Instructions for Healthcare Facilities: Decontamination of Compatible N95 Respirators in ASP STERRAD Sterilization Systems

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Advanced Sterilization Products (ASP) STERRAD Sterilization Systems for use (hereafter referred to as the "STERRAD Sterilization Systems") in decontaminating compatible N95 respirators ("compatible N95 respirators") for single-user reuse by healthcare personnel in healthcare facilities. The ASP STERRAD Sterilization Systems are to be used in the following cycles to decontaminate compatible N95 respirators: the ASP STERRAD 100S Sterilization System is operated in the 100S cycle, the ASP STERRAD NX Sterilization System is operated in the Standard cycle, or the ASP STERRAD 100NX Sterilization System is operated in the Express cycle. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to decontaminate compatible N95 respirators using the STERRAD Sterilization Systems.

The STERRAD Sterilization Systems have been authorized by FDA under an EUA for decontamination of compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates. The STERRAD Sterilization Systems have not been cleared or approved for this use. The STERRAD Sterilization Systems are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices unless the authorization is terminated or revoked sooner.

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.

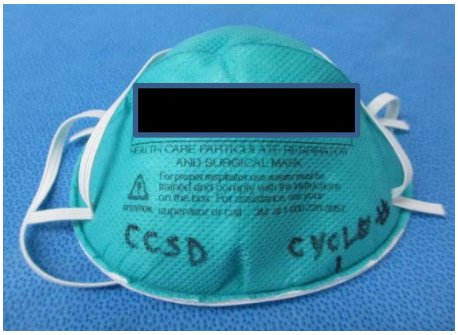
- **The STERRAD Sterilization Systems are not authorized for use with the following:**
  - **Respirators or pouches containing cellulose-based materials;**
  - **Respirators that have exhalation valves; and**
  - **Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.**
- **All compatible N95 respirators used in the STERRAD Sterilization Systems must be free of visible damage and visual soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).**
- **Do not collect compatible N95 respirators that are visually soiled or damaged, and discard such respirators.**
- **Discard compatible N95 respirators after exceeding 2 decontamination cycles.**
- **Discard any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified.**
- **Decontaminated compatible N95 respirators are not sterile.**

Materials Needed:

- Compatible sterilization pouch identified for use in vaporized hydrogen peroxide, such as Tyvek® Pouch with STERRAD Chemical Indicator
- Type 1 chemical indicator for vaporized hydrogen peroxide, such as ASP STERRAD Chemical Indicator Strips, SEALSURE® Chemical Indicator Tape
- VELOCITY Biological Indicator/Process Challenge Device or CYCLESURE Biological Indicator

Compatible N95 Respirator Marking:

The healthcare facility must ensure that the chain of custody is maintained to minimize risk of cross-contamination. Prior to collection by the healthcare facility personnel, the healthcare personnel will label their own individual compatible N95 respirator with their name and/or identifier, and number of decontamination cycles (as shown below) with a permanent marker. The healthcare personnel will pouch the compatible N95 respirator in a Tyvek or other compatible decontamination pouch, label the pouch with the decontamination cycle count, and seal it. The compatible N95 respirator in the Tyvek pouch will be placed at a designated collection station. See the *"Instructions for Healthcare Personnel"* for details.



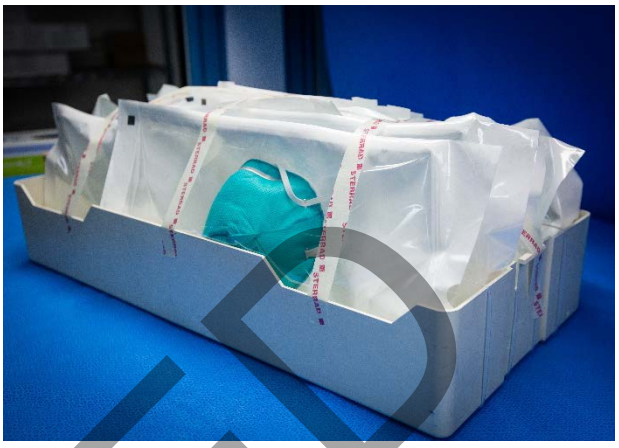
Compatible N95 Respirator Collection and Transportation:

