HEALTHTRUST®
Education & Clinical Resources

Emergency Use of STERRAD Sterilization Systems to Reprocess N95 Respirators

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STERRAD® sterilization systems are general purpose, low-temperature sterilizers that inactivate microorganisms on a variety medical devices and surgical instruments. The sterilization of N95 and similar respirators is outside the scope of currently approved/cleared indications for use; however, under the FDA guidance document, (Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers during Coronavirus Disease 2019 (COVID-19) Public Health Emergency published March 2020, the use of STERRAD sterilization systems in decontaminating N95 respirators is available for emergency use.

Both STERRAD sterilization systems and disinfectants have been tested and found to be efficacious against enveloped, and non-enveloped viruses, mycobacteria and bacterial spores, which represent the most difficult-to-sterilize microorganisms. This testing was previously reviewed and included in the premarket notifications cleared by the FDA. Although COVID-19 has not been specifically tested, as an enveloped virus, the coronavirus is not more resistant then the virus strains used in the verification and validation of STERRAD systems (i.e., Poliovirus Type I or Herpes simplex virus Type I) and is much less resistant than bacterial spores also used to demonstrate sterilization of this system.

This sterilization system ***may be effective*** in preventing healthcare provider exposure to pathogenic airborne particulate matter during insufficient respirator supply with the COVID-19 pandemic, for compatible N95 or N95-equivalent respirators that are contaminated or potentially contaminated.

Advanced Sterilization Products (ASP) STERRAD Sterilization Systems hold 510(k) clearance for the following sterilizers 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 without leaving a toxic residue:

- **STERRAD 100S Sterilizer** can sterilize medical devices with titanium surfaces and medical devices with only a single stainless steel lumen with:
    - Inside diameter of 1 mm or larger and length of 125 mm or shorter
    - Inside diameter of 2 mm or larger and length of 250 mm or shorter

- **STERRAD NX Sterilizer Standard Cycle** can process the following medical device with single channel stainless steel lumen with:
    - Inside diameter of 1 mm or larger and length of 150 mm or shorter
    - Inside diameter of 2 mm or larger and length of 400 mm or shorter
    - Validation testing conducted using a maximum of 10 lumens per load. ***Should not exceed 10 lumens per load***.
- **STERRAD 100 NX Sterilizer Express Cycle** is designed for surface sterilization of both metal and non-metal medical devices with lower temperatures.
    - Sterilizes instrument surfaces and instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
    - Sterilizes rigid and semi-rigid endoscopes without lumens.
    - Validation studies performed using a validation load consisting of a single instrument tray weighing 10.7 pounds placed on the bottom shelf.
- ***ASP is a contracted supplier for low-temperature hydrogen peroxide sterilization systems with HealthTrust.***

Potential Benefits:

- Extends N95 respirator usability 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 severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2)or other pathogens

Warnings and Precautions *(all warnings and precautions identified in the STERRAD Sterilization System User's Guide apply for use of the system in addition to the following):*

- Compatible respirators are those that ***do not contain cellulose (both natural and processed)*** as cellulose-based materials cannot be reprocessed in STERRAD Systems.
- ***Do not use, reprocess or reintroduce visibly soiled and/or damaged masks***.
- ***Maximum of two (2) decontamination cyclers per respirator*** as testing of contaminated N95 respirators demonstrated acceptable performance through two STERRAD System Sterilization cycles.
- ***ASP has not provided information regarding the impact of residual cosmetics on the decontamination of N95 respirators.***

Collection and Preparation of N95 Masks:

- Collect used N95 masks.
- Inspect ***all*** respirators after use and prior to processing.
    - Discard visibly soiled and/or damaged masks per your facility policy on safe handling of contaminated PPE (personal protective equipment).
- Label masks per heath care facility protocol.
    - Ensure the number of times a respirator has been reprocessed is written on the respirator for a ***maximum of 2 decontamination cycles per respirator***.
- Individually package N95 masks in an appropriately-sized Tyvek® self-seal pouch or equivalent product, prior to placing in STERRAD system.

