

FACT SHEET FOR HEALTHCARE PERSONNEL

STERIS Sterilization Systems for Decontaminating Compatible N95 Respirators

January 21, 2020

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, meaning you are receiving the same respirator that you sent for decontamination, for use in a healthcare setting** to prevent 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 *STERIS N95 Respirator Decontamination Cycle (Non-Lumen Cycle) in STERIS V-PRO 1 Plus, V-PRO maX, V-PRO maX2, STERIS V-PRO 60, and V-PRO s2 Sterilizers* (hereafter referred to as “**decontaminated N95 respirators**” and “**STERIS Sterilization Systems**” throughout this Fact Sheet).

Decontaminated N95 respirators that have been decontaminated using the STERIS Sterilization Systems are authorized for single-user reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic.

Whether or not you use a respirator, 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 STERIS Sterilization Systems and decontaminated N95 respirators?

- The STERIS Sterilization Systems have been authorized for emergency use to decontaminate compatible N95 respirators for single-user reuse by healthcare personnel during the COVID-19 pandemic to prevent exposure to pathogenic biological airborne particulates.
- Compatible N95 respirators are those respirators that do not contain cellulose-based materials, exhalation valves, antimicrobial agents, or duck-billed designs and that are either NIOSH-approved and authorized under that EUA or are authorized by the non-NIOSH-approved FFR EUA for FFRs not manufactured in China.
- The STERIS Sterilization Systems are not authorized for use with the following:
 - Respirators or pouches containing cellulose-based materials;
 - Respirators containing exhalation valves;
 - Respirators containing antimicrobial agents;
 - Respirators with duck-billed designs; and
 - Respirators that are authorized in the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through four (4) decontamination cycles for viricidal activity, material compatibility, hydrogen peroxide residue, and filtration performance.
- **Preparing compatible N95 respirators for decontamination:**
 - ✓ Place compatible N95 respirators at the end of use into Tyvek pouches

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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- ✓ Write name and/or other identifier using a permanent marker so the respirator may be returned after successful decontamination
 - ✓ Place a tick mark on respirator and Tyvek pouch each time a respirator is prepared for decontamination
 - ✓ Seal the respirator in the Tyvek pouch, and place it into area for subsequent decontamination per your healthcare facility's procedures
 - ✓ **Discard if decontaminated 4 times** or if visibly soiled or damaged
- **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 decontaminated N95 respirators that are soiled, damaged, or wet
 - ✓ Report problems with decontaminated N95 respirators to your healthcare facility
 - ✓ N95 respirators may be safely stored in pouches after decontamination
 - ✓ Maintain chain of custody on the N95 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 healthcare personnel 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://wwwn.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 by the STERIS Sterilization Systems?

Potential benefits include:

- 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 single-user 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 STERIS Sterilization Systems

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The STERIS Sterilization Systems, including the V-PRO 1 Plus, V-PRO maX, V-PRO maX2, V-PRO 60, and V-PRO s2 models, contain a pre-programmed Non-Lumen Cycle, in addition to other cycles, intended for terminal sterilization of properly prepared (cleaned, rinsed, and dried) medical devices in healthcare facilities. For this emergency use of the STERIS Sterilization Systems, specifically the V-PRO 1 Plus, V-PRO maX, V-PRO maX2, V-PRO 60, and V-PRO s2 sterilizers, the systems must be operated in Non-Lumen Cycle to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

When the Non-Lumen Cycle starts, the load is processed by automatic moisture checks in order to ensure the removal of the moisture from the load. VHP is injected during four sterilization pulses per cycle. The load is automatically aerated after the last segment and the chamber is exhausted through a catalytic converter that decomposes VHP into water and oxygen. The STERIS Sterilization Systems enable 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 FDA has made the emergency use of the STERIS Sterilization Systems to decontaminate compatible N95 respirators for single-user reuse 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 STERIS Sterilization Systems for this use have been made available under an EUA and have 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 the STERIS Sterilization Systems

may be effective at preventing exposure to pathogenic biological airborne particulates when there are insufficient supplies of respirators during the COVID-19 pandemic by decontaminating, for a maximum of 4 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 STERIS Sterilization Systems 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).

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 Personal Protective Equipment:

<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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