

Fact Sheet for Healthcare Personnel on Emergency Use of STERRAD® Sterilization Systems to Reprocess N95 Respirators

Under FDA Guidance, “Enforcement Policy for Sterilizers, Disinfectant Devices and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency,” published March 2020, ASP STERRAD Sterilization Systems can be used to reprocess select N95 (and similar) respirators for reuse by healthcare personnel during the COVID-19 pandemic to prevent wearer exposure to pathogenic airborne particulates. FDA issued this guidance to provide a policy to help expand the availability and capability of sterilizers during this public health emergency. During this public health emergency, FDA does not intend to object to limited modifications to the indications or functionality of FDA-cleared or FDA-approved sterilizers pertaining to a device’s virucidal effectiveness against SARS-CoV-2, where such devices will not create an undue risk in light of the public health emergency.

This Fact Sheet details what you need to know about the emergency use of STERRAD® System reprocessed respirators.

STERRAD Sterilization Systems may be used in reprocessing compatible N95 respirators during the COVID-19 pandemic.

IMPORTANT

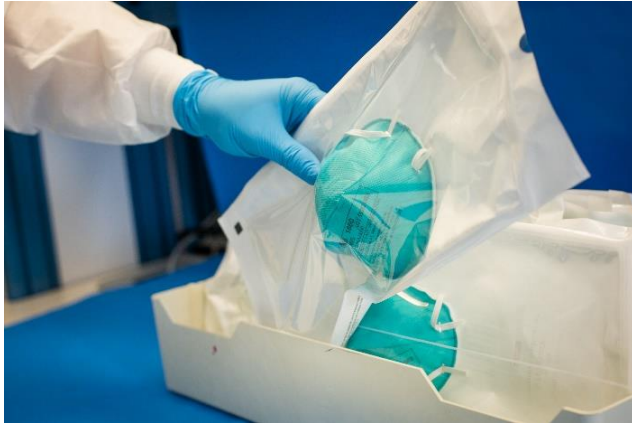
Whether or not you use a respirator, always follow infection control measures: wash hands, cover coughs

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 STERRAD Sterilization Systems to decontaminate N95 (and similar) respirators?



Compatible N95 Respirators

- Compatible N95 respirators are those that do not contain cellulose-based materials.
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through two (2) STERRAD System Sterilization Process cycles.¹

Limits to Respirator Reprocessing

- All respirators should be inspected after use, prior to reprocessing, and again prior to reuse.
- Discard visibly soiled and/or damaged masks per your facility's policy on safe handling of contaminated PPE. Do not use, reprocess or otherwise reintroduce visibly soiled and/or damaged masks.

IMPORTANT

Cellulose-based materials cannot be reprocessed in STERRAD Systems.

Reintroduction of Reprocessed N95 respirators

- Ensure the number of times a respirator has been reprocessed is written on the respirator (maximum 2 times) per your healthcare facility policies.
- Immediately report any suspected problems (damage or discoloration) with processed N95 respirators to your healthcare facility.
- Report potential exposure of healthcare personnel from breaks in or other damage to or degradation of the reprocessed 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)*

¹ Testing conducted with ALLClear® Technology disabled.

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 "Information and Updates" section).

Risks and benefits of using reprocessed N95 respirators

Potential benefits

- Extends usability of N95 respirators by allowing for up to two (2) cycles of reprocessing and reuse
- May help prevent exposure to airborne pathogens

Potential risks

- Failure of filtration efficiency
- Reduced breathability
- Strap failure and/or ineffective face fit
- Reused respirators may not have been effectively decontaminated of SARS-CoV-2 or other pathogens

Monitoring Healthcare Personnel

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 per your facility's process.



Overview of STERRAD System Technology

All ASP STERRAD Sterilization Systems and disinfectant solutions have been tested against enveloped viruses, the family of viruses that includes coronavirus, and have been demonstrated to be efficacious against those viruses.

STERRAD Systems

STERRAD Sterilization Systems are general purpose, low temperature sterilizers which inactivate microorganisms on a broad range of medical devices and surgical instruments.

The STERRAD® 100S Sterilizer, STERRAD NX® Sterilizer, and STERRAD® 100NX Sterilizer are designed to sterilize metal and non-metal medical devices by diffusing hydrogen peroxide vapor into the chamber and then electromagnetically exciting the hydrogen peroxide molecules into a low-temperature plasma state. The

combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes medical instruments and materials without leaving toxic residue. All stages of the sterilization cycle operate within a dry environment at a low temperature, and thus the cycle is not damaging to compatible items that are sensitive to heat and moisture.

The use of the STERRAD Sterilization Systems in decontamination of N95 respirators is available for emergency use and has not undergone the same type of review as an FDA-approved or cleared use. It is reasonable to believe that the STERRAD Sterilization Systems 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 respirator, compatible N95 or N95-equivalent respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

INFORMATION AND UPDATES

CDC

COVID-19 Resource Center:

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>

Guidance for 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

Coronavirus Disease 2019 (COVID-19):

www.fda.gov/novelcoronavirus

This emergency use is in effect for the duration of the COVID-19 public health emergency, unless terminated or revoked (after which the products may no longer be used).

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.

Important information: Prior to use, refer to the instructions for use supplied with the STERRAD Sterilization Systems for standard indications, contraindications, warnings and precautions.

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