Instructions for Healthcare Facilities: Decontamination of Compatible N95 Respirators in 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 Sterilizers") in decontaminating compatible N95 respirators ("compatible N95 respirators") for single-user reuse by healthcare personnel in healthcare facilities. The STERRAD Sterilizer cycles to be used in decontamination of compatible N95 respirators are: **STERRAD 100S Cycle**, **STERRAD NX Standard Cycle,** and **STERRAD 100NX 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.

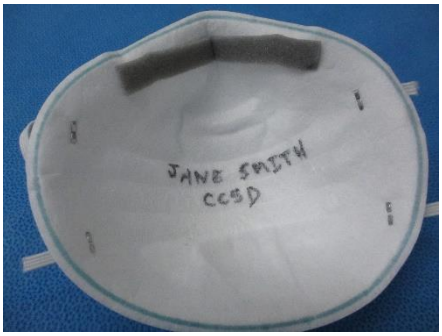
- **Due to incompatibility, the STERRAD Sterilization Systems are not authorized for use with respirators containing cellulose-based or paper materials.**
- **Compatible N95 respirators that are visibly soiled (e.g., blood, dried sputum, makeup, soil, bodily fluids) or damaged must be discarded and not reused or decontaminated.**
- **Compatible N95 respirators should be discarded after 2 decontamination cycles.**
- **Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.**
- **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 should 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 should 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 should pouch the compatible N95 respirator in a sterilization pouch, label the pouch with the decontamination cycle count, and seal it. The compatible N95 respirator in the sterilization pouch should be placed at a designated collection station. See the *"Instructions for Healthcare Personnel"* for details.

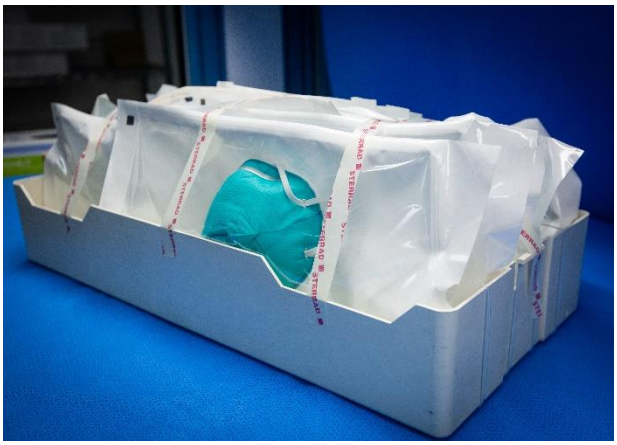


Compatible N95 Respirator Collection and Transportation:

1. The healthcare facility should create a collection station at the point of generation (i.e., hospital floor/unit). Each station should 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 compatible sterilization 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) should collect the sterilization 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 should have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized.
3. The case cart should be transported to healthcare facility's decontamination area.

Use of the STERRAD Sterilization Systems:

To decontaminate compatible N95 respirators in a STERRAD 100S Cycle, STERRAD NX Standard Cycle, or STERRAD 100NX 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.**

After the STERRAD Sterilization Systems Cycle is complete:

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.
2. Utilize existing facility processes to decontaminate case carts and sterilize transport trays or container for reuse and delivery of decontaminated compatible N95 respirators back to patient areas.
3. Successfully decontaminated, compatible N95 respirators should be 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. ASP recommends that the healthcare facility follow similar protocol for identifying processed

loads to transport to the operating room for surgical cases. Documentation should 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 should 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. Any compatible N95 respirator that is visually damaged or soiled should be discarded.
   c. Any compatible N95 respirator that has exceeded 2 decontamination cycles should be discarded.
   d. Ensure that the compatible N95 respirator is returned to its previous user.
5. The healthcare facility should 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.

Reporting to ASP

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

Healthcare facilities using the decontaminated, compatible N95 respirators should monitor healthcare personnel who use such respirators for the signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to ASP, so that ASP can provide a weekly report to FDA. Reports of adverse events should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

Customer Service:
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