FACT SHEET FOR HEALTHCARE PERSONNEL

Nova2200 for Decontaminating Compatible N95 Respirators   **August 20, 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 (only 3M Model 1860 or Halyard FLUIDSHIELD 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 (hereafter referred to as "**decontaminated N95 respirators**" throughout this Fact Sheet) have been decontaminated with the Nova2200 using the NovaClean decontamination process (hereafter referred to as "**Nova2200**").

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 Nova2200 and decontaminated N95 respirators?

Nova2200 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.

- o Compatible N95 respirators are limited to 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators. These N95 respirators contain polypropylene/polyester-based materials.
  o The Nova2200 is **not authorized** for use with any other N95 respirators.

- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through one (1) decontamination cycle for sporicidal activity, viricidal activity, filtration efficiency, breathability, form fit testing, and strap integrity testing.

- **Use of decontaminated N95 respirators:**
  ✓ You will receive your decontaminated N95 respirator in a sealed, transparent plastic bag.
  ✓ 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 1 time).
  ✓ Perform a user seal check of the decontaminated N95 respirator prior to entering the workplace. If a successful user seal check cannot be performed, return the respirator to the healthcare facility for quarantine.
  ✓ Report problems with decontaminated N95 respirators to your healthcare facility.

- **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://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.

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 Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings, 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 Nova2200?

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

Potential risks include:
- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit

- Reused N95 respirators may not have been effectively decontaminated of SARS-CoV-2 or other pathogens
- Skin sensitivity and rash resulting from exposure to low levels of peracetic acid

Overview of the Nova2200

The Nova2200 consists of the Nova2200 equipment platform, a chemical additive (NovaKill), supercritical carbon dioxide, and a software-controlled decontamination cycle, which are all required to perform the NovaClean decontamination process. The Nova2200 requires a footprint of 46"x 24"x70" space within the healthcare facility and is operational in a room with at least two (2) air changes per hour.

Prior to decontamination, compatible N95 respirators are packaged in gas permeable packaging (Tyvek pouch referred to as a NovaPouch). Two NovaPouches, each containing 25 compatible N95 respirators, are authorized to be decontaminated per cycle in the Nova2200. 3M Attest 1295 Biological Indicators must be placed on the outside of one of the NovaPouches so that the Biological Indicators can be used to verify successful decontamination.

When exposed to relatively low pressures and temperatures in the Nova2200, liquid carbon dioxide (CO_2) that is added to the system transitions to a supercritical state (above 1099 psi, 31.1°C), and acts as a carrier for the NovaKill additive, a chemical additive containing a mixture of peracetic acid and hydrogen peroxide. This supercritical state allows for penetration of materials by the supercritical CO_2/NovaKill mixture, which acts to inactivate spores and viruses through membrane damage, alteration of fatty acids, and inactivation of ion transport proteins and key metabolic enzymes. Once the temperature and pressure reach the appropriate setpoints (35 °C and 1450 psi) while CO_2 is pumped into the Nova2200, the cycle is held for 90 minutes, after which the Nova2200 vessel exhausts the CO_2 to reduce the pressure. The Nova2200 monitors the specific parameters for decontamination (temperature, pressure, stir speed) and provides a printout of the parameters at the end of the cycle, which notes if the

decontamination run passed or failed the specific parameters needed for decontamination.

Nova2200 is authorized for use with the 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators. These N95 respirators contain polypropylene/polyester-based materials and are authorized to be decontaminated using the Nova2200 through one (1) decontamination cycle. Nova2200 is not authorized for use with any other N95 respirator models.

What is an EUA?

The United States Food and Drug Administration (FDA) has made the emergency use of the Nova2200 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 Nova2200 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 Nova2200 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 one (1) decontamination cycle per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the Nova2200 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 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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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**