FACT SHEET FOR HEALTHCARE PERSONNEL

STRYKER Decontamination Cycle for Decontaminating Compatible N95 Respirators **April 14, 2020**

Coronavirus Disease 2019 (COVID-19)

You have been given an **N95 or N95-equivalent respirator** that has been decontaminated using a decontamination system **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. Compatible N95 respirators are those that do not contain cellulose-based or paper materials, natural rubber, or latex.

These compatible N95 respirators have been decontaminated using the Stryker *STERIZONE VP4 N95 Respirator Decontamination Cycle* in the *STERIZONE VP4 Sterilizer.*

Decontaminated N95 or N95-equivalent respirators that have been decontaminated using the STERIZONE VP4 N95 Respirator Decontamination Cycle 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 compatible N95 respirators?

- The Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle 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.

- The Stryker 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.

- **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

Report Adverse events, including problems with test performance or results, 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**

FACT SHEET FOR HEALTHCARE PERSONNEL

STRYKER Decontamination Cycle for Decontaminating Compatible N95 Respirators **April 14, 2020**

Coronavirus Disease 2019 (COVID-19)

- **Use of decontaminated N95 respirators:**
  - ✓ Decontaminated compatible N95 respirators are Not Sterile.
  - ✓ Inspect respirators after each use prior to submission for decontamination.
  - ✓ If decontaminated compatible N95 respirators are soiled or damaged, they should be discarded.
  - ✓ N95 respirators with cellulose, paper, natural rubber, or latex should not be processed in the STERIZONE VP4 Sterilizer
  - ✓ The number of times a respirator has been decontaminated should be 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 compatible 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 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 Stryker.

- **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 compatible 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. The availability of respirators are critical to healthcare workers in the diagnosis and treatment of patients with COVID-19

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 N95 Respirator Decontamination Cycle

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. Compatible N95 respirators containing paper, cellulose-based materials, natural rubber, or latex are incompatible with the STERIZONE VP4 N95 Respirator Decontamination Cycle.
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 immediately; no additional aeration is required. If the indicator does not match the "PASS" criteria, the N95 masks should not be considered decontaminated and either reprocessed or discarded. The STERIZONE VP4 N95 Decontamination Cycle 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 STERIZONE VP4 N95 Respirator Decontamination Cycle to reprocess 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 STERIZONE VP4 Sterilizer, when used in the described fashion, has been made available under an EUA, and has not undergone the same type of review as an FDA-approved or cleared device for the reuse of single use compatible N95 Respirators. 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 N95 Respirator Decontamination Cycle may be effective at preventing healthcare personnel exposure to pathogenic airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of 2 decontamination cycles per compatible N95 or N95-equivalent respirator that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the STERIZONE VP4 N95 Respirator Decontamination Cycle in 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 for this purpose).

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