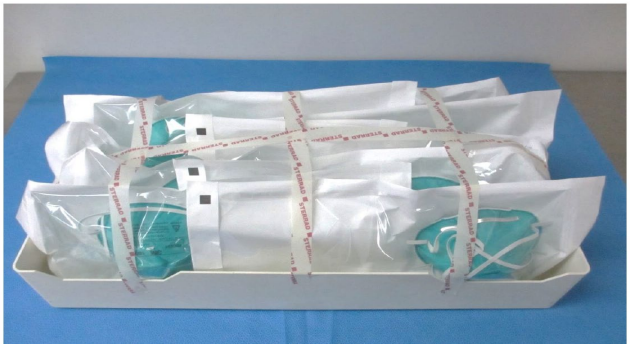
- **Tested and Qualified Pouches for Reprocessing N95 masks in STERRAD Sterilization Systems:**

Product	Packaging	ASP Item Code
Tyvek Pouch with STERRAD chemical indicator, self-seal, 6" X 12.5"	2 X 250 shelf packs; 500/case	12332
Tyvek Pouch with STERRAD chemical indicator, self-seal, 8" X 16"	2 X 250 shelf packs; 500/case	12340

Sterilization Cycles and Loads:

- After packaging, load masks into the STERRAD sterilizer.
- Follow the appropriate STERRAD Sterilizer User's Guide for loading the chamber, including weight limits and placement in addition to the following:
    - ***Pouches should be placed on edge so that they are not layered on top of each other***.
    - ***Use STERRAD Systems compatible tape to secure pouches so they do not move during the sterilization process and block system sensors***.
    - ***Ensure masks are not crushed or damaged when packaged or placed in the sterilization chamber***.

Figure 1: Example of Packaging N95 masks for Loading



- **STERRAD Sterilizer Cycle and Loading Parameters:**

ASP System	Cycle	Cycle Time	Placement
STERRAD 100s Sterilizer	Short	55 minutes	Both shelves
STERRAD NX Sterilizer	Standard	28 minutes	Both shelves
STERRAD 100NX Sterilizer	Express	24 minutes	Bottom shelf ***only***

- Follow operating instructions for use of your particular STERRAD sterilization system.
- Place a STERRAD Velocity biological indicator in the chamber per standard instructions for use for monitoring each load processed.

Post-Processing Instructions:

- Visibly inspect pouches and masks for physical damage.
  - Immediately report any suspected problems (damage or discoloration) with processed N95 respirators to your healthcare facility
  - Discard any mask that appears physically damaged.
- Aerate undamaged masks for one (1) hour prior to returning masks for use.
- Process STERRAD Velocity biological indicator per standard instructions for use prior to release of masks for use by healthcare personnel (HCP).
- Report any potential exposure of HCP from breaks in, other damage to, or degradation of the reprocessed N95 respirators.
  - Monitor HCP for signs and symptoms of potential COVID-19 infection or other respiratory infection for up to and including 14 days after last contact with SARS-CoV-2 and related material and promptly report the information per your facility's reporting process.

These additional materials may be used in STERRAD sterilization systems for reprocessing N95 masks:

Product	Packaging	ASP Item Code
STERRAD Chemical indicator strip	250/pack; 4 packs/case	14100
STERRAD Sealsure Chemical indicator tape	60 yd/roll; 6 rolls/case	14202
STERRAD Velocity Biological indicator	30/box; 2 boxes/case	43210
Tyvek Roll with STERRAD Chemical Indicator 6" x 228'	4/case	12415
Tyvek Roll with STERRAD Chemical Indicator 8" x 228'	4/case	12420
Tyvek Pouch with STERRAD Chemical Indicator, heat-seal, 6" x 12.5"	2 x 250 shelf packs; 500/case	12532

References:

Fact Sheet for Healthcare Personnel on Emergency Use of STERRAD Sterilization Systems to Reprocess N95 Respirators provided by Advanced Sterilization Products.

Instructions for Use for Reprocessing N95 Masks in STERRAD Sterilization Systems during the COVID-19 Public Health Emergency provided by Advanced Sterilization Products.

Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus 2019 (COVID-19 Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff (2020). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease. Retrieved 3.30.20.