You have been given a **decontaminated N95 respirator** that has been decontaminated using a sterilization system that is authorized to return **the same respirator for reuse that you packaged 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 (hereafter referred to as "decontaminated N95 respirators"). These compatible N95 respirators have been decontaminated using one of three Advanced Sterilization Products, Inc. STERRAD Sterilization Systems: ASP STERRAD 100S Sterilization System in the 100S cycle, the ASP STERRAD NX Sterilization System in the Standard cycle, or the ASP STERRAD 100NX Sterilization System in the Express cycle (hereafter referred to as "**STERRAD Sterilization Systems**" throughout this Fact Sheet).
.

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 STERRAD Sterilization System and decontaminated N95 respirators?

- The STERRAD Sterilization Systems have been authorized for emergency use to decontaminate compatible N95 respirators for single-user reuse by HCP during the COVID-19 pandemic to prevent exposure to pathogenic biological airborne particulates.
  o Compatible N95 respirators are those without exhalation valves that do not contain cellulose-based materials and are either NIOSH-approved and authorized by that EUA or authorized under the non-NIOSH-approved FFR EUA for respirators not manufactured in China.
  o The STERRAD Sterilization Systems are not authorized for use with the following:
    - Respirators or pouches containing cellulose-based materials;
    - Respirators that have exhalation valves; 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 2 decontamination cycles for viricidal activity, material compatibility, hydrogen peroxide residue, and filtration performance.

- **Preparing compatible N95 respirators for decontamination:**
  ✓ Place compatible N95 respirators after use into a compatible sterilization pouch identified for use in vaporized hydrogen peroxide, such as a Tyvek® pouch with STERRAD Chemical Indicator
  ✓ 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 more than 2 times** or if visibly soiled or damaged

---

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**

- **Decontaminated N95 respirators:**
  - ✓ DecontaminatedN95 respirators are not sterile
  - ✓ 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.

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 by the STERRAD Sterilization System?

Potential benefits include:
- Extends the usability of compatible N95 respirators by allowing for decontamination and single-user reuse, thereby potentially helping to prevent exposure to airborne pathogens and risk of infection or illness

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 ASP STERRAD Sterilization Systems

The STERRAD Sterilization Systems, in their authorized cycles, are intended for terminal sterilization of properly prepared (cleaned, rinsed, and dried) medical devices in healthcare facilities. For this emergency use of the STERRAD Sterilization Systems, specifically the ASP STERRAD 100S in the 100S cycle, the ASP STERRAD NX in the Standard cycle, and the ASP STERRAD 100NX in the Express cycle, to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms so that the respirators can be reused by HCP. **N95 respirators containing cellulose-based materials or those that have exhalation valves are not compatible with the STERRAD Sterilization Systems.**

The ASP STERRAD Sterilization System decontaminates utilizing hydrogen peroxide vapor. The vaporized hydrogen peroxide is introduced to allow perfusion of the hydrogen peroxide throughout the chamber, facilitating hydrogen peroxide contact with the surfaces to be decontaminated. The STERRAD Sterilization System enables single-user reuse of decontaminated, 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 STERRAD Sterilization Systems 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 STERRAD 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 STERRAD Sterilization Systems may be effective in decontaminating, for a maximum of 2 decontamination cycles per respirator, compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of respirators during the COVID-19 pandemic.

The EUA for the STERRAD 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
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