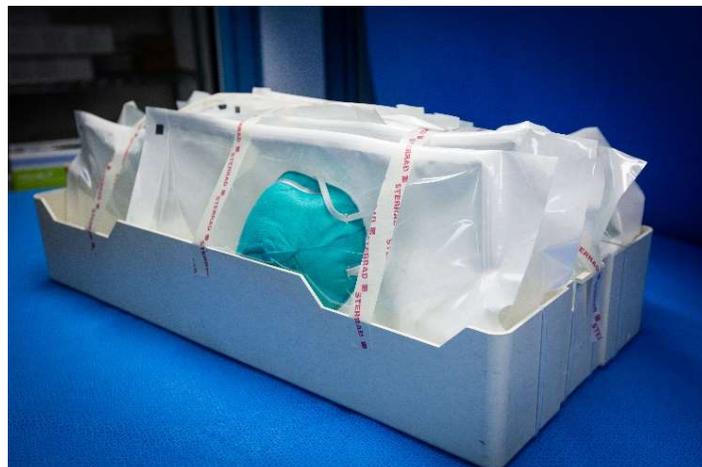


**Guidance for Healthcare Facilities: Emergency Decontamination of Compatible N95 or N95-equivalent Respirators in STERRAD® Sterilization Systems.**

Advanced Sterilization Products (ASP) continues to monitor the outbreak of the respiratory illness caused by a new coronavirus (COVID-19) which has been classified as a world pandemic by the World Health Organization. The rapidly spreading COVID-19 has caused a worldwide shortage in personal protective equipment, specifically single use N95 and similar filtering facepiece respirators. In order to minimize the risk of misuse of the STERRAD® Systems and maximize the potential for public safety ASP has issued emergency instructions for the decontamination of single use N95 and similar filtering face piece respirators in the ASP STERRAD® Sterilization Systems, during the COVID-19 public health emergency.



The STERRAD Sterilizer cycles to be used in decontamination of compatible N95 respirators are: **STERRAD100S Sterilizer Short Cycle**, **STERRAD NX® Sterilizer Standard Cycle** and **STERRAD 100NX Sterilizer Express Cycle**. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination in a STERRAD Sterilizer; please refer to the STERRAD Sterilizer User’s Guide for complete instructions for use.

**This guidance is not intended to replace the IFU provided by the respirator manufacturer but may be used to help define standard operating procedure in the context of the COVID-19 emergency.**

ASP is aware that single-use N95 respirators may not be used in all countries and is collaborating with the relevant healthcare authorities, to ensure that the decontamination of similar filtering facepiece respirators, such as FFP2 masks, is also done safely during this public emergency.

- **Due to incompatibility, the STERRAD Sterilization Systems are not authorized for use with respirators containing cellulose-based or paper materials.**
- **If N95 respirators are soiled or damaged, they should be disposed of and not returned after decontamination.**

**Materials Needed:**

- Tyvek® pouch identified for use in vaporized hydrogen peroxide, for example ASP Tyvek Pouch with STERRAD Chemical Indicator.
- Type 1 chemical indicator for vaporized hydrogen peroxide, for example ASP STERRAD Chemical Indicator Strips or SEALSURE® Chemical Indicator Tape.
- STERRAD VELOCITY Biological Indicator/Process Challenge Device or CycleSure® 24 Hour Biological Indicator

**To decontaminate compatible N95 respirators in a STERRAD100S Sterilizer Short Cycle, STERRAD NX® Sterilizer Standard Cycle or STERRAD 100NX Sterilizer Express Cycle:**

1. A compatible N95 Respirator should be placed in a Tyvek pouch.
2. Place individually pouched compatible N95 respirators in a STERRAD Sterilizer; each cycle can process groups of respirators up to the weight and loading limits identified for the specific cycle in the relevant STERRAD Sterilizer User's Guide.
3. A specific orientation of the mask in the Tyvek pouch or pouches in the sterilizer is not required.
4. Pouches should not overlap or cover other pouches.
5. A Type 1 indicator for vaporized hydrogen peroxide (for example, a chemical indicator or chemical indicator tape) may be used to monitor the cycle. The indicators may be placed on the pouch, inside a pouch or within the chamber to provide an indicator that sterilant has been delivered. One indicator per cycle is recommended.
6. Follow STERRAD Sterilizer User's Guide instructions on how to initiate a cycle and verify successful cycle completion.
7. Upon completion of the cycle, the compatible N95 respirators should be aerated in an opened pouch for 1 hour after which they are ready for use.
8. Compatible N95 Respirators may be processed a maximum of 2 times.

Upon completion of the cycle required to reprocess the masks, the masks should be loaded back in sterilized trays or containers and placed in a closed case cart following department policy for identifying/labeling processed loads. The department should follow similar protocol for identifying processed loads to transport to the OR for surgical cases. The documentation needs to include a clean copy of the location identifier to ensure return of the respirators to the original location in the facility for distribution to healthcare workers.

Upon return of the masks to the appropriate individuals, the mask should be checked to ensure that the name or other identifier is still legible. If not legible, or the mask is damaged, the mask should be discarded.

**Marking:**

1. Your organization should create a collection station at the point of generation (i.e. hospital floor/unit)
2. Each station should have a bag provided by the healthcare facility to collect compatible N95 respirators with the following note.  
**NOTE: Bags are for compatible N95 respirators only. Do not place other personal protective equipment (such as gloves), paper towels, or waste in the collection bag.**
3. With a permanent marker, the healthcare personnel should label their own individual compatible N95 respirators with their name, identifier(s), and number of reprocessing cycles.
4. Healthcare personnel should follow the instructions provided by ASP in *Instructions for Healthcare Personnel: Preparation of Compatible N95 or N95-equivalent Respirators for Decontamination in STERRAD Sterilization Systems*.

**Notes:**

1. Prior to use, compatible N95 respirators should be inspected for visible damage and/or excessive soil (i.e., blood, dried sputum, makeup, soil). Masks that are visibly damaged or soiled should be discarded.
2. N95 respirators with cellulose or paper should not be processed in a STERRAD Sterilizer.
3. N95 respirators may be safely stored in pouches.
4. It is strongly recommended to maintain chain of custody for the N95 respirators to minimize the risk of cross-contamination.

**Reuse Information:**

Following decontamination, healthcare personnel will be provided with **decontaminated compatible N95 respirators** that have been processed through STERRAD Sterilizer for reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic. Before reuse, the healthcare facility should inspect each returned, decontaminated compatible N95 respirator for:

1. Numeric indication of the decontamination cycle number.

**NOTE: Compatible N95 respirators will be disposed of after 2 decontamination cycles.**

2. Legible identifier, visible damage or soiling.

**NOTE: Compatible N95 Respirators should be discarded and not reused if the name or other identifier are illegible or the mask is visually damaged or soiled.**



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