

FACT SHEET FOR HEALTHCARE PERSONNEL

Sterilucient Sterilization System 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 Sterilucient HC 80TT Vaporized Hydrogen Peroxide (VHP) Sterilizer (hereafter referred to as "**decontaminated N95 respirators**" and "**Sterilucient Sterilization System**" 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 Sterilucient Sterilization System and decontaminated N95 respirators?

- The Sterilucient Sterilization System 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 Sterilucient Sterilization System 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.
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through 4 decontamination cycles for sporicidal activity, material compatibility, hydrogen peroxide residue, and filtration performance and fit-test data.
- **Preparing compatible N95 respirators for decontamination:**
 - ✓ Place compatible N95 respirators at the end of use into a VHP-compatible Tyvek Self-Seal pouch or equivalent.
 - ✓ 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 each time a respirator is prepared for decontamination.

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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- ✓ Seal the respirator in the Tyvek pouch, and place it into area for subsequent decontamination per your healthcare facility's procedures.
- ✓ **Discard if decontaminated more than 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 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 4 times).
 - ✓ Report problems with decontaminated N95 respirators to your healthcare facility.
 - ✓ 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 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 Sterilucient Sterilization System?

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 reuse
- Greater supply of compatible N95 respirators available for use by healthcare personnel

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 Sterilucient Sterilization System

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Sterilucent Sterilization System for Decontaminating Compatible N95 Respirators

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The Sterilucent Sterilization System is a self-contained table top sterilizer that utilizes vaporized hydrogen peroxide to sterilize reusable metal and non-metal medical devices that are used in healthcare facilities. The sterilizer operates at low pressure and low temperature and is therefore suitable for reprocessing medical devices sensitive to heat and moisture. It features two preprogrammed sterilization cycles, the Lumen Cycle and the Flexible Cycle.

For this emergency use of the Sterilucent Sterilization System, the system must be operated using only the Flexible Cycle to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms. N95 respirators containing cellulose-based materials, antimicrobial agents, a duck-billed design, or exhalation valves are not compatible with the Sterilucent Sterilization System. Tyvek pouches containing cellulose-based materials are not compatible with the Sterilucent Sterilization System.

What is an EUA?

The United States Food and Drug Administration (FDA) has made the emergency use of the Sterilucent Sterilization System 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 Sterilucent Sterilization System 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 Sterilucent Sterilization System 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 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 Sterilucent Sterilization System 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 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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