1. The healthcare facility will create a collection station at the point of generation (i.e., hospital floor/unit). Each station will have a tray or container provided by the healthcare facility to collect the pouches containing the compatible N95 respirators for decontamination with the following note:
   NOTE: Only compatible N95 respirators in Tyvek pouches should be placed at this collection station for decontamination. No other items will be decontaminated in the same decontamination cycle.
2. The healthcare personnel who are assigned to decontamination (i.e., those with training for collection/transport of such materials) collect the Tyvek pouches containing the compatible N95 respirators at the collection stations, and place them into the appropriate container for transportation, such as a closed case cart, to minimize risk of environmental contamination. The case cart will have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized.
3. The case cart will be transported to healthcare facility's decontamination area.

Use of the STERRAD Sterilization Systems:

To decontaminate compatible N95 respirators using 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:

1. Place individually pouched compatible N95 respirators in a STERRAD Sterilizer; each cycle can decontaminate 10 pouches per sterilizer load.
2. A specific orientation of the mask in the sterilization pouch or pouches in the sterilizer is not required.
3. Pouches should not overlap or cover other pouches.
4. 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.
5. Follow STERRAD Sterilizer User's Guide instructions on how to initiate a cycle and verify successful cycle completion.
6. 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.
7. **Compatible N95 Respirators may be decontaminated a maximum of 2 times.**



<u>After the STERRAD Sterilization Systems Cycle is complete:</u>

1. Following completion of the cycle in the STERRAD Sterilizer, the chemical indicator's color should be compared to the "PASS" reference color. If the colors matched or the color present is lighter, the compatible N95 respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the "PASS" criteria, the compatible N95 respirators should not be considered decontaminated and either re-run through the cycle in the STERRAD Sterilizer or discarded. Please note that successful completion of the cycle and passing chemical indicator signifies appropriately decontaminated compatible N95 respirators. These results do not indicate sterility of the decontaminated, compatible N95 respirators.
2. Healthcare facilities utilize existing processes to decontaminate the case carts and sterilize the transport trays or container for reuse and delivery of decontaminated, compatible N95 respirators back to patient areas.
3. Decontaminated, compatible N95 respirators that match the "PASS" criteria are loaded back in sterilized trays or containers and placed in a closed case cart following the healthcare facility's policy for identifying/labeling processed loads. The healthcare facility should follow similar protocol for identifying processed loads to transport to the operating room 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.
4. The healthcare facility must ensure that the chain of custody is maintained to minimize risk of cross-contamination. Upon return of the decontaminated, compatible N95 respirators to the appropriate individuals, the respirator should be checked for the following:
   a. Ensure that the name or other identifier and number of decontamination cycles is still legible. Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified it should be discarded.
   b. Discard any compatible N95 respirator that is visually damaged or soiled.
   c. Discard any compatible N95 respirator that has exceeded 2 decontamination cycles.
   d. Ensure that the compatible N95 respirator is returned to its previous user.
5. The healthcare facility must make available the "Fact Sheet for Healthcare Personnel: ASP STERRAD Sterilization Systems for Decontaminating Compatible N95 Respirators" upon return of the decontaminated, compatible N95 respirators.

<u>Reporting to ASP</u>

Healthcare facilities will report any discoloration or other signs of degradation with a decontaminated, compatible N95 respirator to ASP, and the healthcare facility must discard the respirator.

Healthcare facilities will report adverse events of which they become aware related to the STERRAD Sterilization Systems and the decontaminated, compatible N95 respirators. This includes monitoring personnel using the STERRAD Sterilization Systems and healthcare personnel using the decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections. **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.**

Customer Service:
Phone: 888-783-7723
Fax: 949-266-5990
www.asp.com