizer**" throughout this Fact Sheet).

Whether or not you use a surgical mask, respirator, or face shield, always follow infection control measures: wash hands, cover coughs and sneezes, stay home if you may be sick.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of the STERIZONE VP4 Sterilizer and decontaminated N95 respirators?

- The STERIZONE VP4 Sterilizer has been authorized for emergency use to decontaminate compatible N95 respirators for single-user reuse by HCP during the COVID-19 pandemic to prevent wearer exposure to pathogenic biological airborne particulates, including SARS-CoV-2.
- Compatible N95 respirators are either authorized NIOSH-approved respirators or respirators that are authorized and listed in Exhibit 1 to FDA's emergency use authorization (EUA) for non-NIOSH-approved imported filtering facepiece respirators (FFRs) that are not manufactured in China, and that do not have exhalation valves or a duck-billed design, and do not contain cellulose-based materials or antimicrobial agents.
- The STERIZONE VP4 Sterilizer is **not authorized** for use with the following:
 - Respirators containing cellulose-based materials;
 - Respirators containing exhalation valves;
 - Respirators containing antimicrobial agents;
 - Respirators with duck-billed designs; and
 - Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.
- The STERIZONE VP4 Sterilizer has previously received FDA clearance for other uses. In submissions supporting clearance, testing was submitted to FDA that spanned more than 21 different types of polymer materials, including materials consistent with those found in compatible N95 respirators. FDA has leveraged the performance data (e.g., half cycle test, sporicidal test, compatibility, residual analysis, functionality) from the previous submissions to support this emergency use, which repurposes the Stryker STERIZONE VP4 Sterilizer to be used for decontamination of N95 respirators for single-user reuse up to 2 times during the COVID-19 pandemic.

Report Adverse events to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088

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- **Preparing compatible N95 respirators for decontamination:**
 - ✓ Discard if decontaminated two (2) times or visibly soiled or damaged
 - ✓ Place compatible N95 respirators at the end of use into Tyvek pouches
 - ✓ Write your name and/or other identifier using a permanent marker so the respirator may be returned to you after successful decontamination
 - ✓ Place a tick mark on the respirator and Tyvek pouch each time a respirator is prepared for decontamination
 - ✓ Ensure there is a STERIZONE CI+ chemical indicator strip on the Tyvek pouch
 - ✓ Seal the respirator in the Tyvek pouch and place it into area for subsequent decontamination per your healthcare facility's procedures

- **Use of decontaminated N95 respirators:**
 - ✓ Decontaminated N95 respirators are not sterile
 - ✓ HCP must perform a user seal check of the decontaminated N95 respirator according to OSHA standards prior to beginning a shift. If the user seal check does not pass, the respirator must be discarded
 - ✓ Inspect respirators after each use prior to submission for decontamination
 - ✓ Discard respirators with visible soiling (e.g., blood) or damage – do not use and do not send for decontamination
 - ✓ The number of times a respirator has been decontaminated is written on the respirator (maximum 2 times)
 - ✓ Inspect respirator upon its return after decontamination and prior to use to assure that you are the appropriate individual, that the chemical indicator strip (color strip at the top) has changed to be equal to or lighter than the reference color, and that there is proper facial fit
 - ✓ Report problems with decontaminated N95 respirators to your healthcare facility
 - ✓ Respirators may be safely stored in pouches after decontamination
 - ✓ Maintain chain of custody on the respirator to minimize the risk of cross-contamination

- **Monitor yourself for signs and symptoms** of potential infection with SARS-CoV-2 or other respiratory infection for up to and including 14 days after last contact with the SARS-CoV-2 virus and related material, and promptly report such information to your healthcare facility.
- **Report damage or discoloration** observed upon receipt of the decontaminated N95 respirators, and potential exposure of HCP from breaks in or other damage to or degradation of the decontaminated N95 respirators to your healthcare facility.
- Respirators that are NIOSH-approved before decontamination (<https://www.cdc.gov/niosh-cel/>) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

Use appropriate personal protective equipment (PPE) when caring for individuals suspected of having COVID-19 as outlined in the CDC webpages, including *Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the COVID-19 Pandemic*, *Infection Control*, and *FAQ on PPE*.

Current information on COVID-19 for healthcare personnel is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of using decontaminated N95 respirators that were decontaminated using the STERIZONE VP4 Sterilizer?

Potential benefits include:

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- May help prevent exposure to airborne pathogens, and therefore reduce the risk of infection or illness
- Extends the usability of compatible N95 respirators by allowing for decontamination and reuse.

Potential risks include:

- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- Reused respirators may not have been effectively decontaminated of SARS-CoV-2 or other pathogens

Overview of the STERIZONE VP4 Sterilizer

The STERIZONE VP4 Sterilizer is a device that uses hydrogen peroxide and ozone to decontaminate general instruments, flexible endoscopes (including single, dual, and multi-channel devices), and rigid-channel devices (including single-channel and double-channel rigid endoscopes).

For this emergency use, the STERIZONE VP4 Sterilizer is intended for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2.

During this single pre-set cycle, the injection of vaporized hydrogen peroxide is followed by the injection of ozone, which reacts with residual hydrogen peroxide to form hydroxyl radicals. A chemical indicator may be placed in the chamber to verify sterilant exposure. Following completion of the cycle, the chemical indicator's color should be compared to the "PASS" reference color. If the colors matched or the color present is lighter, the masks have been exposed to the vaporized hydrogen peroxide. The respirators may be used after a 24-hour aeration period. If the indicator does not match the "PASS" criteria, the compatible N95 respirators must not be considered decontaminated and either rerun through the decontamination cycle or discarded. The STERIZONE VP4 Sterilizer enables single-user reuse of compatible N95 respirators that would otherwise be disposed of after a single use.

However, respirators that are visibly soiled must be discarded and not reused or decontaminated.

What is an EUA?

The United States Food and Drug Administration (FDA) has made the emergency use of the STERIZONE VP4 Sterilizer to decontaminate compatible N95 respirators available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices due to insufficient supply during the COVID-19 pandemic.

The STERIZONE VP4 Sterilizer has been made available under an EUA and has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the STERIZONE VP4 Sterilizer may be effective at preventing HCP exposure to pathogenic biological airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of 2 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the STERIZONE VP4 Sterilizer is in effect for the duration of the COVID-19 declaration justifying emergency use of medical devices, unless terminated or revoked (after which the products may no longer be used).

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Where can I go for updates and more information?

CDC webpages:

General: <https://www.cdc.gov/COVID19>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the COVID-19 Pandemic:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

FAQ on PPE:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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