FACT SHEET FOR HEALTHCARE PERSONNEL

STERIS Sterilization Systems for Decontaminating Compatible N95 Respirators **April 9, 2020**

Coronavirus Disease 2019 (COVID-19)

You have been given a **N95 or N95-equivalent respirator** ("compatible N95 respirator") that has been decontaminated **for single-user reuse by healthcare personnel in a healthcare setting** to help prevent exposure to pathogenic biologic 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, and V-PRO maX2 Sterilizers* (hereafter referred to as "**decontaminated N95 respirators**" and "**STERIS Sterilization System**" throughout this Fact Sheet).

Decontaminated N95 respirators that have been decontaminated using STERIS Sterilization System 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. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

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 decontaminated N95 respirators?

- The STERIS Sterilization System has 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 airborne particulates.
  - Compatible N95 or N95-equivalent respirators are those that do not contain cellulose-based materials.

- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through 10 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
  - ✓ 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 10 times** or if visibly soiled or damaged

- **Use of decontaminated N95 respirators:**
  - ✓ Decontaminated N95 respirators are not sterile
  - ✓ Inspect respirators after each use prior to submission for decontamination
  - ✓ If decontaminated N95 respirators are soiled or damaged, they should be discarded
  - ✓ Cellulose-based materials are incompatible with the STERIS Sterilization System

- ✓ 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 healthcare personnel 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 STERIS Corporation.

- **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.

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 Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings, Infection Control, and FAQ about 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?

Potential benefits include:
- May help prevent exposure to airborne pathogens, and therefore 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 System

The STERIS Sterilization System, including of the V-Pro 1 Plus, V-Pro maX, and V-Pro maX2 models vaporized hydrogen peroxide (VHP) sterilizers, 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, and V-PRO maX2 sterilizers, the system must be operated in Non-Lumen Cycle to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms. **N95 or N95-equivalent respirators or Tyvek pouches containing paper or cellulose-based materials are not compatible with the STERIS Sterilization Systems.** The STERIS 60 Liter chamber units (V-PRO 60 and V-PRO s2) are not included in this emergency use.

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 four times during each sterilization cycle (pulse). 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 System 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 FDA has made the emergency use of the STERIS 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, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.
The STERIS 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 the STERIS Sterilization System may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of respirators during the COVID-19 pandemic by decontaminating, for a maximum of 10 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 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
Infection Prevention and Control Recommendations in Healthcare Settings: 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