

Interim Disaster Guidance:

During deployment of Disaster Operations Interim Guidance is issued as needed.

Effective April 1, 2020, for conservation of Personal Protective Equipment (PPE) and in compliance with the Food and Drug Administration (FDA) Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency and with guidance from STERRAD Instructions for Use (IFU), N-95 respirators can be reprocessed to effectively kill SARS-CoV-2 virus.

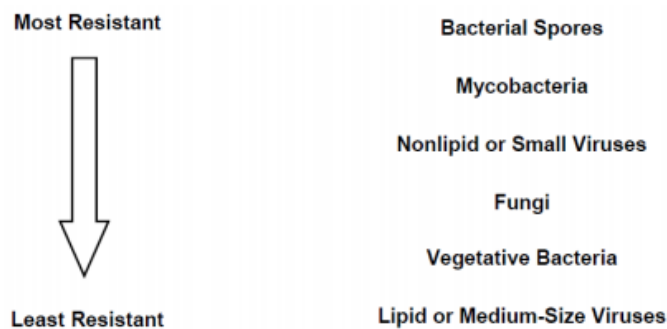
Guidance:

To conserve inventory and prolong use of N-95 respirator masks, it is requested that staff who utilize N-95 respirator masks limit the use of facial make-up, lotions, or other cosmetics that will soil masks.

Additionally, it is critical that whether or not a respirator is utilized, infection control measures to reduce contamination are used at all times.

Background:

The FDA believes that certain sterilizers, disinfectant devices, and air purifiers may help reduce the risk of viral exposure. Coronaviruses are RNA viruses enveloped in a lipid bilayer. SARS-CoV-2 is a type of coronavirus. Lipid viruses are the least resistant microorganisms on the scale of descending order of resistance to germicidal chemicals. Because sterilization processes render medical devices free from viable microorganisms including bacterial spores, and because disinfection kills most recognized pathogenic microorganisms, it can generally be inferred that sterilization and disinfections should minimize the viability of SARS-CoV-2. The STERRAD Sterilization Systems may be used in reprocessing compatible N-95 respirators during the COVID-19 pandemic.



Modified from Favero, M.S. and Bond, W.W., Chemical Disinfection of Medical and Surgical Materials. In: Disinfection, Sterilization, and Preservation, 5th Ed Phila: Lippincott Williams & Wilkins 2001: 881-917.

Figure 1. Descending Order of Resistance of Microorganisms to Germicidal Chemicals.

The STERRAD 100S Sterilizer and STERRAD NX Sterilizer Standard Cycle hold FDA 510(k) clearance for a sterilizer that is intended for sterilization of medical devices in healthcare settings. The STERRAD system sterilization efficacy has been demonstrated against enveloped and non-enveloped viruses, mycobacteria, and bacterial spores which represent the most difficult to sterilize microorganisms. This testing has been previously reviewed and included in the premarket notification cleared by the US FDA. Although COVID-19 has not been specifically tested, as an enveloped virus, coronavirus is not more resistant than the virus strains used in verification and validation of the various STERRAD system cycles and is much less resistant than the bacterial spores used to demonstrate sterilization.

STERRAD Sterilization Systems are low temperature sterilizers which inactivate microorganisms on a broad range of medical devices and surgical instruments. They 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 sterilized 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 N-95 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 period of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of two (2) decontamination cycles per respirator, compatible N-95 or N-95-equivalent respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

In addition to all previous verification and validation testing completed for the STERRAD Sterilization Systems, Advanced Sterilization Products (ASP) has completed testing to demonstrate compatibility and performance of the STERRAD Sterilization Systems for the reprocessing of N-95 and similar masks that do not contain cellulose. N-95 masks were prepared and loaded into the STERRAD systems as described in the IFU.

Warnings:

Due to incompatibility with the STERRAD Sterilization Systems, do not reprocess respirator masks containing cellulose or cellulose based materials.

Compatible respirator masks that are visibly damaged or soiled should not be reprocessed and should be discarded.

Risks and Benefits:

Potential Benefits:

- Extends usability of N-95 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.

Procedure:

Initial Issuance of N-95 masks:

1. Each unit director will issue the appropriately sized N-95 to the appropriate Healthcare Personnel (HCP).
2. The HCP will label their mask with their name and department upon receipt, ie. (J. Smith, ED)
3. Upon discontinuation of use, the HCP will place the mask in the dedicated bin for reprocessing.

Collection and preparation of N-95 Masks for reprocessing:

- N-95 masks will be inspected for compatibility, visible damage, or soil.
- Compatible masks do not contain cellulose or cellulose-based materials.
- Any mask that is visibly damaged or visibly soiled will not be reprocessed and discarded with safe handling of contaminated PPE.

All masks will be labeled with:

- The individual's name and department, ie. (J. Smith, ED)
- The processor's initials and date processed must be written on the outside of the mask to monitor the number of times a single mask has been through reprocessing, ie. (JD 4/2)
- When a mask has two (2) processor's initial and date indicators, the mask is no longer eligible for reprocessing and must be discarded, ie. (JD 4/2) (MV 4/4)
- Masks will only be eligible for reprocessing for a maximum of two (2) times and then discarded with safe handling of contaminated PPE.

Packaging:

1. Prior to placing in the STERRAD system, all compatible N-95 masks will be individually packaged in a Tyvek Pouch with STERRAD Chemical Indicator, Self-Seal, 6" x 12.5" item code 12332.
2. The SPD tech will label the Tyvek Pouch with the HCP owner's name and department as written on the mask, ie (J. Smith ED).
3. The masks will be packaged with label side visible.
4. The individually packaged masks will be loaded into the STERRAD sterilizer per standard IFU.
5. The chamber load should not exceed weight limits of the processor per standard IFU.

6. Pouches should be placed on edge or in a manner that they are not layered on top of each other.
7. If placed on their edge, it is recommended to use STERRAD systems compatible tape to secure pouches so that they do not move during the sterilization process and block sensors within the system.
8. Ensure that masks are not crushed or damaged when packaged or placed in the sterilization chamber.
9. Follow existing IFU for the STERRAD system.
10. It is recommended that a biological indicator is placed in the chamber per standard instructions for use for monitoring each load processed.

Note: The STERRAD Sterilization System will be placed on the dirty side of SPD to avoid cross contamination of other sterile instrumentation while packaging. The SPD technician packaging the masks must be in appropriate decontamination PPE.

System	Cycle	Cycle Time	Placement
STERRAD 100S System	Short	55 minutes	Both Shelves
STERRAD NX System	Standard	28 minutes	Both Shelves

Post Processing Instructions:

- Once the cycle is complete, wearing clean PPE, the load will be removed from the STERRAD and placed into the clean side of SPD.
- The pouches and masks will be visually inspected for physical damage.
- If any mask appears physically damaged it will be discarded.
- Ensure the reprocessing dates have not exceeded the maximum number of two (2) allowable reprocessing cycles.
- All masks that do not appear damaged will be allowed to aerate for one (1) hour prior to returning the masks to the unit director for use.
- Process the biologic indicator per standard instructions for use prior to release of the masks.
- Masks will be given back to unit directors for redistribution to individuals as labeled.

Ongoing monitoring:

Prior to donning the reprocessed N-95 mask, the HCP will visually inspect for damage and assess appropriate fit prior to wearing during the shift. If any damage or poor fit is noted, the mask will be discarded.

Immediately report any suspected problems (damage or discoloration) with processed N-95 respirators to your healthcare facility.

Report potential exposure of HCP from breaks in, other damage to, or degradation of the reprocessed N-95 respirators.

Monitor HCP 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.

References:

Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. *Guidance for Industry and Food and Drug Administration Staff*. (March 2020) <https://www.fda.gov/media/136533/download>

Instructions for Use for Reprocessing N95 Masks in STERRAD Sterilization Systems during the COVID-19 Public Health Emergency. *Advanced Sterilization Products*. (March 2020).
https://www.asp.com/sites/default/files/covid-19/AP-2000011-Instructions_for_Use_for_Reprocessing_N95_Masks_in_STERRAD_Sterilization_Systems.pdf

Fact Sheet for Healthcare Personnel on Emergency Use of STERRAD Sterilization Systems to Reprocess N95 Respirators. *Advanced Sterilization Products*. (March 2020).
https://www.asp.com/sites/default/files/covid-19/2000014-Fact_Sheet_for_Healthcare_Personnel_on_Emergency_Use_of_STERRAD_Sterilization_Systems_to_Reprocess_N95_Respirators.pdf